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BEWARE:

WARNING LABELS ON SOFT DRINKS

By

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The Center for Science in the Public Interest (CSPI) recently called on the Food and Drug Administration (FDA) to require what a Reuters article characterized as “cigarette-style warnings” on the labels of all non-diet soft drinks.¹ In a citizen petition submitted to the agency on July 13, 2005, CSPI requests that FDA initiate rulemaking to require that the labels of soft drinks containing more than 1.1 grams (g) of high fructose corn syrup (HFCS) or other caloric sweetener per fluid ounce (fl oz), i.e., more than approximately 13 g of sugar per typical 12 fl oz serving, bear one of a series of rotating health notices.²

Examples of proposed warnings include:

- “The U.S. Government recommends that you drink less (non-diet) soda to help prevent weight gain, tooth decay, and other health problems.”
- “To help protect your waistline and your teeth, consider drinking diet sodas or water.”
- “Drinking soft drinks instead of milk or calcium-fortified beverages may increase your risk of brittle bones (osteoporosis).”

¹“CSPI Calls on FDA to Require Health Warnings on Sodas,” CSPI Press Release (July 13, 2005) (available at <http://cspinet.org/new/200507131.html>). An example of Reuters’ reporting the petition is available at <http://msnbc.msn.com/id/8562801/>.

²Petition To Require Health Messages on Soft Drinks Containing High-fructose Corn Syrup and Other Caloric Sweeteners (July 13, 2005) (FDA Dkt. No. 2005P-0282) (available at: <http://www.fda.gov/ohrms/dockets/dockets/05p0282/05p-0282-cp00001-vol1.pdf>). The petition indicates that a typical 12 fl oz non-diet soft drink serving provides 40 g of sugar. CSPI itself likens use of rotating warnings to the practice in labeling tobacco products. FDA acknowledged acceptance of the petition for filing in a July 14, 2005, letter to CSPI (available at <http://www.fda.gov/ohrms/dockets/dockets/05p0282/05p-0282-ack0001-vol1.pdf>), which provided the usual admonishment, “acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.”

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

The warnings that CSPI requests are offered to assist in addressing teenage obesity and related national health problems.³ CSPI’s petition accompanied simultaneous publication of an updated edition of its report, “Liquid Candy: How Soft Drinks Are Harming Americans’ Health,” which it represents to be an analysis of soft-drink consumption by teenagers that summarizes scientific research on soft drinks’ health effects.⁴

While apparently well intentioned,⁵ FDA nevertheless would be ill advised to act affirmatively on the supposed merits of CSPI’s petition for a number of reasons.

Requiring Warning Statements on (Non-Diet) Soft Drinks Would Contravene FDA’s Deliberately Nuanced Approach to Regulating Food Labeling. FDA recently reiterated its well-established regulatory approach to determining whether to require a food label warning:

The [Federal Food, Drug, and Cosmetic] Act provides broad authority to the FDA to regulate the labels of food products. However, rather than requiring warnings for every single ingredient or product with possible deleterious effects, FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information, taking action in instances of adulterated or misbranded foods [footnote omitted] and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels [footnote omitted]. As part of this deliberate regulatory approach, FDA has required warnings only in those instances where there is clear evidence of a hazard, in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements, and hence creating a far greater public health problem.⁶

Consistent with this policy, FDA has required label warnings only where other less alarming regulatory approaches would be ineffectual.⁷

³The petition also calls on FDA to require that labels of soft drinks containing more than 10 milligrams (mg) of caffeine per 12 fl oz serving bear a health warning: “This drink contains __ milligrams of caffeine, a mildly addictive stimulant drug. Not appropriate for children.” This petitioned warning suffers the same infirmities as the other soft drink label warnings that CSPI proposes.

⁴Statement of CSPI Executive Director, Michael F. Jacobson, Ph.D., at July 13, 2005 press conference (available at http://cspinet.org/new/pdf/final_mfj_soda_statement.pdf). CSPI’s updated (the first edition was released in 1998) report, “Liquid Candy,” is available at http://www.cspinet.org/new/pdf/liquid_candy_final_w_new_supplement.pdf.

⁵CSPI’s petition is supported by a coalition of scientists, health professionals, and organizations that urge the new label warnings and request Department of Health and Human Services (DHHS) funding of major mass-media campaigns to reduce soft drink consumption and to promote better overall nutrition. Coalition letter dated July 13, 2005, to Secretary Michael Leavitt, DHHS (available at <http://www.fda.gov/ohrms/dockets/dockets/05p0282/05p-0282-c000002-vol1.pdf>).

⁶Letter dated August 12, 2005, from Lester M. Crawford, D.V.M., Ph.D., Commissioner of Food and Drugs, to Bill Lockyer, Attorney General of the State of California (asserting federal preemption of warnings California seeks to impose under Proposition 65 concerning mercury and mercury compounds in canned tuna) (available at: <http://www.cfsan.fda.gov/~dms/fl-ltr65.html>); see also Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28592, 28615 (June 21, 1991) (“When confronted with a problem that threatens the general public, FDA has promulgated regulations requiring placement of warning statements on the food label. *** However, FDA is unwilling to require a warning statement in the absence of clear evidence of a hazard... [as the agency] is concerned that it would overexpose consumers to warnings. As a result, consumers may ignore, and become inattentive to, all such statements.”).

⁷For example, 21 C.F.R. § 172.804(e)(2) (for aspartame: “Phenylketonurics: contains phenylalanine”); 21 C.F.R. §

With respect to caloric sweeteners in non-diet soft drinks, however, rather than label warnings, FDA has relied on nutrition and ingredient declarations, already required on labels, to facilitate informed purchasing decisions by consumers.⁸ Soft drink labels' Nutrition Facts provide the number of calories and grams of sugars in a serving.⁹ The labels also specifically name added sweeteners (e.g., HFCS, sugar/sucrose, corn sugar, corn syrup, invert sugar).¹⁰ Moreover, inasmuch as scientific studies yield, at best, mixed and incomplete results regarding a connection between soft drinks and teenage obesity,¹¹ the "exceptional circumstances" and "clear evidence of a hazard" typically prerequisite to imposition of a label warning are lacking.

FDA's Regulations Already Provide Alternative Means for Highlighting the Nutritional and Health Attributes of Diet Soft Drinks, and for Restricting Use of Caloric Sweeteners. As a better alternative to imposing a mandatory label warning on a widely consumed food, FDA's regulations contemplate permitting and motivating manufacturers on a voluntary basis to formulate and promote foods for their nutritional and health benefits. This was the congressional intent behind the Nutrition Labeling and Education Act of 1990.¹² Pursuant to implementing regulations, manufacturers may develop and label qualifying soft drinks with consumer-friendly nutrient content claims (e.g., "calorie free," "low calorie," "reduced calorie," "no sugar," "no sugar added," "sugar reduced").¹³ The industry also may, if science supports it, petition FDA for a label health claim relating reduced consumption of calories and/or sugars to lowered risk of obesity and/or other chronic diseases.¹⁴ These types of voluntary declarations can distinguish among soft drinks and inform consumers' purchasing decisions.

Moreover, a label warning implicating the soft drink sweeteners that CSPI's petition identifies would be incongruous from a regulatory perspective, inasmuch as FDA has affirmed each of them as generally recognized as safe (GRAS).¹⁵ Amending these GRAS regulations reasonably might be a necessary prelude

101.17(g) (for unprocessed juice: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems"); 21 C.F.R. § 101.17(f) (for psyllium: "NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty in swallowing."); 21 C.F.R. § 101.17(e) (for dietary supplements containing iron: "WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately"); and 21 C.F.R. § 101.17(d) (for protein products: "WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women.")

⁸Additional consumer guidance also is readily available in the Dietary Guidelines for Americans (available at <http://www.healthierus.gov/dietaryguidelines/>), the MyPyramid Food Guidance System (available at <http://www.mypyramid.gov/>), and the recently released MyPyramid for Kids (available at <http://www.mypyramid.gov/kids/index.html>), published by the federal government.

⁹21 C.F.R. § 101.9(c)(1) and (6)(ii).

¹⁰21 C.F.R. § 101.4(a).

¹¹For example, countering CSPI's "Liquid Candy" report is a study of 14,000 American adolescents in which a team of six Harvard doctors found that snack food and soda do not contribute to childhood obesity. INT'L J. OF OBESITY (Oct. 2004) 28, 12101216.

¹²Pub. L. No. 101-535, 104 Stat. 2353 (Nov. 8, 1990).

¹³21 C.F.R. §§ 101.13, 101.60.

¹⁴21 C.F.R. §§ 101.14, 101.70. FDA already has promulgated a regulation authorizing health claims relating consumption of foods containing noncariogenic carbohydrate sweeteners (e.g., sugar alcohols replacing sugars) to reduced risk of tooth decay. 21 C.F.R. § 101.80.

¹⁵21 C.F.R. §§ 184.1854 (sucrose/sugar), 184.1857 (corn sugar), 184.1859 (invert sugar), 184.1865 (corn syrup), 184.1866

to, or substitute for,¹⁶ imposition of any label warning on soft drinks containing them.¹⁷

Imposing a Label Warning on Soft Drinks Unwarrantedly Would Raise First Amendment Concerns of Compelled Speech. The First Amendment protects not only freedom of speech, but also the freedom *not* to speak.¹⁸ In analyzing the propriety of any compelled label statement, courts look to (1) whether the expression concerns lawful activity and is not misleading; (2) whether the government’s interest is substantial; (3) whether the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary.¹⁹ Food labeling requirements imposed merely to serve an inchoate public “right to know” are constitutionally suspect.²⁰ Under these standards and relevant precedents, any regulation compelling label warnings for non-diet soft drinks reasonably could be subject to legal challenge. This is especially true considering the lack of significant scientific agreement concerning a link between soft drink consumption and obesity, absence of evidence that soft drink label warnings would advance nutritional and regulatory policy, and the availability of less onerous and already implemented or existing alternatives, better tailored to the regulatory interests at issue.

Warning Labels on Soft Drinks Would Reflect Poor Nutritional and Regulatory Policy. Obesity is a complex nutritional and health issue that cannot be addressed with facile solutions. Singling out foods as “good” or “bad” is a disservice to consumer dietary practices. Much more beneficial are informational campaigns prompting inclusion of a variety of foods in a well-balanced diet that complements a healthy lifestyle incorporating physical activity. Consumer and school educational initiatives highlighting messages like “calories count” and “calories in must equal calories out,” such as FDA already has proposed (along with other measures) as part of its action plan to implement the final report of its Obesity Working Group (OWG),²¹ will advance nutritional and regulatory policy towards curbing adult and teenage obesity much further than the CSPI-petitioned label warnings on soft drinks ever could.

Conclusion. The deliberately nuanced approach that FDA historically has employed in determining the need for a label warning has worked well and militates against requiring health notices on non-diet soft drinks, especially because mandatory nutrition and ingredient labeling and voluntary nutrient content and health claims, coupled with consumer educational initiatives, already provide less alarming informational alternatives that are no more extensive than necessary to serve the regulatory interests at stake in addressing our nation’s obesity epidemic. FDA should move forward with implementing the recommendations of its OWG. The agency need not – and should not – add to the “culture of fear” that pervades U.S. society by imposing warning labels on non-diet soft drinks pursuant to CSPI’s petition.

(HFCS).

¹⁶CSPI acknowledges amending the GRAS regulations as an alternative in its petition.

¹⁷FDA may require label warnings in connection with the use of a GRAS ingredient whose excess consumption raises a health concern. *E.g.*, 21 C.F.R. § 184.1835(e) (“Excess consumption may have a laxative effect” in labeling some sorbitol-containing food).

¹⁸*E.g.*, *Wooley v. Maynard*, 430 U.S. 705, 713-715 (1977); *West Virginia Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943).

¹⁹*Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n*, 447 U.S. 557, 566 (1980).

²⁰*International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996) (Vermont law requiring dairy products made from the milk of cows treated with recombinant bovine somatotropin to be so identified in labeling).

²¹Actions recommended by the OWG include: enhancing the food label to display calorie count more prominently and to use meaningful serving sizes; initiating a consumer education campaign focusing on the “Calories Count” message; encouraging restaurants to provide nutritional information to consumers; stepping up enforcement actions concerning accuracy of food labels; revising FDA guidance for developing drugs to treat obesity; and working cooperatively with other government agencies, non-profits, industry, and academia on obesity research. Materials regarding FDA’s proposed action plan to confront our nation’s obesity problem are available at <http://www.fda.gov/oc/initiatives/obesity/>.