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

Petition To Require Health Messages on Soft Drinks  
Containing High-fructose Corn Syrup and other  
Caloric Sweeteners

Docket No. \_\_\_\_\_

submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

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

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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**

The enormous consumption of soft drinks<sup>1</sup> (both carbonated and non-carbonated; 52.4 gallons per person per year) sweetened mainly with high-fructose corn syrup (“HFCS”), though sometimes with sugar (sucrose), is a major contributor to Americans’ calorie intake and likely a significant cause of overweight and obesity. As discussed below in section III.B., in 2004 the average American consumed 37 gallons – 59,000 calories – of carbonated, non-diet soft drinks. In addition, Americans consume large quantities of sweetened non-carbonated beverages (bottled ice teas, fruit drinks and ades, etc.) that are essentially nutritionally equivalent to carbonated beverages (most such products contain less than 10 percent, if any, fruit juice). An analysis of dietary intake surveys found that per capita consumption of those drinks is about 30 percent<sup>2</sup> of total carbonated soft-drink consumption, providing thousands of additional calories. The tens of thousands of calories coming from empty-calorie beverages each year could contribute to significant weight gain.<sup>3</sup> Moreover, as some Americans do not consume sugars-sweetened soft drinks,<sup>4</sup> the impact on the weight of those who do is much larger than indicated by the average consumption.

The Food and Drug Administration (“FDA”) has recognized the serious public health implications of overweight and obesity. The Acting Commissioner of the FDA said in 2004 that there is an “epidemic of overweight and obesity....Overweight and obesity increase the risk for

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<sup>1</sup> Carbonated soft drinks, soda pop, and pop are used interchangeably in this petition. Soft drinks usually refers to carbonated drinks, except where it is indicated that they include non-carbonated soft drinks (usually fruit drinks that contain small amounts of fruit juice). They include artificially sweetened “diet” drinks, except where indicated.

<sup>2</sup> Popkin BM, Nielsen SJ. The sweetening of the world’s diet. *Obesity Res.* 2003;11:1325-32.

<sup>3</sup> Using a conversion ratio of 3,500 calories per pound of weight, 84,000 calories translates into about 24 pounds. See Rosenbaum M., Leibel RL, and Hirsch J. Obesity. *New Engl J Med.* 1997;337:396-407. That calculation assumes, among other things, that soft drinks would always supplement the rest of the diet and never replace other sources of calories; in reality, of course, soft drinks often replace other foods or caloric beverages. (But see notes 97-98 infra regarding studies suggesting that sodas tend to be consumed in addition to solid foods rather than as a replacement.)

<sup>4</sup> Some people drink “diet” sodas (which contain little or no HFCS, sucrose, or other sweeteners), and others do not drink soft drinks of any kind.

coronary heart disease, hypertension, type 2 diabetes, osteoarthritis and certain cancers....”<sup>5</sup> Moreover, more and more nutritionists and health experts are recognizing that caloric soft drinks are a significant contributor to obesity.

It is urgent that the FDA act on that recognition by requiring a series of rotating health messages on non-diet soft drinks and certain caffeine-containing soft drinks so that Americans will be better informed about the serious public risk associated with the consumption of such drinks. Such labeling, bolstered by an education campaign and other measures, should help reduce consumption of soft drinks.<sup>6</sup>

## II. ACTION REQUESTED

Domestic usage of HFCS was about 9.2 million (short) tons in 2003<sup>7</sup> (or about 63 pounds per capita). About three-quarters of HFCS is now used in soft drinks.<sup>8</sup> HFCS has largely replaced sugar in beverages, but beverages sweetened with sugar provide the same number of calories and amount of sweetener.

The Center for Science in the Public Interest (“CSPI”)<sup>9</sup> requests<sup>10</sup> that the FDA initiate a rulemaking (1) to require that the labels of carbonated or non-carbonated soft drinks containing more than 1.1 grams<sup>11</sup> of HFCS or other caloric sweeteners per ounce bear a series of rotating

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<sup>5</sup> Speech by Lester M. Crawford before National Medical Association (August 4, 2004).

<sup>6</sup> In August 1999 CSPI filed a petition—which is still pending—asking for (i) a rule establishing a daily reference value (DV) for added sugars and requiring nutrition labeling of added sugars and (ii) corresponding changes to the nutrient-content and health-claim regulations (docket number 99P-2630/CP1). The action we now request complements the action we requested in 1999.

<sup>7</sup> USDA Economic Research Service, *Sugar and Sweeteners Outlook/SSS-240* (May 27, 2004) at Table 6. Annual usage has remained at about 9.2 million tons since 1999, whereas it had grown steadily from 6.7 million tons in 1992.

<sup>8</sup> *Id.* at Figure 2.

<sup>9</sup> Petitioner Center for Science in the Public Interest, a nonprofit organization based in Washington, D.C., is supported largely by about 900,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation’s health through better nutrition and safer food since 1971.

<sup>10</sup> 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.

<sup>11</sup> A typical soft drink contains 40 grams of sugar per 12 ounces, or 3.33 grams per ounce. Setting the threshold for requiring health messages at 1.1 grams per ounce would encourage companies to market beverages with one-third or less the usual amount of caloric sweeteners.

health messages,<sup>12</sup> and (2) to require that labels of soft drinks that contain more than 10 milligrams (mg) of caffeine per 12-ounce serving bear a health message and the number of mg of caffeine.<sup>13</sup>

We suggest requiring a variety of health messages so as to overcome, at least in part, the fatigue factor that results when people see the very same message in the very same place over an extended period of time. Tobacco products bear rotating warnings addressing different problems that may result from smoking. Messages on soft drinks might include:

- \* The U.S. Government recommends that you drink less (non-diet) soft drinks to help prevent weight gain, tooth decay, and other health problems.
- \* Drink less (non-diet) soft drinks to help prevent tooth decay.
- \* Drinking too much (non-diet) soft drinks may contribute to weight gain.
- \* For better health, the U.S. Government recommends that you limit your consumption of (non-diet) soft drinks.
- \* To help protect your waistline and your teeth, consider switching to soft drinks.
- \* Drinking soft drinks instead of milk or calcium-fortified beverages may increase your risk of brittle bones (osteoporosis).
- \* A \_\_\_-ounce serving of this drink contains x milligrams of caffeine, a mildly addictive stimulant drug. Not appropriate for children.

Other messages could refer to the five diseases mentioned by Acting Commissioner Crawford: type 2 diabetes, coronary heart disease, hypertension, osteoarthritis, and certain cancers:

- \* Drinking too many (non-diet) soft drinks could cause diabetes [or heart disease, high blood pressure, osteoarthritis, cancer] by increasing your weight.

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<sup>12</sup> We recognize that requiring a health message on labels will not be sufficient on its own to reduce soft-drink consumption to safe levels. Hence, we urge the FDA to initiate education programs regarding soft-drink consumption. More broadly, we urge the Department of Health and Human Services, through its Centers for Disease Control and Prevention, to mount well-funded mass-media campaigns to encourage people to choose more-healthy diets, including reduced consumption of soft drinks (especially non-diet, caffeinated beverages).

<sup>13</sup> The message should state, in a clear and conspicuous manner: "Caffeine content: X milligrams per Y-ounce serving." See CSPI petition to FDA on caffeine labeling (July 31, 1997).

The FDA could conduct consumer research to determine the most effective, precise wording and format<sup>14</sup> of such label messages.

As explained in more detail in Section IV, the FDA has ample legal authority to require those health messages on soft drinks. The FDA could either (1) revoke the “Generally Recognized As Safe” (“GRAS”) status of corn sugar (21 C.F.R. 184.1857), corn syrup (21 C.F.R. 184.1865), invert sugar (21 C.F.R. 184.1859), sucrose (21 C.F.R. 184.1854), and HFCS (21 C.F.R. 184.1866)<sup>15</sup> or (2) determine that current soft drink labels are misbranded even if the FDA were to reaffirm that those sweeteners are safe.

### III. BACKGROUND

**A. In 1988 the FDA determined that at current consumption levels corn sugar, corn syrup, invert sugar, and sucrose are “Generally Recognized As Safe,” and in 1996 the FDA determined that high-fructose corn syrup is “Generally Recognized As Safe.”**

In 1976 the Federation of American Societies for Experimental Biology (“FASEB”) concluded that at the current levels of consumption the only health risk from added sweeteners was their contribution to dental cavities.<sup>16</sup> In July 1981 CSPI wrote to the FDA and requested an updated safety review of sweeteners, asserting that current sweetener consumption posed risks to public health, including dental caries, heart disease, type 2 diabetes, hypertension, nutrient deficiencies, and behavior disorders. In November 1982 the FDA proposed to affirm that corn sugar, corn syrup, invert sugar, and sucrose are GRAS,<sup>17</sup> and in November 1983 the FDA established a Sugars Task Force to assess the safety of dietary sugars. The Task Force published its report in 1986. In November 1988 the FDA – after reviewing the comments from CSPI and

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<sup>14</sup> The FDA could use the format that it used for the olestra notice: The messages on soft drinks should appear either on the principal display panel or on the information panel; be enclosed by a 0.5 point box rule with 2.5 points of space around the statement; utilize at least one point leading; have type that is kerned so the letters do not touch; be all black or one color type and be printed on a white or other neutral contrasting background whenever possible; utilize a single easy-to-read type style such as Helvetica Regular and upper and lower case letters; and be in type size no smaller than 8 points. 21 C.F.R. 172.867(e)(2)(2002 edition). (The olestra-notice requirement was revoked in 2003. 68 Fed. Reg. 46363 (August 5, 2003).)

<sup>15</sup> The FDA could, in the alternative, simply amend those five regulations rather than revoke them.

<sup>16</sup> “Evaluation of the Health Aspects of Sucrose as a Food Ingredient,” Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology (1976), and “Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar and Food Ingredients,” Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology (1976).

<sup>17</sup> 47 Fed. Reg. 53917 and 53923 (November 30, 1982).

others – published a final rule affirming that the use of corn sugar, corn syrup, invert sugar, and sucrose in food is GRAS.<sup>18</sup>

The FDA agreed in 1988 with both the FASEB and the Sugars Task Force that “there is no conclusive evidence that sugars consumption at present levels poses a health hazard to the general public, other than a contribution to dental caries.”<sup>19</sup>

In November 1988 the FDA proposed to amend its regulations to affirm that HFCS in food is also GRAS. In August 1996, following its review of the comments submitted and without discussing recent trends in consumption of HFCS, the FDA issued a final rule declaring that HFCS is also GRAS.<sup>20</sup>

The FDA’s 1988 rule was limited or antiquated in certain regards. For instance, FDA estimated in 1988 that the “average American consumes less than 1 pound of added sugars per week,” based on dietary-recall surveys.<sup>21</sup> The FDA concluded that “the data show that the availability of sweeteners remained fairly constant from 1970 through 1985, suggesting that total sweetener consumption has remained relatively constant since” the 1976 review.<sup>22</sup> Since the FDA’s statement, the U.S. Department of Agriculture (“USDA”) estimated, based on the 1994-96 national dietary-recall survey, that the average American consumes about 20 teaspoons per day of refined sugars, equivalent to about 64 pounds per year, reflecting increased consumption since the FDA’s report.<sup>23</sup> Because people typically under-report consumption of sugary foods, all dietary recall studies likely under-estimate consumption of refined sugars (and it was

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<sup>18</sup> 53 Fed. Reg. 44862 (November 7, 1988). Those regulations are now codified at 21 C.F.R. 184.1854, 184.1857, 184.1859, and 184.1865.

<sup>19</sup> 53 Fed. Reg. 44865 (November 7, 1988).

<sup>20</sup> 61 Fed. Reg. 43447 (August 23, 1996). That regulation is now codified at 21 C.F.R. 184.1866.

<sup>21</sup> 53 Fed. Reg. at 44871 (November 7, 1988).

<sup>22</sup> 53 Fed. Reg. at 44872 (November 7, 1988).

<sup>23</sup> 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” includes “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.” 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/Csfi3yr.pdf>> [accessed July 7, 1999].

disingenuous of the FDA not to acknowledge that inaccuracy in dietary-recall data). (Underreporting should not affect trends data based on commercial shipments of caloric sweeteners.) Indeed, when USDA estimates refined-sugars consumption on the basis of production minus waste/spoilage, it concludes that per-capita consumption is actually 32 teaspoons per day or 103 pounds per year.<sup>24</sup>

Furthermore, the FDA rule addressed refined sugars, not soft drinks. The FDA stated that “excess sugars consumption may contribute to obesity as a nonspecific source of calories but not because of any special property of sugars.”<sup>25</sup> The FDA also stated that sugars are not unique causes of nutritional deficiencies: “...sweeteners do not have a unique ability to cause dietary imbalances.”<sup>26</sup> Since the FDA wrote that Federal Register notice, studies (as well as everyday experience) indicate that soft drinks replace milk, a far better source of nutrients, in the diets of youths, and expert committees of the HHS/USDA and the Institute of Medicine have urged Americans to consume less soft drinks.

**B. Data published since 1996 indicate that non-diet soft drinks are a major source of calories for Americans of all ages.**

Production of carbonated soft drinks in the United States exploded over the past 50 years, including a doubling since 1971.<sup>27</sup> (See Figure 1.) Those drinks now account for one out of four beverages consumed in America.<sup>28</sup> In 2004, Americans spent \$66 billion on soft drinks.<sup>29</sup> The industry produced enough soda pop to provide the average person with about 52 gallons. That is equivalent to 557 12-ounce servings per year, or 1½ 12-ounce cans per day, for every man, woman, and child.<sup>30</sup> Sweetened soft drinks are the single-most-consumed food in the American diet, providing about 7 percent of all calories, according to the government-sponsored (Department of Health and Human Services) 1999–2000 National Health and Nutrition

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<sup>24</sup> USDA, Economic Research Service. Frazao, E., ed. *America’s Eating Habits: Changes and Consequences*. Agriculture Information Bulletin No. 750, 1997, p. 87.

<sup>25</sup> 53 Fed. Reg. at 44867 (November 7, 1988).

<sup>26</sup> 53 Fed. Reg. at 44870 (November 7, 1988).

<sup>27</sup> Production was 26.1 gallons in 1971 (Maxwell, JW. *Soda’s In, Water’s Out*. Beverage Industry, Feb. 1986) and 52.4 gallons in 2004 (Press release. U.S. soft drink sales up slightly in 2004, Beverage Marketing Corporation reports. Beverage Marketing Corporation, NY, March 4, 2005 <http://www.beveragemarketing.com/pressreleases> [accessed March 29, 2005].)

<sup>28</sup> National Soft Drink Assoc., <http://www.nsd.com/SoftDrinks/index.html> [accessed, July 5, 2002].

<sup>29</sup> Press release. Beverage Digest. March 4, 2005. [http://www.beverage-digest.com/pdf/top-10\\_2005.pdf](http://www.beverage-digest.com/pdf/top-10_2005.pdf) [accessed, March 29, 2005].

<sup>30</sup> *Ibid.*

Examination Survey (NHANES).<sup>31</sup> Other researchers found that carbonated soft drinks and fruit drinks/ades provided 13 percent of teenagers' calories.<sup>32</sup>

The one bit of good news is that soda-pop sales declined from a peak of 56.1 gallons per person in 1998 to 52.4 gallons in 2004.<sup>33</sup> Also, reflecting the increased concern about obesity and consumer interest in low-carb diets, artificially sweetened diet sodas are grabbing a larger share of the market. Diet sodas accounted for 29 percent of total carbonated soft-drink sales in 2004, up several percentage points in the last few years and up from just 9 percent in 1970.<sup>34</sup> (As discussed in section III.C. below, diet-soda consumption by teenagers is very low.) Thus, while overall carbonated soft-drink consumption declined by 7 percent between 1998 and 2004, non-diet soft-drink consumption declined by 12 percent.

Those data do not include sweetened *non*-carbonated beverages (bottled ice teas, fruit drinks and ades, etc.), which are nutritionally equivalent to carbonated beverages. Most of those products contain between 0 and 10 percent fruit juice. If they were included, many of the consumption figures would be as much as 30 percent higher.<sup>35</sup>

### 1. Youths' Consumption of Soda Pop Through 1994-96

Children start drinking soda pop at a remarkably young age, and consumption increases through young adulthood. One-fifth of one- and two-year-old children consume soft drinks.<sup>36</sup> In

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<sup>31</sup> Block G. Foods contributing to energy intake in the US: data from NHANES III and NHANES 1999-2000. *J Food Comp Anal.* 2004;17:439-47.

<sup>32</sup> Murphy M, Douglass J, Latulippe M, et al. Beverages as a source of energy and nutrients in diets of children and adolescents. *Exper Biol.* 2005, Abstract #275.4. Also see: New study documents the detrimental impact of teen beverage choices. *Market Wire.* April 3, 2005.

<sup>33</sup> Prince GW. Twin Towers. *Beverage World.* Mar. 1999, P. 34. Beverage Marketing Corporation. U.S. soft drink sales flat in 2003. Press release. Mar. 4, 2004. [www.beveragemarketing.com/news200.htm](http://www.beveragemarketing.com/news200.htm) (accessed Nov. 7, 2004). Press release. U.S. soft drink sales up slightly in 2004, Beverage Marketing Corporation reports. Beverage Marketing Corporation, op cit.

<sup>34</sup> Elliott S. For its reintroduction, Pepsi One goes on a television-free, celebrity-free commercial diet. *New York Times.* Mar. 16, 2005. p. C7. USDA, Economic Research Service. Beverages, per capita consumption, 1970-2000. <http://www.ers.usda.gov/Data/FoodConsumption/Spreadsheets/beverage.xls> [accessed Aug. 7, 2002].

<sup>35</sup> Popkin BM, Nielsen SJ, op cit.

<sup>36</sup> Unless otherwise specified, all data on consumption of soft drinks, milk, and calorie intake were obtained or calculated from USDA surveys, including the Continuing Survey of Food Intakes of Individuals (CSFII), 1994-96 (Data Tables 9.4, 9.7, 10.4, 10.7); 1987-88 (Report No. 87+1, Tables 1.2-1 and -2; 1.7-1 and -2); Nationwide Food Consumption Surveys, 1977-78 (Tables A1.2-1 and -2; A1.7-1 and -2). Intake of added sugars by age was obtained from USDA's analysis for purposes of the Food

1994–96 those toddlers drank an average of seven ounces—nearly one cup—per day. Toddlers’ consumption changed little between the late 1970s and mid 1990s.

Almost half of all children between 6 and 11 drank soda pop in 1994–96, with the average drinker consuming 15 ounces per day. That 1994–96 figure was up slightly from 12 ounces in 1977–78.

The most avid soft-drink consumers of all are 12- to 29-year-old males. In 1994–96, boys 12 to 19 drank an average of 1½ 12-ounce cans of soda pop per day. (See Table 1.) Omitting boys who did not imbibe soda pop, the average soda drinker drank an average of almost 2½ 12-ounce sodas (28.5 ounces) per day. (See Table 2.) One-fourth of 13- to 18-year-old male pop-drinkers drink 2½ or more cans per day, and one out of 20 drinks five cans or more.<sup>37</sup> (See Table 3.) (Again, actual intakes probably were higher, because dietary surveys underestimate the quantities of foods people consume, and people may be particularly likely to underestimate foods perceived as “bad.”)

**Table 1. Consumption of non-diet soft drinks by 12- to 19-year-olds (ounces per day) and percent of caloric intakes (all figures include non-drinkers).**

Year	Ounces per day		Percent of calories	
	<u>boys</u>	<u>girls</u>	<u>boys</u>	<u>girls</u>
1977–78	7	6	3	4
1987–88	12	7	6	5
1994–96	19	12	9	8

Source: Calculated from U.S. Dept. Agr. Nationwide Food Consumption Survey, 1977–78; Continuing Survey of Food Intakes by Individuals, 1987–88, 1994–96.

**Table 2. Consumption of regular and diet soft drinks by 12- to 19-year-olds (ounces per day; excludes non-drinkers).**

	<u>boys</u>	<u>girls</u>
1977–78	16	15
1987–88	23	18
1994–96	28	21

Source: USDA Nationwide Food Consumption Survey, 1977–78; Continuing Survey of Food Intakes by Individuals, 1987–88, 1994–96.

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Guide Pyramid (1996 data, Table 6). Teens’ consumption of vegetables, fruit, and other foods is from Pyramid Servings Data, USDA, March 1997, based on CSFII, 1994.

<sup>37</sup> Calculations conducted in September 1998 for the Center for Science in the Public Interest by Environ, Inc., Arlington, Va., based on USDA CSFII 1994–96 Data Tables (see previous note).

**Table 3. Consumption of regular and diet soft drinks by 13- to 18-year-olds (ounces per day; excludes non-drinkers).**

	---- percentiles ----					
	<u>5</u>	<u>25</u>	<u>50</u>	<u>75</u>	<u>90</u>	<u>95</u>
1994-96: boys	6	12	20	30	44	57
1994-96: girls	4	6	14	23	32	40
1977-78: boys and girls	3	5	9	15	-	27

Source: Percentile calculations by Environ, Inc., for Center for Science in the Public Interest; data from USDA, CSFII, 1994-96. Figures for 1977-78 calculated from P.M. Guenther, *J Am Diet Assoc.* 1986;86:493-9.

Teenage girls also drink large amounts of soda pop. In 1994-96, girls averaged 12 ounces of soda pop per day. (See Table 1.) Among only those girls who drank soft drinks, the average girl consumed about  $1\frac{3}{4}$  sodas per day. (See Table 2.) One-fourth of 13- to 18-year-old female soda pop-drinkers drank two or more cans per day, and one out of 20 drank three cans or more.<sup>38</sup> (See Table 3.) (Women in their twenties averaged slightly more: two 12-ounce sodas per day.)

By contrast, 20 years earlier, the typical (50th-percentile) 13- to 18-year-old consumer of soft drinks (boys and girls together) drank  $\frac{3}{4}$  of a can per day, while the 95th-percentile teen drank  $2\frac{1}{4}$  cans. (See Table 3.) That's slightly more than one-half of 1994-96 consumption.

## **2. New Data for 1999-2002 Indicate Increased Soft Drink Consumption by Teens**

The trajectory of soft-drink consumption by teenagers appears to be continuing upward (compare Table 1 to Table 4), according to new analyses of the latest food-consumption surveys.<sup>39</sup> (Because the new data come from the National Health and Nutrition Examination Survey and are for 13- to 18-year-olds, the data may not be exactly comparable to the 1994-96 data for 12- 19-year-olds from USDA's CSFII shown above, but they are the most accurate, most recent data available and likely to be reasonably comparable.)

In 1999-2002 the average 13- to 18-year-old boy consumed two 12-ounce cans of soda pop a day, the average girl  $1\frac{1}{2}$  cans per day. (See Table 4.) Adding in fruit drinks, which are basically non-carbonated soft drinks, the totals rise to  $2\frac{1}{2}$  cans for boys and  $1\frac{3}{4}$  cans for girls. That compares to only 11 ounces of milk for boys and 7 ounces for girls. Teens were consuming

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<sup>38</sup> Ibid.

<sup>39</sup> All the data in this section were calculated from the 1999-2002 National Health and Nutrition Examination Survey 1999-2002 for CSPI by Barry Popkin and Dan Blanchette, University of North Carolina School of Public Health (July 2005). Totals may not add up due to rounding.

more than two times as much carbonated soft drinks as milk, up slightly from 1994–96, and more than three times as much total soft drinks (including fruit drinks) as milk.

**Table 4. Beverage Consumption By All 13- to 18-year-olds (1999-2002)**

<u>Beverage</u>	Boys		Girls		All	
	<u>Oz./day</u>	<u>Cal/day</u>	<u>Oz./day</u>	<u>Cal/day</u>	<u>Oz./day</u>	<u>Cal/day</u>
Carbonated soft drinks						
Caloric	25	303	16	193	20	249
Diet	1	0	1	0	1	0
<b>Total</b>	<b>25</b>	<b>303</b>	<b>17</b>	<b>194</b>	<b>21</b>	<b>250</b>
Fruit drinks	5	60	5	61	5	60
Caloric carbonated + fruit drinks	29	363	21	254	25	310
<b>All carbonated + fruit drinks</b>	<b>30</b>	<b>363</b>	<b>22</b>	<b>254</b>	<b>26</b>	<b>310</b>
Milk	11	160	7	98	9	130

Excluding those youths who did not drink any soft drinks or fruit drinks, the consumption figures rise to 3 12-ounce cans per day for the average boy and over 2 cans for the average girl. (See Table 5.) Those teens were getting 15 percent of their calories from soda pop and fruit drinks. The boys in the 90<sup>th</sup> percentile of consumption were drinking over 5 cans a day, and the girls 4 cans. (See Table 6.) (In 1994–96, those figures were less than 4 cans for boys and less than 3 cans for girls.) In the 95<sup>th</sup> percentile of consumption, boys drank 7 cans a day and girls drank 5 cans a day. (In 1994–96, those figures were about 5 cans for boys and 3 cans for girls.)

**Table 5. Beverage consumption by 13- to 18-year-olds, excluding non-consumers (1999-2002)**

<u>Beverage</u>	Boys		Girls		All	
	<u>Oz./day</u>	<u>Cal/day</u>	<u>Oz./day</u>	<u>Cal/day</u>	<u>Oz./day</u>	<u>Cal/day</u>
Carbonated soft drinks						
Caloric	32	390	23	286	28	343
Diet	20	4	19	5	19	4
<b>Total<sup>40</sup></b>	<b>32</b>	<b>379</b>	<b>23</b>	<b>267</b>	<b>28</b>	<b>326</b>
Fruit drinks	22	267	17	215	19	238
Caloric carbonated + fruit drinks	35	427	26	318	30	375
<b>All carbonated + fruit drinks</b>	<b>35</b>	<b>416</b>	<b>26</b>	<b>302</b>	<b>31</b>	<b>361</b>
Milk	19	277	14	205	17	245

<sup>40</sup> Total soft drink consumption is not the sum of the amounts of caloric and diet sodas consumed per drinker. That is because so few youths drink diet soda. The same reasoning applies to the sum of all carbonated drinks plus fruit drinks.

**Table 6. Consumption of regular carbonated soft drinks and fruit drinks by 13- to 18-year-olds, excluding nondrinkers (oz./day)**

<u>Year/gender</u>	<u>Percentile</u>					
	<u>10th</u>	<u>30th</u>	<u>50th</u>	<u>80th</u>	<u>90th</u>	<u>95th</u>
boys	12	19	27	49	66	83
girls	9	13	21	38	48	61
boys and girls <sup>41</sup>	9	15	25	44	59	74

Notwithstanding high rates of overweight and obesity, few boys and girls have switched to diet soft drinks: only 4 percent of boys and girls reported drinking diet sodas, while 85 percent reported drinking non-diet soft drinks or fruit drinks. Teenagers drank 22 times as much regular soda and fruit drinks as diet soda.

### **3. Large Packages and Low Prices Help Increase Soft Drink Sales**

One reason, aside from the ubiquitous advertising, for increasing consumption is that the industry has steadily increased container sizes. In the 1950s, Coca-Cola's 6½-ounce bottle was the standard serving. That grew into the 12-ounce can, and now those are being supplanted by 20-ounce bottles (and gargantuan products like the 64-ounce Double Gulp at 7-Eleven stores). (See Figure 2.) The larger the container, the more people are likely to drink, especially when they assume they are buying single-serving containers.

Also, pricing practices encourage people to purchase large servings. For instance, at McDonald's restaurants a 16-ounce ("small") drink costs about \$1.05, while a drink 100 percent larger (32-ounce "large") costs only 50 percent more (about \$1.57).<sup>42</sup> At one multiplex theater in Maryland, a 16-ounce ("small") drink costs \$3.25, while a drink 175 percent larger (44-ounce "large") costs only 30 percent more (\$4.25).<sup>43</sup> Prices at grocery and drug stores can be quite low. In July 2005, CVS drug stores in Washington, D.C., were selling 3-liter bottles of cola for \$1, or 8 cents per 8-ounce serving.

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<sup>41</sup> The bottom row is not the average of the two other rows, because girls are more highly represented in the lower percentiles of consumption, while boys are more represented in the higher percentiles.

<sup>42</sup> National Alliance for Nutrition and Activity. From wallet to waistline: the hidden costs of super sizing. (Washington, DC) June 18, 2002.

<sup>43</sup> Kentlands Stadium 10 in Gaithersburg, Maryland. Mar. 2005. Several other theaters surveyed had similar prices for soft drinks.

### C. Nutritional Impact of Soft Drinks

Regular soft drinks provide youths and young adults with hefty amounts of refined sugars (usually in the form of high-fructose corn syrup)<sup>44</sup> and calories. Even diet sodas may replace more nutritious foods and beverages and decrease consumption of various nutrients.

#### 1. Sugars Intake

Carbonated drinks are the single biggest source of refined sugars in the American diet in both 1988–94 and 1999–2000.<sup>45</sup> According to dietary surveys,<sup>46</sup> soda pop provides the average American with seven teaspoons of sugars per day, out of a total of about 20 teaspoons. Teenage boys get 44 percent of their 34 teaspoons of refined sugars a day from soft drinks.<sup>47</sup> Teenage girls get 40 percent of their 24 teaspoons of sugars from soft drinks. Because some people drink little or no soda pop, the percentage of refined sugars provided by soda pop is higher among actual drinkers.

The USDA has recommended that people eating 1,600 calories a day eat no more than six teaspoons a day of refined sugars, 12 teaspoons for those eating 2,200 calories, and 18 teaspoons for those eating 2,800 calories (from 6 percent to 10 percent of calories).<sup>48</sup> To put those numbers into perspective, consider that in 1999–2002 the average 13- to 18-year-old boy consumed about 2,700 calories and 2 12-ounce cans of soda with 20 teaspoons of sugars a day; the average girl

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<sup>44</sup> High-fructose corn syrup has been criticized by some people as being more harmful to health than regular sugar. However, the average of the several varieties of high-fructose corn syrup used in processed foods consists of 50 percent fructose and 50 percent glucose. Sucrose (ordinary table sugar), when degraded by acids in soft drinks or when it is digested, provides the body with exactly the same mix of fructose and glucose. Instead of being particularly concerned about high-fructose corn syrup, we should be concerned about over-consumption of *all* types of refined sugars.

<sup>45</sup> Gibney M, Sigman-Grant M, Stanton Jr. JL, et al. Consumption of sugars. *Am J Clin Nutr.* 1995;62(suppl):178S-94S.

<sup>46</sup> Those dietary surveys find that consumers report drinking only 57 percent of all soft drinks produced. While some soft drinks are wasted or returned to manufacturers, that fact suggests the extent to which the surveys underestimate actual consumption.

<sup>47</sup> Boys: 33.6 teaspoons/day of added sugars (USDA. Agricultural Research Service, Beltsville Human Nutrition Research Center. Pyramid Servings Data: Results from USDA's 1995 and 1996 Continuing Survey of Food Intakes by Individuals. Dec. 1997.) and 584 g/day of caloric soft drinks (CSFII 1994-96) equates to 49% of added sugars from soft drinks. Girls: 24.1 teaspoons/day of added sugars (USDA. Agricultural Research Service, Beltsville Human Nutrition Research Center. Pyramid Servings Data: Results from USDA's 1995 and 1996 Continuing Survey of Food Intakes by Individuals. Dec. 1997.) and 349 g/day of caloric carbonated soft drinks (CSFII 1994-96) equates to 41 percent.

<sup>48</sup> USDA. The Food Guide Pyramid. Home and Garden Bulletin No. 252, Oct. 1996. By interpolation, a 2,000-calorie diet should contain up to 10 teaspoons of sugars.

consumed about 2,000 calories and 1½ cans with 13 teaspoons of sugars.<sup>49</sup> Thus, typical teens exceeded their recommended refined-sugars limits from soft drinks alone. Adding in fruit drinks, candy, cookies, cake, ice cream, and other sugary foods, most teenagers exceed those recommendations by a large margin. Using a line of reasoning similar to USDA's, the 2005 edition of *Dietary Guidelines for Americans*, which is published by the USDA and the Department of Health and Human Services, noted that someone who is eating a healthy 2,000-calorie diet (with 29 percent of calories from fat) has room for only 8 teaspoons of added sugars per day.<sup>50</sup>

## 2. Calorie Intake

Consuming large amounts of soda pop means consuming a lot of sugars (in the form of high-fructose corn syrup) and a lot of calories. Among all Americans, carbonated soft drinks provide 7 percent of calories.<sup>51</sup> Adding in non-carbonated soft drinks brings that figure up to 9 percent. Among children 2 to 18 years old, the percentage of calories provided by carbonated and non-carbonated soft drinks more than doubled (from 4.8 to 10.3) between 1977-78 and 1999-2001.<sup>52</sup> In 1999-2002, among 13- to 18-year-olds, carbonated soft drinks provided 10.7 percent of calories,<sup>53</sup> about one-fourth more than in 1994-96 and at least triple what it was in 1977-78. (See Table 1.) Adding in fruit drinks, in 1999-2002 teens consumed 13 percent of their calories from all soft drinks. In 1994-96, among 13- to 18-year-olds who drank soft drinks, boys and girls in the 75th percentile of consumption obtained 12 percent of their calories from soft drinks. Those in the 90th percentile obtained about 18 percent of their calories from soft drinks.<sup>54</sup> (Similar data for 1999-2002 are not available.)

## 3. Nutrient Intakes

Some nutritionists in and out of industry emphasize that soft drinks and other nutrient-poor foods can fit into a healthful diet. In theory, they may be correct, but they ignore the fact

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<sup>49</sup> See note 39.

<sup>50</sup> USDA, U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2005*. (Washington, DC) Ch. 7. [www.healthierus.gov/dietaryguidelines](http://www.healthierus.gov/dietaryguidelines) (accessed March 14, 2005)

<sup>51</sup> Block G. op. cit.

<sup>52</sup> Nielsen SJ, Popkin BM. Changes in Beverage Intake Between 1977 and 2001. *Am J Prev Med* 2004;27:205-210.

<sup>53</sup> See footnote 39 for 1999-2002 data. In 1994-96, no-calorie diet sodas constituted only 4 percent of soft-drink consumption by teenage boys and 11 percent by teenage girls, according to USDA's CSFII survey. In 1999-2002 that figure dropped to 3 percent for boys and 5 percent for girls. (See footnote 39.)

<sup>54</sup> Analyses by Environ, see note 37.

that many people consume great quantities of soft drinks—along with chips, candy, pastries, hot dogs, French fries, and other low-nutrition foods—and meager quantities of the nutrient-packed foods that should constitute the bulk of the diet. One government study found that only 2 percent of 2- to 19-year-olds met all five federal recommendations for a healthy diet.<sup>55</sup> USDA's Healthy Eating Index found that on a scale of 0-100, teenagers had scores in the low 60s (as did most other age-sex groups). Scores between 51 and 80 indicate that a diet "needs improvement."<sup>56</sup>

Dietary surveys<sup>57</sup> of teenagers found that in 1994:

- \* Only 39 percent of boys and 31 percent of girls consumed the number of servings of vegetables recommended by USDA's Food Pyramid.
- \* Only 13 percent of boys and 15 percent of girls consumed the recommended amount of fruit.
- \* Only 29 percent of boys and 12 percent of girls consumed the recommended amount of dairy foods.

Those surveys<sup>58</sup> also found that few 12- to 19-year-olds consumed the recommended amounts of certain nutrients, including:

- \* calcium: Only 36 percent of boys and 14 percent of girls consumed 100 percent of the Recommended Dietary Allowance ("RDA").
- \* vitamin A: Only 36 percent of boys and 31 percent of girls consumed 100 percent of the RDA.
- \* magnesium: Only 34 percent of boys and 18 percent of girls consumed 100 percent of the RDA.

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<sup>55</sup> 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. Correction: *Pediatrics*. 1998;101:952-3.

<sup>56</sup> USDA, Center for Nutrition Policy and Promotion, CNPP-5; The Healthy Eating Index, 1994-96, July 1998.

<sup>57</sup> USDA, Agricultural Research Service, Food Surveys Research Group. Pyramid Servings Data: Results from USDA's 1995 and 1996 Continuing Survey of Food Intakes by Individuals. 1996 Pyramid servings, Tables 2B, 3B, 4B. Dec. 1997. <http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm> [accessed Oct. 7, 1998].

<sup>58</sup> USDA, Agricultural Research Service, Food Surveys Research Group. Data Tables: Results from USDA's 1994-96 Continuing Survey of Food Intakes by Individual and 1994-96 Diet and Health Knowledge Survey. Table 3. Dec. 1997. <http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm> [accessed Oct. 7, 1998].

As teens doubled or tripled their consumption of soft drinks, they cut their consumption of milk by more than 40 percent. In 1977–78, boys consumed more than twice as much milk as soft drinks, and girls consumed 50 percent more milk than soft drinks. (See Figure 3.) By 1994–96, both boys and girls consumed twice as much soda pop as milk (and 20- to 29-year-olds consumed three times as much). Teenage boys consumed about 2 $\frac{2}{3}$  cups of carbonated soft drinks per day but only 1 $\frac{1}{4}$  cups of fluid milk. Girls consumed about 1 $\frac{1}{2}$  cups of soft drinks per day, but less than 1 cup of milk. Compared to adolescent non-drinkers, heavy drinkers of soda pop (26 ounces per day or more) are almost four times more likely to drink less than one glass of milk a day.<sup>59</sup> Five years later, in 1999–2002, 13- to 18-year-olds consumed three times as much soft drinks (carbonated and noncarbonated) as milk.<sup>60</sup>

In 1977–78, teenage boys and girls who frequently drank soft drinks consumed about 20 percent less calcium than non-drinkers. Heavy soft-drink consumption also correlated with low intake of magnesium, ascorbic acid, riboflavin, and vitamin A, as well as high intake of calories, fat, and carbohydrate.<sup>61</sup> In 1994–96, calcium continued to be a special problem for girls who consume soft drinks.<sup>62</sup> (Boys likely were getting more calcium from pizza and cheeseburgers.)

Studies highlight the impact of soft drinks on calcium intake. A 1996 USDA study examined calcium consumption in a large sample of nonpregnant, nonlactating women.<sup>63</sup> High intakes of soft drinks (added sugars was not analyzed) were associated with low calcium intakes. The author stated:

[W]omen who failed to meet their calcium RDA consumed less milk and milk products than those who did meet their RDA. . . . They also consumed more regular soda.

Women who met their calcium RDA consumed an average of 99 grams (3 fluid ounces) of regular sodas per day, while those who did not meet their calcium RDA consumed 47 percent more regular soda, 146 grams (5 fluid ounces) per day. Another study found that drinking more soda pop was correlated with children of all ages consuming too little vitamin A, children younger than 12 consuming too little calcium, and children six and older consuming too little magnesium.<sup>64</sup> The authors of that study concluded:

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<sup>59</sup> Lisa Harnack, University of Minnesota, Division of Epidemiology. Pers. Comm. Sept. 22, 1998.

<sup>60</sup> See footnote 39.

<sup>61</sup> Guenther PM. Beverages in the diets of American teenagers. *J am Diet Assoc.* 1986;86:493-9.

<sup>62</sup> Analyses by Environ, Inc., see note 37. Calcium was the only micronutrient examined.

<sup>63</sup> Guthrie JF. Dietary patterns and personal characteristics of women consuming recommended amounts of calcium. *Family Econ Nutr Rev.* 1996;9(3):33-49

<sup>64</sup> Ballew C, Kuester S, Gillespie C. Beverage choices affect adequacy of children's nutrient intakes. *Arch Pediatr Adolesc Med.* 2000;154:1148-52.

A decrease of one glass of carbonated soda coupled with an increase of one glass of milk or juice could have a substantial effect on a child's daily nutrient intake.

A study by USDA's Agricultural Research Service analyzed 1994–96 dietary-intake data to understand the relationship between intake of added sugars (much of which comes from soft drinks) and other nutrients.<sup>65</sup> That study provides strong evidence that foods and beverages high in added sugars are displacing more nutrient-rich foods in the American diet.

The researcher divided individuals into thirds by added-sugars intake: light (under 10 percent of calories), medium (10 percent to 18 percent of calories), and heavy (more than 18 percent of calories) consumers. She found that the medium and heavy consumers consumed 10 percent more calories than the light consumers. There was no difference in fat intake (grams) between light and heavy consumers of added sugars. The surprising finding was that heavy consumers, despite their higher caloric intake, consumed:

- \* 24 percent *less* fiber than light consumers
- \* *less* of 15 different vitamins and minerals than light consumers
- \* 15 percent to 20 percent *less* vitamin A, vitamin C, folate, vitamin B-12, and magnesium than light consumers and 6 percent less calcium

The study concluded: "A remarkably lower percentage of [heavy consumers of added sugars] met their RDA for many micronutrients." It also found that disproportionately high percentages of lower-income Americans (40 percent) and African-Americans (44 percent) were heavy consumers of added sugars. (Those figures compare to 33 percent of all individuals.)

The author added:

Because of the increasing prevalence of obesity, consumers will be benefited by limiting intake of 'empty' calories, especially during childhood and adolescence....It is important for consumers to recognize that they get large amounts of added sugars through processed foods and beverages.

Another study reviewed adolescents' food consumption, based on USDA's national dietary surveys between 1965 and 1996.<sup>66</sup> The study found that decreases in raw fruits, non-potato vegetables, and calcium-rich dairy foods coincided with "greatly increased" soft-drink consumption. Between 1965 and 1996, adolescent boys increased their consumption of soft drinks (carbonated and fruit drinks) from 19 to 50 ounces per day and consumption by girls

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<sup>65</sup> Bowman S. Diets of individuals based on energy intakes from added sugars. *Family Econ Nutr Rev.* 1999(summer);12(2):31-8.

<sup>66</sup> Cavadini C, Siega-Riz AM, Popkin BM. US adolescent food intake trends from 1965 to 1996. *Arch Dis Child.* 2000;83:18-24.

climbed from 16 to 35 ounces per day. The paper notes that those trends “are of most concern for females, who may be at greater risk of developing osteoporosis later in life.”

One of the authors of that study said that the dietary changes over the past several decades may leave teenagers at higher risk of chronic ailments later in life, including heart disease, osteoporosis, and type 2 diabetes. He stated, “Sugar-loaded beverages are really just empty calories that block out healthy foods. I would tell parents to restrict their kids’ soft-drink and fruit-drink consumption.”<sup>67</sup> He said that people who indulge in too many soft drinks either get fewer nutrients or eat more food than they should. A spokesperson for the American Dietetic Association expressed concern that:

Soda is no longer considered a treat. Soda is now considered a given at a lot of peoples’ tables. You’re replacing nutritious calories with empty calories.<sup>68</sup>

In a small study of 6- to 13-year-old children, researchers found that kids who drank more sweetened beverages (fruit-flavored drinks, soft drinks, iced teas, and the like) drank less milk.<sup>69</sup> Children who consumed more than 16 ounces of sweetened beverages per day had lower intakes of calcium, magnesium, zinc, vitamin A, and other nutrients.

A study of children in grades 4 to 6 (10 to 12 years old) also found reason for concern.<sup>70</sup> Compared to children who did not drink soft drinks, children who consumed an average of 20 ounces of soft drinks per day consumed substantially less fruit and more high-fat vegetables (such as French fries).

The 2005 edition of *Dietary Guidelines for Americans* summarized the effects of sugary foods, such as soft drinks, on nutritional status by stating:

Individuals who consume food or beverages high in added sugars tend to consume more calories than those who consume food or beverages low in added sugars; they also tend to consume lower amounts of micronutrients. Although more research is needed, available prospective studies show a positive association between the consumption of calorically sweetened beverages and weight gain. For this reason, decreased intake of

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<sup>67</sup> Vergano D, Sternberg S. Teens’ thirst for sugar may mean bitter medicine later. USA Today. July 24, 2000, p. 1D.

<sup>68</sup> Warner J. Teens drinking too much soda, not enough milk. CBS HealthWatch. July 24, 2000. [wysiwyg://15/http://cbshealthwatch.../HNews/HnewsPrint.asp?RecID=219641](http://www.cbshealthwatch.com/HNews/HnewsPrint.asp?RecID=219641) [accessed Aug. 21, 2000].

<sup>69</sup> Mrdjenovic G, Levitsky DA. Nutritional and energetic consequences of sweetened drink consumption in 6- to 13-year-old children. J Pediatr. 2003;142:604-10.

<sup>70</sup> Cullen KW, Ash DM, Warneke C, de Moor C. Intake of soft drinks, fruit-flavored beverages, and fruits and vegetables by children in grades 4 through 6. Am J Pub Health. 2002;92:1475-8.

such foods, especially beverages with caloric sweeteners, is recommended to reduce calorie intake and help achieve recommended nutrient intakes and weight control.<sup>71</sup>

#### **D. Health Impact of Soft Drinks**

The soft-drink industry has consistently portrayed its products as being positively healthful, saying they are 90 percent water and contain sugars found in nature. A poster that the National Soft Drink Association (now called the American Beverage Association) once provided to teachers stated:

As refreshing sources of needed liquids and energy, soft drinks represent a positive addition to a well-balanced diet....These same three sugars also occur naturally, for example, in fruits....In your body it makes no difference whether the sugar is from a soft drink or a peach.<sup>72</sup>

Currently, in a desperate attempt to link soft drinks to good health, the industry emphasizes that soda contains water, an essential nutrient:

Drink Plenty of Fluids: Consume at least eight glasses of fluids daily, even more when you exercise. A variety of beverages, including soft drinks, can contribute to proper hydration.<sup>73</sup>

A similar claim was made in 1998 by M. Douglas Ivester, then Coca-Cola's chairman and CEO, when he defended the marketing of soft drinks in Africa. He said, "Actually, our product is quite healthy. Fluid replenishment is a key to health....Coca-Cola does a great service because it encourages people to take in more and more liquids."<sup>74</sup>

In fact, soft drinks pose health risks both because of what they *contain* (for example, extra calories, sugar, and various additives) and what they *replace* in the diet (beverages and foods that provide vitamins, minerals, and other nutrients). The 2000 edition of *Dietary Guidelines for Americans* recognizes the potential for adverse health effects from over-consumption of refined sugars. It states:

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<sup>71</sup> *Dietary Guidelines for Americans*, 2005, op cit.

<sup>72</sup> National Soft Drink Association. *Soft Drinks and Nutrition*. Washington, D.C. (undated).

<sup>73</sup> National Soft Drink Association. *Soft drinks. Balance, variety, moderation*. <http://www.nsd.org/softdrinks/CSDHealth/1layout.pdf> [accessed, July 4, 2004].

<sup>74</sup> Hays CL, McNeil, Jr. DG. *Putting Africa on Coke's Map*. *New York Times*, May 26, 1998, p. D1.

Intake of a lot of foods high in added sugars, like soft drinks, is of concern. Consuming excess calories from these foods may contribute to weight gain or lower consumption of more nutritious foods....Limit your use of these beverages and foods.<sup>75</sup>

The 2005 edition of *Dietary Guidelines for Americans* reaffirmed that conclusion. It says:

Individuals who consume food or beverages high in added sugars tend to consume more calories than those who consume food or beverages low in added sugars; they also tend to consume lower amounts of micronutrients....decreased intake of such foods, especially beverages with caloric sweeteners, is recommended to reduce calorie intake and help achieve recommended nutrient intakes and weight control.<sup>76</sup>

We discuss below the impact of HFCS (and other sweeteners) on obesity, bones and osteoporosis, tooth decay and erosion, and heart disease.

### 1. Obesity

Being overweight or obese increases the risk of type 2 diabetes, heart disease, stroke, cancer, and other diseases and causes severe social and psychological problems in millions of Americans.<sup>77</sup> Being overweight (for adults, a body mass index ("BMI") between 25 and <30) is often a stepping stone to being obese (BMI of 30 or higher), a condition associated with 112,000 premature deaths annually.<sup>78,79</sup>

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<sup>75</sup> USDA, U.S. Department of Health and Human Services. *Nutrition and Your Health: Dietary Guidelines for Americans*. 2000. Pp. 32-3.  
<http://www.health.gov/dietaryguidelines/dga2000/document/frontcover.htm> [accessed July 5, 2002].

<sup>76</sup> *Dietary Guidelines for Americans*, 2005, op cit.

<sup>77</sup> U.S. Surgeon General. U.S. Department of Health and Human Services. *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity*. 2001.  
[www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf](http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf).

<sup>78</sup> Flegal, KM, Graubard BI, Williamson DF, et al. Excess Deaths Associated With Underweight, Overweight, and Obesity. *JAMA*. 2005;293:1861-7.

<sup>79</sup> The terminology is different for children and teens. Body mass index is used to assess underweight, overweight, and being at risk for overweight. Children's body fatness changes over the years as they grow, and girls and boys differ in their body fatness as they mature. That is why BMI for children, also referred to as BMI-for-age, is gender and age specific. BMI-for-age is plotted on gender-specific growth charts, which are used for children and teens 2-20 years of age. Centers for Disease Control and Prevention. Overweight and obesity: defining overweight and obesity.  
<http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm> [accessed June 14, 2005].

Between 1971–74 and 1999–2002, rates of being overweight/obese ( $\geq 95^{\text{th}}$  percentile) in teenagers soared from 6 percent to 16 percent.<sup>80</sup> (See Table 7.) (About the same percentage was considered at the risk of being overweight/obese.)

**Table 7. Prevalence of American Children Who Are Overweight/Obese**

<u>Age (years)</u>	<u>1971–74</u>	<u>1976–80</u>	<u>1988–94</u>	<u>1999–2002</u>
6–11	4	7	11	16
12–19	6	5	11	16

Source: National Center for Health Statistics.<sup>81</sup>

Among adults, between 1976–80 and 1999–2002, the rate of obesity more than doubled, from 15 percent to 31 percent.<sup>82</sup> (See Table 8.) The overall rates of obesity plus overweight were 47 percent in 1976–80 and 65 percent in 1999–2002.

**Table 8. Prevalence of Overweight and Obesity Among American Adults, 20–74 years.**

	<u>1976–80</u>	<u>1988–94</u>	<u>1999–2002</u>
Overweight	32	33	34
Obese	15	23	31
Overweight or obese	47	56	65

Source: National Center for Health Statistics.<sup>83</sup>

Numerous factors—from lack of exercise to eating too many calories to genetics—contribute to obesity. Non-diet soda pop contains calories without nutrients. Because it may add calories to the diet, soda pop may promote obesity. Nutritionists and weight-loss

<sup>80</sup> Centers for Disease Control and Prevention, National Center for Health Statistics. Prevalence of overweight and children and adolescents: United States, 1999–2000. Table 71. <http://www.cdc.gov/nchs/products/pubs/pubd/hs/tables/2002/02hus071.pdf> [accessed Oct. 14, 2002].

<sup>81</sup> Ogden CL, Flegal KM, Carroll MD, et al. Prevalence and trends in overweight among US children and adolescents, 1999–2000. *JAMA* 2002; 288:1728–32. Hedley AA, Ogden CL, Johnson CL, et al. Prevalence of overweight and obesity among US children, adolescents, and adults, 1999–2002. *JAMA*. 2004;291:2847–59.

<sup>82</sup> Centers for Disease Control and Prevention, National Center for Health Statistics. Prevalence of overweight and obesity among adults, op cit. Table 70.

<sup>83</sup> National Center for Health Statistics. Prevalence of overweight and obesity among adults: United States, 1999–2002. Health E-Stats. [www.cdc.gov/nchs/products/pubs/pubd/hestats/obese/obse99.htm](http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese/obse99.htm) (accessed Apr. 12, 2005)

experts routinely advise overweight individuals to consume fewer calories, especially from such empty-calorie foods as soft drinks.<sup>84</sup> The National Institutes of Health recommends that people who are trying to lose or control their weight should drink water instead of soft drinks with sugar.<sup>85</sup>

It is only in the last 10 years that researchers have begun to find statistical and experimental evidence that soft drinks do, in fact, promote obesity. An analysis of USDA's 1994-1996 dietary-intake data found that obesity rates have risen in tandem with soft-drink consumption and that heavy consumers of soda pop have higher calorie intakes.<sup>86</sup> A study of middle-school children in Santa Barbara County, California found a strong association between obesity and consumption of both regular and diet soft drinks.<sup>87</sup> (The link between diet soda and obesity may reflect that some overweight children have made dietary changes or that children may consume excess snack foods along with the sodas.)

National Cancer Institute scientists found that soft drinks provide a larger percentage of calories to overweight youths than to other youths. The difference was most striking among teenage boys: Soft drinks provided 10.3 percent of the calories consumed by overweight boys, but only 7.6 percent of the calories consumed by other boys. Those findings suggest that soft drinks contribute to obesity, even though in this study no difference was observed in the overall caloric intake of the two groups.<sup>88</sup>

A 19-month observational study on the relationship between soft-drinks and obesity in children involved 548 children whose average age was just under 12 years.<sup>89</sup> It found that the chances of becoming obese increased significantly with each additional daily serving of sugar-

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<sup>84</sup> Also, the drinking of soda pop may be likelier (compared to the drinking of, for example, orange juice or milk) to accompany the consumption of foods with relatively low nutrient density or high calorie and fat content, such as potato chips, French fries, hamburgers, and pizza. Such foods not only are rich in calories, but also may displace foods with high nutrient density and few calories (such as vegetables and fruits) that would tend to reduce weight gain.

<sup>85</sup> NHLBI and Office of Research on Minority Health. Embrace Your Health! Lose Weight if You Are Overweight. NIH Publication No. 97-4061, Sept. 1997.  
<http://www.nhlbi.nih.gov/health/public/heart/other/chdblack/embrace.pdf> (accessed Mar. 20, 2005)

<sup>86</sup> Analyses by Environ, see note 37.

<sup>87</sup> Giammattei J, Blix G, Marshak HH, et al. Television watching and soft drink consumption. *Arch Pediatr Adolesc Med.* 2003;157:882-6.

<sup>88</sup> Troiano RP, Briefel RR, Carroll MD, Bialostosky K. Energy and fat intakes of children and adolescents in the United States: data from the National Health and Nutrition Examination Surveys. *Am J Clin Nutr.* 2000;72(suppl):1343S-53S.

<sup>89</sup> Ludwig DS, Peterson KE, Gortmaker SL. Relationship between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis. *Lancet.* 2001;357:505-8.

sweetened drink. It also found that at the beginning of the study children's consumption of sugar-sweetened drinks was associated with increased BMI. Though the study was relatively small (37 children became obese over the course of 19 months), it adds to the evidence that soft drinks are contributing to the obesity epidemic.

A much larger observational study, the Growing Up Today Study, involved more than 12,000 children between 9 and 14 years old and found that greater consumption of soft drinks was associated with small increases in BMI over a two-year period.<sup>90,91</sup> The authors concluded that "consumption of sugar-added beverages may contribute to weight gain among adolescents, probably due to their contribution to total energy intake."

That soft drinks contribute to obesity in adults, not just children, was indicated by a study of tens of thousands of nurses over an eight-year period.<sup>92</sup> Women who increased their consumption of soft drinks from less than one a week to one or more per day gained an average of 18 pounds. Women who originally drank one or more soft drinks per day but then cut back to no more than one drink per week gained the least weight (about six pounds). That study also found that women who drank soft drinks daily had almost twice the risk of type 2 diabetes as women who drank little or no soda pop. Fruit drinks also promoted weight gain and diabetes.

In an accompanying editorial, a researcher at the Boston University School of Medicine commented that the study "provides strong, scientifically sound evidence that excess calories from soft drinks are directly contributing to the epidemics of obesity and type 2 diabetes" and that "reducing sugar-sweetened beverage consumption may be the best single opportunity to curb the obesity epidemic."<sup>93</sup>

Intervention studies can identify cause-and-effect relationships with greater certainty than observational studies like the ones discussed above. One such study involved 644 students between 7 and 11 years old in 29 school classes in England. The researchers studied the effect of strongly encouraging the children in half the classes to drink less "fizzy" drinks.<sup>94</sup> After one

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<sup>90</sup> Berkey CS, Rockett HR, Field AE, et al. Sugar-added beverages and adolescent weight change. *Obes Res.* 2004;12:778-88.

<sup>91</sup> Some of the same researchers subsequently found that weight gain in the same cohort of children was also correlated with milk consumption. Berkey CS, Rockett HR, Willett WC, et al. Milk, dairy fat, dietary calcium, and weight gain. *Arch Pediatr Adolesc Med.* 2005;159:543-550.

<sup>92</sup> Schulze MB, Manson JE, Ludwig DS, et al. Sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes in young and middle-aged women. *JAMA.* 2004;292:927-34.

<sup>93</sup> Apovian CM. Sugar-sweetened soft drinks, obesity, and type 2 diabetes. *JAMA.* 2004;292:978-9.

<sup>94</sup> James J, Thomas P, Cavan D, et al. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomized controlled trial. *BMJ.* 2004;328:1237.

year, the percentage of overweight and obese children in the test group remained the same, but increased by 7.5 percent in the control group.

Another intervention study, this one in Denmark, compared the health effects of sugar-sweetened and diet soft drinks.<sup>95</sup> For ten weeks, overweight adults consumed, among other foods, either 600 calories' worth of beverages and foods sweetened with sugar or similar foods prepared with artificial sweeteners. The group that ate the sugar-sweetened beverages and foods gained an average of 3.5 pounds, while those who consumed the artificially sweetened products lost an average of 2 pounds.

One way that soft drinks might contribute to weight gain is by increasing dietary intakes of fructose. That fructose comes from either high-fructose corn syrup or sugar (sugar molecules are made up of fructose and glucose). Fructose appears to affect blood levels of such hormones as insulin, leptin, and ghrelin. According to one group of researchers, because of fructose's effects on hormones, "prolonged consumption of diets high in energy from fructose could lead to increased caloric intake and contribute to weight gain and obesity."<sup>96</sup>

Another line of research indicates that calories consumed in the form of liquids (like soda pop), rather than solids, are more likely to promote obesity. In one study, subjects added 450 calories a day to their diets from either soft drinks or jelly beans during two four-week periods.<sup>97</sup> When they ate jelly beans, the subjects compensated for the added calories by consuming roughly 450 fewer calories from other foods. However, when they drank soft drinks, the subjects failed to compensate, adding 450 calories to their previous diet. Other studies support that finding,<sup>98</sup> but some research does not.<sup>99</sup> The differing results may be due to the foods tested, the subjects

<sup>95</sup> Raben A, Vasilaras TH, Møller AC, et al. Sucrose compared with artificial sweeteners: different effects on ad libitum food intake and body weight after 10 wk of supplementation in overweight subjects. *Am J Clin Nutr.* 2002;76:721-9. An earlier, shorter study that compared soft drinks containing aspartame and high-fructose corn syrup found similar results. Tordoff MG, Alleva AM. Effect of drinking soda sweetened with aspartame or high-fructose corn syrup on food intake and body weight. *Am J Clin Nutr.* 1990;51:963-9.

<sup>96</sup> Teff KL, Elliott SS, Tschop M, et al. Dietary fructose reduces circulating insulin and leptin, attenuates postprandial suppression of ghrelin, and increases triglycerides in women. *J Clin Endocrinol Metab.* 2004;89:2963-72.

<sup>97</sup> DiMeglio DP, Mattes RD. Liquid versus solid carbohydrate: effects on food intake and body weight. *Intern J. Obesity.* 2000;24:794-800.

<sup>98</sup> DeCastro JM. The effects of spontaneous ingestion of particular food or beverages on the meal pattern and overall nutrient intake of humans. *Physiol Behav.* 1993;53:1133-44. Mattes RD. Dietary compensation by humans for supplemental energy provided as ethanol or carbohydrate in fluids. *Physiol Behav.* 1996;59:179-87. Rolls BJ, Kim S, Federoff IC. Effects of drinks with sucrose or aspartame on hunger, thirst and food intake in men. *Physiol Behav.* 1990;48:19-26.

<sup>99</sup> 2005 Dietary Guidelines Advisory Committee Report, Part D, Section 2, pp. 18-9.

tested, the length of the tests, or other reasons. (Though few studies have compared the effects of different liquids on weight gain, two small clinical studies did not find any difference in caloric intake at lunches that were either preceded or accompanied by drinking equal numbers of calories in the form of cola, orange juice, or low-fat milk.<sup>100</sup> However, such clinical studies have not evaluated whether the drinking of particular beverages, because of their customary roles in the diet, conventional serving sizes, or tastes, affects how much of those beverages one drinks and what solid foods one eats.) Meanwhile, prudence would suggest that we pay heed to the possibility that liquid calories are particularly conducive to weight gain.

The body of research on soft drinks' contribution to overweight and obesity is still modest, but the studies to date certainly indicate that soft drinks are a special problem. That is why in 2004 the committee that advised the government on *Dietary Guidelines for Americans* concluded:

In summary, although the evidence is not large and there are methodologic problems with this research, the preponderance of prospective data available suggest that added sugars (particularly in beverages) are associated with an increase in energy intake. As a result, decreasing the intake of added sugars (particularly in beverages) may help prevent weight gain and may aid in weight loss.<sup>101</sup>

The committee's conclusion was based on its review of eight cross-sectional studies (only one of which was published before 1996, when HFCS was affirmed as GRAS), six prospective studies (all published since 1996), and two intervention studies (both published since 1996).

As noted above, the 2005 *Dietary Guidelines for Americans* itself emphasizes the same concern.

The fear that soft drinks are fueling the epidemic of overweight and obesity was echoed by the Institute of Medicine's Committee on Prevention of Obesity in Children and Youth.<sup>102</sup> It acknowledged the lack of "definitive proof" that soft drinks cause obesity, but still declared:

Because of concerns about excessive consumption of sweetened beverages in place of more nutrient-rich or lower-calorie alternatives, children should be encouraged to avoid high-calorie, nutrient-poor beverages.

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<sup>100</sup> Almiron-Roig E, Drewnowski A. Hunger, thirst, and energy intakes following consumption of caloric beverages. *Physiol Behav.* 2003;79:767-73. DellaValle DM, Roe LS, Rolls BJ. Does the consumption of caloric and non-caloric beverages with a meal affect energy intake? *Appetite.* 2005;44:187-93. Such clinical studies cannot evaluate whether the drinking of particular beverages (because of their cultural uses, sizes, or tastes) changes what solid foods a person eats.

<sup>101</sup> 2005 Dietary Guidelines Advisory Committee Report, Part D, Section 5.

<sup>102</sup> Committee on Prevention of Obesity in Children and Youth, Institute of Medicine. Fact Sheet, Parents can play a role in preventing childhood obesity. Sept. 2004.

## 2. Bones and Osteoporosis

People who drink soft drinks instead of milk or other dairy products likely will have lower calcium intakes. Low calcium intake contributes to osteoporosis, a disease leading to fragile and broken bones. In 2002, the National Osteoporosis Foundation estimated that 10 million Americans had osteoporosis. Another 34 million had low bone mass and were at increased risk of osteoporosis.<sup>103</sup> Women are more frequently affected than men. Considering the low calcium intake of today's teenage girls, osteoporosis likely will continue to be a problem.

The risk of osteoporosis depends in part on how much bone mass is built up early in life. Girls build 92 percent of their bone mass by age 18,<sup>104</sup> but if they don't consume enough calcium in their teenage years they cannot "catch up" later. That is why experts recommend higher calcium intakes for youths aged 9 to 18 than for adults aged 19 to 50. Teenage girls in 1994-96 were consuming only 60 percent of the recommended amount, with soft-drink drinkers consuming almost one-fifth less than non-drinkers.<sup>105</sup>

While osteoporosis takes decades to develop, preliminary research suggests that the lower calcium intake that may result from drinking soda pop instead of milk can contribute to broken bones in children. In a study of 200 girls 3 to 15 years old, the 100 who had suffered broken bones had lower bone density than another 100 who had not.<sup>106</sup> In another study, Mayo Clinic researchers studied rates of bone fracture in residents under the age of 35 in Rochester, Minnesota. They found a 32 percent increase between 1969-71 and 1999-2001 in distal forearm bone fractures in males and a 56 percent increase in females. Among 10- to 14-year-olds, the increase was 63 percent. That study couldn't establish a cause-and-effect relationship, but the researchers suggested that increasing obesity rates, increased soft-drink and decreased milk consumption, and sub-optimal calcium consumption could be the culprits.<sup>107</sup>

Canadian researchers found that over a two-year period during adolescence—the peak period for building bone mass—girls who drank more soft drinks and other beverages with few

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<sup>103</sup> National Osteoporosis Foundation. <http://www.nof.org/advocacy/prevalence/index.htm> [accessed July 5, 2002].

<sup>104</sup> Institute of Medicine. *Dietary Reference Intakes: Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. 1997; pp.4-28.

<sup>105</sup> Analyses by Environ, see note 37.

<sup>106</sup> Goulding A, Cannan R, Williams SM, et al. Bone mineral density in girls with forearm fractures. *J Bone Miner Res*. 1998;13:143-8.

<sup>107</sup> Khosla S, Melton LJ, Dekutoski MB, et al. Incidence of childhood distal forearm fractures over 30 years. *JAMA*. 2003;290:1479-85.

nutrients (fruit drinks, coffee, tea) built up less bone mass.<sup>108</sup> The same association was not found in boys, perhaps because boys eat more calcium-rich cheese than do girls.

A small study found strong associations between consumption of carbonated beverages and bone fractures in teenage girls.<sup>109</sup> Among active girls, the risk of bone fracture was almost five times greater in girls who consumed colas compared to girls who did not. Among all girls in this study, the risk of bone fracture in girls who consumed carbonated beverages was more than three times that in girls who did not consume carbonated beverages. The author acknowledges limitations in the study (for example, failure to ascertain the amounts of soft drinks and milk consumed), but stated:

In conclusion, nationally, there is great concern about the effects of carbonated-beverage consumption on obesity, tooth decay, osteoporosis, and other health problems. Concern about the health impact of carbonated-beverage consumption, in particular, the association with bone fractures in adolescent girls, is validated by our findings. Our findings have implications both for the health of teenagers and for the health of women at later ages.

In an editorial accompanying that paper, a specialist in adolescent medicine stated that those “findings are alarming and warrant confirmation.”<sup>110</sup> He highlighted the sharp increase in soft-drink consumption and the sharp drop in milk consumption.

### **3. Tooth Decay (Caries) and Dental Erosion**

Refined sugars are one of several important factors that promote dental caries. Regular soft drinks promote caries because they bathe the teeth of frequent consumers in sugar-water for long periods of time during the day. An analysis of data from 1971–74 found a strong association between the frequency of between-meal consumption of soda pop and caries.<sup>111</sup> (Those researchers were able to separate the effects of soft drinks from the effects of sugary desserts.) In a large study of young children in Iowa, “intake of regular soda pop was the strongest predictor of the extent of caries.”<sup>112</sup>

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<sup>108</sup> Whiting SJ, Healey A, Psiuk S. Relationship between carbonated and other low nutrient dense beverages and bone mineral content of adolescents. *Nutr Res.* 2001;21:1107-15.

<sup>109</sup> Wyshak, G. Teenaged girls, carbonated beverage consumption, and bone fractures. *Arch Pediatr Adolesc Med.* 2000;154:610-3.

<sup>110</sup> Golden NH. Osteoporosis prevention. A pediatric challenge. *Arch Pediatr Adolesc Med.* 2000;154:542-3.

<sup>111</sup> Ismail AI, Burt BA, Eklund SA. The cariogenicity of soft drinks in the United States. *J Am Dent Assoc.* 1984; 109:241-5

<sup>112</sup> Marshall TA, Levy SM, Broffitt T, et al. Dental caries and beverage consumption in young children. *Pediatrics.* 2003;112:e184-91.

Tooth-decay rates in the U.S. have declined considerably in recent decades, thanks to such preventive factors as fluoride-containing toothpaste, fluoridated water, tooth sealants, and others. That may be why one study that used data from 1988-1994 found an association between soda consumption and caries in people over 25, but not in younger people.<sup>113</sup> Americans consume so many sugary foods that it simply may not be possible to tease out the effects on teeth of individual foods.<sup>114</sup> Nevertheless, caries remains a problem, especially for low-income and minority children. A large survey in California found that children (ages 6 to 8 and 15) of less-educated parents have 20 percent higher rates of decayed and filled teeth.<sup>115</sup> A national study found that African-American and Mexican-American children (6 to 18 years old) are about twice as likely to have untreated caries as their white counterparts.<sup>116</sup> For people in high-risk groups, prevention is particularly important.

To prevent tooth decay, health experts—and even the Canadian Soft Drink Association (now called Refreshments Canada)—recommend eating sugary foods and beverages with meals and limiting between-meal snacking of sugary and starchy foods.<sup>117</sup> Unfortunately, many heavy drinkers of soft drinks ignore both of those precepts.

The American Dental Association sums up the matter this way:

Though there is limited epidemiological evidence assessing the association between oral health and soft-drink consumption, it consistently indicates that soft drinks adversely affect dental caries and enamel erosion. Moreover, numerous in vitro and animal studies have consistently shown enamel erosion with the use of soft drinks. Given this evidence it would seem appropriate to encourage children and adolescents to limit their intake of soda.<sup>118</sup>

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<sup>113</sup> Heller KE, Burt BA, Eklund SA. Sugared soda consumption and dental caries in the United States. *J Dent Res.* 2001;80:1949-53.

<sup>114</sup> Ismail AI. University of Michigan School of Dentistry. Pers. Comm. Dec. 22, 2004.

<sup>115</sup> The Dental Health Foundation. *A Neglected Epidemic: The Oral Health of California's Children.* (San Rafael, 1997).

<sup>116</sup> Vargas CM, Orall JJ, Schneider DA. Sociodemographic distribution of pediatric dental caries: NHANES III, 1988-1994. *J Am Dent Assoc.* 1998;129:1229-38.

<sup>117</sup> Canadian Soft Drink Association, [www.softdrink.ca](http://www.softdrink.ca) [accessed Nov. 28, 2001].

<sup>118</sup> Joint report of the American Dental Association Council on Access, Prevention and Interprofessional Relations and Council on Scientific Affairs to the House of Delegates: Response to Resolution 73H-2000; Oct. 2001.

#### 4. Heart Disease

Heart disease is the nation's number-one killer. Some of the most important causes are diets high in saturated and *trans* fats and cholesterol; cigarette smoking; and a sedentary lifestyle. In addition, in many adults a diet high in sugars may also promote heart disease.

High-sugar diets may contribute to heart disease in people who are "insulin resistant" or have "syndrome X." Those people, an estimated one-fourth of adults, frequently have high levels of triglycerides and low levels of HDL ("good") cholesterol in their blood, abdominal obesity, and elevated blood pressure and blood sugar. When they eat a diet high in carbohydrates, their triglyceride and insulin levels rise. In some studies, sugar has a greater effect than other carbohydrates.<sup>119</sup> The high triglyceride levels are associated with a higher risk of heart disease and type 2 diabetes.<sup>120</sup>

A study of young adults (19 to 38 years old) in Louisiana found a strong association between consumption of sweetened beverages and risk factors for syndrome X.<sup>121</sup> That finding, according to the researchers, was not simply due to the subjects consuming excess calories or being overweight.

It would make sense for insulin-resistant people, in particular, to consume low levels of regular soft drinks and other sugary foods, though more researchers are urging that everyone reduce their intake of refined carbohydrates.<sup>122</sup> Research is needed on insulin resistance in adolescents.

#### 5. Caffeine

Several additives in soft drinks raise health concerns. Caffeine, a mildly addictive stimulant drug, is present in most cola and "pepper" drinks, as well as some orange and lemon-lime sodas and other products. Caffeine's addictiveness may be one reason why six of the seven

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<sup>119</sup> Hollenbeck CB. Dietary fructose effects on lipoprotein metabolism and risk for coronary artery disease. *Am J Clin Nutr.* 1993;58:800S-9S. Liu G, Coulston A, Hollenbeck C, Reaven G. The Effect of Sucrose Content in High and Low Carbohydrate Diets on Plasma Glucose, Insulin, and Lipid Responses in Hypertriglyceridemic Humans. *J Clin Endocrin Metab.* 1984;59:636-42. While those studies involved sucrose, the high-fructose corn syrup used in soft drinks is likely to have the same effect.

<sup>120</sup> Stampfer MJ, Krauss RM, Ma J, et al. A prospective study of triglyceride level, low-density lipoprotein particle diameter, and risk of myocardial infarction. *J Am Med Assoc.* 1996;276:882-8.

<sup>121</sup> Yoo S, Nicklas T, Baranowski T, et al. Comparison of dietary intakes associated with metabolic syndrome risk factors in young adults: the Bogalusa Heart Study. *Am J Clin Nutr.* 2004;80:841-8.

<sup>122</sup> Ludwig D. The glycemic index: physiological mechanisms relating to obesity, diabetes, and cardiovascular disease. *JAMA.* 2002;287:2414-23.

most popular soft drinks contain caffeine.<sup>123</sup> Caffeine-free colas are produced, but are not widely distributed or consumed (they account for only about five percent of colas made by Coca-Cola<sup>124</sup>).

Companies say they add caffeine as a flavoring. However, most regular cola-soft-drink consumers cannot detect caffeine's flavor when the substance is consumed in soft drinks.<sup>125</sup> That suggests that companies add caffeine primarily for its physiological and psychological effects, not for flavor. Indeed, an official of a British soft-drinks maker, Hero Drinks Group, stated that caffeine "is added mainly for its stimulatory effects."<sup>126</sup>

In 1994–96, the average 13- to 18-year-old boy who drank soft drinks consumed about 1 $\frac{2}{3}$  cans per day. Those drinking Mountain Dew would have ingested 92 milligrams (mg) of caffeine from that source (55 mg caffeine/12 ounces). That is equivalent to a six-ounce cup of brewed coffee. Boys in the 90th-percentile of soft-drink consumption consume as much caffeine as is in 2 cups of coffee; for girls the figure is 1 $\frac{1}{2}$  cups of coffee.

One problem with caffeine is that it increases the excretion of calcium in urine.<sup>127</sup> Drinking 12 ounces of caffeine-containing soft drink causes the loss of about 20 mg of calcium, or two percent of the U.S. RDA (or Daily Value). That loss, compounded by the relatively low calcium intake in girls who are heavy consumers of soda pop, may increase the risk of osteoporosis. (The loss of calcium could be mitigated either by decreasing caffeine or increasing calcium consumption.)

The amounts of caffeine in soft drinks can have distinct pharmacological and behavioral effects. One positive effect is that caffeine can increase alertness, which is why some late-night drivers drink caffeinated coffee or take over-the-counter medications that contain caffeine. However, in addition, caffeine can cause nervousness, irritability, sleeplessness, and rapid heart beat.<sup>128</sup> Caffeine causes children who normally do not consume much caffeine to be restless and

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<sup>123</sup> Beverage Digest. Beverage Digest/Maxwell ranks U.S. soft drink industry for 2004. Press release. Mar. 4, 2005. (Of the seven most-consumed drinks, only Sprite lacks caffeine.)

<sup>124</sup> Beverage Digest. [<http://www.beverage-digest.com/editorial/990212s.html>; accessed Sept. 9, 2002].

<sup>125</sup> Griffiths RR, Vernotica EM. Is caffeine a flavoring agent in cola soft drinks? *Arch Fam Med.* 2000;9:727-34.

<sup>126</sup> Tompsett A. Product formulation. *In* The Chemistry and Technology of Soft Drinks and Fruit Juices. (Boca Raton: CRC Press) 1998. P. 75.

<sup>127</sup> Barger-Lux MJ, Heaney RP. Caffeine and the calcium economy revisited. *Osteoporosis Intern.* 1995;5:97-102.

<sup>128</sup> American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. (Washington, D.C.), 4th ed. 1994.

fidgety, develop headaches, and have difficulty going to sleep.<sup>129</sup> Also, caffeine's addictiveness may keep people hooked on soft drinks (or other caffeine-containing beverages).<sup>130</sup> One reflection of the drug's addictiveness is that when children aged six to 12 stop consuming caffeine, they suffer withdrawal symptoms that impair their attention span and performance.<sup>131</sup> However, two researchers stated in a review that the effects of caffeine on children are "modest and typically innocuous," though they acknowledged that some research (including some of their own) found that some children (such as low consumers of caffeine) are more affected by the drug.<sup>132</sup>

In another study, the caffeine equivalent of two to three cans of soft drink per day (100 mg/day) was sufficient to produce physical dependence, characterized by withdrawal symptoms of tiredness and headache if consumption is stopped. That study also found that 25 mg of caffeine is sufficient to suppress caffeine-withdrawal headache.<sup>133</sup> Another study shows that 40 mg of caffeine (roughly the amount in one can of soda) produces mood and performance effects,<sup>134</sup> while yet another shows that low doses of caffeine can have cognitive and performance effects, including cognitive effects at doses as low as 12.5 mg.<sup>135</sup>

The Australia New Zealand Food Authority has concluded that (a) the amounts of caffeine in one or two cans of caffeinated soft drink can affect performance and mood, increase anxiety in children, and reduce the ability to sleep, though "the threshold dose for possible behavioral effects in children remains unclear...."; (b) typical doses of caffeine "may lead to

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<sup>129</sup> Rapoport JL, Jensvold M, Elkins R, et al. Behavioral and cognitive effects of caffeine in boys and adult males. *J Nervous Mental Disease*. 1981;169:726-32; Rapoport JL, Berg CJ, Ismond DR, et al. Behavioral effects of caffeine in children. *Arch Gen Psychiat*. 1984;41:1073-9.

<sup>130</sup> Juliano LM, Griffiths RR. Caffeine. In Lowinson JH, Ruiz P, Milman RB, et al. (Eds.) *Substance Abuse: A Comprehensive Textbook, Fourth Edition*. (pp. 403-421). Baltimore: Lippincott, Williams, & Wilkins.

<sup>131</sup> Bernstein GA, Carroll, ME, Dean NW, et al. Caffeine withdrawal in normal school-age children. *J Am Acad Child Adolesc Psychiatry*. 1998;37:858-65

<sup>132</sup> Castellanos FX, Rapoport JL. Effects of caffeine on development and behavior in infancy and childhood: a review of the published literature. *Food Chem Toxicol*. 2002;40:1235-42. (The authors have consulted for the International Life Sciences Institute, which receives major funding from makers of coffee and soft drinks. [www.cspinet.org/integrity](http://www.cspinet.org/integrity) [accessed May 18, 2005] )

<sup>133</sup> Evans SM, Griffiths RR. Caffeine withdrawal: parametric analysis of caffeine dosing conditions. *J Pharmacol and Exp Ther*. 1999;289,285-94

<sup>134</sup> Smith A, Sturgess W, Gallagher J. Effects of a low dose of caffeine given in different drinks on mood and performance. *Hum Psychopharmacol Clin Exp*. 1999;14:473-82.

<sup>135</sup> Smit HJ, Rogers PJ. Effects of low doses of caffeine on cognitive performance, mood and thirst in low and higher caffeine consumers. *Psychopharmacology (Berl)*. 2000 Oct;152(2):167-73.

withdrawal effects and some physical dependence in adults....Further research will be required...in children”; (c) there is little evidence for adverse cardiovascular effects.<sup>136</sup>

The European Union has concluded that “for children, an increase in the daily intake of caffeine to a certain level of consumption per day may bring about temporary changes in behavior, such as increased excitability, irritability, nervousness or anxiety. In addition, for pregnant women, the Committee’s view is that moderation of caffeine intake is advisable.”<sup>137</sup> The EU requires beverages containing more than 150 milligrams of caffeine per liter to declare “High caffeine content” and to declare the caffeine content in terms of milligrams per 100 milliliters.<sup>138</sup>

#### **IV. THE FDA HAS AMPLE LEGAL AUTHORITY TO REQUIRE HEALTH MESSAGES ON THOSE SOFT DRINKS THAT CONTAIN HIGH-FRUCTOSE CORN SYRUP AND OTHER CALORIC SWEETENERS.**

##### **A. High-fructose corn syrup and other sweeteners are no longer “Generally Recognized As Safe” by scientists and so are food additives within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.**

As discussed above in section III.A., in 1988 the FDA determined that corn sugar, corn syrup, invert sugar, and sucrose are GRAS, and in 1996 the FDA determined that HFCS is GRAS. However, the FDA’s regulations provide that ingredients:

which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1) [of the Federal Food, Drug, and Cosmetic Act], or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.<sup>139</sup>

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<sup>136</sup> Australia New Zealand Food Authority. Report from the expert working group on the safety aspects of dietary caffeine. June 2000. [http://www.anzfa.gov.au/documents/pub04\\_00.asp](http://www.anzfa.gov.au/documents/pub04_00.asp) [accessed July 6, 2000].

<sup>137</sup> Commission Directive 2002/67/EC of 18 July 2002 on the labelling of foodstuffs containing quinine, and of foodstuffs containing caffeine. [http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l\\_191/l\\_19120020719en00200021.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_191/l_19120020719en00200021.pdf) [accessed May 18, 2005]. (Typical soft drinks contain less than 150 mg/l and would not have to be labeled.)

<sup>138</sup> CSPI and numerous academic experts on caffeine have petitioned the FDA to require the amount of caffeine per serving to be listed on labels of caffeine-containing products. July 31, 1997. See Docket No. 97P-0498/CPI.

<sup>139</sup> 21 C.F.R. 170.6(c)

The regulatory scheme established by the Federal Food, Drug, and Cosmetic Act (“FFDCA”) divides food ingredients into those that are “food additives” and those that are not. This distinction is important because section 409(a)(2) of the FFDCA provides that the former may be legally used only if the FDA has issued a regulation “prescribing the conditions under which such additive may be safely used.”

Section 201(s) of the FFDCA provides, in pertinent part, a two-part test for defining when an ingredient is a food additive:<sup>140</sup>

any substance [1] the intended use of which results or may reasonably be expected to result, directly, or indirectly, in its becoming a component or otherwise affecting the characteristics of any food...[and] [2] if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use of food) to be safe under the conditions of its intended use...

Section 201(u) of the FFDCA says “The term ‘safe,’ as used in paragraph [201](s)...has reference to the health of man or animal.”

There can be no doubt that HFCS and other sweeteners meet the first part of this legal test, as their purpose is to sweeten soft drinks (and other foods).

The new scientific evidence linking the heavy consumption of added sugars to nutritional imbalances and obesity (discussed above in Sections III.C. and III.D.) demonstrates that HFCS and other sweeteners now also meet the second part of the legal definition of a food additive because they contribute to overweight and obesity and, as recognized by the Acting Commissioner of the FDA, their sequelae: an increased risk of coronary heart disease, hypertension, type 2 diabetes, osteoarthritis, and certain cancers. HFCS and other sweeteners can, therefore, no longer be considered GRAS. Those who wish to continue using HFCS and

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<sup>140</sup> Section 203(s)(4) of the FFDCA also excludes from the definition of a food additive “any substance used in accordance with a sanction or approval granted prior to” September 6, 1958. However, prior sanctions different from the uses established by the GRAS regulations “do not exist or have been waived” for sucrose, corn syrup, invert sugar, and corn syrup. 21 C.F.R. 184.1854(d), 184.1857(d), 184.1859(d), and 184.1865(d). We are not aware of any prior sanction for HFCS. If there were such a prior sanction for HFCS, the FDA’s current regulations provide that “Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health,...the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.” 21 C.F.R. 181.1(b). The scientific evidence discussed in sections III.C. and III.D. demonstrates that the current use of HFCS may be injurious to health.

other sweeteners can no longer meet their burden<sup>141</sup> of showing that they are GRAS “under the [current] conditions of its intended use.”

Consequently, the FDA should amend its regulations to revoke the GRAS status of HFCS and other sweeteners, reclassify HFCS and other sweeteners as food additives, and require health messages on labels on soft drinks as a condition of use.

**B. Relying on section 409 of the Federal Food, Drug, and Cosmetic Act, the FDA should require health messages on soft drinks containing high-fructose corn syrup and other caloric sweeteners, as well as caffeine.**

Section 409(a)(2) of the FFDCCA bars the use of a food additive unless “there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.” Section 409(c)(1)(A) of the FFDCCA says that those conditions may include “any...labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use.” Section 409(d) of the FFDCCA provides that “The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons thereof.” Section 201(u) of the FFDCCA says “The term ‘safe,’ as used...in sections 409, 512, 571, and 721, has reference to the health of man or animal.”

Those statutory provisions clearly give FDA the authority to require on soft drinks containing HFCS and other sweeteners a series of rotating health messages that the consumption of such soft drinks contributes to overweight and obesity and thus to the five diseases that the Acting Commissioner has linked to overweight and obesity: coronary heart disease, hypertension, type 2 diabetes, osteoarthritis, and certain cancers, as well as to other dietary and health problems related to over-consumption of soft drinks. Similarly, messages pertaining to the health effects of caffeine should be required. The FDA has required additional label information for the retail food sales of other food additives or of foods in which they are used, such as aspartame,<sup>142</sup> olestra,<sup>143</sup> and whole fish protein concentrate.<sup>144</sup>

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<sup>141</sup> The FDA’s regulations provide that the Commissioner, after reviewing the evidence, will revoke the GRAS status of an ingredient “[i]f he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the Act...” 21 C.F.R. 170.38(b)(3). Citing *United States v. Article of Food and Drug Consisting of Coli-Trol 80*, 518 F.2d 743,745 (5th Cir. 1975), the FDA said in 1997 that the proponent of an exemption from the definition of a food additive “has the burden of proving that the use of the substance is ‘generally recognized’ as safe.” 62 Fed. Reg. 18937 (April 17, 1997) at 18939.

<sup>142</sup> 21 C.F.R. 172.804(d) The label of any food containing aspartame shall say “PHENYLKETONURICS; CONTAINS PHENYLALANINE.”

<sup>143</sup> 21 C.F.R. 172.867(e) (2002 edition). The label for any food containing olestra should say “THIS  
(continued...)

**C. Current soft drink labels are misbranded because they are misleading within the meaning of section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act even if the FDA were to deny that high-fructose corn syrup and other sweeteners are not generally recognized as safe.**

Section 403(a) of the FFDCA says, in pertinent part, that a “food shall be deemed to be misbranded if its labeling is....misleading in any particular.” Section 201(n) of the FFDCA provides, in pertinent part, “in determining whether the labeling...is misleading there shall be taken into account (among other things) not only representations made or suggested...but also *the extent to which the labeling...fails to reveal... consequences which may result from the use of the article to which the labeling relates...under such conditions of use as are customary or usual.*” (emphasis added)

The FDA’s regulations provide that affirmative disclosure of material facts pursuant to those statutory requirements may be required through regulations.<sup>145</sup> The FDA has said that it “has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product.”<sup>146</sup> For example, the FDA has issued final regulations concerning certain ingredients:

- the term “milk derivative” must follow the ingredient declaration of sodium caseinate, which is GRAS,<sup>147</sup> when it is used in a food product labeled “non-dairy,”<sup>148</sup>

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(...continued)

PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.” The requirement for a notice on products containing olestra was revoked in 2003. 68 Fed. Reg. 46363 (August 5, 2003).

<sup>144</sup> 21 C.F.R. 172.385(f)(3). The labels of manufactured foods containing the additive shall say in the ingredient list “whole fish protein concentrate.”

<sup>145</sup> 21 C.F.R. 1.21(b).

<sup>146</sup> 61 Fed. Reg. 3117 (January 30, 1996) at 3160.

<sup>147</sup> 21 C.F.R. 182.1748.

<sup>148</sup> 21 C.F.R. 101.4(d). The Food Allergen Labeling and Consumer Protection Act of 1990, Title II of P.L. 108-282, requires that a milk derivative be so identified (along with derivatives of seven other major allergens) for all foods.

- food labels must disclose the presence of FD&C Yellow No. 5.<sup>149</sup> The FDA said that such labeling was necessary because of the “life-threatening nature of the reaction in those people who are sensitive to the dye;”<sup>150</sup> and
- in 1996 the FDA required a warning label on foods containing olestra even though it had determined that olestra was a safe food additive.<sup>151</sup>

The FDA also relied on the statutory misbranding provisions when in July 1990 it issued a proposed rule to expand the scope of mandatory nutrition labeling.<sup>152</sup> The FDA said that it had concluded that the misbranding provisions of the FFDCA “can be reasonably interpreted to require nutrition labeling on all foods that are meaningful sources of nutrition.”<sup>153</sup> However, the FDA acknowledged at that time that it had made a contrary statement in 1981 and that it had acknowledged in 1979 and 1989 that there were legal questions about its authority.<sup>154</sup> The final nutrition labeling regulations relied on the Nutrition Labeling and Education Act of 1990 (“NLEA”). The Committee on Energy and Commerce said that “the purpose of this legislation [the NLEA] is to clarify and to strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods...”<sup>155</sup>

It is certainly material information for consumers that drinking non-diet soft drinks may contribute to weight gain and – by leading to weight gain – increase the risks of coronary heart disease, hypertension, type 2 diabetes, osteoarthritis, and certain cancers; it is also material that

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<sup>149</sup> 21 C.F.R. 74.705(d)(2). Section 7 of the Nutrition Education and Labeling Act of 1990, P.L. 101-535, amended section 403(i) of the FFDCA to require that all colors certified under what is now section 721(c) of the FFDCA must be shown as a separate ingredient.

<sup>150</sup> 45 Fed. Reg. 60419 (September 12, 1980) at 60419.

<sup>151</sup> In 1996 the FDA required that the label for any food containing olestra should say “THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.” 21 C.F.R. 172.867(e) (2002 edition). The requirement for a notice on products containing olestra was revoked in 2003, in part because the FDA determined that evidence gathered in consumer surveys after 1996 showed that there was “a high degree of awareness among the public” about the possible effects of olestra. 68 Fed. Reg. 46363 (August 5, 2003) at 46387.

<sup>152</sup> At that time nutrition labeling was mandatory “only when a nutrient has been added to the food, or when the labeling or advertising for the food includes a claim or other representation about the food’s nutritional properties, its fat or caloric content, or its usefulness in the daily diet.” 55 Fed. Reg. 29487 (July 19, 1990) at 29491.

<sup>153</sup> 55 Fed. Reg. 29487 (July 19, 1990) at 29491.

<sup>154</sup> 55 Fed. Reg. at 29491 fn. 1.

<sup>155</sup> H.R. Rept. 101-538, 101<sup>st</sup> Cong., 2d Sess (June 13, 1990) at 7.

soft drinks may replace more nutritious beverages or foods in a diet and that drinking caffeine-containing soft drinks may lead to addiction and may increase the risk of osteoporosis.<sup>156</sup>

## V. CONCLUSION

For the reasons stated above, the FDA should immediately initiate a rulemaking to require a series of rotating health messages on those soft drinks that contain more than a specified amount of those sweeteners, as well as references to other health effects of common soft drink ingredients.

## VI. ENVIRONMENTAL IMPACT

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

## VII. ECONOMIC IMPACT

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.<sup>157</sup>

## VIII. CERTIFICATION

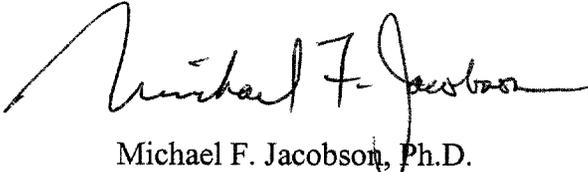
The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner which are unfavorable to the petition.

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<sup>156</sup> Some might contend that everyone knows that soft drinks contribute to weight gain and cause other problems and that health messages on labels are unnecessary. That ignores basic learning theory, which posits that knowledge is only the first step of a multi-factorial process, which includes a supportive environment, that leads to behavior change (e.g., Perry CL, Baranowski T, Parcel GS. (1990). How individuals, environments, and health behavior interact: Social Learning Theory. In Glans K, Lewis K, River R. (Ens.), Health Behavior and Health Education: Theory Research and Practice (pp. 161-186). San Francisco: Jossey-Bass Publishers). Obviously, McDonald's does not rely on a person's knowledge that its restaurants are available to provide victuals; rather, it spends \$1.4 billion on measured and unmeasured media advertising per year reminding people to act on that knowledge. Similarly, while people may have a vague awareness that consuming excessive amounts of soft drinks may contribute to health problems, people need reminders of all sorts—on packages, in the media, from health professionals—to encourage behavior change based on that knowledge. Moreover, in the case of soft drinks, a large, vocal industry spends hundreds of millions of dollars each year encouraging people to consume more soft drinks and additional sums obfuscating or denying the adverse health consequences of soft drinks or distracting people from thinking about those health consequences.

<sup>157</sup> 21 C.F.R. 10.30(b).

Respectfully submitted,



Michael F. Jacobson, Ph.D.  
Executive Director



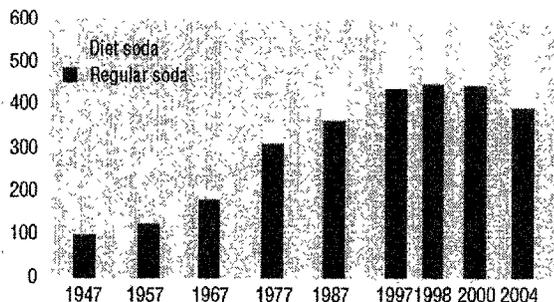
Benjamin Cohen  
Senior Staff Attorney

Attachments: Figure 1. Annual soft drink production in the United States (12-oz. cans/person)

Figure 2. Growth in soda container (oz.)

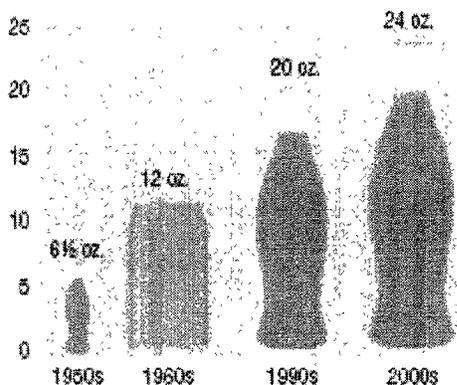
Figure 3. Boys' and girls', aged 12-19, average daily consumption of milk and soft drinks (oz.)

**Figure 1**  
**Annual soft drink production in the United States**  
**(12-oz. cans/person)**

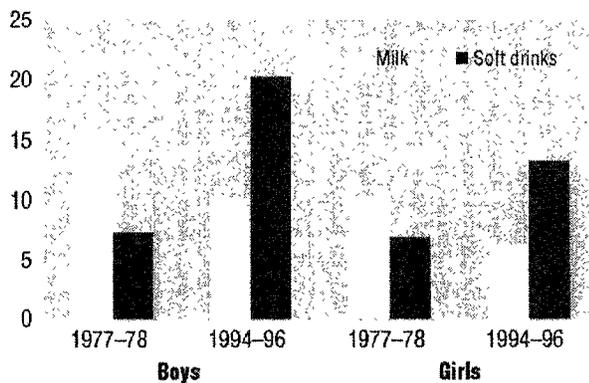


Sources: USDA Economic Research Service (1947-87); Beverage Digest (1997-2004).

**Figure 2**  
**Growth in soda container size (oz.)**



**Figure 3**  
**Boys' and girls', aged 12-19, average daily**  
**consumption of milk and soft drinks (oz.)**



Source: USDA food consumption surveys (see text).

**CSPI** Center for  
Science in the  
Public  
Interest

nonprofit  
publisher of

**Nutrition Action Healthletter**

July 13, 2005

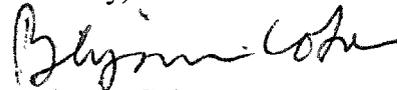
Dockets Management Division  
Food and Drug Administration  
Room 1061 (HFA-305)  
5630 Fishers Lane  
Rockville, MD 20852

Dear Sir or Madam:

Enclosed are: (1) the original and three copies of a petition we are submitting and (2) four copies of a letter in support of our petition. Please docket both documents.

Please call me at 202-332-9110 ext. 321 if you have any questions about either of these documents.

Sincerely,



Benjamin Cohen  
Senior Staff Attorney

enclosures