

**United States Department of Health and Human Services
Food and Drug Administration**

Food Labeling: Revision of the Nutrition
and Supplement Facts Label

Docket No. FDA-2012-N-1210.

COMMENTS OF THE CENTER FOR SCIENCE IN THE PUBLIC INTEREST

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August 1, 2014

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20093

Re: **Food Labeling: Revision of the Nutrition and Supplement Facts Labels**; Docket No. FDA-2012-N-1210

Dear Commissioner Hamburg:

The Center for Science in the Public Interest (CSPI) strongly supports the United States Department of Health and Human Services (HHS), Food and Drug Administration's (FDA) proposal to revise the Nutrition and Supplements Facts labels.

CSPI is a non-profit consumer education and advocacy organization that since 1971 has been working to improve the public's health through better nutrition and food safety policies. CSPI's work is supported primarily by its 900,000 subscribers to its *Nutrition Action Healthletter*, the nation's largest-circulation health newsletter. CSPI is an independent organization that does not accept any government or corporate funding.

We respectfully submit the following comments, outlined below:

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We urge the FDA to expeditiously finalize this rule, as well as the companion proposal regarding serving size revisions.

I. CSPI supports revisions to the Nutrition and Supplement Facts labels.

CSPI applauds the FDA for proposing revisions to the Nutrition and Supplement Facts label. We agree that a revision is needed in light of current scientific evidence and dietary recommendations. The FDA has not updated the Nutrition Facts label since the 2003 *trans* fat rulemaking or established new or updated DVs for nutrients since 1995. Since that time, as the agency notes, the public health profile of the U.S. population has changed (i.e., two out of three adults and one out of three children are overweight or obese); new dietary recommendations have been published; and new information has become available about nutrient definitions (e.g., vitamin E), reference intake values, and analytical methods.¹

Below we would like to highlight CSPI's major points of agreement and suggest areas for further improvement.

II. Added Sugars

A. We strongly support the mandatory declaration of added sugars on the Nutrition Facts label.

We strongly support the FDA's proposal to require a declaration of added sugars on the label. In 2003–2006, added sugars (sugar, high-fructose corn syrup (HFCS), etc.) provided about 14 percent of total calories for the average American, and 25 percent or more of calories for over 36 million Americans.² On average, Americans have consumed between 18 and 23 teaspoons (about 300 to 390 calories worth) of added sugars per day, according to National Health and Nutrition Examination Survey (NHANES) data and United States Department of Agriculture (USDA) average per-capita loss-adjusted food availability data, though consumption has declined modestly in the last several years.^{3,4}

Current consumption levels of added sugars can lead to serious health problems. The higher diets are in added sugars, the lower they are in a variety of vitamins and minerals, including calcium, vitamin A, iron, and zinc.² Strong evidence shows that consuming sugar-sweetened beverages – the largest source of added sugars in Americans' diets – leads to weight gain.⁵ Additionally, sugar-sweetened beverages have been associated with an increased risk of cardiovascular disease (CVD), type 2 diabetes, the metabolic syndrome, gout, and dental caries.^{6,7,8,9}

The current Nutrition Facts label does not provide information on the amount of added sugars in foods, and such information is crucial to help consumers comply with the *Dietary Guidelines for Americans (DGA), 2010's* key recommendation to reduce intake of calories from *added* sugars.¹⁰ Additionally, consumers may not recognize all of the forms of added sugar listed in the ingredient label, such as fructose, maltose, sucrose, honey, evaporated cane juice, and concentrated fruit juice. The FDA's proposal to require declaration of added sugars on the Nutrition Facts label is of great public health importance, especially given that two out of three adults and one out of three children are overweight or obese, more than one out of three adults now has prediabetes, and an estimated one out of three adults

will have diabetes by 2050.^{11,12,13} On the other hand, people should be consuming *more* naturally occurring sugars, which come mostly from fruit and dairy products and are associated with a wide variety of micronutrients.

B. FDA should propose a DV for added sugars to provide much-needed context for consumers.

To make the information provided by the added sugars declaration most useful to consumers, the FDA should specify a DV for added sugars. Without a DV, consumers could only compare the relative amounts of added sugars among products, but would not know how much of a day's worth of added sugars a food contains. When a 2014 online survey commissioned by CSPI (conducted among a demographically representative U.S. sample of 1,000 adults) showed 500 people a Nutrition Facts label with added sugars listed only in gram amounts, 78 percent of people said they did not know how much of their recommended daily limit of added sugars was in one serving of the food or they could not tell from the label (see Appendix 1).¹⁴

In its proposal, FDA notes:

Section 2(b)(1)(A) of the 1990 amendments mandated that FDA regulations implementing section 403(q) of the FD&C Act require that nutrition labeling must be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. **In particular, the percent DV of a nutrient present in food is declared on food labels to help consumers understand the relative significance of nutrition information in the context of a total daily diet, compare the nutritional values of food products, and to plan general diets. We also noted that the percent DV information advises the consumer how much of a recommended intake of that nutrient is provided by the food.** See 79 F.R. 11880, 11887 (*Emphasis added; citations omitted.*).

To provide needed context for an acceptable intake of added sugars, FDA should specify a DV for added sugars and require a percent DV on the added sugars line. Doing so would greatly assist effectuating FDA's purpose in requiring mandatory declaration of added sugars on the label. As the agency makes clear, the rationale for including added sugars on the label is grounded in FDA's concern for overall dietary health:

Our review [of the information related to added sugars] is not based on the factors we have traditionally considered for mandatory declaration that are related to chronic disease, health-related condition, or health-related physiological endpoint linked to the particular nutrient. Instead, **our review is based on the need for nutrient information for consumers to implement key dietary recommendations to assist consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet.** See 79 F.R. at 11880, 11891 (*Emphasis added.*).

In 2002, the Institute of Medicine (IOM) published the Dietary Reference Intakes (DRI) for energy, carbohydrate, and other nutrients.¹⁵ The advice for a maximum intake of added sugars was based on nutrient dilution (i.e., how much added sugars one could consume before experiencing reductions in intakes of essential nutrients). While the IOM report stated that “a maximal intake of 25 percent or less of energy from added sugars is suggested,” IOM President Harvey Fineberg later qualified that statement in an April 15, 2003, letter (see Appendix 2) to Secretary of Health and Human Services Tommy Thompson, noting:

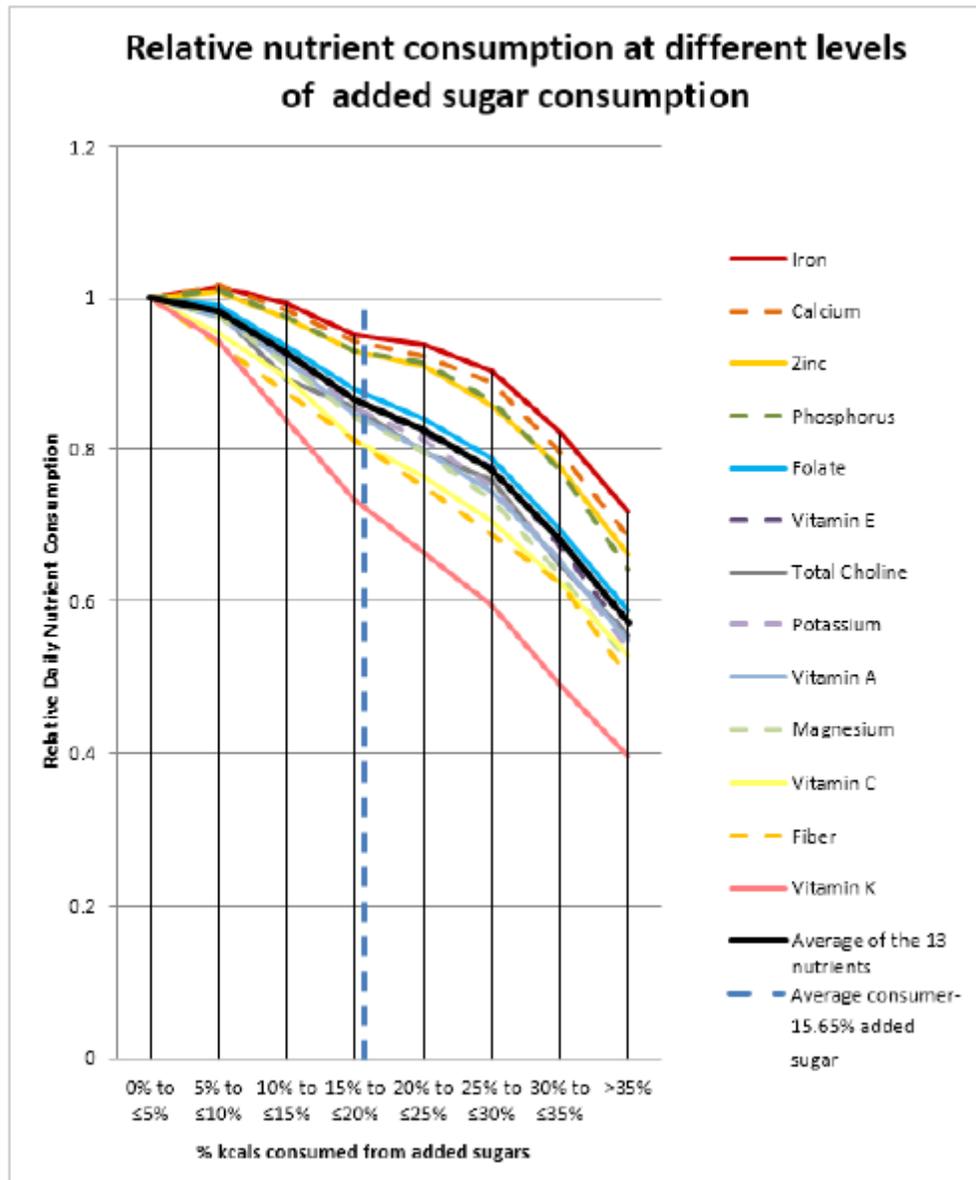
This language is not meant to convey a desirable or even acceptable standard intake. The report states that persons whose intake of added sugars is 25 percent or more of total calories are more likely to have poorer intakes of important essential nutrients. It does not address the issue that added sugar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

In recent years, a great deal of additional evidence has emerged to demonstrate that added sugars, at the levels currently consumed by tens of millions of Americans, are harmful to health. Some key findings:

1. National survey data shows a pattern of monotonically decreasing nutrient intakes with incremental increases in added sugars intake.

Marriott et al. compared the median intake of selected nutrients and added sugars intake among more than 15,100 people in NHANES 2003–2006. They observed a pattern of monotonically decreasing nutrient intakes, with lower median intake levels for all nutrients with each five percent increase in added sugars intake (see Figure 1).²

Figure 1. Relationship of sugar intake to added-sugar consumption. (Based on Marriott et al. 2010. Ref. 2)



The table below shows that when added sugars intake is **10 to 15 percent of calories**, the median intakes of *nine* nutrients (vitamin A, vitamin E, vitamin C, folate, magnesium, potassium, vitamin K, fiber, and total choline) are significantly lower than the median intakes of those nutrients for someone consuming 0 to 5 percent of their calories from added sugars. Potassium and fiber are nutrients of public health concern, as indicated in the 2010 DGA.¹⁰

Unpaired t-test results based on Marriott et al. 2010, Table 3, Page 238

Comparison of increasing added sugars intakes to median nutrient intakes with 0% to ≤ 5% of calories from added sugars.

Nutrient	% of kcals coming from added sugars daily							
	N	0% to ≤5%	5% to ≤10%	p-value	10% to ≤15%	p-value	15% to ≤20%	p-value
		1,387	2,877		3,666		3,311	
					Median (SE)			
Vitamin A, µg RAE	603 (13.8)	588 (14.3)	0.51	552 (9.6)	0.004*	510 (22.3)	0.009*	
Vitamin E, mg α-tocopherol	6.7 (0.15)	6.6 (0.09)	0.55	6.2 (0.10)	0.008*	5.8 (0.20)	0.006*	
Vitamin C, mg	85 (2.6)	81 (1.9)	0.22	76 (1.8)	0.007*	69 (1.5)	<0.0001*	
Folate, µg	398 (5.5)	394 (6.3)	0.68	373 (3.4)	<0.0001*	350 (12.8)	0.017*	
Iron, mg	14.6 (0.25)	14.8 (0.21)	0.57	14.5 (0.15)	0.729	13.9 (0.52)	0.393	
Zinc, mg	11.2 (0.21)	11.3 (0.17)	0.73	10.9 (0.14)	0.252	10.4 (0.43)	0.238	
Magnesium, mg	285 (4.1)	278 (3.4)	0.22	260 (3.2)	<0.0001*	240 (8.1)	0.0004*	
Phosphorus, mg	1,267 (18.7)	1,279 (22.0)	0.73	1,236 (18.8)	0.343	1,177 (42.8)	0.181	
Calcium, mg	865 (13.5)	879 (16.0)	0.57	852 (9.9)	0.473	816 (27.1)	0.252	
Potassium, mg	2,710 (33.9)	2,656 (35.0)	0.33	2,497 (25.2)	<0.0001*	2,321 (86.2)	0.004*	
Vitamin K, µg	86 (2.5)	81 (1.9)	0.13	72 (2.3)	0.0005*	63 (1.3)	<0.0001*	
Fiber, g	16 (0.2)	15 (0.3)	0.03*	14 (0.2)	<0.0001*	13 (0.5)	0.0001*	
Total Choline, mg ¹	319 (6.1)	313 (9.4)	0.68	285 (6.2)	0.024*	273 (5.7)	0.0005*	

¹Total choline values available for NHANES 2005-2006 only and sample sizes for choline are as follows: 0% to ≤5% (645), 5% to ≤10% (2,372), 10% to ≤15% (1,725), 15% to ≤20% (1,523)

* p-value ≤0.05

2. Evidence from clinical studies shows that added sugars, particularly fructose-containing sugars, increases markers for CVD, diabetes, and the metabolic syndrome.

More than 2,150 Americans die of CVD each day, an average of one death every 40 seconds. Although death rates attributable to CVD declined by 31 percent over the past decade, heart disease remained the number-one killer of men and women in 2010. About one in every six deaths is caused by coronary heart disease (about 380,000 deaths) and one in 19 deaths is caused by stroke (about 130,000 deaths). The annual cost of CVD and stroke in the United States is estimated to be more than \$315 billion, which includes \$122 billion in lost future productivity attributed to premature CVD and stroke mortality.¹⁶

Diabetes affects 29 million Americans (9 percent of the population), including eight million people who are undiagnosed. In 2012, there were 400,000 new diabetes cases diagnosed among people aged 65 and older. In addition, an estimated 37 percent of adults—86 million Americans—have prediabetes, based on fasting glucose or hemoglobin A1C levels. People with diabetes have two to four times the risk of heart attack and stroke, compared to people without diabetes. Diabetes also increases the risk of eye, nerve, and kidney disease and dementia.¹² The risk of these complications is elevated in people with prediabetes.^{17,18}

The metabolic syndrome, a group of risk factors that raises the risk of heart disease and diabetes, affects one out of four Americans.¹⁹ A diagnosis of metabolic syndrome requires at least three of the following risk factors: a large waistline, low HDL cholesterol level, and higher-than-normal blood pressure, triglycerides, and high fasting blood sugar levels.²⁰

Recent clinical studies have found that high intakes of fructose-containing sugars raise levels of triglycerides, visceral fat, blood glucose, insulin, and small, dense low-density lipoprotein (LDL) “bad” cholesterol. For instance:

- When University of California researchers gave 32 overweight or obese middle-aged adults 25 percent of their calories from beverages sweetened with either fructose or glucose for 10 weeks, those consuming fructose had higher levels of visceral fat and postprandial triglycerides and higher fasting levels of glucose, insulin, LDL cholesterol, and small, dense LDL cholesterol.²¹
- When University of California researchers gave 48 adults (aged 18 to 40) 25 percent of their calories from beverages sweetened with HFCS, fructose, or glucose for 2 weeks, those consuming either HFCS or fructose (but not glucose) had higher 24-hour triglyceride levels and higher fasting LDL levels.²²
- When Danish scientists randomly assigned 47 overweight subjects to consume one liter a day of one of four test drinks (sucrose-sweetened cola, isocaloric semi-skim milk, aspartame-sweetened diet cola, or water) for six months, those consuming regular cola had a significant increase in visceral fat, skeletal muscle fat, and blood triglycerides.²³ Sucrose is half glucose and half fructose.
- When Swiss researchers randomly assigned 29 healthy, normal-weight men to avoid fructose-containing foods or to consume beverages containing either 40 or 80 grams of fructose, 40 or 80 grams of glucose, or 80 grams of sucrose per day, waist-to-hip ratio rose significantly and a smaller class of LDL was found in those consuming beverages containing 80 grams of fructose or 80 grams of sucrose after three weeks. Note that those changes occurred after only three weeks in men who consumed either 6.5 or 13 percent of their calories from added sugars.²⁴ Those levels are typical in American diets.
- University of California researchers randomly assigned 85 adults (aged 18 to 40) to consume beverages sweetened with HFCS at one of four amounts: 0 percent (aspartame), 10 percent, 17.5 percent, or 25 percent of energy requirements. After two weeks, there was a dose-dependent increase in postprandial triglycerides, fasting LDL cholesterol, and 24-hour average uric acid concentrations for those who drank the beverages sweetened with HFCS. Compared to baseline, consumption of HFCS-sweetened beverages significantly increased postprandial triglycerides, and fasting and postprandial LDL cholesterol, non-high-density lipoprotein cholesterol, and apolipoprotein B, even among subjects consuming 10 percent of calories from HFCS.²⁵

3. Evidence from trials shows that added sugars, particularly fructose-containing sugars, contribute to non-alcoholic fatty liver disease (NAFLD).

Nearly 29 million American adults have NAFLD, the most common chronic liver disease in Western countries.²⁶ In the past two decades, the prevalence of NAFLD has more than doubled among adolescents, from about 4 percent in 1988–1994 to about 11 percent in 2007–2010.²⁷ NAFLD occurs when extra fat builds up in the liver cells, which could lead to

insulin resistance. Insulin resistance, which may be the underlying cause of the metabolic syndrome, can lead to diabetes and heart disease. Obesity, type 2 diabetes, and higher-than-normal cholesterol and triglycerides are risk factors for NAFLD.²⁸ Evidence from clinical trials suggests that consumption of fructose-containing sugars leads to increases in liver fat. For instance:

- In the University of California study (Ref. 21), those who consumed 25 percent of calories fructose-sweetened, but not glucose-sweetened, beverages for 10 weeks had increased hepatic de novo lipogenesis, which can lead to increased liver fat.²¹
- In the Danish study (ref 23), those who drank one liter of sucrose-sweetened cola per day for six months had a significant increase in liver fat (between 132 and 143 percent), compared to those who drank semi-skim milk, aspartame-sweetened cola, or water.²³

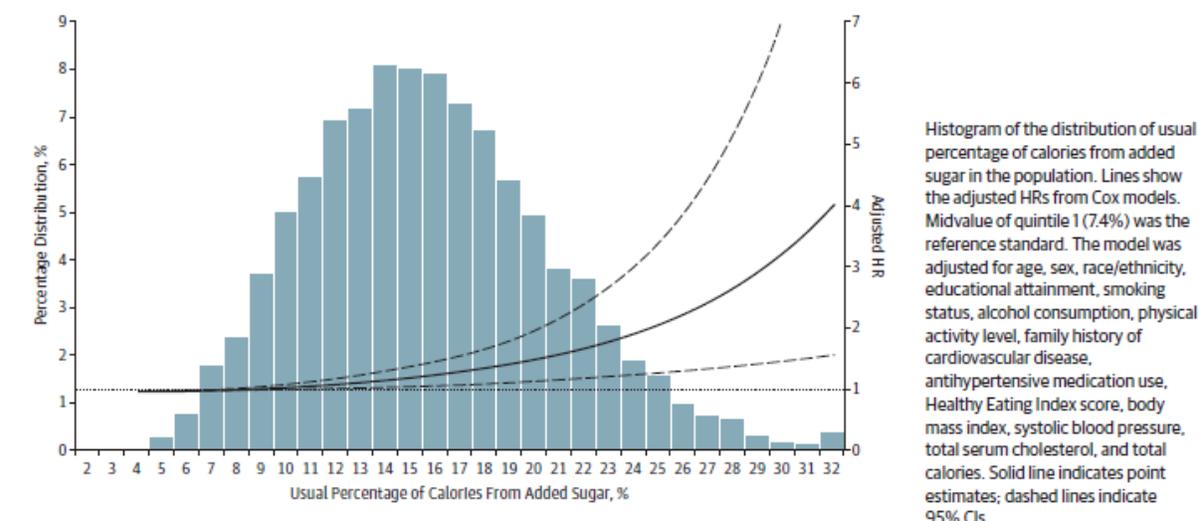
There are no medical treatments available for people with NAFLD, so lifestyle changes – dietary modifications and exercise – are recommended to prevent liver damage or reverse NAFLD in the early stages.²⁸

4. Epidemiological evidence shows that added-sugars consumption is associated with CVD mortality.

An important recent prospective study of more than 11,000 people in NHANES III – a nationally representative sample of Americans – followed for 15 years found a higher risk of cardiovascular mortality with increasing added-sugars consumption. In 2005–2010, the average consumption of added sugars was 14.9 percent of calories. Those who got **at least 10 percent but less than 25 percent** (71 percent of participants) of their calories from added sugars had a 30 percent higher risk of dying of heart attack, stroke, or other cardiovascular event than those who got less than 10 percent of their calories from added sugars. The risk was nearly three times higher for those who consumed at least 25 percent of their calories from added sugars (10 percent of the study population).²⁹

Figure from Yang et al. 2014 (Ref. 29):

Figure 1. Adjusted Hazard Ratio (HR) of the Usual Percentage of Calories From Added Sugar for Cardiovascular Disease Mortality Among US Adults 20 Years or Older: National Health and Nutrition Examination Survey Linked Mortality Files, 1988-2006



In 2013, CSPI petitioned the FDA to initiate a rule-making proceeding to ensure that the content of sucrose and HFCS in beverages is limited to safe levels.ⁱ As noted in that petition, which was supported by numerous researchers and health officials, “a mountain of evidence has emerged to demonstrate that added sugars, at the levels they are currently consumed by Americans *today*, are harmful to the public health.”³⁰ The Yang et al. study adds to that mountain of evidence.

5. FDA should set a DV for added sugars.

In 1999, CSPI, along with leading health experts and organizations, petitioned the FDA to adopt a DV of 10 teaspoons, or about 40 grams, of added sugars (160 calories or 8 percent of a 2,000-calorie diet).³¹ That was based on the USDA’s recommendation that people consuming a 2,000-calorie diet limit their consumption of added sugars to 10 teaspoons per day (8.4 percent of calories).³² Lower- and higher-sugar intakes were recommended for lower- and higher-calorie diets.

Proposing a DV for sugars would align the FDA with other major health authorities that have recommended a safe limit (about 6 to 10 percent of calories) for daily consumption of added sugars. For instance,

ⁱ We ask the FDA to incorporate that petition, and the letter of support from health experts, by reference in this comment.

- In 2003, the World Health Organization (WHO) recommended that individuals consume less than 10 percent of their calories from “free” sugars. That includes added sugars, but also the “free” sugars in fruit juices, honey, and syrups.ⁱⁱ For example, an individual who consumes a 2,000-calorie diet could consume up to 200 calories’ worth (50 grams, 12 teaspoons) of added sugar.³³ In March 2014, the WHO released a draft guideline recommending again that intake of free sugars not exceed 10 percent of total calories and suggested that further reduction to less than 5 percent of energy would have additional benefits.³⁴
- In 2009, the American Heart Association (AHA) recommended that women and men consume no more than 100 calories (25 grams) or 150 calories (37.5 grams) per day from added sugars, respectively. That is equivalent to roughly 6 percent of total calories (based on intakes of 1,800 calories for women and 2,200 for men).³⁵
- In 2005, the *DGA* set a quantitative limit for added sugars (together with solid fats), based on the discretionary calorie allowance for each level of calorie intake.³⁶ For example, after nutrient-dense foods in each food group are selected, someone consuming a 2,000-calorie diet would have no more than 267 discretionary calories to expend on solid fats and added sugars (assuming no alcohol were consumed). Dividing those calories equally between solid fats and added sugars would mean no more than 133 calories’ worth (33 grams or 8 teaspoons) per day. That amounts to 6 percent of calories as added sugars in a 2,000-calorie diet.

Given the known adverse effects of added sugars on obesity, CVD, and diabetes, as well as dilution of healthful nutrients, we recommend that the FDA set a DV for added sugars. If the FDA believes it needs to base the DV on advice from the IOM, we urge the FDA to promptly commission the institute to review the evidence and recommend a figure that could be used as the basis for a DV.

C. FDA should require that the amount of added sugars shown on Nutrition Facts labels be expressed in teaspoons, as well as in grams.

Few Americans are familiar or facile with the metric measure (grams) used for total sugars, but virtually everyone understands standard household measures (as are used on labels for serving sizes). Therefore, for reasons that are similar to those provided by FDA in the original ruling stating that serving sizes must be listed in household measures,³⁷ we urge the FDA to require the amount of added sugars be listed on the label in teaspoons, in addition to grams. The USDA Food Availability (Per Capita) Data System expresses sugar availability in terms of calories, grams, and teaspoons.⁴

A 2010 national telephone survey commissioned by CSPI found that 72 percent of respondents favored listing teaspoons of added sugars on the label (38 percent preferred listing only teaspoons, while 34 percent preferred both teaspoons and grams). Just 20 percent of those polled preferred listing sugar amounts in grams only.³⁸ Because it would improve the clarity of the information provided about added sugars, listing the amount of

ⁱⁱ On beverages containing a percent juice declaration, the FDA should consider whether the Nutrition Facts panel should include a line for “Juice Sugars.”

added sugars in both teaspoons and grams would be consistent with FDA's purpose for including the line for added sugars on the Nutrition Facts label, which was, as noted above, "based on the need for consumers to be able to readily observe and comprehend the information on sugars and to understand its relative significance in the context of a total daily diet."³⁹

D. FDA should propose a Nutrition Facts label format that clearly distinguishes added sugars from naturally occurring sugars in whole fruit and from sugars from dairy ingredients.

Consuming foods high in added sugars (e.g., cakes, cookies, candies, frozen desserts, and sugar-sweetened beverages, including fruit drinks, energy drinks, and sports drinks) makes it more difficult to meet nutrient needs and stay within calorie limits. In contrast, fruits and some dairy products are often high in other nutrients. FDA's proposed label format is confusing to consumers who may not understand that "Sugars" includes both added sugars and naturally occurring sugars (or that "Added Sugars" is a subset of "Sugars").

When 500 participants in CSPI's online survey were shown the FDA's proposed label and asked, "How much naturally occurring sugar, such as from fruit or milk, does one serving of this food contain?", only 28 percent answered correctly. Almost half of participants incorrectly reported the number of grams on the "Sugars," line (which represent the amount of total sugars), and 3 percent added the amount of "Added Sugars" to the amount of "Sugars." However, when another 500 adults were shown an equivalent Nutrition Facts label in which the "Sugars" line was replaced by a line listing "Fruit & Milk Sugars," 77 percent of people correctly identified the amount of naturally occurring sugars in one serving of the food.¹⁴ (see Appendix 1).

We recommend that the FDA replace the "Sugars" line on the Nutrition Facts panel with "Fruit & Milk Sugars" and align both directly under "Dietary Fiber." That would clearly distinguish between the two different types of sugars and eliminate the need for a double indentation under the "Total Carbs" heading. The double indentation is an extremely subtle signal that millions of consumers are likely to miss or misinterpret. At a minimum, the FDA should clarify that "Added Sugars" is a subset of "Sugars" by replacing the word "Sugars" with "Total Sugars," similar to the headings "Total Fat" and "Total Carbs." In the CSPI online survey, only 44 percent of participants who were shown FDA's proposed label correctly identified the amount of total sugar in one serving of the food, but 65 percent of participants shown a label using the word "Total Sugars" correctly identified the amount of total sugars in one serving of the food.¹⁴ However, "Milk & Fruit Sugars" would be a better solution because many consumers do not know what comprises "Total Sugars," other than added sugars. (FDA could require foods that contain a significant amount of sugars from vegetables to list "Vegetable & Milk Sugars" instead of "Fruit & Milk Sugars.") (see Appendix 1).

Finally, we support the FDA's proposal to continue to require a declaration of total carbohydrate in grams, but the Nutrition Facts panel should list "Total Carbohydrates."

“Carbohydrates” is a term used by both the IOM and *DGA*, and consumers may not understand the term “Carbs” on the label. We also recommend that the FDA no longer require a percent DV disclosure for total carbohydrates, given that consumption of some carbohydrates, such as naturally occurring sugars from fruit and milk, are not a public health concern.

III. Sodium

A. We support FDA’s proposal to lower the Daily Reference Value (DRV) for sodium.

We strongly support the FDA’s proposal to lower the DRV for sodium. The current DRV of 2,400 milligrams (mg), established in the 1993 final rule,⁴⁰ is outdated and inconsistent with key consensus reports and prevailing public health guidelines. For instance:

- The 2010 *DGA* recommends that Americans consume less than 2,300 mg of sodium per day and that middle-aged and older adults, African-Americans, and individuals with hypertension, diabetes, or chronic kidney disease consume no more than 1,500 mg of sodium per day.¹⁰
- The WHO recommends that adults limit sodium intake to less than 2,000 mg per day, and a further reduction for children based on calorie requirements.⁴¹
- The AHA and the American Public Health Association recommend a daily sodium intake of no more than 1,500 mg for the entire population.^{42,43,44}
- The 2010 Dietary Guidelines Advisory Committee (DGAC) recommended that all Americans consume no more than 1,500 mg of sodium per day.⁴⁵

B. FDA should propose a DV for sodium of 1,500 mg per day.

The proposed reduction in the DRV for sodium from 2,400 mg to 2,300 mg does not go far enough. Instead, we urge the FDA to set a DV for sodium at 1,500 mg. As described in the proposed rule, FDA selected 2,300 mg as the revised DRV because it represents the Tolerable Upper Intake Level (UL) for persons aged 14 and older and because this amount is consistent with the 2005 and 2010 *DGA* recommendations.⁴⁶ We respectfully disagree with that justification.

According to the IOM, the UL represents the highest tolerable intake level that is likely to pose no risk of adverse health effects, and it is not intended to be a recommended intake.⁴⁷ The 2010 *DGA* indicates that 2,300 mg is too high, or *intolerable*, for middle-aged and older adults, African-Americans, and individuals with hypertension, diabetes, or chronic kidney disease – approximately half of Americans. The *DGA* advises those individuals to consume no more than 1,500 mg of sodium per day.¹⁰ A 2010 IOM report, *Strategies to Reduce Sodium Intake in the United States*, recommended that the FDA lower the DV for sodium to 1,500 mg based on the Adequate Intake (AI) established in the 2005 DRI report (which, of course, was unavailable at the time of the 1993 ruling).^{47,48} As noted above, that intake level is consistent with advice from the AHA and other prominent public health authorities

that recommend limiting sodium intake to no more than 1,500 mg per day for the entire population.

Data from the NHANES 2003–2008 estimated that American adults aged 20 and older consume, on average, nearly 3,400 mg of sodium per day.⁴⁹ However, that level is likely an underestimate because it does not include salt added at the table and because people under-report intake on dietary questionnaires.^{49,50} Those excessive intakes raise the risk of hypertension, stroke, heart attacks, heart failure, and kidney disease.⁵¹ NHANES data also estimated that 99 percent of adults who are advised to further reduce sodium intake to 1,500 mg (i.e., people aged 51 years and older, African-Americans, and those with hypertension) exceeded that recommendation, and consume, on average, 3,200 mg of sodium per day.⁴⁹ To protect that large and vulnerable segment of the population, the FDA should lower the DV for sodium to 1,500 mg.

The FDA expressed concern that lowering the DV for sodium to 1,500 mg would conflict with a 2013 IOM report, *Sodium Intake in Populations: Assessment of Evidence*, which found insufficient evidence to support a reduction in sodium to levels below 2,300 mg for the general population.⁵² However, the report had several key flaws, and we caution the FDA against using its conclusions in setting a DV.

1. The IOM Committee did not consider hypertension itself as a health outcome.

The IOM report found too little evidence to conclude that reducing sodium intake below 2,300 mg per day would either increase or decrease the risk of CVD outcomes (including stroke and CVD mortality) or all-cause mortality in the U.S. population. However, the IOM Committee did not consider hypertension itself as a health outcome, despite the indisputable relationship between blood pressure and CVD. As the IOM report itself concluded (Conclusion 1, page 4), the research “indicates a positive relationship between higher levels of sodium intake and risk of CVD.” Furthermore, the IOM stated that “blood pressure is widely recognized as a strong surrogate indicator for primary CVD clinical endpoints, such as myocardial infarction and stroke.” (page 40). There is clear evidence from the Dietary Approaches to Stop Hypertension (DASH)–Sodium study that reducing sodium intake from 2,300 to 1,500 mg per day lowers blood pressure in individuals with and without hypertension.⁵³ⁱⁱⁱ Furthermore, it is extremely difficult to conduct large, long-term, controlled trials that compare heart attack and stroke rates in people who consume considerably less than 2,300 mg of sodium a day, given the high sodium content of the American food supply. In other words, the IOM committee was asking for evidence that is difficult, if not impossible, to obtain.

2. Methodological concerns with observational studies relating sodium intake to heart disease outcomes may account for inconsistent findings.

Much of the evidence considered by the IOM Committee relating sodium intakes to CVD, stroke, and mortality outcomes was based on observational studies. A recent systematic

ⁱⁱⁱ Sodium intakes in the DASH study varied with caloric intake.

review by the AHA Council on Lifestyle and Metabolic Health concluded that widespread methodological issues could account for the inconsistent findings in 26 observational studies that examined the association between sodium intake and cardiovascular outcomes studies.⁵⁴

Among the methodological flaws that can invalidate the findings of observational studies:

- **Errors in dietary data.** Dietary questionnaires can suffer from measurement error due to inaccurate reporting by participants; failure to include information on salt added at the table, in condiments, or used in cooking; or a reliance on incomplete or outdated food composition tables to determine the sodium content in foods, especially foods eaten outside the home.⁴³ Those random errors could lead to studies that miss a relationship between sodium intake and blood pressure.
- **Errors in urine collection.** Random error in estimating sodium intake can also occur in studies that collect only a single urine sample to assess sodium intake (i.e., overnight, or “spot” urine) or just one 24-hour collection.^{43,55} Because sodium intake vary from day to day, relying on a single 24-hour urine collection may yield an inaccurate estimate of usual intake.⁵⁴ (Ideally, studies should use multiple collections that exclude incomplete collections.)
- **Reverse causality.** Some observational studies have reported a J-shaped relationship showing an increased risk of CVD at both high and low sodium intakes.^{56,57} However, those studies often include sick individuals with a high prevalence of hypertension and other disease risk factors. Reverse causality may be driving the higher risk in people with low sodium intakes because medical advice, drug therapies, or a loss of appetite due to illness could have led those individuals to reduce their sodium intake.⁴³
- **Residual confounding.** Some studies fail to adjust for body weight, cholesterol, diabetes, socioeconomic status, and other potential known and unknown confounders.⁵⁴
- **Overadjustment.** Studies that adjust for blood pressure or the presence of hypertension could nullify a true effect of sodium intake on CVD risk.⁵⁵

Those and other methodological issues may account for the inconsistent findings in observational studies and limit their usefulness in setting dietary recommendations for sodium intakes for the general population. As the AHA concluded, “until well-designed cohort studies in the general population are available, it remains appropriate to base Na guidelines on the robust body of evidence linking Na with elevated blood pressure and the few existing general population trials of the effects of Na reduction on CVD.”⁵⁴

3. The IOM Committee’s conclusions were based, in part, on suspect evidence from trials of people with heart failure.

The IOM committee found possible harm of very low sodium intakes in people with heart failure. However, that conclusion was based largely on suspect evidence from one group of Italian researchers who randomly assigned patients with heart failure to normal or very-

low sodium diets. Those results are not applicable to the general population, or even to patients with heart failure, because those studies also severely restricted the patients' water intake and gave them high doses of diuretics. This aggressive treatment, which is not used in the United States, can deplete blood volume. In June, the journal *Heart* retracted a meta-analysis from the same research group because two of the studies had duplicate data,⁵⁸ thus calling into question the researchers' findings.

4. FDA's decision to revise the DV for sodium should be based on the best available evidence.

We caution the FDA against using the 2013 IOM report as partial justification for not proposing a further reduction in the sodium DV. The 2013 IOM report focused on limited evidence (only including studies published after 2003) and limited clinical outcomes. Some of the studies reviewed by the IOM have also been criticized for conflicts of interest.⁵⁹ Therefore, it remains appropriate for the FDA to base the sodium DV on the "robust body of evidence linking sodium intake with elevated blood pressure and on the few existing trials of sodium reduction and cardiovascular disease," as the AHA has recommended.^{60,61,62,iv}

Among those population trials is the Trials of Hypertension Prevention (TOHP I and II), which randomly assigned 3,126 people with pre-hypertension aged 30 to 54 to either a sodium-reduction group or a usual-care group for 18 months (TOHP I) or 3 to 4 years (TOHP II). A long-term follow-up of 2,415 participants 10 to 15 years after the trials ended found a 30 percent reduction in the risk of a cardiovascular events among those in the reduced-sodium group, which cut its sodium intake by 20 to 30 percent.^{63,64} The follow-up found a continued decrease in CVD events among those with sodium levels as low as 1,500 mg per day, with no evidence of a J shape curve. Those who excreted less than 2,300 mg a day had a 32 percent reduction in risk, which was not statistically significant due to the small numbers in this subgroup and limited power.⁶⁵

Roughly 90 percent of American adults consume more than 2,300 mg of sodium a day,⁴⁹ and two-thirds of adults have hypertension or prehypertension.⁶⁶ Lowering the DV for sodium to 1,500 mg would subtly encourage a large and vulnerable segment of the population (as well as the general public) to look for lower-sodium foods and encourage food manufacturers and restaurants to lower sodium levels in their products.

D. Lowering the sodium DRV to 1,500 mg is an urgent public health issue.

Revising the DV for sodium to 1,500 mg is an urgent public health issue. One study, for example, found that reducing sodium intake by 1,200 mg daily could result in 60,000 to 120,000 fewer coronary heart disease events, 32,000 to 66,000 fewer strokes, 54,000 to 99,000 fewer myocardial infarctions, and 44,000 to 92,000 fewer deaths from any cause, as well as save \$10 billion to \$24 billion in health care costs each year.⁶⁷ Another study projected that a modest reduction in sodium intake of 4 percent per year would save 250,000 to 500,000 lives over the next 10 years.⁶⁸ In England, gradual reductions in the

^{iv} The Chang et al. trial involved potassium supplementation, as well as a reduction in sodium intake.

sodium content of processed foods from 2003 to 2011 resulted in a 15 percent decline in average sodium intake. During that time, systolic blood pressure dropped by 3 points, deaths from stroke dropped by 42 percent, and deaths from ischemic heart disease fell by 40 percent. Although other factors contributed to those declines, it is likely that the fall in sodium consumption played a significant role.^{69,v} Following that example, FDA's DV should be based on the best available evidence, which strongly supports a DV of 1,500 mg for sodium.

E. FDA should require that the Nutrition Facts panel disclose the amount of salt, rather than sodium, in milligrams.

Sodium is a scientific term that has no intuitive meaning to the average person. On the other hand, salt is a word that everyone understands. Food packages use both terms, which can be confusing to consumers. For instance, the Nutrition Facts label uses "sodium" whereas claims on the front of package may read "salt free," "unsalted," "no salt," or "no salt added."⁷⁰ Roughly 90 percent of the sodium we consume is in the form of salt.⁴⁷ Other countries, such as the United Kingdom, use the term "salt" on food labels. That is analogous to the requirement that Nutrition Facts labels state "Fat," not "Triglycerides;" "Sugars," instead of "Monosaccharides" and "Disaccharides;" and "Calories," not "Kilocalories." The FDA should state "Salt" on Nutrition Facts labels instead of "Sodium." Labels would calculate the salt content as 2.5 times the sodium content and would include sodium from all sources, including sodium chloride, sodium bicarbonate, sodium glutamate, etc. It is critical that FDA continue to require companies to express the amount of salt in mg, because expressing salt in grams would require a greater understanding of tenths, hundredths, or thousandths of a gram. Requiring declarations of salt rather than sodium also would mean that consumers would see a larger number on labels, which could discourage people from eating high-sodium foods.

F. FDA's Failure to set a health-protective DV for sodium is arbitrary and capricious.

The FDA's proposal to reduce the recommended DV for sodium only slightly from 2,400 mg to 2,300 mg is arbitrary and capricious. Agency action is arbitrary and capricious if it departs from prior agency policy without explanation or with disregard for factual determinations that it made in the past.⁷¹ Although the agency presents several alternatives to the DV of 2,300 mg, including considering proposals for DVs of 1,500 or 1,900 mg, as well as a brief discussion of a "tiered approach," the agency's explanation regarding its proposal to set the DV at 2,300 mg lacks an adequate basis in the record. Moreover, FDA's proposal for a DV of 2,300 mg is not protective of vulnerable populations for sodium, a critical nutrient that majorly impacts public health.

^v The authors note that it is likely that several factors contributed to the decline in stroke and CVD mortality, including "the fall in blood pressure, total cholesterol and smoking prevalence, the reduction in salt intake and the increase in the consumption of fruit and vegetables, along with improvements in the treatments of blood pressure, cholesterol, and CVD." (He FJ et al. 2014, page 3).

While “arbitrary and capricious” is a narrow standard of review,⁷² courts must assess “whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.”⁷³ This involves reviewing both the agency’s reasons for its decisions and the agency’s failure to state reasons for its decisions.⁷⁴ Courts “must reverse an agency policy when [it] cannot discern a reason for it.”⁷⁵

In this instance, the FDA arbitrarily and capriciously has failed to propose a health-protective DV for sodium. As the agency notes in the proposal, “[m]ost of the DRVs have been based on quantitative intake recommendations associated with chronic disease risk or a health-related condition (*e.g.*, total fat, saturated fat, cholesterol, and dietary fiber).” *See* 79 F.R. 11892. For another example, for iron, the FDA set the DV to protect those population subgroups that require more iron, including young children (1 to 4 years of age), women of childbearing age (12 to 49 years of age), and pregnant women.⁷⁶

In contrast, for sodium, FDA acknowledges that it is proposing a DV that is a UL for the all of the population over 14 years of age and substantially in excess of that for younger children. FDA notes:

The ULs for sodium are 2,300 mg/d for all individuals ages 14 years and older, 1,900 mg/d for children 4 to 8 years old, and 2,200 mg/d for adolescents 9 to 13 years old. The UL is not intended to be a recommended intake level to encourage, but rather a level not to exceed. *See* 79 FR 11914.

Indeed, FDA acknowledges that roughly *one-half* of the adult population should be consuming lower levels of sodium, namely African Americans, individuals ages 51 years or older, and individuals with hypertension, chronic kidney disease, or diabetes.⁷⁷ For those subgroups, 1,500 mg is the recommended maximum intake for sodium.⁷⁸ Yet, FDA has set the DV at a level that will affirmatively mislead the most affected but suggesting a much higher target for their consumption than is healthy or medically appropriate.

The rule notes the following in support of setting a DV of 1,500 mg:

- “[T]he [IOM Sodium Strategies Report] recommended that FDA adopt 1,500 mg as the DV for sodium, given that sodium is an essential nutrient and that, unlike in 1993 (58 FR 2206 at 2224), a reference value of adequacy is now available (*i.e.*, the AI of 1,500 mg/d).” *See* 79 FR 11914.
- “The 2010 DGAC report noted that 1,500 mg/d should be the intake goal for the general population. Further, the DGAC noted that, given the current U.S. marketplace and the resulting excessively high sodium intake, it will be challenging to achieve the lower level. The 2010 *DGA*, considering the 2010 DGAC conclusions, recommended a reduction in sodium intake to less than 2,300 mg/d and a further reduction to 1,500 mg/d among African Americans, individuals with hypertension, diabetes, or chronic kidney disease, and individuals ages 51 years or older.” *See* 79 FR 11914-11915.

- “Subgroups that have been reported to have a high prevalence of salt sensitivity include individuals 51 years of age and older, African Americans, and individuals with hypertension, diabetes or chronic kidney disease. The 2010 *DGA* recommended that Americans reduce sodium intakes and also noted that these population subgroups, representing nearly half of the U.S. population, would benefit from even greater reductions in sodium intake than the general population.” *See* 79 FR 11915.
- “Using the population-coverage AI to set the RDI for sodium would be consistent with the proposed RDIs for other essential vitamins and minerals or which AIs are established (e.g., vitamin K and choline). AIs are similar to RDAs in that they meet the needs of essentially all members of the population. Thus, using an AI as a quantitative intake recommendation for setting an RDI would be consistent with the proposed RDIs for other essential minerals that have AIs or RDAs, such as potassium and calcium. Traditionally, we have based the RDI for essential nutrients on quantitative intake recommendations that reflect the intake level necessary to meet the daily physiological needs for that nutrient. However, unlike the consumption of other vitamins and minerals, the majority of the population consumes sodium at levels that exceed the AI and the UL. This makes sodium unique in comparison to other vitamins and minerals for which people generally must strive to meet their daily needs.” *See* 79 FR 11915.
- “[A]n RDI of 1,500 mg would be consistent with the 2010 IOM Sodium Strategies Report (Ref. 89). The IOM recommended that FDA base the DV for sodium on the AI of 1,500 mg/d. First, the IOM stated that using the AI is consistent with the approach used for all other essential nutrients, where the DV is based on a reference value of adequacy rather than a reference value of safety. Second, although consumer data were not provided, the IOM strategies report argued that the use of the AI could better inform consumers of the actual contribution of sodium content to total sodium needs as an essential nutrient. Third, the IOM stated that adopting the AI would avoid misleading consumers into thinking that the sodium content of foods is more favorable than is actually the case. As such, from a public health perspective, the AI would provide a truer picture for the consumer of the contribution of the particular foods in assembling a healthful diet and is preferable for this purpose over the UL. Finally, the IOM opined that lowering the DV might act as an incentive for companies to reduce the sodium content of their foods because reducing the DV would result in a higher value of percent DV declared on the label if sodium content remained unchanged.” *See* 79 FR 11915.
- Last, FDA’s proposal makes clear that the 2013 IOM Report on sodium that recommends a DV of 2,300 mg failed to address “blood pressure or essentiality,” in addition to the numerous flaws detailed above. *See* 79 FR 11915.

In contrast to this ample record, the agency’s proposal provides scant support for setting the level for the DV at the proposal of 2,300 mg. The agency focuses inappropriately on the flawed 2013 IOM report, which we have discussed above in detail, and notes that consumer education would be necessary should it set a lower DV for sodium. Of course, the need to

contextualize label changes for the public through public education and other means does not, in and of itself, indicate anything regarding the appropriate DV for sodium.

We agree with the 2010 IOM report that the public health perspective demonstrates clear and unequivocal public health benefits for the use of a DV of 1,500 mg, including providing clear notice to vulnerable consumers and assuring the health of children, whose blood pressure rises beginning at a young age and tends to remain high in adulthood, and incentivizing changes by industry to the salt content of foods.⁵¹

Moreover, the statutory design clearly emphasizes the consideration of the impact of labeling changes on public health, and charges FDA with notifying the public of nutrients based on their public health significance (*see* 21 USC 343 (q), providing legal authority for labeling requirements that “will assist consumers in maintaining healthy dietary practices”). FDA further states with regard to its legal authority regarding DVs that:

Section 2(b)(1)(A) of the 1990 amendments mandated that FDA regulations implementing section 403(q) of the FD&C Act require that nutrition labeling must be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. In particular, the percent DV of a nutrient present in food is declared on food labels to help consumers understand the relative significance of nutrition information in the context of a total daily diet, compare the nutritional values of food products, and to plan general diets (58 FR 2206 at 2213; January 6, 1993). We also noted that the percent DV information advises the consumer how much of a recommended intake of that nutrient is provided by the food (58 FR 2079 at 2123; January 6, 1993). *See* 79 FR 11887.

FDA also makes reference to this broad authority in the service of public health with regard to its authority to require labeling of added sugars (noting that its “review is based on the need for nutrient information for consumers to implement key dietary recommendations to assist consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet.” (*Emphasis added.*) *See* 79 FR 11891.)

The agency’s brief discussion of market feasibility and consumer acceptance of lowered sodium levels are therefore irrelevant to the decision to set a DV for labeling purposes. As FDA notes, “DV’s are based on scientific data supporting healthy dietary practices, not on the levels of a nutrient present in the food supply.”⁷⁹

In addition, the mere labeling of a DV does not mean that consumers will consume that recommended level of sodium or that manufacturers will bring all products below that DV per serving. Currently, consumption of sodium considerably exceeds 2,400 mg/day, amounting to as much as 3,650 mg/day for Americans aged 4 and older, despite the fact that, as the agency notes, consumers are largely aware of some risks from sodium and the DV should provide some incentive to lower consumption from current levels.⁸⁰ While market feasibility could be a consideration for some future action by FDA in setting a time-

table for regulatory limits on the amount of sodium in products, the sole consideration for FDA in the labeling context must be the anticipated impact of a labeling change on public health.

Last, we note that the agency is far too quick to dismiss the so-called “tiered approach.” Should the FDA set the level of 1500 mg for a future date (we propose five years following the effective date of the requirements in the final rule), it would also retain ample discretion to set a mid-point for labeling purposes in the interim, as a temporary measure, of a different DV, such as 1,900 or 2,000 mg. Because the decision to set the eventual DV of 1,500 is grounded in public health research, an interim step in achieving that important goal would be easily accommodated by the agency’s current authority to provide waivers for particular industries and set general time-tables for regulatory compliance.

By setting a concrete timeline to reduce the DV for sodium, FDA would incentivize industry to invest in innovative approaches, such as hollow salt crystals or mixtures of sodium and potassium chlorides. Industry, recognizing widespread consumer demand and increasing regulation,⁸¹ as well as the inherent harm in high sodium diets,⁸² is already innovating sodium reduction solutions. Salt substitutes,⁸³ product reformulation,⁸⁴ changes in the manufacturing process,⁸⁵ and development of different shapes of salt crystals⁸⁶ have successfully resulted in a reduction of sodium content across a variety of food items. These innovations have spurred a secondary business of salt reduction services to develop.⁸⁷ A firm and transparent move by FDA to reduce the DV for sodium, even if it applied a tiered approach, would encourage industry to continue to innovate and invest in research while maintaining the agency’s loyalty to its public health mission.

IV. Dietary Fiber

A. CSPI opposes the FDA’s proposal to allow Nutrition Facts labels to include added fiber in the declaration of dietary fiber.

CSPI opposes the FDA’s proposal to allow Nutrition Facts labels to include added fiber (“isolated or synthetic non-digestible carbohydrates that have beneficial physiological effects in humans”) in the declaration of dietary fiber. This proposal would encourage the food industry to market cookies, candies, ice cream, refined grains, and other highly processed and relatively non-nutritious foods that would compete with the fiber-rich fruits, vegetables, beans, and whole grains that are linked to a lower risk of disease. If the FDA decides to proceed with its proposal, it should (a) allow the declaration of dietary fiber on labels to include only added fibers that are the subject of an authorized health claim, (b) require labels with added fiber to disclose the grams of “processed fibers” or “added fibers” on one line and the “unprocessed fiber” or “natural fiber” on another line of the Nutrition Facts label so that consumers who want to increase their intake of intact fiber only are able to do so, and (c) require labels to disclose the Daily Value for intact fiber only, because the IOM relied on evidence from studies of intact fiber to set the AI.

1. Processed foods with added fibers compete with foods rich in intact fiber.

The food industry markets a variety of highly processed, relatively non-nutritious foods with added fiber, including frozen desserts, cookies, brownies, bars, muffins, and white-flour pastas, breads, and English muffins (see Appendix 3). These foods compete with vegetables, fruits, beans, and whole grains that are not backed by major marketing campaigns and often have no Nutrition Facts labels. The competition from processed foods hinders the efforts of health authorities that have urged people to consume more fruits, vegetables, beans, and grains not just because they are rich in intact fiber, but because they may promote satiety, they have a low calorie density, and they are rich in potassium and other nutrients of concern. In short, the food industry has and will continue to hijack the advice of health authorities to consume more fiber-rich foods in order to sell more processed junk foods.

Some food manufacturers have already outlined a strategy to convince dietitians and other health professionals to encourage people to consume more foods with added fiber. A roundtable sponsored by Kellogg in 2012 lamented “that educators and communicators often take a binary approach, suggesting the same solutions to ongoing problems, such as the general advice to ‘choose more fruit, vegetables, and whole grains to improve fiber intakes.’”⁸⁸ The roundtable experts noted that “RD participants expressed concern that some fiber-added foods may not offer the same benefits as natural fiber sources.” To “help RD and other health professionals overcome these knowledge gaps,” the experts recommended strategies to “debunk common myths about fiber, including...concerns about added-fiber sources, such as isolated and synthesized fibers” and to “help consumers understand that all types of fiber deliver important physiologic benefits.” The roundtable also noted that “although fiber is recognized by the 2010 DGA as a nutrient of concern, recommendations to improve fiber intakes focus on increased consumption of fruit, vegetables, and whole grains, with little recognition of the effect on total energy intake and the positive role of adding fibers to foods to help close the fiber intake gap.”

2. Allowing labels to combine intact and added fiber misleads consumers to believe that added fiber has the same health benefits as intact fiber.

The FDA has tentatively concluded that there is little benefit for consumers in distinguishing between intact and added fiber on the Nutrition Facts label because “both have beneficial health effects.” However, the two types of fiber do not necessarily have *equivalent* health effects, as labels would imply.

a) The evidence that fiber lowers the risk of disease comes from studies of people who consume foods rich in the intrinsic, intact fiber in plants.

In its 2002 report on fiber, the IOM notes that “it should be kept in mind that although high *Dietary Fiber* intake is associated with decreased risk or improvements in several chronic diseases, a report of the National Academy of Sciences states ‘there is no conclusive evidence that it is dietary fiber rather than the other components of vegetables, fruits, and cereal products that reduces the risk of those diseases.’” (p. 362)¹⁵ In establishing the AI for fiber, which was “based on the intake level observed to protect against coronary heart disease,” (p. 339)¹⁵ the IOM stated that an “important consideration for establishing a

requirement for fiber is the fact that the dietary intake data from epidemiological studies are on fiber-containing foods, which are considered *Dietary Fiber*” (as opposed to *Functional Fiber*, the IOM’s term for added fibers). Furthermore, some of those studies “used indicators of *Dietary Fiber* intake such as cereals, vegetables, whole grains, or legumes,” cautioned the IOM, and “there are many constituents of whole grains, in addition to *Dietary Fiber*, that may reduce the risk of CHD.” (p. 387)¹⁵ Moreover, the IOM noted, “there are no epidemiological studies that have evaluated the relationship between *Functional Fiber* and the risk of coronary heart disease (CHD).”

Although the IOM concluded that *Functional Fiber* should be included in *Total Fiber*, the IOM clearly had more confidence in the benefits of foods rich in intact fiber than in the benefits of added fiber. In the years since the IOM report was issued, the evidence that fiber lowers the risk of heart disease, diabetes, and diverticular disease continues to come from studies of people who consume foods rich in intact fiber, especially whole grains and wheat bran.^{89,90,91,92} However, the FDA’s current proposal would give consumers no way of knowing how much of the fiber in many foods has been linked to a lower risk of disease and how much has some “physiological benefit” that may be far less consequential.

b) The evidence that added fibers are beneficial is often inconsistent and based on poorly established biomarkers.

Some food manufacturers and companies that produce fiber have already concluded that every added fiber has some beneficial physiologic effect.⁸⁸ (See Appendix 4). Yet those effects are based on the results of small, short-term studies of biomarkers that may not be well-established indicators of risk. Furthermore, many of those effects are not seen consistently.

For example, many labels imply that fiber can aid weight loss by improving satiety (see Appendix 3). Yet the evidence that added fiber can improve satiety or curb short-term food intake is inconsistent:

- **Polydextrose.** According to a 2012 study on 34 volunteers, a yogurt-based drink containing 6.25 or 12.5 grams of polydextrose “increased satiety and decreased appetite” on visual analog scales compared to a drink with 0 grams of polydextrose, and those who were given the drink with 12.5 grams (but not 6.25 grams) consumed fewer calories at lunch.⁹³ However, in a 2009 study of 20 volunteers fed a muffin containing 9.5 grams of polydextrose reported no less hunger and no more fullness or satisfaction than when they were fed a low-fiber muffin.⁹⁴
- **Maltodextrin.** When 20 volunteers were fed a muffin containing 8 grams of added resistant starch, they reported less hunger and more fullness and satisfaction than when they ate a low-fiber muffin.[ref 11] However, when subjects were given a breakfast of fruit juice and skim milk made with 10 grams of added maltodextrin (Fibersol-2), they reported more hunger than after consuming 10 grams of intact fiber in a breakfast consisting of oatmeal, blueberries, and apples.⁹⁵

- **Inulin.** When researchers fed 33 men a breakfast including a sausage patty made with 24 grams of inulin, they consumed fewer calories during the test day than when they ate a full-fat sausage patty.⁹⁶ However, when researchers gave 22 women a chocolate crisp bars with 10 grams of fiber from one of four sources (oligofructose, inulin, soluble corn fiber, resistant wheat starch) at dinner and the next morning, the women felt no more full and ate no less at lunch or during the next 24 hours than when they consumed a bar with no added fiber.⁹⁷

Furthermore, short-term satiety may not be a valid biomarker of long-term weight loss or weight maintenance. Few consumers would recognize that claims such as “satisfies hunger longer” are not backed by evidence that a food (or its fiber) would help them lose weight or keep it off.

c) Added fiber may have less benefit than its intact counterpart.

Some added fibers may have a well-documented benefit, but the benefit may be substantially smaller than the benefit of a comparable intact fiber. For example, some fibers (like "wheat fiber") increase stool weight (which presumably aids laxation), but not as much as bran. In a meta-analysis of 100 studies on stool weight, bran increased fecal bulk by 5.7 grams per gram of bran, considerably more than cellulose (3 g/g) and by fermentable fibers such as pectin (1.3 g/g).¹⁵

Most consumers would have no way of knowing that discrepancies in benefits exist. Someone looking for a food to improve laxation could easily choose to get 6 grams of fiber from two pouches of Fiber One Fruit Flavored Snacks instead of 5 grams of fiber from one serving of Kellogg's All-Bran Complete Wheat Flakes. The Fiber One label offers no clue that its soluble corn fiber and modified corn starch are less likely than bran cereal to increase stool weight or promote laxation.

Even the few astute consumers who know that some added fibers are less beneficial would have no way of knowing how much of each fiber foods contain. For example, Fiber One Caramel Delight has 9 grams of fiber per serving, but consumers have no way of knowing how much comes from the cereal's whole grain wheat and corn bran (which may promote laxation) and how much comes from its chicory root extract (which does not). Yet consumers may choose the Fiber One cereal over Kellogg's Raisin Bran, which gets 7 grams of fiber from whole grain wheat and wheat bran (which has the most benefit for laxation). Unless the FDA requires companies to disclose added fibers on a separate line, shoppers could not compare the intact fiber content of competing foods.

d) The food industry will be able to demonstrate at least one physiological effect for each type of added fiber, though those effects may be less significant than the benefits from intact fiber.

If the FDA finalizes its proposal, the food industry would likely submit a raft of studies to support the benefits of all the commonly used added fibers. There would be no shortage of funding to produce any additional studies requested by the FDA. However, relatively little funding would be available for studies that challenge the benefits of added fibers.

The European Food Safety Authority has already issued a number of Scientific Opinions on the substantiation of proposed health claims for non-digestible carbohydrates, many of which opinions denied the proposed claims.^{98,99,100} However, the industry is likely to demonstrate at least one physiological benefit for every added fiber. For example, EFSA concluded that “a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates instead of sugar and a reduction of post-prandial glycaemic responses as compared to sugar-containing foods/beverages.” (Those non-digestible carbohydrates include inulin, non-starch polysaccharides, resistant oligosaccharides, and resistant starches.)¹⁰¹ That “benefit” is likely to apply to virtually all fiber, because, by definition, fiber is more poorly absorbed than sugars, and would therefore lead to lower postprandial increases in blood sugar levels.

Furthermore, the food industry would need to identify only one benefit for each added fiber. For example, the resistant maltodextrin Fibersol appears to have little effect on appetite, yet its manufacturer, Archer Daniels Midland, claims that it reduces peak blood glucose and insulin levels, “helps support or maintain intestinal regularity,” and “helps to relieve occasional constipation” (see Appendix 4). Once the FDA has approved a fiber as having *any* “physiological benefit,” labels could simply claim “5 grams fiber,” leading consumers to assume that the food provides all the benefits of intact fibers. (In contrast, whole grains, beans, fruits, and vegetables often contain a mix of fibers, so consumers are less likely to be misled if they assume that “5 grams fiber” on, say, a package of beans, provides all the benefits of fiber.) Furthermore, labels on foods with added fiber could make structure/function claims such as “fiber satisfies hunger longer,” regardless of whether that food’s added fiber has been approved for that or some other physiological benefit.

e) Some added fibers have adverse effects that outweigh their benefits.

Many added fibers are simply poorly absorbed carbohydrates that have significant adverse effects including abdominal discomfort, flatus, and diarrhea.¹⁰² For example, inulin, which is added to many foods because it is an oligosaccharide with sweetening properties, significantly increases flatulence (with little benefit for increasing stool weight or speeding up intestinal transit time) at doses of 10 grams a day, which is easily achievable from one or two servings of a variety of Fiber One products.¹⁰³ Although flatulence and abdominal discomfort are transient in most people, they may lead some consumers to avoid all sources of fiber, including beans and vegetables, because people might assume that all sources of fiber cause flatulence.

Furthermore, a growing body of evidence indicates that inulin and other fermentable oligosaccharides can exacerbate the symptoms of irritable bowel syndrome. Recent studies

indicate that a diet low in FODMAPS (fermentable oligosaccharides, disaccharides, monosaccharides, and polyols) can reduce gastrointestinal symptoms in patients with irritable bowel syndrome.¹⁰⁴

3. FDA should require an authorized health claim in order for companies to include added fibers in the declaration of dietary fiber.

CSPI opposes FDA's proposal to allow isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) to be included in the definition of dietary fiber "in response to a petition submitted to FDA under § 10.30 (21 CFR 10.30) demonstrating that such carbohydrates have a physiological effect."^{vi} We urge the agency to define dietary fiber as (1) Nondigestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; or (2) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that are the subject of an authorized health claim.

Requiring an authorized health claim for added fibers would have several benefits. It would require that FDA determine, based on the totality of publicly available scientific evidence, that there is significant scientific agreement to support the claim. Small, short-term studies of varying quality with conflicting results would not suffice. Furthermore, a health claim authorization would require FDA to consider whether the levels of added fiber in foods are sufficient to cause the physiological effect. In addition, FDA could authorize only specific formulations of the added fiber. A generic approval of many added fibers, such as fructo-oligosaccharides, resistant maltodextrin, or inulin, is inappropriate because companies produce a wide variety of each fiber, which may or may not have the specified physiological effect.¹⁰⁵ The FDA has already authorized a health claim for beta-glucan and psyllium husk, demonstrating that it is feasible for companies to provide sufficient evidence to warrant a claim.

4. If FDA allows added fibers to count as fiber, it should require labels to list them on a separate line.

Requiring labels to list added fiber on a separate line would enable consumers who want to increase their intake of intact fiber to compare the intact fiber content of various foods. Without a required disclosure, consumers would have no way of acquiring that information. As fiber claims proliferate, a growing number of products, such as cereals, granola bars,^{vii} and bread, have begun to combine intact and added fibers to compete with other brands. Whole wheat bread with no added fiber has just 3 grams of fiber per slice, a rather paltry number next to breads like Arnold Double Fiber, which has 6 grams of fiber per slice, thanks to added inulin, wheat fiber, cellulose fiber, and polydextrose.

^{vi} We note that isolated and synthetic non-digestible carbohydrates with fewer than 10 monomeric units are extremely popular food ingredients because companies can use them to produce highly processed sweets.

^{vii} Many bars are now simply called "chewy bars" or "nutrition bars," rather than granola bars because they are typically dipped in chocolate and may contain little or no oats.

Requiring an extra line on the Nutrition Facts label does add to label clutter. However, the additional line would need only appear on foods with added fiber. Furthermore, requiring labels to distinguish between intact and added fiber might serve as a mild discouragement to companies to make claims about those fibers. Companies are likely to use added fibers in any case, because they have useful properties (e.g., some of them can replace “added sugars”), and because companies can subtract some or all of their calories on the Nutrition Facts label. However, a separate disclosure would give consumers the tools to find out how much added fiber a food contains.

V. Fats

A. Total Fat

1. CSPI supports the mandatory declaration of total fat on the Nutrition Facts label.

We support the FDA’s proposal to continue to require a declaration of total fat on the Nutrition Facts label.¹⁰⁶ Fat is a major source of calories and an important component of the macronutrient profile of a food.

The 2002 IOM report on macronutrients established an Acceptable Macronutrient Distribution Range (AMDR) for total fat of 20 to 35 percent of calories for adults aged 19 and older. That recommendation was based partly on evidence from studies demonstrating that a diet with less than 20 percent of calories from fat (which is high in carbohydrates) lowers blood high-density lipoprotein (HDL) “good” cholesterol levels and raises triglyceride levels. Elevated triglycerides are associated with an increased risk of CVD. Given the typical American diet, which is rich in meat and dairy foods, consumers who get more than 35 percent of calories from fat are likely to increase their intakes of saturated fat, which raises blood LDL cholesterol levels and increases CVD risk (see Comment section I.B.).^{15,45}

Retaining the declaration for total fat would also help consumers who are trying to consume foods with lower calorie density.^{viii} Foods that are higher in fat are generally higher in calorie density. Long-term weight-loss trials have found that dieters who cut the most calories lose the most weight.¹⁰⁷ However, limiting higher-fat foods can be one of several successful strategies for cutting calories. For example, the Diabetes Prevention Program reduced the risk of diabetes by 58 percent in people with pre-diabetes using a lower-calorie, lower-fat (less than 30 percent of calories) diet to achieve weight loss.¹⁰⁸ Similar lower-calorie, lower-fat diets have been used in the NEW trial, the Look AHEAD Study, and other randomized clinical trials.^{109,110} Many members of the National Weight Control Registry, who have lost an average of 33 kg and maintained the loss for more than 5 years, eat a lower-fat, lower-calorie diet.¹¹¹

^{viii} Caloric density is the amount of calories per unit of food weight.

Furthermore, consumers can use a food's total and saturated fat content to estimate its unsaturated fat content. Replacing saturated fat with unsaturated fats, especially polyunsaturated fats, can lower LDL cholesterol levels and the risk of CVD. While FDA could encourage the public to make those substitutions by requiring labels to disclose polyunsaturated and monounsaturated fats, that would add complexity to a label that is already too complicated for many consumers to understand. Therefore, we support FDA's proposal to continue requiring a mandatory declaration of total fat on the Nutrition Facts label.

2. FDA should no longer require a percent DV declaration for total fat.

The types of fats consumed are more important in influencing the risk of heart disease than is the total amount of fat.¹⁰ Current dietary recommendations and clinical guidelines recommend replacing saturated and *trans* fats with polyunsaturated and monounsaturated fats to reduce the risk of heart disease (see Comment sections V.B-D.). Therefore, the percent DV declaration on Nutrition Facts labels, (65g based on the DRV of 30 percent of calories), should be eliminated to allow consumers to focus on replacing saturated fats with unsaturated fats.

B. Saturated Fat

1. We strongly support the mandatory declaration of saturated fat on the Nutrition Facts label.

We strongly support the FDA's proposal to continue to require a declaration of saturated fat on the Nutrition Facts label.¹¹² In 2013, the AHA and the American College of Cardiology (ACC) issued guidelines for lowering CVD risk, which recommended reducing saturated fat intakes to 5 to 6 percent of calories, even further than previous recommendations from the National Heart, Lung & Blood Institute.¹¹³

The findings of a recent, misleading meta-analysis that examined the effects of saturated fat and other fatty acids on heart disease risk,¹¹⁴ as well as misinformed media reports based on the meta-analysis,^{115,116,117} should not change the FDA's tentative conclusion to continue to require a declaration of saturated fat on the Nutrition Facts label.^{ix}

The authors of that meta-analysis concluded, "Current evidence does not clearly support cardiovascular guidelines that encourage high consumption of polyunsaturated fatty acids and low consumption of total saturated fats."¹¹⁴

However, the meta-analysis had several key flaws:

^{ix} The meta-analysis has been heavily criticized in comments on the Annals of Internal Medicine website: See comments available online at <http://annals.org/article.aspx?articleid=1846638>.

- The authors misrepresented the evidence from randomized trials that replaced saturated fat with omega-6 polyunsaturated fats. In Supplement Figure 14, the authors found no lower risk because they included one trial, the Sydney Diet and Heart Study (SDHS), which provided subjects with a margarine high in trans fatty acids (according to the footnote). When the SDHS was excluded, the authors found a significant 19 percent reduction in risk.¹¹⁴ This finding agrees with an earlier meta-analysis of randomized trials that found a reduction in risk of the same magnitude (19 percent) when saturated fat was replaced with polyunsaturated fat.¹¹⁸
- Months after the original paper was published (perhaps in response to criticism), the authors edited the Results section of their article to mention a “subsidiary analysis that omitted the Sydney Diet Heart Study.”¹¹⁴ Several of the paper’s authors then attempted to ignore the findings of the subsidiary analysis—and justify their initial conclusions—by essentially revising their original inclusion criteria from trials reporting at least 50 CHD events to only trials reporting at least 100 CHD events.¹¹⁹
- The authors incorrectly referred to the eight trials as “supplementation” trials. In fact, those trials *reduced* saturated fats and *replaced* them with polyunsaturated fats, precisely what most guidelines recommend. The evidence from these trials trumps observational studies—which are plagued by imprecise dietary intake data and possible residual confounding—that have failed to find an association between fatty acids and heart disease risk.

Strong evidence from controlled trials shows that replacing saturated fat with polyunsaturated fats lowers blood LDL levels and reduces heart disease risk.^{118,120} The 2002 IOM report on macronutrients did not set a UL for saturated fat because any incremental increase in saturated fat increases heart disease risk.¹⁵ Given the robust evidence that saturated fat worsens risk factors and increases the risk of heart disease, we strongly support FDA’s proposal to continue to require a declaration of saturated fat on the Nutrition Facts label.

2. FDA should lower the DRV for saturated fat to 15g (7 percent of calories based on a 2,000-calorie diet).

As stated in the proposed rule, the FDA was not persuaded to revise the DRV for saturated fat, which is currently 20g (10 percent of a 2,000-calorie diet). The FDA considered the saturated fat recommendation of 10 percent of calories “still appropriate for the general U.S. population and that the existing DRV of 20g continues to conform to current dietary recommendations as a maximum intake level that covers the general U.S. population.”¹²¹ We disagree with this rationale and urge the FDA to lower the DRV to 15g (7 percent of calories based on a 2,000-calorie diet).

The 2010 *DGA* acknowledged that reducing saturated fat intake to 7 percent of calories would further reduce the risk of CVD.¹⁰ The 2010 DGAC concluded that a goal of less than 7 percent of calories from saturated fat would have “significant public health impact” and

recommended that individuals reduce their intake of saturated fat to less than 10 percent of calories “as an interim step toward this less than 7 percent goal.”⁴⁵

The AHA currently recommends that healthy Americans over age 2 consume no more than 7 percent of calories from saturated fat.¹²² In 2013, AHA and the ACC recommended that people who would benefit from LDL cholesterol lowering (i.e., those at high risk for CVD and stroke) should reduce saturated fat intake to even lower levels (5 to 6 percent of calories),¹¹³ as used in the DASH, OmniHeart, and Dietary Effects on Lipoproteins and Thrombogenic Activity (DELTA) trials.^{123,124,125} For someone eating a 2,000-calorie diet, that means consuming less than about 13 grams of saturated fat per day.

According to the 2010 *DGA*, the major sources of saturated fat in the American diet include full-fat cheese, pizza, grain and dairy-based desserts, and meat and poultry.¹⁰ Lowering the DRV from 10 to 7 percent of calories would mean consumers would see a greater percent DV on Nutrition Facts labels, which would encourage consumers to reduce their consumption of those foods.

C. Trans Fat

There is a well-established, direct relationship between *trans* fat intake and blood LDL cholesterol levels. The IOM stated that any incremental increase in *trans* fat intake increases the risk of CHD and, therefore, the IOM did not set a UL for *trans* fat.¹⁵ The AHA, WHO, *DGA* and DGAC, Academy of Nutrition and Dietetics, National Cholesterol Education Program, and U.S. FDA Food Advisory Subcommittee have all recommended limiting *trans* fat consumption to reduce the risk of heart disease.¹²⁶

In November 2013, the FDA issued a tentative determination that partially hydrogenated oils (PHOs), the primary dietary source of industrially-produced *trans* fat, are no longer considered “generally recognized as safe” (GRAS). If finalized, the rule would prohibit food manufacturers from including PHO as an ingredient in food products unless companies receive prior FDA approval for use of PHO as a food additive.¹²⁷

CSPI and many public health officials urged the FDA to promptly finalize the determination and eliminate PHOs from the food supply as soon as possible.¹²⁸ By FDA’s estimation, eliminating PHOs from the food supply would prevent 10,000 to 20,000 coronary events and 3,000 to 7,000 coronary deaths each year. Furthermore, the FDA concluded that the economic benefits — between \$117 and \$242 billion over 20 years — of eliminating the use of PHOs greatly outweigh the costs of switching to healthier oils — \$12 billion or \$14 billion over 20 years.¹²⁹ Austria, Denmark, Sweden, Switzerland, and Argentina have largely eliminated PHO from their food supply, and the United States should do likewise.

- 1. If FDA removes PHOs from the GRAS list, the agency should require a declaration of *trans* fat on the Nutrition Facts label only when a product contains 1g or more *trans* fat from natural sources.**

Finalizing the determination that PHO is not GRAS would mean *trans* fat would be largely eliminated from the food supply; thus, there would be no need to continue to require declaration of *trans* fat on the Nutrition Facts label. However, small amounts of *trans* fat occurs naturally in meat and dairy products from ruminants.

Evidence from clinical studies suggests that naturally occurring *trans* fat can adversely affect heart disease risk factors as much as *trans* fat from industrial sources. For instance:

- When French researchers assigned 46 healthy men and women to consume a diet high in *trans* fat (between 11 and 12g a day) from either ruminant or industrial sources for three weeks, women consuming the ruminant *trans* fat had higher LDL cholesterol than those consuming the industrially-produced *trans* fat. (The source of *trans* fat made no difference in men.).¹³⁰
- Canadian researchers assigned 38 healthy men to consume a diet high in ruminant *trans* fat (about 10g per day), moderate in ruminant *trans* fat (about 4g per day), high in industrially-produced *trans* fat (about 10g per day), or a control diet that was relatively low in *trans* fat from any source (about 2g per day) for four weeks, the diet high in ruminant *trans* fat raised LDL cholesterol levels and lowered HDL cholesterol levels as much as the same amount of industrially-produced *trans* fat.¹³¹

Because naturally occurring *trans* fat can have adverse health effects, the FDA should require a declaration of *trans* fat on the label if a food contains 1g (5 percent of calories for a 2,000-calorie diet) or more *trans* fat per serving from natural sources. That would exempt most dairy products from labeling. It's worth noting that any food that contained half a gram or more of naturally occurring *trans* fat would also be high in saturated fat.

2. If the FDA does *not* finalize its tentative determination to remove PHO from the GRAS list, FDA should continue to require a declaration of *trans* fat on the label and allow only products with 0.2g *trans* or less to list “0g *trans*” on the label.

As the FDA acknowledged in the nutrition labeling proposed rule, “...because of its role in causing chronic disease, *trans* fat continues to be a nutrient with public health significance.”¹³² The 2010 *DGA* recommends that consumers keep *trans* fat consumption as low as possible.¹⁰ The AHA recommends a 2-gram daily *trans* fat limit (including naturally occurring *trans*), based on a 2,000-calorie diet (less than 1 percent of calories).¹³³ If the tentative determination to ban PHO from the food supply is not finalized, FDA should continue to require a declaration of *trans* fat on the Nutrition Facts label to help consumers avoid that fatty acid and reduce their risk of heart disease.

Since 2006, the food industry has made major progress in replacing about three-fourths of the PHO in foods by switching to healthier oils. However, progress has slowed in the past several years, particularly from 2008 to 2011, and some restaurants (other than large chains) continue to use, and processed foods continue to contain, significant amounts of PHO and *trans* fat.¹³⁴

For example, popular foods with high levels of *trans* fat include Pop Secret and Jiffy Pop butter-flavored popcorn (3 to 5g per serving), Marie Callender's Chocolate Satin Pie (4g) and Duncan Hines Creamy Home-Style Classic Vanilla Frosting (1.5g). In contrast, competing brands of similar products contain no *trans* fat. In April 2014, CSPI identified several menu items at Joe's Crab Shack that contain high levels of *trans* fat.¹³⁵ For example, Joe's Pasta-laya — a meal containing shrimp and Andouille sausage cooked in garlic butter sauce with mushrooms, bell peppers, tomatoes, and onions served over penne pasta — contained 14g of *trans* fat, which is the AHA recommended limit for a week.¹³³ Currently, many foods contain PHO, but at levels low enough to permit the amount of *trans* fat to be labeled as "0g" (i.e., if a food contains less than 0.5g of *trans* fat per serving, the content, when declared, is expressed as zero).¹³⁶ Even that seemingly small amount promotes heart disease. Furthermore, many people consume more than a single serving of those foods on one eating occasion and multiple servings over the course of the day. Nondairy powdered coffee creamer, frosting, and microwave popcorn are examples of foods that are commonly eaten in larger servings than appear on the label.

Should the FDA fail to finalize its tentative determination and a *trans* fat declaration on the Nutrition Facts label continues to be necessary, the FDA should only allow products with 0.2g *trans* fat or less to be listed as "0g *trans*" on the label.

Similar regulations have been established by the Canadian Food Inspection Agency. A *trans* fat value can only be rounded to zero in the following instances:

- The food contains less than 0.2g of *trans* fat per reference amount and per serving of stated size (or per serving of stated size, in the case of a prepackaged meal);
- The food contains 2g or less of saturated fat and *trans* fat, combined, per reference amount and per serving of stated size (or per 100g, in the case of a prepackaged meal); and
- The food provides 15 percent or less of energy from the sum of saturated fat and *trans* fat.¹³⁷

To protect the public's health, the FDA should promptly finalize its tentative decision that PHO is no longer GRAS. Then, mandatory declaration of *trans* fat on the Nutrition Facts label would no longer be necessary, except in the case when a product contains 1g or more *trans* fat from natural sources.

D. Polyunsaturated and Monounsaturated Fat

1. We support the voluntary declaration of polyunsaturated and monounsaturated fat on the Nutrition Facts label.

We support the FDA's proposal to continue to permit voluntary declaration of polyunsaturated and monounsaturated fats on the Nutrition Facts label.¹³⁸ The 2002 IOM report on macronutrients did not establish a DRI or AMDR for polyunsaturated fat, but

provided AIs and AMDRs for two essential polyunsaturated fatty acids (linoleic acid and α -linolenic acid), based on median intakes from NHANES data. Similarly, the IOM did not establish a DRI for monounsaturated fat because it is not an essential nutrient and has no known independent role in preventing chronic diseases.¹⁵ Although no quantitative intake recommendation has been established for polyunsaturated and monounsaturated fat, those nutrients continue to have public health significance because of their role in heart disease prevention, if only as substitutes for saturated fat. Therefore, polyunsaturated and monounsaturated fat fit FDA's definition for voluntary declaration (79 FR 11898, section I.C.3) and companies should be allowed to voluntarily list those nutrients on the Nutrition Facts label.

More importantly, allowing most labels to omit unsaturated fats would reduce label clutter and, we hope, encourage greater use of the Nutrition Facts panel. Without consumer education, labels that list nutrition information for five types of fat (total fat, saturated, *trans*, polyunsaturated, and monounsaturated fats) would confuse many consumers who may not understand that they should consume more of some types of fat and less of others. Furthermore, it would be easier to focus on saturated and *trans* fat if they were not part of a long list of fatty acids on the label.

VI. Cholesterol

A. We support mandatory declaration of cholesterol on the Nutrition Facts label and the current DRV of 300 mg.

We strongly support the FDA's proposal to retain the mandatory declaration of cholesterol on the Nutrition Facts label.¹³⁹ There is a well-established relationship between dietary cholesterol intake and increased LDL cholesterol levels, which raise the risk of heart disease. A meta-analysis of 17 studies in which people were fed or sent home with either whole eggs (the largest source of dietary cholesterol in Americans' diets) or cholesterol-free egg substitute found that LDL cholesterol levels rose by 2 mg/dL for every 100 mg of cholesterol consumed.¹⁴⁰

A key recommendation in the 2010 *DGA* advised Americans to consume less than 300 mg of dietary cholesterol per day to maintain normal blood cholesterol levels.¹⁰ The 2002 IOM report on macronutrients noted the strong positive relationship between dietary cholesterol intake and increased LDL cholesterol levels and, therefore, did not set a UL for cholesterol because any incremental increase in cholesterol intake increases the risk of heart disease.¹⁵

The state of the scientific evidence has not changed to justify reversing the mandatory declaration of cholesterol on the Nutrition Facts label, nor does the current evidence justify eliminating the percent DV declaration. FDA should retain the current DRV for cholesterol of 300 mg, which is appropriate for most people. The 2010 *DGA* recommends that people at high risk for CVD should limit cholesterol intake to less than 200 mg a day.¹⁰ Retaining

the mandatory declaration of cholesterol on the Nutrition Facts label would help people comply with current dietary recommendations.

VII. Protein

A. FDA should requiring labeling of the percent DV for protein.

We support the FDA's proposal to continue to require a declaration of protein on the Nutrition Facts label,¹⁴¹ but the FDA should also require a percent DV declaration. Consumers may be confused by the presence of a percent DV on foods that make a protein claim, but the absence of a percent DV on many foods without claims. Anecdotally, many people over the years have asked us why the percent DV for protein is not shown on most food labels. The 2010 *DGA* and the IOM emphasize protein's role as an essential nutrient for human health.^{10,15} The IOM established a Recommended Dietary Allowance (RDA) for protein of 0.8 grams (g) per kilogram of body weight per day and an AMDR of 10 to 35 percent of calories for adults aged 19 and older.¹⁵ Without a percent DV on Nutrition Facts labels, consumers would not know how much of a day's worth of protein a food contains.

We respectfully disagree with the FDA's rationale for a voluntary, rather than mandatory, declaration of a percent DV. The FDA stated that the current evidence indicates that protein intake is not a public health concern for the general population.¹⁴² However, emerging evidence suggests that older adults may need more protein than the current RDA. Some metabolic studies suggest that older adults need larger amounts of certain amino acids, particularly leucine, to stimulate muscle protein synthesis than younger individuals.^{143,144,145} To maximally stimulate protein synthesis and prevent sarcopenia (muscle loss with aging), some researchers have proposed that older adults should consume approximately 25 to 30g of protein at each meal, though that hypothesis needs to be tested in randomized controlled trials.^{146,147}

We recommend that the FDA ask the IOM for advice on whether the current DRV of 50g, which represents 10 percent of calories for someone consuming a 2,000-calorie diet, is too low for older people. In the meantime, we urge the FDA to require a percent DV disclosure for protein, based on the current DV, on the Nutrition Facts label to assist consumers in following dietary recommendations.

VIII. Vitamins and Minerals

A. We support the FDA's proposed declaration of essential vitamins and minerals of public health significance.

We support FDA's proposal to continue to require declaration of calcium and iron on the Nutrition Facts label and to begin to require declaration of vitamin D and potassium (instead of vitamins A and C).¹⁴⁸ The 2010 *DGA* considers calcium, vitamin D, and

potassium to be nutrients of concern for the general population and iron to be a nutrient of concern for women capable of becoming pregnant.¹⁰

- **Calcium** continues to be a nutrient of public health significance. According to data from NHANES 2003–2006, 49 percent of Americans aged 4 and older have usual calcium intakes from foods below the Estimated Average Requirement (EAR) and 37 percent have intakes below the EAR from foods plus supplements.¹⁴⁹ The 2011 IOM report established DRIs for calcium based on bone health outcomes.¹⁵⁰ Because adequate calcium intake is important for optimal bone development during childhood and for reducing the rate of bone loss in adulthood, we support FDA's tentative conclusion to continue to require a mandatory declaration of calcium on Nutrition Facts labels.
- **Iron** continues to be a nutrient of public health significance for adolescents and women of childbearing age and pregnant women. Biomarker data from NHANES indicate that 14 percent of women of childbearing age had serum ferritin concentrations less than 15 ng/mL, the generally accepted cut-off level for serum ferritin, below which iron stores are considered to be depleted.^{151,152} However, iron overload is also a concern for some adults and people with hemochromatosis, who have excess iron stores in their body.^{153,154} To assist consumers who may be at risk for consuming too little or too much iron from foods, we support FDA's proposal to continue to require mandatory declaration of iron on Nutrition Facts labels.
- **Vitamin D** meets FDA's definition of a nutrient of public health significance. The 2011 IOM report established DRIs for vitamin D intake at a level that would achieve and maintain serum 25-hydroxyvitamin D concentrations (25(OH)D; a biomarker of vitamin D status from sunlight and diet) that is considered to be adequate for bone health.¹⁵⁰ According to NHANES biomarker data, approximately one-third of Americans aged 4 years and older have serum 25(OH)D concentrations below 50 nmol/L, which indicates that they are at risk for inadequacy or deficiency.¹⁵⁵ Therefore, we support the mandatory declaration of vitamin D on Nutrition Facts labels.
- **Potassium** also meets FDA's definition of a nutrient of public health significance, and we support the mandatory declaration of potassium on Nutrition Facts labels. The 2010 *DGA* and the IOM have highlighted the role of potassium in lowering blood pressure by blunting the adverse effects of sodium on blood pressure (see [sodium section]).^{10,47} According to NHANES 2003–2008, only about 2 percent of the general population has potassium intakes above the AI of 4,700 mg from foods or from foods plus supplements.¹⁵⁶ However, some people with certain medical conditions, such as diabetes, or those taking medications that can impair potassium excretion, such as ACE inhibitors, angiotensin receptor blockers, and potassium-sparing diuretics, may need to avoid consuming too much potassium because of potential adverse cardiac effects (arrhythmias).⁴⁷ A declaration of potassium on the Nutrition Facts label would assist those individuals in complying with medical advice.

Additionally, we support FDA's proposal to permit, but no longer require, voluntary declaration of **vitamins A and C**. Data from NHANES 2003–2008 estimated that vitamin A and C deficiencies were uncommon in the general population.¹⁵⁷

We support FDA's criteria for mandatory and voluntary declaration of essential vitamins and minerals of public health significance on the Nutrition Facts label. As the FDA stated in the proposed rule, mandatory declaration of a nutrient was considered when there is (1) public health significance and (2) a quantitative intake recommendation that can be used for setting a DV (DRV or Recommended Daily Intake) *or* (3) there is evidence highlighting the role of the nutrient in chronic disease risk.^x

Finally, we support FDA's proposed declaration of absolute amounts of vitamins and minerals, in addition to the percent DVs.¹⁵⁸ That would assist consumers who have difficulty understanding how to interpret the percent DV declaration or who are accustomed to dealing with absolute amounts of nutrients.

IX. Label Format

A. We generally support the format changes, including for calories and serving sizes.

We strongly support the FDA's proposal to continue to require total calories to be declared on the label and to increase the prominence of the calorie declaration. One of two key concepts of the 2010 DGA, included because of the high prevalence of overweight and obesity, is to "maintain calorie balance over time to achieve and sustain a healthy weight."¹⁰ To support consumers in selecting, preparing, and consuming foods and beverages with the appropriate number of calories to meet their needs for weight management, consumers must be able to easily see and use the number of calories in a serving of a particular food or beverage. Therefore, we strongly support the proposal to increase the type size for both the "Calories" heading and the numerical value and to require that the information be highlighted in bold or extra bold type.

Specifically, the *DGA* recommends that people "control total calorie intake to manage body weight."¹⁰ For the two-thirds of adults and one-third of youth who are overweight or obese, that means consuming fewer calories. According to the Centers for Disease Control and Prevention,¹⁵⁹ overweight and obesity increase the risk of many of the leading causes of death, including heart disease and stroke, several types of cancer, diabetes, and other conditions, including high blood pressure, high cholesterol, liver disease, sleep apnea, osteoarthritis, and gynecological problems.

Despite the fact that calorie information has been included on the Nutrition Facts label since its inception, it has not been displayed sufficiently prominently. Instead, calorie

^x For example, FDA published a final rule in 2003 requiring a declaration of *trans* fat on the label based on evidence relating *trans* fat intake to coronary heart disease risk (68 FR 41434).

content is shown in the same type size as the levels of cholesterol, sodium, and several other nutrients. While information about other nutrients is important, information on calories is particularly important considering the prevalence of obesity and the resulting diseases, disabilities, and costs.

Calorie information is only useful if consumers understand the amount of food or beverage that contains the specified number of calories (and other nutrients). If an individual's portion size is much larger or smaller than the serving size specified on the label, the calories consumed will vary dramatically. Research has found that people tend to eat more when the portion size or serving container is larger, indicating a need for increased consumer education and awareness about what the labeled serving size means and appropriate portion sizes.¹⁶⁰ Clinical studies suggest that providing children and adults with larger food portions can lead to significant increases in energy intake.¹⁶¹

One recent study found that many consumers are unable to make accurate comparisons among similar products with labels that show different serving sizes and numbers of servings per container.¹⁶² In that study, consumers were more accurate in identifying the number of calories per container when the label listed the calories per container than when the label required the consumer to multiply the number of calories per serving by the number of servings per container. Another recent study found that a significant fraction of consumers who said they look at the Nutrition Facts label and ingredient list when shopping do *not* look at the serving size.¹⁶³

FDA should more closely review existing, and conduct additional, consumer research to determine the value of more prominently providing information about serving size in larger type size than proposed, in addition to the number of servings per container.

Overall, we strongly support and agree with the tentative conclusion that proposed changes to the calorie and serving size declarations would serve as an anchor to the Nutrition Facts label by focusing the reader's attention on that information.

In addition, we think the agency should carefully re-evaluate its tentative decision to abbreviate "% Daily Value" as "% DV." In so doing, we fear that FDA might replace an obscure concept for consumers with a shorthand designation that would render it even more esoteric. In our survey (see Appendix 1), there was a considerable discrepancy in understanding of the concept of DV when comparing respondents with lower vs higher years of education.^{xi} This issue bears further research by FDA, and should be reconsidered fully. In addition, we are skeptical that "carbohydrates" should be shortened to become "carbs." The scientific term is clearer than the shortened version, and slang has no place on a government label. Furthermore, as explained above, we urge FDA to display the measures for added sugars in both teaspoons and grams.

^{xi} Our survey suggested that African-American and Latino respondents were less able to understand the %DV than whites, but the survey included an insufficient number of minority respondents to reach any conclusion.

We urge FDA to explore in consumer research whether moving sodium up even higher on the label could improve consumer understanding of its significance to health. We are concerned about the proposal to shift %DV to the left. For consumers with lower levels of health literacy and numeracy, such a change may present a challenge to comprehensibility at the outset because people are accustomed to reading from left to right. In addition, the placement of %DV on the left does not generally reflect how people would read the label aloud, since most people would say “240 milligrams of sodium is 10 percent of the Daily Value,” rather than “10 percent of the Daily Value is 240 milligrams of sodium,” for example. It requires some unpacking for even the most sophisticated consumer to understand nutrition information, and the left-hand placement may hinder, rather than assist, such understanding. In CSPI’s survey (see Appendix 1), slightly more people answered a question on daily values correctly when the %DV was on the right versus the left (76 percent vs. 69 percent; $p = 0.03^{xii}$). While that survey question is hardly a comprehensive investigation, it fails to demonstrate an advantage for consumer comprehension from moving the %DVs to the left. More consumer research on this question is required.

A *Washington Post* opinion piece by Burkey Belser, a graphic designer who played a role in designing the original Nutrition Facts panel, raises a raft of concerns about the label redesign,¹⁶⁴ some of which we agree merit consideration by FDA. Slight reductions in the relative size of the calories indicated and slight increases in the number of servings per package, relocating the serving size information below “Calories” and including a clear indication of the calories in a single serving below the word “Calories” all make sense as further revisions to the design. In addition, moving carbohydrates and sodium up to the top of that section of the label would better emphasize their importance for health. And we agree, as explained above, that the benefits of moving DVs to the left have not been demonstrated for consumer understanding. Finally, if the FDA does require the %DVs to be shown at the left edge of the label, the agency should consider Belser’s proposal to eliminate the vertical line separating %DV from the nutrient because it could discourage label-reading.

Last, we urge FDA to conduct far more robust research and publish findings concerning the impact of nutrition labeling requirements on fortification of foods and beverages and the impact of that fortification on consumer intake of substances, including fiber, vitamins, and minerals, commonly added to foods and beverages through fortification. Our concern is both that fortification of less unhealthful foods lends them a largely unjustified “health halo,” and that fortification may lead to over-consumption of some vitamins by some consumers, such as children.

X. Alternative Label

A. We urge adoption of the alternative format of the Nutrition Facts label.

^{xii} P-value calculated using a Chi-square test with Yates’ correction.

We strongly prefer the alternative label format over the agency's central proposal, because it would more effectively assist consumers in choosing more foods that are high in nutrients they should consume more of and fewer foods that are high in nutrients they should eat less of.¹⁶⁵ Both the current label and main proposed label are plain lists of information with lots of numbers and include nutrients that may be unfamiliar to many consumers. For certain nutrients, we suspect that some consumers don't even know whether they should consume more or less of them. Providing context and advice within the label would, in effect, constitute part of FDA's education campaign.

According to data from NHANES 2009-2010, 42 percent of working-aged adults and 57 percent of older adults reported using the Nutrition Facts label always or "more of the time" (rather than less) when shopping for food.¹⁶⁶ That percentage varies significantly by demographic group, with a Canadian study finding that individuals of higher income, higher education, and less than age 65 are more likely than other people to use nutrition labels to assess calorie and nutrient information about a product.¹⁶⁷

Research has found that people who use nutrition labels are more likely to have a lower body mass index (BMI) than people who do not, though such studies cannot establish cause and effect. The difference in label usage is particularly striking for women, with women who read nutrition labels having a BMI that is 1.49 points lower than women who do not (for a woman who is 5'5" tall, that represents a difference of about 9 pounds).¹⁶⁸ Again, while such studies cannot establish cause and effect, that finding suggests that increasing the use of nutrition labels could be an important tool for helping people manage their weight. Making the Nutrition Facts label more understandable could help to encourage more people to use nutrition labels, as well as help them to understand it and use it effectively in their food purchase and consumption decisions.

A label that takes a step toward providing interpretive words or data is consistent with the need to make information clearer especially for consumers with lower levels of health literacy and numeracy. Interpreting the data on the current and proposed label requires a high degree of background understanding about healthful and less-healthful nutrients. Grouping nutrients into categories that clearly indicate, in comprehensible language, which nutrients are more or less healthful would help to achieve the purposes underlying most of the FDA's proposed changes to the label, as it would make clear that consumers should consume less sodium and added sugars, among other nutrients.

Following its detailed investigation and a prior report, the 2012 IOM report on front-of-package labeling points out the overall need for interpretive information for consumers.¹⁶⁹ The IOM also highlighted some of the barriers to current consumer understanding, noting studies that demonstrate that:

- "...a lack of nutrition knowledge is a major barrier to effective use of the Nutrition Facts Panel and may actually lower the motivation of some consumers to use the nutrition information on the label;"

- “...some racial groups...are less likely...to use and understand nutrition labels, primarily because of lack of time to read labels and lack of understanding of the nutrition information;”
- “An estimated 90 million U.S. adults have literacy and numeracy skills that are inadequate to function in the current health care environment;”
- “Adults with low health literacy skills are less inclined to use nutrition labels and are at greater risk for diet-related health outcomes;”
- “...interpretational aids that make the nutrition label easier to use and enhance the ability to compare products may help consumers better understand how a product fits into their overall diet;” and
- consumers favor front-of-package interpretive labels, in part, because they “lack the cognitive skills needed to use nutrition information to compare products and interpret the nutrients in the context of their total diet.”

All of those factors equally would support the alternative label as a step in encouraging greater use of the Nutrition Facts Panel. Clearly labeling what consumers *should do* about particular nutrients would represent a massive step forward in popular understanding of basic principles of nutrition and would embed this essential education on every package.

Moreover, we note that Health Canada recently proposed its own slate of improvements to its Nutrition Facts panel.¹⁷⁰ The changes include adding a line for added sugars (as well as a %DV for total sugars), and other changes that are analogous to some of the recommendations in FDA’s proposal. On the issue of the alternative format, we were pleased to see that the revisions to the Canadian label emphasize a little more the “nutrients of public health concern,” such as saturated/trans fat, sodium, and cholesterol, which would be in a slightly more prominent location. The Canadian government’s proposed changes are shown in the graphic.

Proposed Changes to the Nutrition Facts Table

Nutrition Facts Valeur nutritive	
Per 3/4 cup (175 g) / par 3/4 tasse (175 g)	
	% Daily Value (DV) % valeur quotidienne (VQ)
Calories 170	
Fat / Lipides 5 g	1 %
Saturated / saturés 3.5 g	18 %
Trans / trans 0.2 g	10 %
Cholesterol / Cholestérol 20 mg	
Sodium / Sodium 450 mg	20 %
Carbohydrate / Glucides 23 g	
Total Sugars / Sucres totaux 18 g	18 %
Added Sugars / Sucres ajoutés 12 g	
Fibre / Fibres 0 g	
Protein / Protéines 7 g	
Vitamin D / Vitamine D 1.3 µg	9 %
Calcium / Calcium 220 mg	17 %
Iron / Fer 2 mg	10 %
Potassium / Potassium 150 mg	4 %

*5% DV or less is a little, 15% DV or more is a lot
5% VQ ou moins c'est peu; 15% VQ ou plus c'est beaucoup

Proposed Changes:

- Move calories up, bold and increase font size
- Remove thin line between Fat and Saturated
- Nutrients of public health concern to limit have a %DV and are above the thick line
- Nutrients of public health concern to get enough of have a %DV and are below the thick line
- Add footnote explaining how to use % DV
- Right justify Serving Size
- Add asterisk referring to footnote
- Add thick lines (3x)
- Separate DV's for trans and saturated fat
- Updated Daily Values
- Have a %DV for total sugars
- Add a declaration for "added sugars"
- Add absolute amounts for vitamins/minerals; Remove Vitamin A and C, add Vitamin D and Potassium

B. We urge FDA to propose a rule to require a more legible ingredient list on products and to group all sugars in the ingredient list.

We applaud FDA for proposing several key proposed changes to the format of the Nutrition Facts label. However, we encourage the FDA to further improve food labels by proposing regulations to require more legible and useful ingredient lists.

In 1978, the FDA held a series of nationwide hearings and solicited written comments on food labeling.¹⁷¹ Since then, FDA has made no effort to improve the ingredient label. Current guidelines require manufactures to use a type size that is at least 1/16th inch in height, which is now smaller than many print newspapers.^{172,173} Aside from using small print, many manufacturers use all capital letters, a condensed and sans serif font, minimal kerning, and full justification. That squeezes letters and words together, making them even more difficult to read. The format of the ingredient list contrasts sharply with the information presented in the Nutrition Facts panel, which must use upper and lower case letters, ensure that letters never touch, and use at least 1 point of leading (i.e., the space between two lines of text).¹⁷⁴

A difficult-to-read ingredient list is particularly problematic for consumers suffering from food allergies, an estimated 9.7 percent of American adults and 6.5 percent of children.¹⁷⁵ The 2004 Food Allergen Labeling and Consumer Protection Act required that food products containing "major" food allergens (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) clearly declare the allergen in the ingredient list or disclose it separately under the ingredient list by stating "Contains" followed by the allergens.^{176,177} However, the Act allows allergens to be printed in the same small type size as that used in the ingredient list.

In September 2013, legislators proposed the Food Labeling Modernization Act, which would require the FDA to modernize the ingredient list to include upper- and lower-case letters, bullet points between adjacent ingredients, and other changes to improve the readability (see Figure 2).¹⁷⁸ We urge the FDA to adopt those changes to make ingredient labels useful for consumers who want to choose safer, more healthful foods and seek out or avoid specific food ingredients for health, religious, or other reasons.

In addition, added sugars should be grouped together (and listed in parentheses) in the ingredient list. While adding a line in the Nutrition Facts label for added sugars would disclose the amount of those sugars in a product, many consumers read the ingredient list to determine the relative amount of added sugars versus other ingredients in a product. However, when various added sugars are scattered through the ingredient list, it is tough to compare the total amount of those sugars to other ingredients. Furthermore, many consumers may not recognize the many guises of added sugars on food labels, such as corn syrup, dextrose, fructose, HFCS, honey, lactose, maltose, molasses, raw sugar, and sucrose.¹⁷⁹

We further note that Health Canada has proposed many of our recommendations, including grouping sugars and using bullets to separate items in the ingredient list.

Figure 2. Label Makeover

Current Label

INGREDIENTS: ENRICHED BLEACHED FLOUR (WHEAT FLOUR, NIACIN, IRON, THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), SUGAR, SKIM MILK, VEGETABLE OIL (PALM, SOYBEAN AND/OR COTTONSEED OILS), WATER, COCOA PROCESSED WITH ALKALI, EGGS, CORN SYRUP, HIGH FRUCTOSE CORN SYRUP, CHERRIES, WHITE GRAPE JUICE CONCENTRATE. CONTAINS 2% OR LESS OF EACH OF THE FOLLOWING: WHOLE WHEAT FLOUR, CARAMEL COLOR, POLYDEXTROSE, LEAVENING (BAKING SODA, SODIUM ALUMINUM PHOSPHATE, MONOCALCIUM PHOSPHATE), SALT, CORN STARCH, MONO- AND DIGLYCERIDES, NATURAL AND ARTIFICIAL FLAVORS, POLYGLYCEROL ESTERS OF FATTY ACIDS, SODIUM ALGINATE, NATURAL COCOA EXTRACT, PROPYLENE GLYCOL MONO- AND DIESTERS OF FATS AND FATTY ACIDS, MALTODEXTRIN, GELLAN GUM, LACTYLIC ESTERS OF FATTY ACIDS, SOY LECITHIN, POLYSORBATE 60, SOY FLOUR, COFFEE. **CONTAINS MILK, WHEAT, EGGS AND SOY.**

All-capital letters and condensed, sans serif fonts are hard to read.

Bullets separate ingredients. Upper and lower-case serif font is easier to read.

Minor ingredients and allergens are listed separately.

Better Label

Ingredient Facts

Major Ingredients: Sugars (sugar, corn syrup, high-fructose corn syrup, white grape juice concentrate) • Skim milk • Refined bleached flour (wheat flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid) • Vegetable oil (palm, soybean, and/or cottonseed oils) • Water • Cocoa processed with alkali • Eggs • Cherries

Contains 2% or less of: Whole wheat flour • Caramel color • Polydextrose • Leavening (baking soda, sodium aluminum phosphate, monocalcium phosphate) • Salt • Corn starch • Mono- and diglycerides • Natural and artificial flavors • Polyglycerol esters of fatty acids • Sodium alginate • Natural cocoa extract • Propylene glycol • Mono- and diesters of fats and fatty acids • Maltodextrin • Gellan gum • Lactylic esters of fatty acids • Soy lecithin • Polysorbate 60 • Soy flour • Coffee

Allergy Information: Contains MILK • WHEAT • EGGS • SOY

XI. Recordkeeping

- A. The recordkeeping requirements set out in the proposal for enforcement purposes are clearly within the scope of FDA's legal authority. Industry complaints concerning the recordkeeping requirements are unjustified.

As the proposal describes, the legal backdrop for FDA's revisions to the Nutrition Facts Panel is clear: the Nutrition Labeling and Education Act (NLEA) of 1990 provides the FDA with the authority to require nutrition labeling on foods. See 79 FR 11881. The NLEA added Section 403(q) to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which specified nutrition labeling for those nutrients that the Secretary of Health and Human

Services deems “will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices.” *See* 79 FR 11881.

In light of new scientific evidence and in response to the public comments received from the advance notices of proposed rulemaking and citizens’ petitions, FDA issued a Proposed Rule to update the Nutrition Facts panel and labeling (hereafter “Proposed Rule”). *See* 79 FR 11881. The Proposed Rule includes compliance measures specifying the need for entities to maintain records regarding nutrient information for certain nutrients that will facilitate enforcement of the rule.

The recordkeeping requirement is limited to those nutrients that appear on the Nutrition Facts label for which “there is no suitable analytical procedure available to measure the quantity of,” particularly when the final food product includes multiple forms of the nutrient. *See* 79 FR 11955. Specifically, the six nutrients that the recordkeeping requirement applies to are:

- 1) added sugars (“when both naturally occurring and added sugars are present in a food”);
- 2) dietary fiber (“when the dietary fiber present in a food is a mixture of non-digestible carbohydrates that do and that do not meet the definition of dietary fiber”);
- 3) added soluble fiber (“when the soluble dietary fiber present in a food is a mixture of soluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber”);
- 4) added insoluble fiber (“when the insoluble dietary fiber present in a food is a mixture of insoluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber”);
- 5) vitamin E (“when a mixture of [two] forms of vitamin E are present in a food”); and
- 6) folate (“when a mixture of both [folate and folic acid] are present in a food”).

See 79 FR 11957. The requirement includes provisions securing FDA’s access to the records, which are to be maintained on-site by companies. *See* 79 FR 11957.

This approach makes sense because, as FDA notes, “only the manufacturer will have the information required to determine the accuracy of the declared amount.” 79 FR 11956. At FDA’s summer Public Meeting about the Proposed Rules, FDA representatives indicated that the agency does not anticipate that the recordkeeping requirement requires manufacturers to keep records beyond those which they already maintain. *FDA Public Meeting on Proposed Rules on Food Labeling: Nutrition Facts Label and Serving Size*, June 26, 2014.

Contrary to industry representatives’ assertions at the public meeting, it is clear that, as the agency indicates, FDA has the authority to issue the recordkeeping requirement in the final rule.

As an initial matter, under Section 701(a) of the FD&C Act, the FDA has “the authority to promulgate regulations for the efficient enforcement of [the] Act.” *See* 21 U.S.C.S. § 371. As are other agencies under *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837

(1984) (instructing courts to defer to an agency's interpretation of a statute if the interpretation is reasonable and there is no clear, contrasting legislative intent), FDA receives considerable deference when it interprets the scope of its own powers under the FD&C Act. *See, e.g., Ass'n of Am. Physicians and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204, 211 (D.D.C. 2002); *Scott v. FDA*, 728 F.2d 322, 324 (6th Cir. 1984) ("Even when there 'is more than one reasonable interpretation of [the FD&C Act], the court should follow the interpretation urged by the FDA.'").

Further, because the primary objective of the FD&C Act is the enhancement of public health, the FDA's rulemaking authority under Section 701(a) "has been broadly construed to uphold a wide variety of assertions of regulatory power" and is valid so long as it is reasonably related to an authorized regulatory objective. *See Pharm. Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980); *see also U.S. v. Nova Scotia Food Products*, 568 F.2d 240, 246 (2d Cir. 1977) (finding that enforcement-related regulations are valid so long as they are reasonably related to the purposes of the enabling legislation). A regulation has also been deemed to be valid if it is justified in light of the entire broad "statutory scheme." *National Confectioners Ass'n. v. Califano*, 569 F.2d 690, 693 (D.D.C. 1978); *see also Ass'n of Am. Physicians and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204, 212 (D.D.C. 2002). Because the statutory scheme indicates, most logically, that Congress intended for the FDA to enforce regulations that it is directed to promulgate, the recordkeeping requirement is valid.

More specifically, regulations are also deemed consistent with the statutory scheme if they "effectuate a Congressional objective expressed elsewhere in the Act." *See Pharm. Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980); *see also Ass'n of Am. Physicians and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204, 213 (D.D.C. 2002) (D. D. C. 2002). In *Pharm. Mfrs.*, FDA issued a regulation requiring doctors to distribute information about estrogen-containing drugs to patients to whom the drugs were prescribed. *Id.* at 1181. The agency stated it promulgated the regulation to implement Sections 502(a) and 505(d) of the FD&C Act. *Id.* at 1183.

The plaintiffs sued, claiming the regulation was beyond FDA's statutory authority. To determine if the regulation was valid, the District Court of Delaware examined both Sections 502(a) and 505(d). As part of its examination, the District Court also looked to Section 201 of the Act, which defined a "misleading" label as one that "fails to reveal facts material... with respect to consequences which may result from the use of the article to which the labeling relates." *Id.* at 1183. The District Court granted FDA's motion for summary judgment, finding that "[t]hese statutory provisions, combined with Section 701(a), provide direct support for the challenged regulation. Among other things they reflect a clear Congressional objective that the users of drugs ... shall receive facts 'material ... with respect to consequences which may result.'" *Id.* at 1183, 1184; *see also Nat'l Confectioners Ass'n v. Califano*, 569 F. 2d 690, 693 (D.D.C. 1978) ("there is no persuasive evidence that Congress intended to immunize food manufacturers from mandatory source coding and record-keeping," and "the FDA's purposes in enacting the contested provisions of its Regulation ... reflect the objective of the Act and carry out its mandate").

Similarly, a number of statutory provisions in the FD&C Act provide FDA with the authority to issue the recordkeeping requirement in the proposed rule. Section 403(q) of the FD&C Act requires a food to indicate through labeling the amount of nutrients it contains to assist consumers in maintaining healthy dietary practices. Further, as in the above case, other sections of the code (specifically, 21 USC §§ 403(a)(1) and 201(n)) require these nutrient declarations to be truthful and not misleading. Moreover, Section 301(a) prohibits the introduction of misbranded food into interstate commerce. Taken together, these statutory provisions reflect the Congressional objective to ensure that nutrition labels are accurate, truthful and not misleading to enable consumers to make healthy choices. An enforcement mechanism, like recordkeeping, is necessary to achieve this goal and prevent mislabeled foods from entering commerce. Thus, the recordkeeping requirement is consistent with the Congressional objectives expressed throughout the FD&C Act.

Practical enforcement considerations are also evaluated to determine their role in carrying out the statutory scheme. See *Nat'l Confectioners Ass'n v. Califano*, 569 F. 2d 690, 693 (D.D.C. 1978). In *Nat'l Confectioners*, FDA promulgated enforcement regulations to carry out Section 402(a)(4) of the FD&C Act, which prohibits adulterated foods in interstate commerce. *Id.* at 692. The regulation placed two requirements on candymakers: 1) encoding of shipping containers with information about the site at which the candy had been packed; 2) and recordkeeping of the candy's initial distribution for a period of up to two years. *Id.* at 692. FDA justified the regulation by emphasizing that the encoding and recordkeeping measures would "result in increased consumer protection" via expediting recalls of adulterated foods. *Id.* at 692.

FDA pointed out that the recordkeeping provision was a "logical companion" to the encoding requirement and "serves the same purpose in protecting the public health." *Id.* at 692. A trade association of candy-makers sued, arguing that these compliance measures were beyond the statutory authority of the agency. *Id.* at 692. They claimed the literal purpose of Section 402(a)(4) was merely the *prevention* of contaminated foods entering commerce and did not extended to *removal* measures like product recalls, with which the encoding and recordkeeping measures were intended to assist. The District Court disagreed, concluding that the FDA's *practical* duty also includes providing remedies for any adulterated foods present in interstate commerce, such as through product recalls. Thus the court held that the encoding and recordkeeping requirements appropriately assisted the agency in fulfilling its statutory mandate. *Id.* at 694.

Here, like the recordkeeping requirement in *Nat'l Confectioners*, the recordkeeping requirement in the Proposed Rule is necessary for its practical enforcement. As the agency makes clear, unlike other nutrients on the nutrition facts panel (*e.g.*, sodium), there is no suitable analytical or testing procedure to measure the quantity in a final food product of the six nutrients in the Proposed Rule that are subject to the recordkeeping requirement. As FDA indicates, the final food products containing the specified ingredients have a mixture of multiple types of each nutrient that are impossible to measure separately. In addition, it is the case as FDA asserts that food manufacturers are in the best position to know which of its records to provide to FDA to enforce compliance via their records and recipes. Without access to manufacturers' records and recipes indicating the amount of

each nutrient added to foods, there is no way for FDA to enforce its reasonable and authorized labeling rule. As a result, the recordkeeping requirement is necessary for practical enforcement of the rule.

Industry is mistaken to claim that the recordkeeping is “unprecedented” and “novel” and generally a huge burden to industry. *Industry Attorney Questions FDA Authority to Enforce Added Sugars Labelling*. FDA Week, INSIDE HEALTH POLICY. July 4, 2014. First, FDA may permit the use of an alternative means of compliance if the current means are insufficient. See 21 C.F.R. § 101(g)(9). Further, there are limitations on the recordkeeping requirement in the Proposed Rule to ensure it does not become an abuse of FDA authority. The only nutrients that are subject to the recordkeeping requirements are those for which “there is no... official method of analysis or other reliable or appropriate analytical procedure that is available for us to verify the amount of the declared nutrient” and FDA aims to “provide flexibility in what records the manufacturer makes available to [FDA] to verify the declared amount of these nutrients.” See 71 F.R. 11,956. As industry concedes, “methods that companies have generally relied upon to ensure the accuracy of nutrition facts labels are not available in this situation.” See *Industry Attorney Questions FDA Authority to Enforce Added Sugars Labeling*. FDA Week, INSIDE HEALTH POLICY. July 4, 2014.

Further, there is no indication that keeping and maintaining these records will be particularly burdensome or problematic for food manufacturers. According to FDA, “Most manufacturers should already have the type of records needed to validate the declared amount of each of these nutrients.” See 79 FR 11956. FDA emphasized this at the Public Meeting about the Proposed Rules, where representatives stated, “We do not anticipate that the proposed rule on added sugars will require food manufacturers to keep any additional records beyond records they currently keep.” Public Meeting, Proposed Rules on Food Labeling: Nutrition Facts Label and Serving Size. June 26, 2014. In fact, “food manufacturers already must keep records on the content and production process of foods. Requiring added sugar measurement isn’t expected to add to this record-keeping load.” Gretchen Goldman, *Five Things Sugar Interests Get Wrong about FDA Added Sugars Labeling*, THE EQUATION (July 1, 2014), <http://blog.ucsus.org/five-things-sugar-interests-get-wrong-about-fda-added-sugars-labeling-576>.

Anticipating industry claims that it has concerns about maintaining the confidentiality of recipes and records, the FDA further notes in the proposal that “[w]e anticipate that manufacturers may have concerns about the confidentiality of the information inspected by us under this proposal. We would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. § 552(b)(4), 18 U.S.C. § 1905, and 21 C.F.R. part 20.” See 79 FR 11957.

XII. Conclusion

In conclusion, CSPI strongly supports FDA's proposal to update the Nutrition Facts and Supplement Facts labels and urges the agency to finalize the proposed rules expeditiously.

In particular, we support the mandatory declaration of added sugars and the enlarged declaration of calories on labels. With the current obesity epidemic and a type 2 diabetes epidemic expected within a few decades, the FDA has an obligation to ensure that food labels give consumers the tools they need to protect their health.

Respectfully submitted,

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Endnotes

¹ 79 FR 11880 at 11884.

² Marriott BP, Olsho L, Haddad L, et al. Intake of added sugars and selected nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003–2006. *Crit Rev Food Sci Nutr.* 2010; 50:228-58.

³ Welsh JA, Sharma AJ, Grellinger L, et al. Consumption of added sugars is decreasing in the United States. *Am J Clin Nutr.* 2011; 94:726-34.

⁴ U.S. Department of Agriculture, Economic Research Service. Food Availability (Per Capita) Data System. <http://www.ers.usda.gov/data-products/food-availability-%28per-capita%29-data-system.aspx#.U1fvM1dVYdN>. Accessed April 23, 2014.

⁵ De Ruyter JC, Olthof MR, Seidell JC, et al. A trial of sugar-free or sugar-sweetened beverages and body weight in children. *N Eng J Med.* 2012; 367:1397-406.

⁶ Malik VS, Popkin BM, Bray GA, et al. Sugar-sweetened beverages, obesity, type 2 diabetes mellitus, and cardiovascular disease risk. *Circulation.* 2010; 33:2477-83.

⁷ Malik VS, Popkin BM, Bray GA, et al. Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes: a meta-analysis. *Diabetes Care.* 2010; 121:1356-64.

⁸ Choi HK, Curhan G. Soft drinks, fructose consumption, and the risk of gout in men: prospective cohort study. *BMJ.* 2008; 336:309-12.

⁹ Tougher-Decker R, van Louveren C. Sugars and dental caries. *Am J Clin Nutr.* 2003; 78:881S-892S.

¹⁰ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010.* 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010.

¹¹ Centers for Disease Control and Prevention. FastStats – Obesity and Overweight. May 14, 2014. Available online: <http://www.cdc.gov/nchs/fastats/obesity-overweight.htm>. Accessed July 23, 2014.

¹² Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014.* Atlanta, GA: U.S. Department of Health and Human Services; 2014.

¹³ Centers for Disease Control and Prevention. Diabetes – Successes and Opportunities for Population-Based Prevention and Control At A Glance 2011. August 1, 2011. Available online: <http://www.cdc.gov/chronicdisease/resources/publications/aag/ddt.htm>. Accessed July 23, 2014.

¹⁴ Opinion Research Corporation International. Online Caravan Nutrition Facts Label Study. July 10-13, 2014. Princeton, NJ.

¹⁵ National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients).* Washington, DC: National Academies Press, 2002.

¹⁶ Go AS, Mozaffarian D, Roger VL, et al. Heart disease and stroke statistics – A 2014 update: A report from the American Heart Association. *Circulation.* 2014; 129:e28-e292.

-
- ¹⁷ Perreault L, Faerch K. Approaching pre-diabetes. *J Diabetes Complications*. 2014; 28:226-33.
- ¹⁸ Crane PK, Walker R, Hubbard RA, et al. Glucose levels and risk of dementia. *N Engl J Med*. 2013; 369:540-8.
- ¹⁹ American Heart Association. What is metabolic syndrome? 2012. Available online: www.heart.org/idc/.../ucm_300322.pdf. Accessed June 17, 2014.
- ²⁰ Grundy SM, Cleeman JI, Daniels SR, et al. Diagnosis and management of the metabolic syndrome: An American Heart Association/National Heart, Lung, and Blood Institute scientific statement. *Circulation*. 2005;112:2735-52.
- ²¹ Stanhope KL, Schwarz JM, Griffen SC, et al. Consuming fructose-sweetened, not glucose-sweetened beverages increases visceral adiposity and lipids and decreases insulin sensitivity in overweight/obese humans. *J Clin Invest*. 2009; 119:1332-34.
- ²² Stanhope KL, Bremer AA, Medici V, et al. Consumption of fructose and high fructose corn syrup increase postprandial triglycerides, LDL-cholesterol, and apolipoprotein-B in young men and women. *J Clin Endocrinol Metab*. 2011; 96:E1596-605.
- ²³ Maersk M, Belza A, Stødkilde-Jørgensen H, et al. Sucrose-sweetened beverages increase fat storage in the liver, muscle, and visceral fat depot; a 6-mo randomized intervention study. *Am J Clin Nutr*. 2012; 95:283-9.
- ²⁴ Aeberli I, Gerber PA, Hochuli M, et al. Low to moderate sugar-sweetened beverage consumption impairs glucose and lipid metabolism and promotes inflammation in healthy young men: a randomized controlled trial. *Am J Clin Nutr*. 2011; 94:479-85.
- ²⁵ Stanhope KL, Medici V, Bremer AA, et al. The effects of consuming increasing levels of high fructose corn syrup-sweetened beverages on lipid/lipoprotein risk factors for cardiovascular disease in young adults. In preparation. Conference presentation at the National Soda Summit, June 4-5, 2014, Washington, DC.
- ²⁶ Lazo M, Harnaiz R, Eberhardt MS, et al. Prevalence of nonalcoholic fatty liver disease in the United States: the Third National Health and Nutrition Examination Survey, 1988-1994. *Am J Epidemiol*. 2013; 178:38-45.
- ²⁷ Welsh JA, Karpen S, Vos MB. Increasing prevalence of nonalcoholic fatty liver disease among United States adolescents, 1988-1994 to 2007 to 2010. *J Pediatr*. 2013; 162:496-500.
- ²⁸ American Liver Foundation. Non-Alcoholic Fatty Liver Disease. October 4, 2011. Available online: <http://www.liverfoundation.org/abouttheliver/info/naflid/>. Accessed June 16, 2014.
- ²⁹ Yang Q, Zhang Z, Gregg EW, et al. Added sugar intake and cardiovascular disease mortality among US adults. *JAMA Intern Med*. 2014; 174:516-24.
- ³⁰ Center for Science in the Public Interest. Petition to ensure the safe use of added sugars in beverages. February 13, 2013. Available online: <http://www.cspinet.org/new/201302131.html>. Accessed May 16, 2014.
- ³¹ Center for Science in the Public Interest. Petition to the FDA to require better sugar labeling on foods. August 3, 1999. www.cspinet.org/reports/sugar/sugarpet1.pdf. Accessed April 23, 2014.
- ³² U.S. Department of Agriculture, Center for Nutrition Policy and Promotion. *USDA's Food Guide Pyramid Booklet*. April 1992. Available online: <http://fnic.nal.usda.gov/dietary-guidance/myplate-and-historical-food-pyramid-resources/past-food-pyramid-materials>. Accessed May 16, 2014.
- ³³ World Health Organization. Diet, Nutrition, and the Prevention of Chronic Diseases. WHO Technical Report Series 916. 2003. Available online: http://whqlibdoc.who.int/trs/who_trs_916.pdf. Accessed June 17, 2014.

-
- ³⁴ World Health Organization. Draft Guidelines: Sugars intake for adults and children. March 2014. Available online: http://www.who.int/nutrition/sugars_public_consultation/en/. Accessed June 17, 2014.
- ³⁵ Johnson RK, Appel LJ, Brands M, et al. Dietary sugars intake and cardiovascular health: A scientific statement from the American Heart Association. *Circulation*. 2009; 15:1011-20.
- ³⁶ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2005*. 6th Edition, Washington, DC: U.S. Government Printing Office, January 2005.
- ³⁷ 21 CFR 101.9.
- ³⁸ Center for Science in the Public Interest. Unrealistic serving sizes understate calories, sodium, saturated fat, says CSPI. Press Release. August 2, 2011. <http://cspinet.org/new/201108021.html>. Accessed April 23, 2014.
- ³⁹ 79 FR at 11880 at 11883.
- ⁴⁰ 58 FR 2206 at 2224.
- ⁴¹ World Health Organization. Sodium intake guidelines for adults and children. 2012. Geneva, Switzerland: WHO. Available online: http://www.who.int/nutrition/publications/guidelines/sodium_intake/en/. Accessed May 20, 2014.
- ⁴² Lloyd-Jones DM, Hong Y, Labarthe D, et al. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's strategic Impact Goal through 2020 and beyond. *Circulation*. 2010; 121:586-613.
- ⁴³ Whelton PK, Appel LJ, Sacco RL, et al. Sodium, blood pressure, and cardiovascular disease: further evidence supporting the American Heart Association sodium reduction recommendations. *Circulation*. 2012; 126:2880-9.
- ⁴⁴ American Public Health Association. Implementing effective strategies to reduce sodium in the food supply. November 1, 2011. Policy 201120. <http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1412>. Accessed May 16, 2013.
- ⁴⁵ Dietary Guidelines Advisory Committee. 2010. *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, to the Secretary of Agriculture and the Secretary of Health and Human Services*. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.
- ⁴⁶ 79 FR 11880 at 11915.
- ⁴⁷ National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for water, potassium, sodium, chloride, and sulfate*. Washington, DC: National Academies Press, 2005.
- ⁴⁸ National Academy of Sciences, Institute of Medicine. *Strategies to reduce sodium intake in the United States*. Washington, DC: National Academies Press, 2010.
- ⁴⁹ Cogswell ME, Zhang Z, Carriquiry AL, et al. Sodium and potassium intakes among US adults: NHANES 2003–2008. *Am J Clin Nutr*. 2012; 96:647-57.
- ⁵⁰ Archer E, Hand GA, Blair SN. Validity of U.S. nutrition surveillance: National Health and Nutrition Examination Survey caloric energy intake data, 1971–2010. *PLoS One*. 2013; 8:e76632. doi: 10.1371/journal.pone.0076632.
- ⁵¹ He FJ, MacGregor GA. A comprehensive review on salt and health and current experience of worldwide salt reduction programmes. *J Hum Hypertens*. 2009; 23:363-84.

- ⁵² National Academy of Sciences, Institute of Medicine. *Sodium Intake in Populations: Assessment of Evidence*. Washington, DC: National Academies Press, 2013.
- ⁵³ Sacks FM, Svetkey LP, Vollmer WM, et al. Effects of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group. *N Engl J Med*. 2001; 334:3-10.
- ⁵⁴ Cobb LK, Anderson CA, Elliott P, et al. Methodological issues in cohort studies that related sodium intake to cardiovascular disease outcomes: a science advisory from the American Heart Association. *Circulation*. 2014; 129:1173-86.
- ⁵⁵ Cook NR. Salt: How much less should we eat for health?: Understanding the recent IOM report. *Significance*. 2013; 10:6-10.
- ⁵⁶ Thomas MC, Moran J, Forsblom C, et al. The association between dietary sodium intake, ESRD, and all-cause mortality in patients with type 1 diabetes. *Diabetes Care*. 2011; 34:861-6.
- ⁵⁷ O'Donnell MJ, Yusuf S, Mente A, et al. Urinary sodium and potassium excretion and risk of cardiovascular events. *JAMA*. 2011; 306:2229-38.
- ⁵⁸ Retraction. Low sodium versus normal sodium diets in systolic heart failure: systematic review and meta-analysis. *Heart*. 2013; 99:820.
- ⁵⁹ Campbell NR, Lackland DT, MacGregor GA. Dietary sodium: A perspective on recent sodium evidence – Its interpretation and controversies. *J Clin Hypertens*. 2013; 15:765-8.
- ⁶⁰ Aburto NJ, Ziolkovska A, Hooper L, et al. Effect of lower sodium intake on health: systematic review and meta-analysis. *BMJ*. 2013; 346:f1326. doi: 10.1136/bmj.f1326.
- ⁶¹ He FJ, Li J, MacGregor GA. Effect of longer-term modest salt reduction on blood pressure: Cochrane systematic review and meta-analysis of randomized trials. *BMJ*. 2013; 346:f1325. doi: 10.1136/bmj.f1325.
- ⁶² Chang HY, Hu YW, Yue CS, et al. Effect of potassium-enriched salt on cardiovascular mortality and medical expenses of elderly men. *Am J Clin Nutr*. 2006; 83:1289-96.
- ⁶³ Cook NR, Cutler JA, Obarzanek E, et al. Long term effects of dietary sodium reduction on cardiovascular disease outcomes: observational follow-up of the trials of hypertension prevention (TOHP). *BMJ*. 2007; 334:885-8.
- ⁶⁴ Whelton P. Sodium, blood pressure, and cardiovascular disease: a compelling scientific case for improving the health of the public. *Circulation*. 2014; 129:1085-7.
- ⁶⁵ Cook NR, Appel LJ, Whelton PK. Lower levels of sodium intake and reduced cardiovascular risk. *Circulation*. 2014; 129:981-9.
- ⁶⁶ Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics – 2012 update: a report from the American Heart Association. *Circulation*. 2012; 125:e2-e220.
- ⁶⁷ Bibbins-Domingo K, Chertow GM, Coxson PG, et al. Projected effect of dietary salt reductions on future cardiovascular disease. *N Engl J Med*. 2010; 362:590-9.
- ⁶⁸ Coxson PG, Cook NR, Joffres M, et al. Mortality benefits from US population-wide reduction in sodium consumption: projections from three modeling approaches. *Hypertension*. 2013; 61:564-70.

⁶⁹ He FJ, Pombo-Rodrigues S, MacGregor GA. Salt reduction in England from 2003 to 2011: its relationship to blood pressure, stroke, and ischemic heart disease mortality. *BMJ Open*. 2014. doi: 10.1136/bmjopen-2013-004549.

⁷⁰ 21 CFR 101.61

⁷¹ *United States v. Nixon*, 418 U.S. 683, 696 (1974); *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 537 (2009).

⁷² *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U. S. 29, 43 (1983); see *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U. S. 402, 416 (1971).

⁷³ *State Farm*, 463 U. S., at 43 (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U. S. 281, 285, (1974)).

⁷⁴ See *FCC v. Fox Television Stations, Inc.*, 556 U. S. 502, 515 (2009) (noting “the requirement that an agency provide reasoned explanation for its action”).

⁷⁵ *Judulang v. Holder*, 132 S. Ct. at 490.

⁷⁶ 79 FR 11880 at 11879, 11920.

⁷⁷ Food and Drug Administration, *Proposed Changes to the Nutrition Facts Label* (updated 05/28/2014), available at <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm385663.htm> (noting: “the 2010 Dietary Guidelines for Americans recommended a reduction in sodium intake to less than 2,300 mg/day and a further reduction to 1,500 mg/day among groups that are at increased risk of the blood pressure-raising effects of sodium (individuals ages 51 or older, African Americans, and individuals with high blood pressure, chronic kidney disease or diabetes). These groups account for about half the U.S. population”).

⁷⁸ Food and Drug Administration, *Proposed Changes to the Nutrition Facts Label*; Dietary Guidelines for Americas 2010 (Department of Health and Human Services and Department of Agriculture 2010) (2010) at 21.

⁷⁹ 79 FR 11880 at 11879, 11917.

⁸⁰ 79 FR 11880 at 11914.

⁸¹ “Sodium, and by extension salt, has come under increased scrutiny from consumer interest groups, health care organizations and government agencies.” Cargill. 10-Step Guide to Lowering the Sodium in Food and Beverage Products. 2009. Minneapolis, MN: Cargill Salt. Available online: <http://www.cargill.com/salt/wcm/groups/public/@cseg/@salt/@assets/documents/document/na3019695.pdf>. Accessed June 25, 2014.

⁸² “...high-sodium diets have been associated with high blood pressure, heart disease and stroke. It’s now estimated that almost one in three Americans have high blood pressure, but only 30 percent are doing something about it. Current U.S. Department of Agriculture (USDA) dietary guidelines recommend that healthy adults consume no more than 2,300 milligrams of sodium daily. The average American typically consumes around 4,000 milligrams of sodium per day — with an estimated 75 percent of this intake coming from processed foods. These factors are contributing to an increased interest in low-sodium products and commitments from the food industry to develop effective reduced sodium solutions. The market for reduced sodium foods is estimated to be \$6 billion — and growing. In fact, introductions of products carrying low-salt or low-sodium claims more than doubled from 102 in 2002 to 20 in 2007, according to Packaged Facts.” Cargill. 10-Step Guide to Lowering the Sodium in Food and Beverage Products. 2009. Minneapolis, MN: Cargill Salt. Available online:

<http://www.cargill.com/salt/wcm/groups/public/@cseg/@salt/@assets/documents/document/na3019695.pdf>. Accessed June 25, 2014.

⁸³ “This loaf looked fine and tasted fine, and yet it had 33 percent less sodium than normal bread. Cargill’s trick was to replace some of the salt with a chemical compound known as potassium chloride. White and crystalline, potassium chloride looks and feels a lot like salt, but far more importantly, it acts much like salt, chemically speaking.” Moss, Michael (2013). *Salt Fat Sugar: How the Food Giants Hooked Us*. New York: Random House, 293.

⁸⁴ “Campbell had figured out that the way to reduce salt in soup...: adding fresh herbs and spices.” Moss, 300.

⁸⁵ “...a new method that would apply the salt much more judiciously ... used electrostatics to attach the salt to the chips the way a balloon sticks to the wall after its been rubbed on a shirt. In addition to greatly reducing waste, this technique could allow Frito-Lay to control the amount of salt that went onto the chips.” Moss, 311.

⁸⁶ “...initiatives showing the greatest promise included...using a finer grade of salt to minimize the amount of salt needed while maximizing the rush.” Moss, 322. “[Campbell’s] recent achievements included lowering the sodium in V8 from 480 milligrams to 420 milligrams and taking of its Pepperidge Farm bread from 360 milligrams per serving all the way down to 65. This success, they said, was due in large part to a special salt the company had acquired that has 50 percent less sodium than ordinary salt.” Moss, 298-299. “Tate & Lyle has developed several ‘ready-to-use recipes’ helping US firms slash sodium in bread, peanuts and microwave popcorn by using tiny salt ‘microspheres’ which deliver a disproportionately salty taste for their size by maximizing surface area relative to volume...can help firms cut salt by 25-50% in a wide range of applications” Watson, Elaine. “Soda-Lo salt ‘microspheres’ can slash sodium in bread, peanuts and microwave popcorn, says Tate & Lyle.” *Foodnavigator-usa.com* 29 October 2012. Available online: <http://www.foodnavigator-usa.com/Markets/Soda-Lo-salt-microspheres-can-slash-sodium-in-bread-peanuts-and-microwave-popcorn-says-Tate-Lyle>. Accessed June 25, 2014.

⁸⁷ “Today, in addition to simply reducing the amount of salt added through the production process, there is a wide assortment of products available to help manufacturers reduce, replace or eliminate salt, and therefore lower the sodium content of their food and beverage products...Cargill’s SaltWise™ system can help manufacturers reduce sodium levels by 25-50 percent without sacrificing flavor and is designed for a variety of food processing applications,” Cargill. 10-Step Guide to Lowering the Sodium in Food and Beverage Products. 2009. Minneapolis, MN: Cargill Salt. Available online: <http://www.cargill.com/salt/wcm/groups/public/@cseg/@salt/@assets/documents/document/na3019695.pdf>. Accessed June 25, 2014.

⁸⁸ Clemens R, Kranz S, Mobley AR, et al. Filling America’s fiber intake gap: summary of a roundtable to probe realistic solutions with a focus on grain-based foods *J. Nutr.* 2012; 142:1390S–1401S.

⁸⁹ Satija A, Hu FB. Cardiovascular benefits of dietary fiber. *Curr Atheroscler Rep.* 2012;14:505-14.

⁹⁰ He M, van Dam RM, Rimm E, et al. Whole-grain, cereal fiber, bran, and germ intake and the risks of all-cause and cardiovascular disease-specific mortality among women with type 2 diabetes mellitus. *Circulation.* 2010; 121:2162-8.

⁹¹ Schulze MB¹, Schulz M, Heidemann C., et al. Fiber and magnesium intake and incidence of type 2 diabetes: a prospective study and meta-analysis. *Arch Intern Med.* 2007;167:956-65.

⁹² Crowe FL, Balkwill A, Cairns BJ, et al. Source of dietary fibre and diverticular disease incidence: a prospective study of UK women. *Gut.* 2014 Jan 2. doi: 10.1136/gutjnl-2013-304644.

⁹³ Hull S, Re R, Tiihonen K, et al. Consuming polydextrose in a mid-morning snack increases acute satiety

measurements and reduces subsequent energy intake at lunch in healthy human subjects. *Appetite* 2012; 59: 706–12.

⁹⁴ Willis HJ, Eldridge AL, Beiseigel J, et al. Greater satiety response with resistant starch and corn bran in human subjects. *Nutr Res.* 2009; 29:100-5.

⁹⁵ Willis HJ, Thomas W, Willis DJ, et al. Feasibility of measuring gastric emptying time, with a wireless motility device, after subjects consume fiber-matched liquid and solid breakfasts. *Appetite.* 2011; 57:38–44.

⁹⁶ Archer BJ, Johnson SK, Devereux HM, et al. Effect of fat replacement by inulin or lupin-kernel fibre on sausage patty acceptability, post-meal perceptions of satiety and food intake in men. *Br J Nutr.* 2004; 91:591-9.

⁹⁷ Karalus M, Clark M, Greaves K, et al. Fermentable fibers do not affect satiety or food intake by women who do not practice restrained eating. *J Acad Nutr Diet.* 2012;112:1356-62.

⁹⁸ Scientific Opinion on the substantiation of health claims related to dietary fibre (ID 744, 745, 746, 748, 749, 753, 803, 810, 855, 1415, 1416, 4308, 4330) pursuant to Article 13(1) of Regulation (EC) No 1924/20061. *EFSA Journal* 2010;8(10):1735

⁹⁹ Scientific Opinion on the substantiation of health claims related to polydextrose and changes in bowel function (ID 784), changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 784), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 785) and reduction of gastro-intestinal discomfort (ID 784) pursuant to Article 13(1) of Regulation (EC) No 1924/20061. *EFSA Journal* 2011;9(6):2256.

¹⁰⁰ Scientific Opinion on the substantiation of health claims related to resistant maltodextrin and reduction of post-prandial glycaemic responses (ID 796), maintenance of normal blood LDL-cholesterol concentrations (ID 2927), maintenance of normal (fasting) blood concentrations of triglycerides (ID 2927) and changes in bowel function (ID 797) pursuant to Article 13(1) of Regulation (EC) No 1924/20061. *EFSA Journal* 2011;9(4):2070.

¹⁰¹ Scientific Opinion on the substantiation of a health claim related to non-digestible carbohydrates and a reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/20061. *EFSA Journal* 2014;12(1):3513.

¹⁰² Grabitske HA, Slavin JL. Gastrointestinal effects of low-digestible carbohydrates. *Crit Rev Food Sci Nutr.* 2009; 49:327–60.

¹⁰³ Slavin J and Feirtag J. Chicory inulin does not increase stool weight or speed up intestinal transit time in healthy male subjects. *Food Funct.* 2011; 2: 72-7.

¹⁰⁴ Halmos EP, Power VA, Shepherd SJ, et al. A diet low in FODMAPs reduces symptoms of irritable bowel syndrome. *Gastroenterology.* 2014; 146:67–75.

¹⁰⁵ Company URLs:

<http://www.sensus.nl/Product-range.html> <http://www.adm.com/en-US/products/food/fiber/Pages/Fibersol-2AG.aspx>

<http://www.danisco.com/product-range/fiber/litesse/>

<http://www.cargillfoods.com/na/en/products/health-promoting-ingredients/digestive-health/index.jsp>

<http://www.sunopta.com/fiber-ingredients/>

<http://www.foodinnovation.com/foodinnovation/en-us/Ingredients/Pages/Nutritional.aspx>

<http://www.mgpingredients.com/product-list/Fibersym-RW.html>

<http://www.promitorfiber.com/Pages/HomePage.aspx>

<http://www.sunfiber.com/>

¹⁰⁶ 79 FR 11880 at 11893.

¹⁰⁷ Sacks FM, Bray GA, Carey VJ, et al. Comparison of weight loss diets with different compositions of fat, protein, and carbohydrates. *N Engl J Med.* 2009; 360:859-73.

¹⁰⁸ Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002; 346:393-403.

¹⁰⁹ Wadden TA, Bantle JP, Blackburn GL, et al. Eight-year weight losses with an intensive lifestyle intervention: the look AHEAD study. *Obesity.* 2014; 22:5-13.

¹¹⁰ Campbell KL, Foster-Schubert KE, Alfano CM, et al. Reduced-calorie dietary weight loss, exercise, and sex hormones in postmenopausal women: randomized controlled trial. *J Clin Oncol.* 2012; 30:2314-26.

¹¹¹ Wing RR, Phelan S. Long-term weight loss maintenance. *Am J Clin Nutr.* 2005; 82:222S-225S.

¹¹² 79 FR 11880 at 11894.

¹¹³ Eckel RH, Jakicic JM, Ard JD, et al. 2013 AHA/ACC Guideline on lifestyle management to reduce cardiovascular risk: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2013; doi:10.1161/01.cir.0000437740.48606.d1.

¹¹⁴ Chowdhury R, Warnakula S, Kunutsor S, et al. Association of dietary, circulating, and supplement fatty acids with coronary risk: a systematic review and meta-analysis. *Ann Intern Med.* 2014; 160:398-406.

¹¹⁵ O'Connor A. Study questions fat and heart disease link. *New York Times.* March 17, 2014. Available online: http://well.blogs.nytimes.com/2014/03/17/study-questions-fat-and-heart-disease-link/?_php=true&_type=blogs&r=0. Accessed June 5, 2014.

¹¹⁶ Bittman M. Butter is back. *New York Times.* March 25, 2014. Available online: <http://www.nytimes.com/2014/03/26/opinion/bittman-butter-is-back.html>. Accessed June 5, 2014.

¹¹⁷ Aubrey A. Don't fear the fat: Experts question saturated fat guidelines. National Public Radio. Available online: <http://www.npr.org/blogs/thesalt/2014/03/17/290846811/dont-fear-the-fat-experts-question-saturated-fat-guidelines>. Accessed June 5, 2014.

¹¹⁸ Mozaffarian D, Micha R, Wallace S. Effects on coronary heart disease of increasing polyunsaturated fat in place of saturated fat: a systematic review and meta-analysis of randomized controlled trials. *PLoS Med.* 2010; 7: e1000252. doi: 10.1371/journal.pmed.1000252.

¹¹⁹ Di Angelantonio E, Chowdhury R, Forouhi N, et al. Author's response. July 1, 2014. Comments available online at: <http://annals.org/article.aspx?articleid=1846638>. *Ann Intern Med.* 2014; 160: 398-406.

¹²⁰ Mensink RP, Zock PL, Kester AD, et al. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. *Am J Clin Nutr.* 2003; 77:1146-55.

¹²¹ 79 FR 11880 at 11895.

¹²² American Heart Association. Know your fats. May 14, 2014. Available online: http://www.heart.org/HEARTORG/Conditions/Cholesterol/PreventionTreatmentofHighCholesterol/Know-Your-Fats_UCM_305628_Article.jsp. Accessed June 5, 2014.

¹²³ Obarzanek E, Sacks FM, Vollmer WM. Effects on blood lipids of a blood pressure-lowering diet: the Dietary Approaches to Stop Hypertension (DASH) trial. *Am J Clin Nutr*. 2001; 74:80-9.

¹²⁴ Appel LJ, Sacks FM, Carey VJ, et al. Effects of protein, monounsaturated fat, and carbohydrate intake on blood pressure and serum lipids: results of the OmniHeart randomized trial. *JAMA*. 2005; 294:2455-64.

¹²⁵ Ginsberg HN, Kris-Etherton P, Dennis B, et al. Effects of reducing dietary saturated fatty acids on plasma lipids and lipoproteins in healthy subjects: the DELTA study, protocol 1. *Arterioscler Thromb Vasc Biol*. 1998; 18:441-9.

¹²⁶ Memorandum from J. Park to M. Hongfort, August 19, 2010. (Ref. 14 in 78 FR 67169).

¹²⁷ 78 FR 67169 at 67169.

¹²⁸ Center for Science in the Public Interest. Public health officials: FDA needs to ban trans fat. April 9, 2014. Available online: <http://cspinet.org/reports/trans.pdf>. Accessed June 13, 2014.

¹²⁹ 78 FR 67169 at 67173-4.

¹³⁰ Chardigny JM, Destallats F, Malpuech-Brugère C, et al. Do trans fatty acids from industrially produced sources and from natural sources have the same effect on cardiovascular disease risk factors in healthy subjects? Results of the trans Fatty Acids Collaboration (TRANSFACT) study. *Am J Clin Nutr*. 2008; 87:558-66.

¹³¹ Motard-Bélanger A, Charest A, Grenier G, et al. Study of the effect of trans fatty acids from ruminants on blood lipids and other risk factors for cardiovascular disease. *Am J Clin Nutr*. 2008;87:593-9.

¹³² 79 FR 11880 at 11896.

¹³³ American Heart Association. Trans Fats. April 9, 2014. Available online: http://www.heart.org/HEARTORG/GettingHealthy/FatsAndOils/Fats101/Trans-Fats_UCM_301120_Article.jsp. Accessed June 13, 2014.

¹³⁴ Otite FO, Jacobson MF, Dahmubed A, et al. Trends in trans fatty acids reformulations of US supermarket and brand-name foods from 2007 through 2011. *Prev Chronic Dis*. 2013; 10:E85. doi: 10.5888/pcd10.120198.

¹³⁵ Center for Science in the Public Interest. Press Release. April 15, 2014. Joe's Crab Shack swimming in artificial trans fat. Available online: <http://www.cspinet.org/new/201404151.html>. Accessed June 13, 2014.

¹³⁶ 21 CFR 101.9

¹³⁷ Canadian Food Inspection Agency. Labelling of trans fatty acids. March 12, 2014. Available online: <http://www.inspection.gc.ca/english/fssa/labeti/inform/transe.shtml>. Accessed June 16, 2014.

¹³⁸ 79 FR 11880 at 11897-9.

¹³⁹ 79 FR 11880 at 11899.

¹⁴⁰ Weggemans RM, Zock PL, Katan MB. Dietary cholesterol from eggs increases the ratio of total cholesterol to high-density lipoprotein cholesterol in humans: a meta-analysis. *Am J Clin Nutr*. 2001; 73:885-91.

¹⁴¹ 79 FR 11880 at 11912-4.

¹⁴² 79 FR 11990 at 11913.

¹⁴³ Symons TB, Sheffield-Moore M, Wolfe RR, et al. A moderate serving of high-quality protein maximally stimulates skeletal muscle protein synthesis in young and elderly subjects. *J Am Diet Assoc.* 2009; 109:1582-6.

¹⁴⁴ Katsanos CS, Kobayashi H, Sheffield-Moore M, et al. A high proportion of leucine is required for optimal stimulation of the rate of muscle protein synthesis by essential amino acids in the elderly. *Am J Physiol Endocrinol Metab.* 2006; 291:E381-7.

¹⁴⁵ Katsanos CS, Kobayashi H, Sheffield-Moore M, et al. Aging is associated with diminished accretion of muscle proteins after the ingestion of a small bolus of essential amino acids. *Am J Clin Nutr.* 2005; 82:1065-73.

¹⁴⁶ Paddon-Jones D, Rasmussen BB. Dietary protein recommendations and the prevention of sarcopenia. *Curr Opin Clin Nutr Metab Care.* 2009; 12:86-90.

¹⁴⁷ Volpi E, Campbell WW, Dwyer JT, et al. Is the optimal level of protein intake for older adults greater than the recommended dietary allowance? *J Gerontol A Biol Sci Med Sci.* 2013; 68:677-81.

¹⁴⁸ 79 FR 11880 at 11918-25.

¹⁴⁹ 79 FR 11880 at 11924.

¹⁵⁰ National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for vitamin D and calcium.* Washington, DC: National Academies Press, 2011.

¹⁵¹ 79 FR 11880 at 11924.

¹⁵² World Health Organization. *Iron deficiency anaemia – Assessment, prevention, and control. A guide for programme managers.* Geneva: World Health Organization; 2001. Available online: http://www.who.int/nutrition/publications/en/ida_assessment_prevention_control.pdf. Accessed July 11, 2014.

¹⁵³ Jiang R, Manson JE, Meigs JB, et al. Body iron stores in relation to risk of type 2 diabetes in apparently healthy women. *JAMA.* 2004; 291:711-7.

¹⁵⁴ Forouhi NG, Harding AH, Allison M, et al. Elevated serum ferritin levels predict new-onset type 2 diabetes: results from the EPIC-Norfolk prospective study. *Diabetologia.* 2007; 50:949-56.

¹⁵⁵ 79 FR 11880 at 11924.

¹⁵⁶ 79 FR 11880 at 11925.

¹⁵⁷ 79 FR 11880 at 11920-1.

¹⁵⁸ 79 FR 11880 at 11928-30.

¹⁵⁹ Centers for Disease Control and Prevention. The Health Effects of Overweight and Obesity. December 6, 2013. Available online at: <http://www.cdc.gov/healthyweight/effects/index.html>. Accessed April 15, 2014.

¹⁶⁰ Just DR, Mancino L, Wansink B. *Could Behavioral Economics Help Improve Diet Quality for Nutrition Assistance Program Participants?* Report Number 43. Washington, DC: U.S. Department of Agriculture, Economic Research Service, June 2007.

- ¹⁶¹ Ello-Martin JA, Ledikwe JH, Rolls BJ. The influence of food portion size and energy density on energy intake: implications for weight management. *Am J Clin Nutr.* 2005; 82:236S-241S.
- ¹⁶² Lando AM, Lo SC. Single-larger-portion size and dual column labeling may help consumers make healthful food choices. *J Acad Nutr Diet.* 2013; 113: 241-50.
- ¹⁶³ Juan WY, Zhang Y, Kantor M, Ali M. Perceptions and use of nutrition labeling information. *FASEB Journal.* 2013; 27:1065.1.
- ¹⁶⁴ Belser B. "No Appetite for this Nutrition Label Change." *The Washington Post*, April 27, 2014, at B5.
- ¹⁶⁵ 79 FR 11880 at 11954-5.
- ¹⁶⁶ 79 FR 11880 at 11887.
- ¹⁶⁷ Sinclair S, Hammon D, Goodman S. Sociodemographic differences in the comprehension of nutrition labels on food products. *J Nutr Educ Behav.* 2013; 45:767-72.
- ¹⁶⁸ Loureiro ML, Yen ST, Nayga RM. The effects of nutrition labels on obesity. *Agricultural Economics.* 2012; 43:333-42.
- ¹⁶⁹ National Academy of Sciences, Institute of Medicine. *Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices.* Washington, DC: National Academies Press, 2012.
- ¹⁷⁰ "Improving Nutrition Information on Food Labels: Health Canada's Proposed Changes to the Look of the Nutrition Facts Table and the List of Ingredients." Available online at <http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition-facts-valeur-nutritive-fs-fr-eng.php>. Accessed July 27, 2014.
- ¹⁷¹ 43 FR 25296.
- ¹⁷² 21 CFR 101.2. Information panel of package form food.
- ¹⁷³ Legge GE, Bigelow CA. Does print size matter for reading? A review of findings from vision science and typography. *J Vis.* 2011. doi: 10.1167/11.5.8.
- ¹⁷⁴ 21 C.F.R. 101.9. FDA Food Labeling Guide.
- ¹⁷⁵ McGowan EC, Keet CA. Prevalence of self-reported food allergy in the National Health and Nutrition Examination Survey (NHANES) 2007–2010. *J Allergy Clin Immunol.* 2013; 132:1216-9.
- ¹⁷⁶ After the law was passed, FDA required a ninth allergen, carmine/cochineal extract, to be disclosed on labels. See 74 Fed Reg 207 (Jan. 5, 2009).
- ¹⁷⁷ Food Allergen Labeling and Consumer Protection Act of 2004. 21 USC 301.
- ¹⁷⁸ Center for Science in the Public Interest. Legislators propose modernizing food labeling. Press release. Sept. 19, 2013. Available online at <http://www.cspinet.org/new/201309191.html>. Accessed April 11, 2014.
- ¹⁷⁹ United States Department of Agriculture (USDA). What are added sugars? Available online at <http://www.choosemyplate.gov/weight-management-calories/calories/added-sugars.html>. Accessed April 11, 2014.