

2787 '99 AUG -4 A7:46

August 3, 1999

The Honorable Jane Henney, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

We are pleased to enclose a petition that CSPI is submitting today to the FDA. The petition calls for FDA to establish a Daily Value for "added sugars" in foods and to require the amount of added sugars in a serving and the percentage of the Daily Value that that represents to be printed on food labels. The petition is supported by a letter to you from 34 scientists and nutritionists and 39 health and citizen organizations.

In 1986 the FDA published a review of sugar and concluded not only that then-current levels of added-sugars consumption did not pose any health problem other than dental caries, but also that the FDA expected that consumption would decline between 1984 and 1990. In 1993, the FDA, in deciding not to include added sugars on the Nutrition Facts label, cited that review, but added that it would review the matter if consumption increased or if additional evidence about health concerns was produced. The FDA noted in 1993 that in 1982¹ the agency had said that:

it would monitor average daily consumption of these ingredients [sucrose, corn sugar, corn syrup, and invert sugar] and would reevaluate the safety of their use if total dietary consumption were to increase significantly. The agency concluded in those [1982] documents that there could be safety concerns if intake of these ingredients increased significantly over the current levels (approximately 50 gr).²

In fact, since that 1986 review, consumption of added sugars has increased almost every single year. Consumption is now about one-fourth more.

¹ The 1982 commitment to reevaluate added sugars was made in the FDA's proposals to affirm that sucrose, corn sugar, corn syrup, and invert sugar are generally recognized as safe ("GRAS"). 47 Fed. Reg. 53917 (November 30, 1982) at 53920 and 47 Fed. Reg. 53923 (November 30, 1982) at 53927.

99P-2630² 58 Fed. Reg. at 2221.

Furthermore, more and more researchers have expressed concern that heavy consumption of added sugars is contributing to the spectacular rise in obesity and that sugary foods (such as soft drinks and candies) are replacing more nutritious foods in the diet, leading to lower nutrient intakes and possibly to higher risks of chronic diseases ranging from osteoporosis to cancer.

The U.S. Department of Agriculture has pointed to the inadequacy of current labels and to the excessive consumption of added sugars. USDA has estimated that someone eating a 2,000-calorie diet that meets its recommendations for fruits, vegetables, grains, and other nutrient-rich foods would have room for ten teaspoons (40 grams) a day of added sugars. But USDA surveys find that the average consumption is *twice* that, or 20 teaspoons a day.

We urge the FDA to expedite action on this petition to take advantage of its opportunity and obligation under the Nutrition Education and Labeling Act to inform the public about the added-sugars content of foods.

Sincerely,

A handwritten signature in black ink that reads "Michael F. Jacobson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Michael F. Jacobson, Ph.D.
Executive Director

August 3, 1999

The Honorable Jane Henney, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

2788 '99 AUG -4 A7:46

Dear Commissioner Henney:

The undersigned support the petition filed by the Center for Science in the Public Interest (CSPI) asking the Food and Drug Administration to require "Nutrition Facts" labels to disclose the quantity of *added* sugars present in packaged foods and to set a Daily Reference Value (called a Daily Value on labels) for refined sugars added to foods.¹

When the FDA in 1993 issued the current nutrition-labeling regulations, it failed to require disclosure of added sugars and did not establish a Daily Value for added sugars, in part because no health authorities had issued quantitative recommendations on added-sugars intake. However, in 1996, the U.S. Department of Agriculture's "Food Guide Pyramid" recommended that Americans should limit their daily intake of added sugars to about ten teaspoons (40g) for a 2,000-calorie healthful diet (the less healthful the diet, the less room there is for added sugars). We urge the FDA to adopt USDA's recommendation as the Daily Value for added sugars. Without a %DV for added sugars, consumers could not compare the added-sugars content of a food to recommended daily intakes.

The FDA also said it could not determine by chemical analysis the added-sugars content of foods. However, chemists can determine the amount of added sugars in many foods; for other foods, the FDA could obtain information from the producers.

The FDA's 1993 labeling decision concerning sugars was based in part on the agency's 1986 literature review, which, in turn, was based in part on 1977-78 consumption data.² Since then, new information about sugars consumption and the health consequences of consuming excessive levels of added sugars necessitates a revision of the 1993 policy. For example:

1. Consumption of added sugars is soaring. According to data published by FDA and USDA data, since 1977-78 the contribution of calories from added sugars to the American diet jumped from 11 percent to 16 percent.³ In 1996, the *average* teenager got 20 percent of his or her calories from the added sugars in soft drinks, cakes, cookies, and other foods. That's about 34 teaspoons for boys and 24 teaspoons for girls.

2. Added sugars squeeze nutrients and more healthful foods out of the diet. New USDA data indicate that people who consume diets high in added sugars consume lower levels of protein; fiber; vitamins A, E, C, B-2, B-3, B-6, B-12, and folate; calcium; iron; zinc; and magnesium. They also consume fewer servings of grains, fruits, vegetables, meats, and dairy products than people who consume less added sugars.⁴ A healthful diet -- including fruits, vegetables, whole grains, and low-fat dairy products -- appears to lower the risk of cancer, heart disease, stroke, and osteoporosis. Yet a recent study by the National Cancer Institute found that only two percent of 2- to 19-year-olds met all of five federal recommendations for a healthy diet.⁵

3. Added sugars may contribute to obesity. Increasing consumption of foods high in added sugars may be contributing to the nation's epidemic of obesity because they are often calorie-dense. A recent review of clinical studies suggests that diets rich in calorie-dense foods promote obesity.⁶ It states "...when the fat content was controlled but the energy density varied, subjects ate a constant weight of food; therefore, the greater the energy density, the greater was the energy intake." Calorie-dense foods are typically high in fat and/or added sugars. For example, a Pepperidge Farm Black Forest Cake has 27 grams of sugar and a caloric density of 3.6 (290 calories per 2.9 oz.); a Cinnabon contains 49 grams of sugar and has a caloric density of 3.2 (670 calories per 7.5 ounces); an order of Burger King Cini-Minis with icing has 38 grams of sugar and a caloric density of 4.0 (530 calories per 4.7 ounces). Furthermore, soft drinks are the largest and fastest-growing source of added sugars in the average American's diet. New studies suggest that overweight children consume more soft drinks than their normal-weight counterparts and that people are less likely to compensate for excess calories consumed as liquid foods.^{7,8} An analysis of 1994 CSFII data found that school-age children who consumed non-diet soft drinks ingested more calories than children who did not consume soft drinks.

4. Added sugars may contribute to heart disease. Added sugars appear to raise triglyceride levels more than other carbohydrates, especially among people who are insulin-resistant.⁹ Elevated triglycerides may increase the risk of heart disease.

For those and other reasons, we urge the FDA to improve food labeling -- and the public's health -- by requiring disclosure of added sugars. While the naturally occurring sugars in fruit and dairy products may be chemically identical to added sugars, low-fat varieties of those foods clearly help prevent cancer, heart disease, stroke, osteoporosis and other diseases. In contrast, soft drinks, baked goods, candy, and other sources of added sugars may increase the risk of disease either by adding sugars to the diet or by displacing more nutritious foods from the diet.

It is vital that the FDA give consumers the information they need to reduce their intake of added sugars. Without added-sugars labeling, it is very difficult for consumers to know how much of those sugars has been added to yogurt, ice cream, puddings, frozen fruit bars, sorbet, canned or frozen fruit, fruit snacks, juice drinks, jams, breakfast cereals, cereal bars, muffins, cookies, and a host of other foods. Many of those products are marketed with claims like "made with real fruit," but they contain far more nutrient-devoid added sugars than nutrient-rich fruit.

Furthermore, the FDA should define claims such as "low in added sugars" and limit the added sugars in foods that make health claims or are labeled "healthy." The FDA currently limits other nutrients -- fat, saturated fat, cholesterol, and sodium -- in foods that make those claims.

Thank you for your prompt attention to this important public health matter. (Please respond to the cosigners by writing to the Center for Science in the Public Interest.)

Sincerely,

Individuals

Barbara Abrams, DrPH, RD
Associate Professor
School of Public Health
University of California, Berkeley
Berkeley, CA

George L. Blackburn, MD, PhD
Associate Professor in Nutrition Medicine
Harvard Medical School
Boston, MA

Gladys Block, PhD
Professor of Epidemiology,
Director, Public Health Nutrition Program
University of California, Berkeley
Berkeley, CA

Kelly D. Brownell, PhD
Professor of Psychology, Epidemiology, and
Public Health
Yale University
New Haven, CT

Brian A. Burt, BDS, MPH, PhD
Professor of Epidemiology
University of Michigan School of Public
Health
Ann Arbor, MI

William E. Connor, MD
Department of Medicine
Oregon Health Sciences University
Portland, OR

Isobel R. Contento, PhD
Professor and Coordinator
Program in Nutrition and Education
Teachers College, Columbia University
New York, NY

Caldwell B. Esselstyn, Jr., MD
Associate Professor, Department of Surgery
Cleveland Clinic
Cleveland, OH

William J. Evans, PhD
Professor of Geriatrics, Nutrition, and
Physiology
University of Arkansas for Medical Sciences
North Little Rock, AR

Rose E. Frisch, PhD
Associate Professor of Population Sciences
Emerita
Harvard School of Public Health
Cambridge, MA

Christopher Gardner, PhD
Research Associate
Stanford University School of Medicine
Palo Alto, CA

Edward Giovannucci, DSc, MD
Assistant Professor of Medicine
Harvard Medical School
Boston, MA

Joan Dye Gussow, EdD
M. S. Rose Professor Emeritus
Teachers College, Columbia University
New York, NY

Lisa Harnack, DrPH
Assistant Professor, Division of
Epidemiology
University of Minnesota
Minneapolis, MN

Stephen Havas, MD, MPH, MS
Professor, Department of Epidemiology and
Preventive Medicine and Department of
Medicine
University of Maryland School of Medicine
Baltimore, MD

Jerianne Heimendinger, ScD, MPH, RD
Research Scientist
Department of Behavioral Research
AMC Cancer Research Center
Denver, CO

Amid I. Ismail, DDS
Professor, Cariology, Restorative Sciences,
and Endodontics
University of Michigan

Norman M. Kaplan, MD
Professor of Internal Medicine
University of Texas Southwestern Medical
Center
Dallas, TX

David L. Katz, MD, MPH
Director, Yale-Griffin Prevention Research
Center
Griffin Hospital
Derby, CT

William T. Kniker, MD
Clinical Professor of Pediatrics and Internal
Medicine
University of Texas Health Science Center
San Antonio, TX

Georgia Kostas, MPH, RD, LD
Director of Nutrition
Cooper Clinic
Dallas, TX

Ronald M. Krauss, M.D.
Senior Scientist; Head, Department of
Molecular Biology
Lawrence Berkeley Laboratory
University of California at Berkeley
Berkeley, CA

JoAnn E. Manson, MD, DrPH
Co-Director of Women's Health, Division of
Preventive Medicine
Brigham and Women's Hospital/Harvard
Medical School
Boston, MA

Sheldon Margen, MD
Professor of Public Health, Emeritus
University of California, Berkeley
Berkeley, CA

Michael Miller, MD, FACC
Associate Professor of Medicine
Director for Preventive Cardiology
University of Maryland Hospital
Baltimore, MD

Barbara J. Moore, PhD
President and CEO
Shape Up America!
Bethesda, MD

Marion Nestle, PhD
Professor and Chair
Department of Nutrition and Food Studies
New York University
New York, NY

Steven Parker, MD
Director, Division of Behavioral Pediatrics
Boston Medical Center
Boston, MA

Hilary A. Perr, MD
Assistant Professor
Department of Pediatric Gastroenterology,
Hepatology, and Nutrition
University of California
San Francisco, CA

Eric B. Rimm, ScD
Associate Professor of Epidemiology and
Nutrition
Harvard School of Public Health
Boston, MA

Frank Sacks, MD
Associate Professor of Medicine,
Harvard Medical School; Associate
Professor in the Department of Nutrition,
Harvard School of Public Health
Boston, MA

Laura S. Sims, PhD, MPH, RD
Professor of Human Nutrition
University of Maryland
College Park, MD

Mary Story, PhD
Professor, Division of Epidemiology
University of Minnesota
Minneapolis, MN

Patience H. White, MD
Chair, Bone Health Clinic
Chair, Pediatric Rheumatology
Childrens National Medical Center
Washington, DC

Organizations

American Association for Health Education

American Association of Family &
Consumer Sciences

American Chiropractic Association Council
on Nutrition

American Chiropractic Board of Nutrition

American College of Preventive Medicine

American Medical Student Association

American Public Health Association

American Society of Bariatric Physicians

Association of Schools of Public Health

Association of State and Territorial Chronic
Disease Program Directors

Association of State and Territorial Nutrition
Directors

Cancer Research Foundation of America

Center for Communications, Health and the
Environment

Child Health Foundation

The Children's Foundation

Citizens for Public Action on Blood Pressure
and Cholesterol

Consumer Federation of America

Cornell University Medical College Nutrition
Information Center

Girl Scouts of the USA

Harlem Consumer Education Council

International SPA Association

Meals on Wheels Association of America

National Association of School Nurses

National Association of WIC Directors

Oldways Preservation and Exchange Trust

National Black Nurses Association

Pacific Health Education Center

National Black Women's Health Project, Inc.

People's Medical Society

National Consumers League

Produce for Better Health Foundation

National Council of Senior Citizens

Produce Marketing Association

National Education Association's Health
Information Network

Shape Up America!

National Student Nurses Association

Texas Dept. of Health, Bureau for Disease
and Injury Prevention, Chronic Disease
Community and Worksite Wellness Program

National Women's Health Network

YMCA of the USA

Endnotes

1. DHHS and USDA noted in "Dietary Guidelines for Americans" (p. 34) that added sugars include brown sugar, corn sweetener, corn syrup, fructose, fruit juice concentrate, glucose (dextrose), high-fructose corn syrup, honey, invert sugar, lactose, maltose, molasses, raw sugar, [table] sugar (sucrose), and syrup. "Added sugars" does not include sugars that occur naturally in foods such as fruit and milk.
2. Glinsmann WH, Irausquin H, Park YK. "Evaluation of health aspects of sugars contained in carbohydrate sweeteners." *J Nutr.* 1998;116(11S):S1-S216
3. Glinsmann WH, Irausquin H, Park YK. "Evaluation of health aspects of sugars contained in carbohydrate sweeteners." *J Nutr.* 1998;116(11S):S1-S216. USDA, Agricultural Research Service. 1997. Pyramid Servings Data: Results from USDA's 1995 and 1996 Continuing Survey of Food Intakes by Individuals, [Online]. ARS Food Surveys Research Group. Available (under "Releases") <<http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm>> (visited Oct. 7, 1998).
4. Testimony by Rachel Johnson, Dietary Guidelines Advisory Committee Meeting, Washington, D.C., March 9, 1999, p. 364.
5. Munoz KA, Krebs-Smith SM, Ballard-Barbash R, et al. "Food intakes of U.S. children and adolescents compared with recommendations." *Pediatrics.* 1997;100:323-9. 1998;101:952-3.
6. S.B. Roberts et al. "Physiology of fat replacement and fat reduction: effects of dietary fat and fat substitutes on energy regulation," 56 *Nutrition Reviews* S29-41 (1998).
7. Personal communication from Troiano RP. *Am J Clin Nutr* (forthcoming).
8. Harnack L, et al. "Soft Drink Consumption Among U.S. Children and Adolescents: Nutritional Consequences." *J Am Diet Asso.* 1999;99:436-41.
9. Daly ME, et al. "Dietary Carbohydrates and Insulin Sensitivity: A Review of the Evidence and Clinical Implications." *Am J Clin Nutr.* 1997;66:1072-85. Hollenbeck CB. "Dietary Fructose Effects on Lipoprotein Metabolism and Risk for Coronary Artery Disease." *Am J Clin Nutr.* 1993; 99:800S-809S; Frayn KN, et al. "Dietary Sugars and Lipid Metabolism in Humans." *Am J Clin Nutr.* 1995;62:250S-261S.

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

Petition for Proposed Rulemaking) 2789 '99 AUG -4 A7:46
to Establish a Daily Reference Value for) Docket No. _____
"Added Sugars," to Require Nutrition)
Labeling of "Added Sugars," and to Make)
Corresponding Changes to Nutrient Content)
and Health Claim Regulations)

Submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

August 3, 1999

Michael F. Jacobson, Ph.D.
Executive Director
1875 Connecticut Ave. NW #300
Washington, D.C. 20009-5728
202-332-9110

CONTENTS

	Page
I. PRELIMINARY STATEMENT	1
II. ACTION REQUESTED	4
III. STATEMENT OF FACTUAL GROUNDS	9
A. Introduction	9
B. Health experts have made recommendations for appropriate intakes of added sugars ...	10
C. New information invalidates the reasons given by the FDA in 1993 for not establishing a daily reference value and requiring nutrition labeling for added sugars	13
(1) Contrary to the FDA's 1993 conclusion, there is a public health interest in reducing the consumption of added sugars	13
(a) Americans are consuming substantially more added sugars since the FDA's reviews in 1986 and 1993	14
(b) Added sugars have different nutritional consequences compared to naturally occurring sugars, because of the foods in which they occur	19
(i) Fruit	21
(ii) Low-fat dairy products	21
(c) Foods high in added sugars squeeze more healthful foods out of the diet	23
(d) Added sugars increase blood-triglyceride levels and the risk of heart disease ..	29
(i) Sugars increase blood triglyceride levels in certain individuals	30
(ii) Elevated blood triglycerides appears to be an independent risk factor for coronary heart disease	35
(e) Added sugars contribute to obesity	39
(f) Added sugars contribute to tooth decay	44
(2) Contrary to the FDA's 1993 conclusion, there are ways to enforce regulations requiring disclosure of added sugars	47

(a) Analytical methods can distinguish added sugars from naturally occurring sugars in many foods	47
(b) The enforcement of several existing FDA regulations requires distinguishing added sugars from naturally occurring sugars	51
(i) Sugars in ingredient lists	51
(ii) Claims such as “no added sugar”	51
(iii) Percentages of fruit or vegetable juice	52
(iv) Standards of identity	52
(3) Contrary to the FDA’s 1993 conclusion, consumers would not be misled by information about added sugars	54
(4) The FDA’s conclusion in 1993 that naturally occurring sugars and added sugars have the same physiological impact ignores the adverse health impact of diets high in added sugars	56
(5) The FDA’s conclusion in 1993 that there is no consensus on a daily reference value for added sugars ignored important information, which has been buttressed by new information	58
D. Consumers need a disclosure of both the amount of added sugars and the “%DV” to help them gauge their added-sugars intake against recommended levels	60
(1) Consumers need a disclosure of the amount of added sugars	60
(2) Consumers need a disclosure of the “%DV”	62
E. Nutrient-content and health claims about added sugars should be held to the same standards as claims about fat, saturated fat, cholesterol, and sodium	63
IV. STATEMENT OF LEGAL GROUNDS	66
A. In 1990 Congress decided that to assist consumers in maintaining healthy diets, the FDA should ensure that its nutrition-labeling regulations are consistent with new research and other information	66
B. In 1993 the FDA decided that using a “%DV” disclosure best complied with its Congressional mandate to present nutrition information in a way that facilitates the public’s understanding	68

C. Congress directed the FDA to prohibit nutrient-content, and health claims on food labels unless they are made in accordance with regulations issued by the Secretary 69

V. CONCLUSION 70

VI. ENVIRONMENTAL IMPACT 71

VII. ECONOMIC IMPACT 71

VIII. CERTIFICATION 71

Exhibits

1. Letter to FDA in support of petition
2. Proposed label
3. Added sugar contained in 28 different foods
4. Comparison of trends in consumption of milk and soda
5. Some current labels

August 3, 1999

Dockets Management Branch
United States Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

I. PRELIMINARY STATEMENT

In 1982, the Food and Drug Administration (“FDA”) proposed to affirm that various added sugars -- corn sugar, corn syrup, invert sugar, and sucrose -- posed no risk to public health at the levels that were then being consumed.¹ At that time the FDA said: “The agency *will* undertake a new safety evaluation if total dietary consumption increases significantly.”² [emphasis added]

The *per capita* consumption of added sugars³ has risen by 28 percent since 1983. The Center for the Science in the Public Interest (“CSPI”)⁴ and other organizations, researchers, and

¹ 47 Fed. Reg. 53917 (November 30, 1982) and 47 Fed. Reg. 53923 (November 30, 1982). The FDA determined that corn sugar, corn syrup, invert sugar, and sucrose are generally recognized as safe as direct human food ingredients. See 21 C.F.R. §§ 184.1854-184.1865.

² 47 Fed. Reg. at 53920 and 47 Fed. Reg. at 53927.

³ Caloric sweeteners include cane and beet sugar, high-fructose corn syrup, glucose, dextrose, edible syrups (sorgo, maple and sugarcane syrup, edible molasses, and edible refiner’s syrup), and honey. USDA, Economic Research Service. *Food Consumption, Prices, and Expenditures, 1970-97* (1999) at 76. USDA, Economic Research Service, *Sugar and Sweetener*. Publication SSS-225, May 1999, at 87 (Table 59).

⁴ Petitioner Center for Science in the Public Interest, a nonprofit organization based in Washington, D.C., is supported by approximately one million members 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.

nutritionists⁵ believe that the time has come for the FDA to honor that commitment by initiating a rulemaking to establish a Daily Reference Value (“DRV”) for added sugars, to require nutrition labeling of added sugars, and to make corresponding changes to regulations regarding nutrient-content and health claims.

Reducing the consumption of added sugars is an essential public health measure. Diets high in added sugars -- from such foods as soft drinks, fruit drinks, candy, cakes, and cookies -- squeeze healthier foods out of the diet, thereby displacing foods that provide nutrients that reduce the risk of osteoporosis, cancer, heart disease, stroke, and other health problems. In some people, diets rich in added sugars contribute to obesity, the prevalence of which has risen dramatically in the last two decades in both youths and adults. Obesity, in turn, increases the risk of diabetes, heart disease, high blood pressure, and other health problems. In people who are “insulin resistant,” high intakes of added sugars increase levels of blood triglycerides, which may increase the risk of heart disease. In addition, frequent consumption of foods rich in added sugars promote tooth decay.

Using current labels, it is impossible for consumers to determine how much sugar has been added to foods such as yogurt, ice cream, puddings, frozen fruit bars, sorbet, canned or frozen fruit, fruit snacks, juice drinks (beverages, cocktails, etc.), jams, jellies, breakfast cereals, cereal bars, blueberry (or other fruit) muffins, and raisin (or other fruit) cookies. In addition, current labels fail to inform consumers how much of a reasonable day’s intake of added sugars a serving of any food -- from ice cream to soda pop -- provides.

Action by the FDA is necessary to help consumers monitor -- and, if appropriate, reduce

⁵ See Exhibit 1 for a letter to the FDA from organizations, researchers, and nutritionists who support the thrust of this petition.

-- their added-sugars consumption. Though the U.S. Department of Agriculture (“USDA”) provided quantitative dietary recommendations for added sugars in *The Food Guide Pyramid* (“*Pyramid*”), without labeling of added sugars it is difficult for consumers to follow such recommendations. In 1999, the USDA recognized that Americans were consuming far more added sugars than can fit into a healthy diet and observed that the current nutrition label is not as helpful as it could be. USDA stated that “Added sugar consumption exceeds dietary targets” and that:

The ability of consumers to moderate their consumption of added sugars and sweeteners is complicated by the fact that many added sweeteners are likely to be “hidden” in prepared foods....the [food] label does not distinguish total from added sugars, which may sometimes make it difficult for consumers to determine how much added sugar they are actually consuming.⁶

Action by the FDA is also necessary to comply with the bipartisan judgment of Congress when it passed the law mandating nutrition labeling on packaged foods. Section 2(a) of the Nutrition Labeling and Education Act of 1990 (“NLEA”)⁷ directs the Secretary of Health and Human Services to require labeling information about any specific nutrient if the Secretary determines that such information “will assist consumers in maintaining healthy dietary practices.” The FDA should recognize that good dietary practices can promote general health and should not insist that to be listed on labels nutrients must be directly linked to specific illnesses such as cancer and heart disease.

While we recognize that there are costs involved when food labels are changed, we

⁶ Frazao E, ed. Economic Research Service, USDA. *America’s Eating Habits: Changes and Consequences* (1999). Agriculture Information Bulletin No. 750, at 87-8.

⁷ 21 U.S.C. § 343(q)(2).

believe the action requested here⁸ represents a critical public health measure to give consumers the tools they need to reduce their intake of added sugars and that the compliance costs are reasonable in light of the public health benefits. In any case, the costs of adding an additional line to the food label would generally be modest (some producers of cereals already voluntarily include a line disclosing the amount of “other carbohydrates,” and some companies list many more nutrients than are required to be listed).⁹ Moreover, the costs of complying with the regulations requested in this petition would, of course, be reduced greatly if the FDA required the changes we request be implemented at the same time as other changes.

II. ACTION REQUESTED

Specifically, CSPI requests that the FDA establish a Daily Reference Value (“DRV”) for “added sugars” of 40 grams and require a mandatory disclosure of added sugars in both grams per serving and % Daily Value, i.e., the percentage of that DRV. (See Exhibit 2 for a mock-up of the proposed label.) CSPI also requests corresponding changes to the FDA’s labeling regulations prescribing nutrient-content and health claims.

Those actions will require changes in the FDA’s nutrition-labeling regulations that include but are not limited to the following:

1. After 21 C.F.R. § 101.9(c)(6)(ii) -- dealing with nutrition labeling of sugars in food -- add a new subsection (iii) and renumber accordingly:

“(iii) ‘Added sugars’: A statement of the number of grams of added sugars, as defined in

⁸ This petition is submitted pursuant to section 4(e) of the Administrative Procedure Act, 5 U.S.C. § 553(e), and 21 C.F.R. §§10.25 and 10.30.

⁹ This voluntary disclosure is authorized by 21 C.F.R. § 101.9(c)(6)(iv).

21 C.F.R. § 101.60(c)(2)(i)-(iii),¹⁰ in a serving, except that label declaration of added-sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about added sweeteners, added sugars, or added sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the added-sugars content is not required and, as a result, not declared, the statement ‘Not a significant source of added sugars’ shall be placed at the bottom of the table of nutrient values in the same type size. Added-sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ‘contains less than 1 gram’ or ‘less than 1 gram’ may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.”

2. In 21 C.F.R. § 101.9(c)(9) -- dealing with DRVs -- add the following to the table: under the food component column add “added sugars”; under the unit-of-measurement column add “grams (g)”; and under the DRV column add “40”.

3. In 21 C.F.R. § 101.9(d)(9) -- dealing with DRVs for diets of 2,000 and 2,500 calories -- add the following to the table after the “dietary fiber” line: under the food-component column add “added sugars”; under the 2,000 column add “40 g”; and under the 2,500 column add “60”.

4. In 21 C.F.R. §§ 101.9(d)(12), (13) and 101.9(e)(5) -- dealing with alternative sample labels -- in the sample label in section 101.9(d)(12) change “Sugars” to “Total Sugars” and add a line after “sugars” stating “Added Sugars 3 g 8%”; in the sample label in section 101.9(d)(13)

¹⁰ In 1993 the FDA explained that stripped fruit juice is a juice-derived, rather than sugar-derived, sweetening ingredient “whose nutrient profile has been diminished to a level below the normal nutrient range for the juice.” 58 Fed. Reg. at 2922-23. We believe that stripped juices, as defined in 21 C.F.R. §102.33(f), are included in the FDA’s current definition of added sugars.

We note that a more encompassing definition -- which includes oligosaccharides from corn syrup -- is provided in USDA and HHS's *Dietary Guidelines for Americans* (1995) at 33-4.

delete “Sugars” and add a line after “Dietary Fiber” stating “Added Sugars 8 g 20% 6 g 153% 13 g 33%”; and in the sample label in section 101.9(e)(5) delete “Sugars” and add a line after “Dietary Fiber” stating “Added Sugars 6 g 15% 15%”.¹¹

5. In 21 C.F.R. § 101.9(f) -- dealing with a simplified format -- add “Added Sugars,” after the word “Sugars” throughout.

6. In 21 C.F.R. §§ 101.9(g)(5) and(6) -- dealing with compliance -- add “added sugars,” after “sugars”.

7. In 21 C.F.R. § 101.13(h) -- dealing with disclosure of additional nutrient information for certain foods making a nutrient claim -- in the first sentence of subsection (1) after “cholesterol,” add “8.0 grams of added sugars,”; in the first sentence of subsection (2) after “cholesterol,” add “16.0 grams of added sugars,”; and in the first sentence of subsection (3) after “cholesterol,” add “12.0 grams of added sugars.”¹²

8. In 21 C.F.R. § 101.14(a)(4) -- prohibiting health claims for certain foods -- in the first sentence after “cholesterol,” add “added sugars,” and in the second sentence after “cholesterol,” add “8.0 grams of added sugars,”;¹³ in subsection (i) -- dealing with a meal product -- after “cholesterol,” add “16.0 g of added sugars,”; and in subsection (ii) -- dealing with a main dish product -- after “cholesterol,” add “12.0 g of added sugars.”

¹¹ If all the sugar in the food is “added sugars,” there is no need for a “Total Sugars” line.

¹² This provision has separate parts dealing with food, “a meal product,” and “a main dish product.” For each of those parts we apply the same percentage of the DRV -- 20 percent, 40 percent, and 30 percent respectively -- for added sugars as is now used for fat, saturated fat, cholesterol, and sodium.

¹³ We apply a standard of 20 percent of the DRV for added sugars, which is the same standard currently used for fat, saturated fat, cholesterol, and sodium in this provision.

9. In 21 C.F.R. § 101.60(c) -- dealing with sugar-content claims -- add after subsection (4) a new subsection (5) and renumber accordingly:

“(5) the terms ‘low added sugars,’ ‘few added sugars,’ ‘contains a small amount of added sugars,’ ‘low source of added sugars,’ or ‘low in added sugars’ may be used on the label or in labeling of foods, except meal products as defined in subsection 101.13(1) and main dish products as defined in subsection 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 2.0 grams of added sugars per reference amount customarily consumed;¹⁴ or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 2.0 grams of added sugars per reference amount customarily consumed and per 50 g (for dehydrated food that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in subsection 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the ‘as prepared’ form).

(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the added-sugars content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(iii) The terms defined in paragraph (c)(5) of this section may be used on the label or in labeling of meal products as defined in § 101.13(1) or main dish products as defined in

¹⁴ We apply a standard of 5 percent of the DRV for added sugars, as the current standard applies 5 percent of the DRV for fat and saturated fat, 5.8 percent of the DRV for sodium, and 6.8 percent of the DRV for cholesterol.

§ 101.12(m) provided that:

(A) the product contains 2.4 g of added sugars or less per 100 g;¹⁵ and

(B) if the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the added sugar content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which it attaches.”

10. In 21 C.F.R. § 101.60 (c)(5) -- dealing with when reduced-sugar or less-sugar claims can be made about the sugar content of a food -- add “or added sugar” each time after “sugar” and add a new “and (iii) if the total amount of all sugars in the food does not meet the requirements for ‘reduced’ or ‘less’ in subsections (i) and (ii), then the claim shall contain the statement ‘not reduced in total sugars’.”

11. In 21 C. F. R. § 101.65(d) -- dealing with “healthy” food claims -- make the following two changes:

(a) After subsection 101.65(d)(2)(iii) -- dealing with general “healthy” food claims -- add a new subsection and renumber accordingly:

“(iv) Added sugars are not present at a level exceeding the disclosure level described in §101.13(h);” and

(b) After subsection 101.65(d)(4)(iii) -- dealing with “healthy” claims for main-dish and meal products -- add a new subsection and renumber accordingly:

“(iv) Added sugars are not present at a level exceeding 12 grams per labeled serving.”

¹⁵ We apply a standard of 6 percent of the DRV, as that is the standard applied for “low” for calories. 21 C.F.R. § 101.60(b)(3)(i).

III. STATEMENT OF FACTUAL GROUNDS

A. Introduction

In early 1993 the FDA promulgated final regulations for nutrition labeling, as required by the NLEA.¹⁶ At that time, the FDA decided against establishing a DRV for added sugars and requiring nutrition labeling of added sugars.

The FDA should now amend its food-labeling regulations to provide consumers with badly needed guidance on added sugars. The FDA should amend those regulations by embodying USDA's quantitative recommendation in the form of a DRV for added sugars of 40 grams and requiring an "added sugars" declaration in the Nutrition Facts label. The FDA also should amend its regulations dealing with nutrient-content and health claims so as to treat added sugars in the same way as other nutrients that are associated with health problems are treated.

Those amendments are essential because, as discussed below, the consumption of added sugars currently is far higher than recommended and is projected to rise even higher. New data from the USDA indicate that people who consume diets high in added sugars consume lower levels of a wide variety of nutrients. Those people also consume fewer servings of grains, fruits, vegetables, meats, and dairy products than people who consume less added sugars. By displacing protective nutrients and foods in the diet, added sugars may increase the risk of osteoporosis, cancer, high blood pressure, heart disease, and other health problems. Other research has indicated that consuming a diet high in added sugars can, in some "insulin-resistant" individuals, increase blood-triglyceride levels. Those higher levels, in turn, may increase the risk of coronary heart disease. And, of course, other research has demonstrated that added sugars promote dental caries.

¹⁶ P. L. 101-535.

Furthermore, the incidence of obesity has increased dramatically over the last two decades. During that time, calorie intakes also rose, due partly to an increase in the consumption of added sugars. Recent studies suggest that people do not compensate as efficiently for excess calories consumed as liquid as for those consumed as solids. That finding suggests that soft drinks, the single biggest source of added sugars, and fruit drinks, the third largest source of added sugars, have contributed to the rise in obesity. Additional research indicates that calorie-dense foods, which are typically high in sugar and/or fat, contribute to obesity. Those and other findings suggest that the recent increase in added-sugars consumption has contributed to the increased rates of obesity.

The FDA should comply with the Congressional intent that the FDA's labeling regulations be consistent with new research and other information. As discussed below, the new research and other information has invalidated each of the reasons given by the FDA in 1993 for not establishing a DRV and not requiring nutrition labeling for added sugars.

B. Health experts have made recommendations for appropriate intakes of added sugars.

In 1977, based on advice from its academic consultants and expert witnesses, the Senate Select Committee on Nutrition and Human Needs recommended that people limit their intake to ten percent of calories (see Section III.C(5) below).¹⁷ In the next 15 years, health agencies in numerous other nations developed similar guidelines. The average recommendation was to reduce consumption of added sugars to 10 percent of calories. (See II.C.(5) below.)

In 1990, the World Health Organization (WHO), in *Diet, Nutrition and the Prevention of*

¹⁷ *Dietary Goals for the United States*, second edition, December, 1977, at 27-34.

Chronic Diseases, provided one of the first quantitative recommendations for consumption levels of added sugars.¹⁸ The WHO recommended that consumption of those sugars be limited to 10 percent of calories, or 50 grams per day for someone consuming 2,000 calories. The WHO was concerned about added sugars because of their ability to cause dental caries and because “free sugars” provide energy without associated nutrients and hence displace nutrient-containing foods.

In 1992, the USDA offered the American public a more sophisticated recommendation for added-sugars intake in *Food Guide Pyramid*.¹⁹ *Pyramid*'s advice to consumers is based on nutrition research at the USDA and HHS and is designed to give consumers information on choosing a diet that will promote better health and reduce the risks of certain diseases.

Pyramid recommends that Americans consuming 1,600 calories a day should “try to limit” their consumption of added sugars to 6 teaspoons (about 24 g), people consuming 2,200 calories a day should limit their added sugars to 12 teaspoons (48 g), and people consuming 2,800 calories should limit their added sugars to 18 teaspoons (72 g).²⁰ By interpolation, the recommendation for a 2,000-calorie diet is 10 teaspoons (about 40 g). Those recommendations recognize that someone who consumes fewer calories has less room in his or her diet for the empty calories provided by added sugars, and that someone who consumes large quantities of

¹⁸ World Health Organization. *Diet, Nutrition, and the Prevention of Chronic Diseases*. Tech. Rep. Series 797, 1990, at 113.

¹⁹ USDA, Center for Nutrition Policy and Promotion. *USDA's Food Guide Pyramid* (April, 1992). That pamphlet, revised slightly in 1996 [hereafter referred to as *Pyramid*], lists the content of added sugars in each of 28 different foods (see Exhibit 3). Those foods are a sample of the information the USDA has collected about the amounts of added sugars and other nutrients in about 6,000 foods.

²⁰ *Ibid.* at 17.

calories, such as a teenage boy, should have more room for the pure energy provided by added sugars. Thus, the suggested limits for a 1,600-calorie represents 6 percent of calories; the suggested limit for a 2,000-calorie represents 8 percent of calories (by interpolation); the suggested limit for a 2,200-calorie represents 9 percent of calories; and the suggested limit for a 2,800-calorie diet represents 10 percent of calories.

The 1992 recommendation was reaffirmed in the 1996 edition of the *Pyramid*, which states on the first page that complying with that 40-gram 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.”²¹ While various Federal agencies and private health organizations had previously used generalities -- “moderation” or “avoid too much sugar” -- of limited utility, the *Pyramid* was the first time that a Federal agency issued a *quantitative* recommendation. The recommended levels are both warranted and reasonable.

To derive its quantitative recommendations, USDA calculated the number of calories in a diet of given calories that come from the recommended number of servings of each nutrient-bearing food group (i.e., bread, vegetable, fruit, milk, and meat groups). USDA assumed that the foods are in their lowest-fat form and contain no added sugars. Then USDA adjusted the diet to contain 30 percent of calories from fat. To determine the quantity of added sugars that could be added to the diet, USDA calculated the difference between the total-calorie level of the diet and the calories provided by the recommended servings from the nutrient-bearing food groups with the adjusted fat intake.

²¹ USDA, Center for Nutrition Policy and Promotion. *The Food Guide Pyramid* (October, 1996).

C. New information invalidates the reasons given by the FDA in 1993 for not establishing a daily reference value and requiring nutrition labeling for added sugars.

In 1993, the FDA issued final regulations for nutrition labeling,²² but rejected CSPI's request that a DRV for added sugars be established.²³ As discussed below, none of the reasons given by the FDA for rejecting CSPI's request remains valid in light of current information.

(1) Contrary to the FDA's 1993 conclusion, there is a public health interest in reducing the consumption of added sugars.

In 1993 the FDA concluded that "Other than dental caries -- the incidence of which has been declining considerably among the American population -- no public health concern [relating to consumption of added sugars are] articulated by the comment [from a consumer group] or in the relevant reports."²⁴

As discussed below, consumption of added sugars has been increasing significantly in recent years. That increase may be squeezing health-promoting foods, such as fruits, vegetables, and low-fat dairy foods, out of the diet. The displacement of those foods -- and the vitamins, minerals, fiber, and phytochemicals they contain -- contributes to a variety of chronic diseases. If those added sugars lead to caloric intakes that exceed caloric expenditures, obesity, with its various sequelae, is a likely consequence. In recent years, evidence has accumulated that heavy consumption of added sugars can raise blood-triglyceride levels, which may increase the risk of

²² 58 Fed. Reg. 2070-2964 (January 6, 1993).

²³ CSPI suggested a DRV of 50 grams based on a 1986 FDA study estimating that the average daily per capita consumption of added sugars was 53 grams.

²⁴ 58 Fed. Reg. at 2221.

heart disease. The consequences of heavy consumption of added sugars may be particularly detrimental to certain segments of the population, including insulin-resistant individuals; children and teenagers; people who consume few fruits, vegetables, and whole grains; and people prone to obesity and tooth decay.

(a) Americans are consuming substantially more added sugars since the FDA's reviews in 1986 and 1993.

One of the reasons given by the FDA in January 1993 for not requiring the disclosure of added sugars was that -- based on then-current levels of sugar consumption and a special review conducted by the agency in the mid-1980s -- "FDA concluded that other than the contribution to dental caries, there is no conclusive evidence that demonstrates that sugars intake from any source is associated with chronic disease conditions."²⁵ The FDA's 1986 sugars report estimated that in 1977-78 Americans consumed 11 percent of calories from added sugars and predicted that *per capita* availability of sweeteners would *decline* slowly between 1984 and 1990.²⁶ Similarly, in a detailed analysis of added-sugars intake based on its 1977-78 Nationwide Food Consumption Survey, USDA estimated that the average American was getting 12 percent of calories from added sugars, with teenagers and some younger children averaging as much as 13 percent to 15 percent of calories from added sugars.²⁷

²⁵ 58 Fed. Reg. at 2221.

²⁶ Glinsmann WH, *et al.* "Evaluation of health aspects of sugars contained in carbohydrate sweeteners. Report from FDA's Sugars Task Force, 1986." *J Nutr.* 1986;116 (11S):S1-S216.

²⁷ Woteki CE, Welsh SO, Raper N, *et al.* "Recent trends and levels of dietary sugars and other caloric sweeteners." In *Metabolic Effects of Utilizable Dietary Carbohydrates*. Reiser S., Ed. (New York and Basil: Marcel Dekker Inc., 1982), 1-27.

Data not available to the FDA in 1993 show that *per capita* consumption of added sugars has increased markedly since 1977-78 and the mid-1980s. While *per capita* consumption, as reflected in “disappearance” data, of caloric sweeteners rose by only 4 percent between 1970 (122.3 pounds) and 1986 (127.0) pounds, it increased by 23 percent between 1986 and 1998 (155.6 pounds).²⁸

Furthermore, USDA’s 1997 *Pyramid Servings Data* indicates that in 1996 the average American consumed 16 percent of calories from added sugars, as compared to the 11 percent or 12 percent in 1977-78.²⁹ *Pyramid Servings Data* indicates that in 1996 the average American consumed 1,969 calories per day and 20.1 teaspoons of sugar (*twice* what *Pyramid* recommends).³⁰ The average teenager consumed 20 percent of calories from added sugar. Males 12 to 19 consumed an average of 2,739 calories and almost 34 teaspoons of sugar. Females 12 to 19 consumed 1,809 calories and almost 24 teaspoons of sugar. Indeed, in 1996 the average

²⁸ USDA, Economic Research Service. *Food Consumption, Prices, and Expenditures, 1970-97* (1999) at 76. USDA, Economic Research Service, *Sugar and Sweetener*. Publication SSS-225, May 1999, at 87 (Table 59).

²⁹ Cleveland LE, *et al.* *Pyramid Servings Data: Results from USDA’s 1996 Continuing Survey of Food Intakes by Individuals* (USDA Agricultural Research Service, Beltsville Human Nutrition Research Center, 1997) at 26 (Table 6). “Added sugars” include “white sugar, brown sugar, raw sugar, corn syrup, honey, molasses, and artificial sweeteners containing carbohydrate that were eaten separately or used as ingredients in processed or prepared foods such as breads, cakes, soft drinks, jams, and ice cream.”

³⁰ The 20-teaspoon figure is inflated by about 0.5 teaspoons due to sugars that are consumed by yeast in bread and rolls. That assumes that 75% of sugars in bread are eliminated by yeast or Maillard reaction, that 100 g of bread is made with 1.3 teaspoons of sugars, and that the average consumption of yeast breads and rolls is 50 g/d/person. Personal communication, Linda Cleveland, Agricultural Research Service, USDA, July 7, 1999, and <<http://www.barc.usda.gov/bhnrc/foodsurvey/pdf/Csfii3yr.pdf>> [accessed July 7, 1999].

teenager got nine percent of his or her calories just from the sugars in soda pop.³¹ Teenagers, even though they have larger calorie intakes and commensurately larger sugar allowances, also consumed about *twice* as much added sugars as USDA advises.

Two-day intake data from USDA's Continuing Survey of Food Intakes of Individuals ("CSFII") for 1994-96³² indicate that the percentage of calories from added sugars is extremely high in some segments of the population:

- * Among individuals aged 2 and over, the median intake of added sugars accounted for 14 percent of calories. (The mean intake was 16 percent of calories from added sugars.) However, 25 percent of the population consumed 21 percent or more of their calories from added sugars, and 5 percent of the population got 32 percent or more of their calories from added sugars.
- * Among children aged 6 to 11, median intake of added sugars was 18 percent of calories. However, 25 percent of this age group consumed 24 percent or more of their calories from added sugars, and 5 percent got 32 percent or more of their calories from added sugars.
- * Among aged 12 to 19, median intake of added sugars was 19 percent of calories. However, 25 percent of teens consumed 25 percent or more of their calories from added sugars, and 5 percent consumed 37 percent or more of their calories from added sugars.

Several considerations make it likely that the impact of added sugars on the diet and on health is greater than even those troubling figures indicate. First, *Pyramid's* recommendations for added sugars presume that consumers have eaten the recommended quantities of fruits, vegetables, and other nutritious foods and obtained only 30 percent of their calories from fat.³³

³¹ Michael Jacobson, *Liquid Candy* (Washington, D.C.: CSPI, 1998). Diet sodas, which provide no calories, constitute only 4% of soft-drink consumption by teenage boys and 11% by teenage girls. Footnote 17.

³² Personal communication, from Shanthy Bowman, USDA/ARS, July 29, 1999.

³³ USDA, Human Nutrition Information Service. "USDA's Food Guide: background and development." Misc. Pub. No. 1514, Sept., 1993, at 14.

In fact, the vast majority of Americans does not consume such a diet and should consume even *less* added sugars than the USDA recommended.³⁴

Second, it is widely recognized that dietary-recall surveys, such as CSFII on which *Pyramid Servings Data* is based, generally underestimate actual food intakes, particularly of fat and added sugars:

- A Medical Research Council study in Cambridge, UK found: “Available evidence suggests that fat and sucrose are under reported, but not micronutrients such as vitamin C.”³⁵
- A study conducted by the United Fresh Fruit and Vegetable Association that compared food diaries from 2,000 households with consumers’ self-reported food intake found that consumers overestimated fruit and vegetable consumption by up to one-third and underestimated consumption of fats and sweets by one-half.³⁶

Third, USDA, using adjusted disappearance data, finds that the CSFII dietary recalls may underestimate sugar intake. USDA estimates that total disappearance of added sugars is 53 teaspoons per day.³⁷ Because some of that sugar is wasted (by retailers, consumers, or food service) or lost due to other reasons (exported in processed foods, fermented in bread, etc.),³⁸ the

³⁴ Krebs-Smith SM, Cleveland LE, Ballard-Barbash R, *et al.* “Characterizing food intake patterns of American adults.” *Am J Clin Nutr.* 1997;65(4suppl):1264S-8S.

³⁵ Bingham SA. “The use of 24-h urine samples and energy expenditure to validate dietary assessments.” *Am J Clin Nutr.* 1994;59(1suppl):227S-31S.

³⁶ United Fresh Fruit and Vegetable Association. *Fruit and Vegetable Consumption: Consumer Attitudes vs. Behavior*, 1995, as cited in Kantor LS, *A Dietary Assessment of the U.S. Food Supply: Comparing Per Capita Food Consumption with Food Guide Pyramid Serving Recommendations*. Washington, D.C.: USDA, Economic Research Service, Agricultural Economic Report No. 772, Dec. 1998, at 5.

³⁷ USDA, *America’s Eating Habits*, p. 153.

³⁸ Kantor LS, Lipton K, Manchester A, *et al.* Economic Research Service, USDA. “Estimating and addressing America’s food losses.” *FoodReview* Jan-Apr., 1997;20(1):2-12.

USDA reduces that level to an estimated 32 teaspoons per day.³⁹ That intake is 60 percent higher than the 20 teaspoons a day of intake based on dietary recall (CSFII). Presumably, the actual amount of added sugars consumed by the average American is somewhere between 20 and 32 teaspoons per day. In any case, Americans are consuming far more than the FDA estimated in its earlier reviews.

Added sugars may make up even a bigger part of the American diet a decade from now unless preventive actions are taken. The USDA recently projected that if the consumption trend between 1992 and 1996 continues, *per capita* consumption of added sugars will increase almost 20 percent between 1996 and 2005.⁴⁰ It is worth noting that consumption (as indicated by disappearance data) increased by 3.3 percent between 1996 and 1998.

It is especially significant that added-sugars consumption has continued to rise sharply in recent years given the FDA's comment in 1993 in which the agency recalled that in 1982⁴¹ it had said that:

it would monitor average daily consumption of these ingredients [sucrose, corn sugar, corn syrup, and invert sugar] and would reevaluate the safety of their use if total dietary consumption were to increase significantly. The agency concluded in those [1982] documents that there could be safety concerns if intake of these ingredients increased significantly over the current levels (approximately 50 gr).⁴²

In fact, since the 1982 and 1986 reviews of sucrose and corn sugars, average consumption increased by more than 20 percent and is now about 80 grams per day, a far cry from that

³⁹ *Ibid.* at 7, Table 1.

⁴⁰ USDA, *America's Eating Habits*, at 91.

⁴¹ The 1982 comment was made in the FDA's proposals to affirm that sucrose, corn sugar, corn syrup, and invert sugar are generally recognized as safe ("GRAS").

⁴² 58 Fed. Reg. at 2221.

“approximately 50 gr.”⁴³

(b) Added sugars have different nutritional consequences compared to naturally occurring sugars, because of the foods in which they occur.

FDA’s current regulations -- which require food labels to disclose only the amount of total sugar -- fail to assist consumers in choosing a healthy diet because they treat all sugars as equal. While naturally occurring sugars are chemically identical to added sugars, treating them as equal for labeling purposes provides misleading dietary guidance. As USDA states:

Although the human body cannot distinguish between naturally occurring and added sugars, dietary guidance focuses on added sugars because foods high in added sugars often supply calories but few nutrients. To the extent that consumers substitute the calories from less nutrient-dense sugary snacks like sweetened soft drinks and candy for nutrient-rich foods like fruits, vegetables, and whole grains, dietary intake of the fiber, vitamins, minerals, and other nutrients found in these foods may be reduced.⁴⁴

Added sugars are found largely in soft drinks, sweet baked goods, fruit drinks, candies, and other empty-calorie or nutrient-poor foods that most Americans should eat in smaller quantities.

⁴³ We do not argue here that the substantial increases in consumption since previous FDA safety reviews warrants revocation of GRAS status, reducing the added-sugars content of certain foods, or restricting the production of certain foods. However, at the very least, that increased consumption warrants greatly expanded educational programs, including disclosures on labels of the amount of added sugars in a serving and the percentage of a Daily Value.

⁴⁴ USDA, *America’s Eating Habits*, at 87.

According to CSFII 1994-96 data, the largest sources of added sugars are:⁴⁵

Soft drinks	33%
Cakes, cookies, pies, etc.	14%
Fruit drinks, ades, etc.	10%
Dairy desserts	6%
Candy	5%
Breakfast cereals	4%
Tea	3%
Other	25%

In contrast, naturally occurring sugars are found in fruits and dairy products. Fruits and low-fat dairy products are nutrient-dense foods that are associated with a lower risk of disease and that Americans should eat in greater quantities.

The Dietary Guidelines Advisory Committee⁴⁶ observed in 1995 that “sugars and starches occur naturally in many foods -- including milk, fruit, some vegetables, breads, cereals and grains -- that also supply other nutrients.”⁴⁷ The Advisory Committee then noted that some foods that are high in added sugars “supply calories but few or no nutrients.”⁴⁸

Growing evidence makes it clear that the public should consume greater quantities of fruit and low-fat dairy products, notwithstanding their content of sugars. For example:

⁴⁵ Personal communication, Shanthy Bowman, USDA/ARS, based on CSFII 1994-96 1-day data, July 30, 1999.

⁴⁶ The Advisory Committee was appointed because section 301 of the National Nutrition Monitoring and Related Research Act of 1990, P. L. 101-445, directs the Secretary of Health and Human Services and the Secretary of Agriculture to jointly issue at least every five years a reported entitled *Dietary Guidelines for Americans*, that contains nutritional and dietary information and guidelines for the general public that are based on the preponderance of scientific and medical knowledge current at the time of publication.

⁴⁷ *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans* (1995) at 16.

⁴⁸ *Ibid.* at 16.

(i) Fruit.

Numerous studies suggest that a diet rich in fruits (and vegetables) is associated with a lower risk of several cancers.⁴⁹ Other studies have found lower rates of stroke in people who eat more fruits and vegetables.⁵⁰ That finding is supported by the recent DASH study, which found that a low-fat diet rich in fruits (as well as vegetables, low-fat dairy products, etc.) lowered blood pressure in people with high-normal levels.⁵¹ Research is ongoing to determine the contribution of the phytochemicals, fiber, folic acid, potassium, or other components of fruit to the reduced risk of cancer, stroke, and other health problems. However, regardless of which nutrients provide which benefits, the *Dietary Guidelines*, the National Cancer Institute, and other health authorities agree that the public should eat more fruit. Food labels should provide information that enables consumers to distinguish added sugars from the naturally occurring sugars in such essential foods as fruits and vegetables.

(ii) Low-fat dairy products.

Milk and many other dairy products contain lactose. A large body of research indicates that adequate calcium intakes reduce the risk of osteoporosis by increasing peak bone mass or by raising (or maintaining) bone density. Low-fat and fat-free milk are rich in calcium. Yet average calcium intakes fall far below recommended levels, especially among teenage girls and women, who face a high risk of osteoporosis in their later years. In addition, in a recent clinical trial,

⁴⁹ *Food, Nutrition and the Prevention of Cancer: A Global Perspective* (Washington, D.C.: World Cancer Research Fund/American Institute for Cancer Research, 1997).

⁵⁰ Gillman MW. "Protective effect of fruits and vegetables on development of stroke in men." *JAMA*. 1995;273:1113-7.

⁵¹ Appel LJ. "A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group." *N Engl J Med*. 1997;336:1117-24 (1997).

calcium supplements lowered the risk of adenomas of the colon in people who had already had at least one adenoma removed.⁵² While the trial used calcium supplements, not calcium-rich foods, the results suggest that calcium-rich, low-fat dairy products may reduce the risk of colon cancer. Furthermore, low-fat dairy products were a component of the DASH diet, which lowered blood pressure in a clinical study. It is impossible to attribute the reduction in blood pressure to low-fat dairy products alone or to the specific nutrients in low-fat dairy products. However, it is clear that food labels should provide information that enables consumers to distinguish added sugars from the naturally occurring sugars (for instance, lactose) in such valuable foods as low-fat dairy products.

While fruit and low-fat dairy products appear to lower the risk of major illnesses that threaten Americans' health, foods that are high in added sugars offer no known benefits other than providing calories. Instead, they increase the risk of health problems or displace foods and nutrients that appear to reduce the risk of disease. The added sugars they provide should be distinguished on food labels from naturally occurring sugars. Without that information, it is difficult for consumers to know how much of the total sugar in numerous processed foods is added and how much comes from fruit or dairy products. Those foods include fruit snacks; fruit yogurt; cereal bars; ice cream; frozen yogurt; canned or frozen fruit; puddings; juice drinks; jams; jellies; sorbet; frozen fruit bars; and breakfast cereals, cookies or muffins that contain fruit.

⁵² Baron JA. "Calcium supplements for the prevention of colorectal adenomas. Calcium Polyp Prevention Study Group." *N Engl J Med.* 1999;340:101-7.

(c) Foods high in added sugars squeeze more healthful foods out of the diet.

In its 1986 sugars report, the FDA concluded:

There is no firm evidence that sugars as currently consumed interfere with the bioavailability of vitamins, minerals, or trace nutrients, nor is there scientific evidence supporting the notion that dietary imbalances are *preferentially caused* by increased sugars consumption.⁵³ [emphasis added]

More specifically, the report stated:

...there is not persuasive evidence that sugars as they are commonly used and consumed: (1) have *unique* properties or uses relative to the production of “empty calorie” diets; (2) [nor is there persuasive evidence that added sugars] have been identified as a significant cause of nutrient deficiencies with [sic] the U.S....⁵⁴ [emphasis added]

Contrary to the FDA’s 1986 thinking, we do not believe that it should be essential to demonstrate that added sugars are *uniquely* responsible for nutrient-poor diets in order to require labeling that would help consumers to lower their intake of added sugars. Indeed, the Select Committee on GRAS Substances reported to the FDA in 1976: “. . . It is likely that some individuals may eat enough [sucrose] to exclude adequate amounts of other foods that furnish required nutrients.”⁵⁵ Furthermore, there is compelling new evidence that a high intake of added sugars *does* compromise the nutrient content and healthfulness of the diet.

Since the FDA’s report was issued, the added-sugars content of the average American’s diet has jumped from an estimated 11-12 percent of calories in 1986 to 16 percent in 1996. That increase is particularly disturbing because few Americans are consuming the recommended

⁵³ Glinsmann *et al.* at S15.

⁵⁴ *Ibid.* at S112.

⁵⁵ Life Sciences Research Office, Federation of American Societies for Experimental Biology. *Evaluation of the Health Aspects of Sucrose As A Food Ingredient.* 1976 at 13.

minimum of five servings of fruits and vegetables a day, more low-fat dairy products, and more fiber-rich whole grains and beans.

New data from the USDA indicate that people who consume diets high in added sugars consume lower levels of protein; fiber; vitamins A, E, C, B-6, B-12, riboflavin, niacin, and folate; calcium; iron; zinc; and magnesium.^{56,57} They also consume fewer servings of grains, fruits, vegetables, meats, and dairy products than people who consume less added sugar.⁵⁸ In addition, a recent study indicates that the small percentage of Americans who consume the number of servings from each food group recommended by USDA's *Food Guide Pyramid* consumes less sugars than others.⁵⁹ As Meir Stampfer of the Harvard School of Public Health said at the March 9, 1999, meeting of the Dietary Guidelines Advisory Committee, added sugars'

⁵⁶ Testimony by Rachel Johnson, Dietary Guidelines Advisory Committee, meeting, March 9, 1999, at 354. <<http://www.usda.gov/cnpp/DG2000/March9.htm>> [accessed June 24, 1999]. Personal communication, Shanthy Bowman, Agricultural Research Service, USDA, March 26, 1999.

⁵⁷ Earlier studies also found that higher intakes of sugars are associated with a lower intake of vitamins, minerals, and other nutrients. Lewis CJ, *et al.* "Nutrient intakes and body weights of persons consuming high and moderate levels of added sugars." *J Am Diet Asso.* 1992;92:708-13; Gibney M, *et al.* "Consumption of sugars." *Am J Clin Nutr.* 1995;62(1 Suppl):178S-94S. Those studies minimized the impact of added sugars because the authors failed to separate the naturally occurring sugars in fruit from the added sugars in soft drinks, pastries, etc. For instance, had the studies excluded fruit sugar, people consuming high levels of added sugars probably would have been more likely to get less than the RDA for vitamin C.

Furthermore, Gibney *et al.* argue that the most nutritious diets are those with intermediate levels of sugar, because the people who eat the least sugar also have lower nutrient intakes. In fact, that observation does not exonerate added-sugars' impact on nutrient density. It simply raises questions about whether the group with the low-sugar intakes was consuming large quantities of fat, and/or reporting inaccurate food intakes.

⁵⁸ Johnson testimony, at 364.

⁵⁹ Krebs-Smith, *et al.*

“main adverse effect is that it’s displacing foods that do provide nutrients.”⁶⁰ At the same meeting, committee member Shiriki Kumanyiki added, “[I]t’s very clear that it’s a displacement issue . . . it’s replacing things that are needed.”⁶¹

The impact of added sugars on the nutrient quality of Americans’ diets and the public’s health is substantial. Many of the 14 nutrients that are negatively associated with added-sugars consumption have a key role in promoting health and preventing disease. For example:

* **Calcium.** Adequate intakes of calcium can help reduce the risk of osteoporosis⁶² and possibly high blood pressure⁶³ and colon cancer.⁶⁴

* **Fiber.** High intakes of fiber are associated with a lower risk of heart disease⁶⁵ and diabetes.⁶⁶

⁶⁰ Dietary Guidelines Advisory Committee meeting, March 9, 1999, at 372.
<<http://www.usda.gov/cnpp/DG2000/March9.htm>> [accessed June 24, 1999].

⁶¹ *Ibid.* at 375.

⁶² Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Food and Nutrition Board. Institute of Medicine. *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride* (Washington, D.C.: National Academy Press, 1997).

⁶³ Appel.

⁶⁴ Baron.

⁶⁵ Rimm EB, *et al.* “Vegetable, fruit, and cereal fiber intake and risk of coronary heart disease among men.” *JAMA*. 1996;275:447-51; Pietinen P, *et al.* “Intake of dietary fiber and risk of coronary heart disease in a cohort of Finnish men. The Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study.” *Circulation*. 1996;94:2720-7; Wolk A, *et al.* “Long-term intake of dietary fiber and decreased risk of coronary heart disease among women.” *JAMA*. 1999;281:1998-2004.

⁶⁶ Salmeron J, *et al.* “Dietary fiber, glycemic load, and risk of non-insulin-dependent diabetes mellitus in women.” *JAMA*. 1997;277:472-7; Salmeron J, *et al.* “Dietary fiber, glycemic load, and risk of NIDDM in men.” *Diabetes Care*. 1997;20:545-50.

* **Vitamin E.** Women who consume more vitamin E from foods have a lower risk of heart disease.⁶⁷

* **Folate.** Diets rich in folate may help prevent heart disease, colon cancer, and birth defects.^{68,69,70,71}

* **Vitamin B-6.** Women who consume more vitamin B-6 (from foods or supplements) have a lower risk of heart disease.⁷²

Soda pop, the single biggest source of added sugars for the average American, illustrates why the FDA must consider not just the impact on health of added sugars, *per se*, but also the impact of *foods* high in added sugars. Higher intakes of soft drinks are associated with lower intakes of more healthful beverages. For example, among children aged 2 to 17, those who consume the most soft drinks consume lower levels of milk and fruit juice.⁷³ A study of 105 children aged 24 to 36 months found a similar inverse relationship between consumption of soft

⁶⁷ Kushi L. "Dietary antioxidant vitamins and death from coronary heart disease in postmenopausal women." *N Engl J Med.* 1996;334:1156-62.

⁶⁸ Giovannucci E, *et al.* "Multivitamin use, folate, and colon cancer in women in the nurses' health study." *Annals of Internal Medicine.* 1998;129:517-24.

⁶⁹ Rimm EB, *et al.* "Folate and vitamin B6 from diet and supplements in relation to risk of coronary heart disease among women." *JAMA.* 1998;279:359-64.

⁷⁰ Boushey CJ, *et al.* "A quantitative assessment of plasma homocysteine as a risk factor for vascular disease. Probable benefits of increasing folic acid intakes." *JAMA.* 1995;274:1049-57.

⁷¹ Centers for Disease Control. "Recommendations for the use of folic acid to reduce the number of cases of spina bifida and other neural tube defects." *MMWR.* 1992;41(No. RR-14):1-7.

⁷² Rimm 1998.

⁷³ Harnack L, *et al.* "Soft drink consumption among U.S. children and adolescents: nutritional consequences." *J Am Diet Assoc.* 1999;99:436-41.

drinks versus milk and fruit juice.⁷⁴ Researchers at USDA reported an inverse relationship between milk and soft-drink consumption in the late 1970s, when soda consumption was significantly lower than it is now.⁷⁵ Using data from USDA surveys, twenty years ago teenagers consumed twice as much milk as soft drinks; in 1994-96 they consumed twice as much soft drinks as milk (see Exhibit 4). The potential impact on osteoporosis rates several decades from now is obvious. Preliminary research indicates that drinking soft drinks instead of milk contributes to broken bones in children and adults. One study found that children 3 to 15 years old who had suffered broken bones had lower bone density, which can result from low calcium intake.⁷⁶ Another study found a significantly higher rate of bone fractures among former college athletes who consumed more soft drinks.⁷⁷ The authors concluded:

These results, if confirmed, may have important public health implications because of the 300% increase in carbonated beverage consumption combined with a decline in milk consumption in the U.S. over the last three decades.

In addition to the impact of soft drinks on milk consumption, new data from USDA indicate that foods high in added sugars also replace fruit, vegetables, low-fat dairy products, high-fiber whole grains, and other healthful foods.⁷⁸ Diets rich in those foods are associated

⁷⁴ Skinner JD, *et al.* "Fruit juice intake is not related to children's growth." *Pediatrics*. 1999;103:58-64.

⁷⁵ Guenther PM. "Beverages in the diets of American teenagers." *J Am Diet Assoc*. 1986;86:493-9.

⁷⁶ Goulding A, Cannan R, Williams SM, *et al.* "Bone mineral density in girls with forearm fractures." *J Bone Miner Res*. 1998;13:143-8.

⁷⁷ Wyshak G, Frisch RE, Albright TE, *et al.* "Nonalcoholic carbonated beverage consumption and bone fractures among women former college athletes." *J Orthopedic Res*. 1989;7:91-9.

⁷⁸ Johnson testimony at 364.

with lower risk of cancer,⁷⁹ heart disease,^{80,81} stroke,^{82, 83} diabetes,⁸⁴ and osteoporosis.⁸⁵ However, it is more difficult to consume adequate amounts of foods that reduce the risk of those illnesses if one consumes a diet high in added sugars.

According to a study by USDA and NCI nutrition experts, the fewer nutrition objectives that children age 2 to 11 met, the greater their consumption of added sugars.⁸⁶ Children who met all five guidelines (for grains, vegetables, fruit, dairy, and meat) consumed 11.6 percent of their calories in the form of added sugars. Those meeting two or three guidelines consumed about 14 percent of calories from added sugars. Those who met just one guideline consumed about 17 percent of their calories from added sugars. And children who failed to meet any of the guidelines consumed 20.2 percent of their calories from added sugars.

The landmark report *Food, Nutrition and the Prevention of Cancer: a global perspective* published by the World Cancer Research Fund expressed concern about the impact of added sugars on nutrient intake and cancer risk. The report stated:

In particular, individuals with high sucrose or sugar intakes (proportional to

⁷⁹ World Cancer Research Fund.

⁸⁰ Rimm 1996.

⁸¹ Law MR, Morris JK. "By how much does fruit and vegetable consumption reduce the risk of ischaemic heart disease?" *Eur J Clin Nutr.* 1998;52:549-56.

⁸² Gillman.

⁸³ Appel.

⁸⁴ Salmeron, *JAMA, Diabetes Care.*

⁸⁵ Standing Committee on the Scientific Evaluation of Dietary Reference Intakes.

⁸⁶ Muñoz KA, Krebs-Smith SM, Ballard-Barbash R, *et al.* "Food intakes of US children and adolescents compared with recommendations." *Pediatrics.* 1997;100:323-9; 1998;101:952-3.

energy intake) tend to have lower intakes of a number of foods or dietary constituents which have probable or possible protective roles in colorectal cancer. These include vegetables, fruits, cereals, fibre, folate, carotenoids and other antioxidants. Associations observed between sucrose intake and colorectal cancer could therefore, at least partly, be accounted for by low intake of such protective dietary constituents. . . . On balance, the panel judged the evidence to show a possible causal relationship between refined sugars and colorectal cancer.⁸⁷

That same report's "best-guess" estimate is that increasing consumption of fruits and vegetables (excluding potatoes and legumes) by 1.5 servings per day would reduce overall cancer risk by about 20 percent.⁸⁸ The most conservative estimate was a 7 percent decrease in risk. We would expect, if people reduced overall added-sugars intake, many consumers would replace at least a portion of those calories with fruits and vegetables. That salutary change would be likelier to occur if the FDA accompanied added-sugars labeling with an educational campaign (recall that the "E" of NLEA stands for Education).

(d) Added sugars increase blood-triglyceride levels and the risk of heart disease.

In 1986 the FDA concluded that "Current levels of sugars consumption have not been demonstrated to be an adverse risk factor in terms of blood lipid and lipoprotein profiles for normal individuals."⁸⁹ In 1993, when rejecting the declaration on labels of added sugars, the FDA relied largely on that 1986 report and did not acknowledge recent evidence on blood lipids. In fact, evidence then available, as well as new scientific evidence, indicates that levels of sugar consumption that are now current may raise blood triglycerides in insulin-resistant individuals,

⁸⁷ World Cancer Research Fund at 225, 383.

⁸⁸ *Ibid.* at 540.

⁸⁹ Glinsmann *et al.* at S13.

who comprise a substantial proportion of the population. Higher triglycerides, in turn, appear to increase the risk of heart disease in insulin-resistant individuals.

(i) Sugars increase blood triglyceride levels in certain individuals.

The FDA's dismissal in 1986 of studies by USDA on sugars and blood lipids rested in part on the uncertainty surrounding what the USDA researchers called carbohydrate sensitivity. "Carbohydrate sensitivity has been suggested to be an early manifestation of diabetes; however, an association with diabetes has not been shown," states the FDA 1986 sugars report.⁹⁰ Research has since identified "Syndrome X" or the "Metabolic Syndrome," a constellation of risk factors, including insulin resistance and high triglyceride levels, that are associated with a higher risk of heart disease.⁹¹

The FDA's 1986 sugar report acknowledged that USDA's research showed that "carbohydrate-sensitive males...exhibited adverse blood lipid risk profiles as sucrose was increased in their diet."⁹² However, the report then essentially dismissed that entire series of sugar studies by stating, "when these individuals are fed in a gorging meal pattern (75 to 90% of total daily calories in a single meal), they can demonstrate impaired glucose tolerance as dietary sucrose is increased in amounts above those currently consumed in the U.S."⁹³

It is not clear whether the FDA's criticism about gorging is valid. In any case, FDA's

⁹⁰ *Ibid.* at S90.

⁹¹ Reaven GM. "Role of insulin resistance in human disease." *Diabetes*. 1988;37:1595-607. Grundy SM. "Hypertriglyceridemia, insulin resistance, and the metabolic syndrome." *Am J Cardiology*. 1999;83:25F-9F.

⁹² Glinsmann *et al.* at S13.

⁹³ *Ibid.* at S10.

dismissal was inappropriate because other USDA studies did not use a gorging meal pattern. For example, in one study that found higher triglyceride levels after carbohydrate-sensitive men consumed diets containing 7.5 percent or 15 percent fructose, the researchers fed 15 percent of calories at breakfast, 30 percent at lunch, and 55 percent at dinner.⁹⁴ A second study found higher triglyceride levels in carbohydrate-sensitive men after they and normal men were fed diets containing 20 percent fructose rather than 20 percent starch. In that study, the subjects ate 22 percent of their calories at breakfast, 29 percent at lunch, and 49 percent at dinner.⁹⁵ Moreover, a 1984 study at the Stanford University School of Medicine found similar results without feeding a large number of calories at one meal.⁹⁶

The FDA's 1986 report also dismissed the evidence linking added sugars to high triglyceride levels by noting that "the reports are inconsistent. In some studies, high-sucrose or -fructose intake did not lead to any changes in serum cholesterol, triglyceride or lipoprotein patterns, while in others all these parameters were affected by sugars consumption."⁹⁷ However, those inconsistencies do not warrant a conclusion that large amounts of added sugars are safe. As one reviewer stated:

When those studies that provide the best scientific evidence are reviewed, there is evidence that increasing dietary fructose consumption can significantly increase

⁹⁴ Hallfrisch J, *et al.* "Blood lipid distribution of hyperinsulinemic men consuming three levels of fructose." *Am J Clin Nutr.* 1983;37:740-8.

⁹⁵ Reiser S, *et al.* "Blood lipids, lipoprotein, apoproteins, and uric acid in men fed diets containing fructose or high-amylose cornstarch." *Am J Clin Nutr.* 1989;49:832-9.

⁹⁶ Liu G, *et al.* "The Effect of Sucrose Content in High and Low Carbohydrate Diets on Plasma Glucose, Insulin, and Lipid Responses in Hypertriglyceridemic Humans." *Journal of Clinical Endocrinology and Metabolism* 1984;59:636-42.

⁹⁷ Glinsmann *et al.* at S89.

fasting plasma triglyceride and cholesterol concentrations....It appears that the magnitude of the deleterious effects vary [sic] depending on such factors as age; sex; baseline glucose, insulin, and triglyceride concentrations; the presence of insulin resistance; and the amount of dietary fructose consumed. Finally, not all studies are consistent in these findings, however, the positive data cannot easily be dismissed and may be of substantial clinical importance. This is particularly true given the fact that: 1) these deleterious changes occur in the absence of any beneficial effect on lipoprotein metabolism, and 2) these abnormalities in lipoprotein metabolism appear to be greater in those individuals already at an increased risk of coronary artery disease.⁹⁸

Since the FDA's 1986 report, reviewers have cited the studies that USDA conducted in the 1980s as among the few controlled studies to investigate the impact of added sugars on triglycerides. Those reviewers have noted that, in people with "carbohydrate sensitivity," diets containing roughly 20 percent of calories from added sugars raise triglyceride and insulin levels more than diets containing similar amounts of starch. (Those "carbohydrate-sensitive" people probably now would be called "insulin-resistant.")

For example, according to one review:

These two studies, by Hallfrisch et al and Reiser et al, provide considerable insight into the role of dietary fructose in lipoprotein metabolism. Together they indicate that individuals who are carbohydrate sensitive are very responsive to even small increases in dietary fructose (as little as 7.5% of total energy). Secondly, they suggest that the deleterious effects of dietary fructose observed in these studies was relatively dose dependent. Finally, they indicate that even individuals who are not carbohydrate sensitive, will respond in an adverse manner at the highest intake of dietary fructose (20% of total energy).⁹⁹

Others reached a similar conclusion:

Individuals with hypertriglyceridemia, hyperinsulinemia, or both may be more sensitive than others to any harmful effect of high intakes of fructose or sucrose. For such people there is a particular need for sound evidence on which to base

⁹⁸ Hollenbeck CB. "Dietary fructose effects on lipoprotein metabolism and risk for coronary artery disease." *Am J Clin Nutr.* 1993;58:800S-9S.

⁹⁹ Hollenbeck.

advice on consumption of these sugars. Existing evidence comes largely from studies at one center [USDA's Human Nutrition Research Center], but the strength of evidence from well-designed studies suggests that this is a real problem and should promote further investigations of this important area.¹⁰⁰

In 1984, researchers at Stanford University confirmed USDA's results in people with high triglyceride levels, a marker for insulin resistance.¹⁰¹ Triglyceride and postprandial insulin levels rose more when researchers switched subjects from a low- (40 percent of calories) to a high-carbohydrate (60 percent of calories) diet that was proportionately higher in sucrose -- i.e., when sucrose was increased from 9 percent to 15 percent of calories -- than when they increased carbohydrates but held sucrose constant at 13 percent of calories.

The FDA's 1986 report dismisses the evidence linking added sugars to high triglycerides by noting that the levels of sucrose in USDA's studies are "increased in amounts above those currently consumed in the U.S."¹⁰² In fact, those levels no longer exceed amounts currently consumed in the U.S.

The studies at Stanford found increased triglyceride levels in diets containing 15 percent of calories from sucrose. The USDA studies found a rise in triglycerides in diets containing as little as 7.5 percent of calories from fructose. (If, as some researchers suggest, it is the fructose component of sucrose and high-fructose corn syrup that raises triglycerides, diets containing 7.5 percent fructose and 15 percent sucrose should have roughly comparable effects on triglycerides.) Those levels are similar to the added sugar levels now consumed by millions of

¹⁰⁰ Daly ME, *et al.* "Dietary carbohydrates and insulin sensitivity: a review of the evidence and clinical implications." *Am J Clin Nutr.* 1997;66:1072-85.

¹⁰¹ Liu G, *et al.*

¹⁰² Glinsmann *et al.* p. S10.

Americans. The USDA estimates that the average American now gets 16 percent of his or her calories from added sugars, while teenagers average 20 percent of calories from added sugars. However, many Americans -- including middle-aged and older people, who have an elevated risk of heart disease -- are consuming more than average.

For example, according to USDA (two-day) data, 25 percent of adults aged 30 to 39 consume at least 21 percent of their calories from added sugars, 25 percent of adults aged 40 to 49 consume at least 19 percent of their calories from added sugars, 25 percent of adults aged 50 to 59 consume at least 20 percent of their calories from added sugars, and 25 percent of adults aged 60 to 79 consume at least 16 percent of their calories from added sugars.¹⁰³ Therefore, at least 25 percent of the middle-aged and older population consumes enough sugar to raise triglycerides. Given that median intakes range from 11 to 14 percent of calories for those age groups, considerably more than 25 percent of middle-aged and older Americans may consume enough added sugar (15 percent of calories) to raise triglycerides.¹⁰⁴

A recent pilot study supports the notion that not all carbohydrates have the same impact on triglycerides.¹⁰⁵ In people with hypercholesterolemia, a low-fat, low-fiber “convenience food diet,” in which most of the sugars came from cookies, sweetened yogurt, and fruit juice, raised triglycerides more than a low-fat, high-fiber “plant food diet,” in which most of the sugars came

¹⁰³ Personal communication, Shanthy Bowman, USDA/ARS, July 29, 1999.

¹⁰⁴ Researchers have not established a threshold level for sugars' effects on triglycerides. Considering how small the cited clinical studies are, 7.5 percent fructose is unlikely to be the lowest level that affects blood lipid levels.

¹⁰⁵ Gardner CD, *et al.* “Response of cardiovascular disease risk factors to plant food-based versus convenience food-based approaches for meeting NCEP step one dietary guidelines: pilot study.” *Canadian Journal of Cardiology*. 1997;13:236B.

from fruit. A larger study is under way.

The prevalence of insulin resistance in the United States is uncertain, because it is not measured in clinical practice and there are no widely accepted standards. However, some experts estimate that roughly 25 percent of apparently healthy people are insulin resistant.¹⁰⁶ A recent study in Italy estimates that the insulin-resistant segment of the population may include 66 percent of people with glucose intolerance, 94 percent of people with diabetes, 84 percent of people with high triglycerides, 88 percent of people with low HDL cholesterol, and 20 percent of normal-weight subjects with no metabolic disorders.¹⁰⁷ Furthermore, the incidence of insulin resistance is likely to rise as the population ages and obesity rates rise. It is clear that the prevalence of insulin resistance is sufficiently great as to result in high intakes of sugars posing a public health problem.

(ii) Elevated blood triglycerides appears to be an independent risk factor for coronary heart disease.

The role of high blood-triglyceride levels in promoting heart disease has been an issue of great debate, with one researcher even calling the debate a “war.” The National Cholesterol Education Program (NCEP) has been ambivalent on triglycerides, stating:

It is not clear whether high triglycerides alone increase your risk of heart disease.¹⁰⁸

Elevated serum triglycerides are positively correlated with risk for CHD (coronary heart disease) in univariate analysis, but they lose some or most of their ability to

¹⁰⁶ Reaven GM.

¹⁰⁷ Bonora E, *et al.* “Prevalence of insulin resistance in metabolic disorders: the Bruneck Study.” *Diabetes*. 1998;47:1643-9.

¹⁰⁸ National Cholesterol Education Program, National Heart, Lung and Blood Institute. <<http://www.nhlbi.nih.gov/hnlbi/cardio/chol/gp/fabc/fabc.htm>> [accessed: July 12, 1999]

predict CHD in multivariate analysis.¹⁰⁹

In the view of some workers, the statistical methods used to assign independent relationships to CHD risk among the different lipid fractions are of limited value because of high intercorrelations among various lipoprotein fractions and the greater variability in triglyceride measurements. . . . Nonetheless, the 1992 NIH Consensus Conference indicated that triglyceride reduction should be part of the therapy of certain dyslipidemias that carry an increased risk for CHD.¹¹⁰

Numerous experts are more emphatic than the NCEP and have concluded that triglycerides are, indeed, an independent risk factor for heart disease. For example, in a 1996 nested case-control study of blood samples collected prospectively from 574 men in the Physicians' Health Study, there was a 40 percent increase in the risk of myocardial infarction for every 100 mg/dL increase in nonfasting triglycerides.¹¹¹ Men in the highest triglyceride quintile had roughly 2.5 times the risk of those in the lowest triglyceride quintile. "These findings indicate that nonfasting triglyceride levels appear to be a *strong and independent predictor* of future risk of MI, particularly when the total cholesterol level is also elevated," concluded Meir Stampfer and colleagues at Harvard Medical School and elsewhere. [emphasis added]

In a recent study published in the American Heart Association's journal *Circulation*, Danish researchers examined the relation between fasting triglycerides and risk of ischemic heart

¹⁰⁹ National Cholesterol Education Program, National Heart, Lung and Blood Institute. <http://www.nhlbi.nih.gov/nhlbi/cardio/chol/prof/atp2/atp_sum.htm> [accessed: July 12, 1999]

¹¹⁰ National Cholesterol Education Program, National Heart, Lung and Blood Institute. <<http://www.nhlbi.nih.gov/nhlbi/cardio/chol/prof/atp2/atp.txt>> [accessed: July 12, 1999]

¹¹¹ Stampfer MJ, Krauss RM, *et al.* "A prospective study of triglyceride level, low-density lipoprotein particle diameter, and risk of myocardial infarction." *JAMA*. 1996;276:882-8.

disease (IHD) in middle-aged and elderly white men.¹¹² According to the researchers:

Compared with the lowest third level and adjusted for age, body mass index, alcohol, smoking, physical activity, hypertension, non-insulin-dependent diabetes mellitus, social class, and LDL and HDL cholesterol, relative risks of IHD (95% confidence interval) were 1.5 (1.0 to 2.3; P=.05) and 2.2 (1.4 to 3.4; P<.001) for the middle and highest third of triglyceride levels, respectively. When triglyceride levels were stratified by HDL cholesterol levels (triglyceride third multiplied by HDL cholesterol third), a clear gradient of risk of IHD was found with increasing triglyceride levels within each level of HDL cholesterol, including high HDL cholesterol level, which are thought to provide protection against IHD. CONCLUSIONS: In middle-aged and elderly white men, a high level of fasting triglycerides is a strong risk factor of IHD *independent of other major risk factors*, including HDL cholesterol. [emphasis added]

In an accompanying editorial, Antonio M. Gotto, of Cornell Medical School, noted the difficulty in proving whether triglycerides is an independent risk factor for heart disease.¹¹³ He wrote:

However, the current evidence makes a compelling argument for including TG in the lipoprotein profile in the evaluation of patient risk for coronary disease. . . . The growing attention to hypertriglyceridemia and increased CHD risk is encouraging to veterans of the “triglyceride wars” and congruent with another trend in CHD risk management, namely, the concept of global risk assessment, in which TG and other risk factors are considered in the context of patients’ global risk for developing CHD.

Ronald Krauss, head of molecular medicine at the Lawrence Berkeley Laboratory in California, said that the Danish findings support those scientists, including himself, “who have been absolutely convinced that triglycerides are a part of the missing equation ... above and beyond cholesterol” in predicting the risk of heart disease.¹¹⁴ Krauss is former chairman of the

¹¹² Jeppesen J, Hein HO, Suadicani P, *et al.* “Triglyceride concentration and ischemic heart disease: an eight-year follow-up in the Copenhagen male study.” *Circulation*. 1998;97:1029-36.

¹¹³ Gotto AM. “Triglyceride: the forgotten risk factor.” *Circulation*. 1998;97:1027-8.

¹¹⁴ Saltus R. “New clue in heart disease risk seen. Triglyceride level called key factor.” *Boston Globe*, March 24, 1998, A5.