

March 30, 2018

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Re: Topics and comments to be examined in the review of the scientific evidence supporting the development of the 2020-2025 Dietary Guidelines for Americans;
Docket No. FNS-2018-0005-0001

Dear Dr. Wright, Mr. Lipps, and Ms. Koegel:

The Center for Science in the Public Interest (CSPI) submits these comments in response to the proposed topics for the 2020–2025 *Dietary Guidelines for Americans*. 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. CSPI's work is supported primarily by the 600,000 subscribers to its *Nutrition Action Healthletter*, one of the nation's largest-circulation health newsletters. CSPI is an independent organization that does not accept government or corporate funding.

CSPI would like to underscore that in the past, the process for developing the Guidelines has been driven by strong science, and previous Dietary Guidelines Advisory Committees have exhibited expertise and scientific integrity. The DGA recommendations have remained relatively consistent over the years—encouraging a diet rich in fruits, vegetables, and whole grains, while limiting excess sodium, saturated fat, and sugars. CSPI appreciates the U.S. Departments of Agriculture's and Health and Human Services' efforts to strengthen the process for developing the Guidelines in response to the reports issued by the National

Academy of Medicine and the expansion of the Guidelines to offer recommendations for pregnant women, infants and toddlers up to 24 months of age in response to the Agriculture Act of 2014.

However, CSPI is concerned that determining topics and questions before appointing the Dietary Guidelines Advisory Committee (DGAC) has potential pitfalls. Of greatest concern, it is not clear whether the final Dietary Guidelines for Americans report will include only those topics identified by the agencies. We urge USDA and HHS to include topics of public health importance that are not reviewed by the 2020 DGAC by carrying over advice from the 2015 DGAs. Furthermore, we urge USDA and HHS to:

- Include recommendations on sodium, alcohol, and cholesterol—topics that have been addressed by all previous DGAs. If the DGAC is unable to examine the evidence for these topics, it should incorporate advice from the 2015 Dietary Guidelines for Americans or Dietary Reference Intake committees.
- Ask the DGAC to continue to issue quantitative recommendations for sodium, whole grains, vegetables, fruits, saturated fat, and added sugars to provide actionable advice to the public and to ensure that those recommendations can be translated into nutrition programs.
- Examine the impact of replacing saturated fats with unsaturated fats on the risk of cardiovascular disease.
- Include questions for all relevant life stages: In addition to the proposed life stages, also examine the link between saturated fat and cardiovascular disease in children aged 2–18 and in adults older than 65; the link between dietary patterns and the risk of osteoporosis in adults aged 19–64; and the link between dietary patterns and the risk of obesity, cardiovascular disease, type 2 diabetes, and cancer in children ages 2–18.
- Provide advice on how to reduce or avoid dietary exposures to substances of concern, especially during pregnancy and early in life, including to substances known or reasonably anticipated to cause cancer or affect the developing brain in recognition of increased susceptibility and exposures during these time periods. While evaluating the evidence on carcinogenicity and/or toxicity for many individual substances is beyond the scope of the DGAC, we request that the Committee advise the public regarding how to prevent or reduce exposures to substances of concern.

Below we expand on these and other issues.

I. Introduction

The Dietary Guidelines for Americans for 35 years has provided life-saving advice to consumers who want to lower their risk of diet-related disease. This advice has never been more critical. Two out of three American adults¹ and one out of three children² are overweight or obese. Nearly half of adults have diabetes or prediabetes,³ and roughly half

of adults have high blood pressure,⁴ a major risk factor for heart disease and stroke. Furthermore, 13 cancers, including breast, colorectal, esophageal, and uterine, are linked to overweight or obesity.⁵

However, the Guidelines offer more than advice for individual consumers. The Guidelines are used as the basis for standards for programs such as the National School Lunch and School Breakfast Programs, the Child and Adult Care Food Program, and senior meals through the Older Americans Act. They also are used by state and local governments and health departments across the country as the basis for many of their nutrition policies and programs, including to establish guidelines for healthier food that is sold or served on public property. This broad spectrum of uses makes it essential that the Guidelines provide clear, quantitative recommendations for a healthy diet. Vague advice to consume less saturated fat or added sugar is far less valuable than a recommendation to get less than 10 percent of calories from saturated fat or added sugars. Similarly, recommendations to aim for an intake of saturated fat or sodium within a given range is of limited use. Precise quantitative recommendations are both more understandable to consumers and more useful for application to public health programs. We urge the Departments to keep these important applications of the Guidelines in mind as they proceed.

Furthermore, we have concerns about some of the criteria that USDA and HHS propose using to identify topics and their implications for the continuity of the Guidelines. For instance, the criterion of “importance” states that there might need to be “new, relevant data” to warrant a new review of the evidence. This may be a misapplication of the relevant recommendations: while the National Academy of Medicine’s report suggested that some topics may not warrant a detailed review every five years, it did *not* recommend that such topics be omitted from the Dietary Guidelines for Americans.

Moreover, we have concerns with regard to the “duplication” criterion. Even if a topic is addressed through existing evidence-based federal guidance other than the Dietary Guidelines, we believe it should be included in the Dietary Guidelines if it can help guide individual consumers or institutional policies towards healthier diets. If key topics are omitted at this stage of the process, it is unclear how they would be addressed in the 2020–2025 Guidelines, potentially leaving significant gaps in evidence-based federal guidance for food and nutrition. It is therefore more useful to consumers and agencies to have key nutrition recommendations in one place. This is especially important for those policies and programs that are tied through statute, regulation, or guidance to the recommendations in the Dietary Guidelines.

II. Topics that should be addressed across the lifespan.

We are concerned that the life stages approach fails to address issues in all the relevant life stages.

- **Saturated fat.** The Departments proposed evaluating the relationship between saturated fat and CVD only for adults aged 19 to 64, ignoring children aged 2–18 and adults older than 65. Diet has an impact on CVD at all ages, starting in childhood.

- **Dietary patterns.** For children ages 2–18, the Departments proposed evaluating the link between dietary patterns (e.g., DASH, Mediterranean, vegetarian/vegan, low-carb) and only growth, size, body composition, and bone health. In fact, the DGAC should also evaluate the link between dietary patterns and the risk of obesity, cardiovascular disease, type 2 diabetes, and cancer. These health problems begin in childhood. One out of three children and teens are overweight or obese, and type 2 diabetes now occurs in children as young as 10 years old.⁶ An estimated 11 percent of children aged 8 to 17 have high or borderline high blood pressure, 5.5 percent of male and 7.5 percent of female adolescents have high LDL cholesterol, and 8.7 percent of male adolescents and 6.3 percent of female adolescents have high triglycerides—all risk factors for CVD.⁷
- **Osteoporosis and bone loss.** USDA and HHS proposed evaluating the link between dietary patterns and “bone health” for children aged 2–18 and the “risk of osteoporosis” for ages 65 and older, ignoring adults aged 19 to 64. Similarly, the Departments proposed evaluating the evidence that changes in dietary patterns could prevent or reverse declines in bone density only in adults aged 65 and older. In fact, 54 percent of women aged 50 to 59 have osteopenia and 7 percent have osteoporosis at either the femur neck or lumbar spine.⁸ Although clinical events due to osteoporosis may largely occur in adults older than 65, the risk may depend, in part, on perimenopausal bone loss and on peak bone density acquired decades earlier. Therefore, the DGAC should evaluate the relationship between dietary patterns and both the risk of osteoporosis and declines in bone mass for adults aged 19 to 64.

The Dietary Guidelines should not omit critical topics that were addressed by earlier DGA and apply to all age groups.

a. Sodium

It is troubling that USDA and HHS include no questions on sodium when new expert guidelines⁹ classify roughly one out of two adults as hypertensive, and new data from the CDC indicate that the average American adult consumes 4,000 mg of sodium per day, well above the 2,300 mg per day recommended by the National Academy of Medicine.¹⁰ Furthermore, a convincing body of evidence demonstrates that reducing sodium intake can lower blood pressure and the risk of cardiovascular disease, despite confusion created by studies that do not measure sodium intake accurately.¹¹ We understand that the Academy is in the process of revising the Dietary Reference Intakes for sodium and believe that the DGAC should defer to the DRI committee’s conclusions, if available. The Guidelines should either include the DRI committee’s advice or—if the DRIs are not available before the 2020 Guidelines must be finalized—include advice on sodium from the 2015 Guidelines. Ignoring sodium entirely would put the public’s health at risk.

b. Whole Grains

Previous Guidelines have advised Americans to “make half of all grains whole grains,” yet the Departments’ proposed list of questions lacked any reference to whole grains. Addressing whole grains is critical, given that all age and sex groups fail to meet recommended intakes of whole grains and nearly all exceed recommended intakes of refined grains.¹² Since the publication of the 2015 Guidelines, the evidence supporting advice to replace refined grains with whole grains has grown. For example, in 2016 researchers examining 45 studies reported that people who typically consume three servings of whole grains a day have about a 20 percent lower risk of dying of heart disease and a 15 percent lower risk of dying of stroke or cancer than those who consume no whole grains.¹³ We urge the Departments to either ask the DGAC to provide a quantitative recommendation for whole grain intake, or to continue to advise the public in reliance on the 2015 DGA’s sound and scientific advice to make at least half of the grains consumed be whole grains.

c. Vegetables and Fruit

The 2015 Guidelines recommend a healthy eating pattern with 2½ cup-equivalents of vegetables and 2 cup-equivalents of fruit a day (for a 2,000-calorie diet) and advise consumers that “research has shown that vegetables and fruits are associated with a reduced risk of many chronic diseases, including CVD [cardiovascular disease], and may be protective against certain types of cancers.” Since the publication of the 2015 Guidelines, studies have reported additional evidence that consuming vegetables and fruit protects health. For example, a meta-analysis of 95 studies reported an 8 percent lower risk of heart disease, a 16 percent lower risk of stroke, an 8 percent lower risk of cardiovascular disease, a 3 percent lower risk of total cancer, and a 10 percent lower risk of all-cause mortality for every 200 grams (7 oz.) of fruits and vegetables consumed per day, up to 600 grams per day for cancer and up to 800 grams a day for all other outcomes.¹⁴ We urge the Departments to either ask the DGAC to provide a quantitative recommendation for vegetable and fruit intake or to continue to support the 2015 DGA’s well-founded advice for vegetable and fruit intake.

d. Alcohol

A “key recommendation” of the 2015 Guidelines states that “if alcohol is consumed, it should be consumed in moderation—up to one drink per day for women and up to two drinks per day for men—and only by adults of legal drinking age.” The Guidelines also “does not recommend that individuals begin drinking or drink more for any reason,” and notes that “there are many circumstances in which individuals should not drink, such as during pregnancy.”

Yet in the scoping proposal, the Departments included only a single question about alcoholic beverages (concerning alcohol consumption during lactation and human milk composition and quantity). Alcoholic beverages increase the risk of cirrhosis of the liver

and cancers of the mouth, esophagus, pharynx, larynx, liver, breast, and colon.¹⁵ Given the enormous societal damage caused by excess alcohol consumption, the Guidelines must include recommendations regarding alcohol consumption. We urge the Departments to maintain this 2015 DGA advice as part of the 2020 Guidelines. If the 2020 DGAs include only topics reviewed by the 2020 DGAC, the DGAC should examine the evidence that alcoholic beverages increase the risk of cancer, cirrhosis, and other health and societal problems.

e. Dietary Cholesterol

All previous editions of the Guidelines have included advice on dietary cholesterol, including the 2015 edition. Although that edition deleted previous advice to limit dietary cholesterol to 300 mg per day, it did advise Americans that, “as recommended by the [Institute of Medicine], individuals should eat as little dietary cholesterol as possible while consuming a healthy eating pattern.” In fact, the decision to delete the quantitative advice about dietary cholesterol was ill-founded, as a number of prominent researchers argued in 2015.¹⁶ Therefore, we urge the DGAC to revisit the issue of dietary cholesterol, or at the very least maintain as part of its 2020 recommendations the 2015 DGA advice to eat as little dietary cholesterol as possible.

f. Red and Processed Meats

The 2015 Guidelines advise the public that “strong evidence from mostly prospective cohort studies but also randomized controlled trials has shown that eating patterns that include lower intake of meats as well as processed meats and processed poultry are associated with reduced risk of CVD in adults. Moderate evidence indicates that these eating patterns are associated with reduced risk of obesity, type 2 diabetes, and some types of cancer in adults.” In October 2015, the International Agency for Research on Cancer (IARC) concluded that processed meat is “carcinogenic to humans.”¹⁷ IARC’s monographs on carcinogenesis “are considered the ‘gold’ standard in evaluating evidence on cancer causation,” according to the President’s Cancer Panel, and are used by countries around the world.¹⁸ IARC also concluded that “each 50 gram portion of processed meat eaten daily increases the risk of colorectal cancer by 18 percent.”^{19,20} Therefore, we urge the 2020 DGAC to adopt IARC’s conclusions. If the 2020 DGAs only include topics reviewed by the 2020 DGAC, the committee should evaluate the evidence that processed meats increase the risk of colorectal cancer.

g. Food Safety

As noted in the 2015–2020 Dietary Guidelines, an important part of healthy eating is keeping foods safe. Foodborne illness affects about one in six Americans—648 million people. The 2015 Guidelines provides sound recommendations for the general population, and a paragraph directed towards at-risk populations on how to reduce the risk of foodborne illness. This or similar information should be included in the 2020–2025 edition. However, the inclusion of life stage information in the 2020–2025 Dietary Guidelines provides an opportunity to provide specific information for each age group. For example,

the DGAC could include precautions that parents or caregivers can take to protect against *Cronobacter* in infant formula, which can be fatal for babies. Also, children under the age of five are at the highest risk for *Salmonella* infection,²¹ because their immune systems are still developing. The DGAC could include precautions to protect children from *Salmonella* (e.g., avoiding cake batter and cookie dough, reinforcing the importance of handwashing).

The Departments should amend a number of the proposed topics and questions and consider them for all age groups.

a. Beverages and Added Sugars

The 2020 DGAC should examine the evidence on added sugars and sugar-sweetened beverages (SSB) together, because SSBs are the largest source of added sugars in the average American's diet.

The 2015 Guidelines recommends that people consume less than 10 percent of calories from added sugars to meet their food group and nutrient needs. In addition, the Guidelines noted that an eating pattern that reduces the risk of chronic disease is low in added sugars. The 2015 DGAC examined the evidence on added sugars and SSBs together in part because SSBs are the greatest source of added sugars in the average American's diet (contributing almost half of intake) and in part because SSBs are easier to use in randomized controlled trials and easier to examine in observational studies than are added sugars. The 2020 DGAC should similarly evaluate added sugars and SSBs together. Therefore, the proposed questions for added sugars should more clearly state "added sugars *in food and beverages*."

b. Saturated Fats

The Departments proposed that the DGAC would examine the relationship between saturated fats and risk of cardiovascular disease for adults aged 19–64. Instead, the 2020 DGAC should examine the effect of replacing saturated fatty acids with polyunsaturated fatty acids (and monounsaturated fatty acids) on the risk of CVD for children aged 2–18 and adults aged 19 and over. The 2015 Guidelines recommends that "intake of saturated fats should be limited to less than 10 percent of calories per day by replacing them with unsaturated fats...." The 2020 Guidelines should take a similar approach.

It is not possible to evaluate the effect of saturated fats on the risk of CVD without considering which nutrients would replace it, as explained by a 2017 Presidential Advisory from the American Heart Association.²² Studies that ignore the replacement nutrient are effectively comparing saturated fats to refined carbohydrates (largely white flour and added sugars), which comprise the largest component of the average American diet. As the AHA Advisory explains, meta-analyses of prospective observational studies that did not take the replacement nutrient into account have mistakenly concluded that saturated fat intake had no significant effect on CVD risk.^{23,24} In contrast, meta-analyses that evaluated the effect of replacing saturated fat with polyunsaturated fat reported a lower risk of CVD, while replacing saturated fat with refined carbohydrates yielded no lower risk of CVD.^{25,26}

Similarly, randomized controlled trials that replace saturated fats with polyunsaturated fats report a lower risk of CVD. The 2015 Cochrane Collaboration review of 15 RCTs concluded that reducing saturated fat reduced the risk of cardiovascular events by 17 percent, and subgrouping suggested that the reduction in cardiovascular events was seen in studies that primarily replaced saturated fat calories with polyunsaturated fat.²⁷ As the authors noted, it is not surprising that no effect was seen on all-cause or CVD mortality given that trials lasted an average of 4 to 5 years.²⁸ The AHA Advisory further divided RCTs into “core” trials that met six criteria (e.g., sufficient duration and adherence) and “non-core” trials that failed to meet at least one of those criteria.²⁹ A meta-analysis of core trials that replaced saturated fats with polyunsaturated fats found roughly a 30 percent reduction in CHD events, which is similar to the reduced risk achieved by treatment with statins. Some randomized controlled trials have reported differing results because they replaced saturated fats with margarines that were high in cholesterol-raising trans fat.³⁰

These bodies of evidence are supported by clinical trials demonstrating that replacing saturated fats with polyunsaturated fats lowers LDL cholesterol, a well-established cause of atherosclerosis. That evidence informed the 2013 Lifestyle Management Guideline from the American Heart Association and College of Cardiology,³¹ which includes advice to “aim for a dietary pattern that achieves 5-6 percent of calories from saturated fat.” In 2016, the AHA and ACC translated those guidelines into more specific dietary advice.³²

Furthermore, the DGAC should examine the evidence on saturated fats and CVD for everyone aged 2 or older, not merely for adults 19–64, because atherosclerosis begins in childhood and continues beyond age 64. Based on a thorough review of the evidence in 2011, an expert panel of the National Heart, Lung, and Blood Institute recommended that children and adolescents get 7 to 10 percent of their calories from saturated fat and 20 percent of their fat from a combination of poly- and monounsaturated fat.³³ Similarly, the AHA recommends limits on saturated fat in children aged 2 and older.³⁴ Furthermore, people older than 64 have a high absolute risk of CVD, and many prospective studies and RCTs involve adults older than 65. Recognizing the decades-long atherosclerotic process, AHA and ACC issue guidelines for children over age two and make no distinction between younger and older adults.

The Departments should add topics regarding substances to avoid or minimize for all age groups, especially during critical windows of susceptibility.

People of all ages are exposed to substances that can disrupt health and development. However, some populations receive greater dietary exposures than others, especially children, in part because they have higher food and fluid intake per pound of body weight than do adults. Children can also be exposed *in utero* via placental transfer or after birth via breast milk. Furthermore, it is widely recognized that exposures early in life, during “windows of susceptibility,” when certain tissues and organ systems are developing, are of paramount importance to health. Exposures during pregnancy and early in life are

increasinglyⁱ linked to health outcomes later in life, including cancer, obesity, diabetes, cardiovascular disease, fertility, and neurodevelopmental disease or dysfunction.^{35,36,37}

The American College of Obstetricians and Gynecologists, the American Society for Reproductive Medicine, and others are calling for action to identify and reduce exposure to toxic environmental agents, recognizing that an important outcome of pregnancy is a healthy newborn, as well as a person biologically predisposed to be healthy from birth to old age.^{38,39,40} In particular, it is well established that the developing brain is exquisitely sensitive to toxic insults. In cases where there is ample data, such as with certain heavy metals and alcohol, no “safe” levels for the developing brain have been identified.^{41,42,43} Similarly, the susceptibility to carcinogens from exposures during pregnancy and early in life is a well-recognized public health concern.

Thus, in addition to ensuring good nutrition early in life, every effort should be made to avoid or minimize potentially harmful dietary exposures. While the current Dietary Guidelines address alcohol and provide general advice on caffeine, many other dietary exposures of concern have not been addressed. The decision to provide advice at different life stages in the 2020 Dietary Guidelines provides a new opportunity to address this topic. Consumers need comprehensive advice to help them avoid dietary exposures of concern.

For each life stage, and in particular during pregnancy and early in life, USDA and HHS should add the topic “Avoiding or minimizing dietary exposures of potential concern,” and the question “How can possible dietary exposures of concern be avoided or minimized at this life stage?”, including for:

- a. Contaminants such as lead, arsenic, and persistent pollutants that cause or are reasonably anticipated to cause cancer and/or other toxic effects (e.g., to the developing brain);
- b. Naturally-occurring and added caffeine (especially during pregnancy, childhood, adolescence, and young adulthood);
- c. Additives that cause or are reasonably anticipated to cause cancers, according to U.S. government authorities, including Red 3,^{ii,44,45} BHA, and certain flavors;^{iii,46}
- d. Additives that pose risks to certain individuals, including synthetic food dyes;
- e. Pathogens such as *Salmonella*, *Listeria*, and *Cronobacter*; and

ⁱ For example, the entire issue of *Reprod Toxicol* 2017;68:1-214 is devoted to the environment and Developmental Origins of Health and Diseases.

ⁱⁱ In 1990, the FDA determined that Red 3 caused cancer, on the basis of animal feeding studies, and on that basis terminated provisional uses of the dye in cosmetics, including lipsticks and ingested cosmetics, externally applied drugs, and all uses of Red 3 lake. That same year, the FDA said it would “take steps” to ban the use of Red 3 dye in food and ingested drugs, for which the dyes had been permanently approved. However, it has not done so and those uses remain.

ⁱⁱⁱ For example, the flavoring agents methyleugenol and acetaldehyde are listed as “reasonably anticipated to be a human carcinogen” in the official U.S. government’s Report on Carcinogens. Fourteenth Edition, 2016. <https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html>.

- f. Other substances indirectly added to food from packaging, processing, or cooking, such as acrylamide, polycyclic aromatic hydrocarbons, heterocyclic amines, and phthalates and other plastic-related chemicals that cause or are reasonably anticipated to cause cancer or other toxic effects (e.g., to the developing brain).

It is not necessary for the DGAC to review evidence for each potential exposure of concern. Rather, the focus should be on providing practical, actionable advice and guidance to minimize exposures at the most sensitive times during windows of development, incorporating and building on practical advice^{iv} provided by the 2008–2009 President’s Cancer Panel⁴⁷ and other sources.^v Moreover, if the DGAC declines to address specific exposures of potential concern, it should publicly indicate which it is not addressing, so that consumers are aware that the list of addressed exposures is not exhaustive.

III. Infants and Toddlers

a. Introduction

Good nutrition as well as avoidance of toxic exposures throughout the first two years of life helps to lay the foundation for a child’s future health well into adulthood. New research in the fields of neuroscience and the early origins of adult health is shedding light on how infants’ brains develop, how children and adults become susceptible to diseases, and how capacities and skills are either nourished or thwarted, beginning during pregnancy and through the first two years of life.

In addition to being more susceptible to toxic insults, infants aged 0–6 months may consume a sole source of food—breast milk or infant formula—and consume higher amounts of food relative to body weight compared to adults, during a period of important developmental processes.⁴⁸

A growing body of scientific research indicates that the foundations for lifelong health—including predispositions to obesity and certain chronic diseases—are largely determined during pregnancy and the first two years. Emerging research also indicates that the effects of poor nutrition as well as toxic or carcinogenic exposures early in life impact not only a child’s health but also that of the child’s offspring. In this way, the damaging effects caused by poor nutrition and adverse exposures in early life have the

^{iv} For example, the Panel states, “Avoiding or minimizing consumption of processed, charred, and well-done meats will reduce exposure to carcinogenic heterocyclic amines and polyaromatic hydrocarbons” and, “Microwaving food and beverages in ceramic or glass instead of plastic containers will reduce exposure to endocrine-disrupting chemicals that may leach into food when containers are heated.”

^v For example, the National Institute of Environmental Health Sciences (*see* <https://www.niehs.nih.gov/health/topics/agents/sya-bpa/index.cfm>), noting that animal studies suggest that infants and children may be the most vulnerable to the effects of BPA, provides advice on how to prevent or reduce exposure to BPA, for example by not microwaving polycarbonate plastic food containers, reducing use of canned foods, and when possible, opting for glass, porcelain, or stainless steel containers, particularly for hot foods or liquids.

potential to cascade down through generations of children and lock families into a cycle of poor health.

The DGAC should consider the following additional topic for infants and toddlers.

a. Reducing and Avoiding Exposures of Concern

The DGAC should consider certain chemical exposures as well as *Cronobacter*, which can be found in powdered infant formula. *Cronobacter* illnesses are rare, but they are frequently lethal for infants. The Centers for Disease Control provides guidelines to caregivers to protect babies from *Cronobacter*, and it would be helpful to include similar advice in the Dietary Guidelines.⁴⁹

The DGAC should consider lead and arsenic, which are especially toxic to the developing brain, contributing to learning and behavioral problems in children. In addition, lead and lead compounds are considered “reasonably anticipated to be human carcinogens” and arsenic and inorganic arsenic compounds are listed in the official Report on Carcinogens as “known to be a human carcinogen.”⁵⁰ Analysis of FDA data shows that lead levels in baby food versions of certain foods, such as apple and grape juice, exceed those in the regular versions.⁵¹ Testing has found six times more arsenic in infant rice cereal compared to other types of cereal.⁵²

IV. Children and Adolescents

The DGAC should consider the following additional topics for children and adolescents.

a. Caffeine

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) states that caffeine intoxication can occur “with low doses (e.g., 200 mg) in vulnerable individuals such as children, the elderly, or individuals who have not been exposed to caffeine previously.”⁵³ Children are more vulnerable to adverse effects from caffeine than adults due to their smaller size, developing brain, and lack of habituation. In addition, caffeine is being used in a wide range of food and beverage categories that appeal to children, including gum, candy, popcorn and other snack foods, and waffles and other breakfast foods. Adolescents are also more vulnerable to caffeine than adults, because the brain continues to develop in adolescence, particularly those parts of the brain important in impulse control, and because certain caffeinated products are aggressively marketed and appeal to adolescents, especially energy drinks and energy shots. Sales of energy drinks—which provide far more added caffeine (up to 500 mg per container) than soda (typically 34–53 mg in a 12-ounce soda)⁵⁴—have continued to increase every year since 2011.⁵⁵ The Substance Abuse and Mental Health Services Administration reported more than a 13-fold increase in emergency room visits between 2005 and 2011 due to energy drinks.⁵⁶ Meanwhile, the sale of very large containers of coffee and other traditional beverages

containing caffeine has become commonplace. For example, Starbucks sells 16-ounce and 20-ounce sizes that contain 330 mg and 415 mg of caffeine, respectively,⁵⁷ compared to the standard 100 mg per 5-ounce cup.

Particularly dangerous products include powdered and concentrated liquid caffeine. Just one teaspoon of powdered caffeine is equivalent to about 28 cups of regular coffee. Adverse effects including at least two deaths have been associated with the use of these products.⁵⁸

Concerns about energy drinks and/or caffeine exposure have been expressed by the FDA,^{vi} the Substance Abuse and Mental Health Services Administration,^{vii} Institute of Medicine,^{viii} American Academy of Pediatrics,^{ix} Sports Medicine Advisory Committee of the National Federation of State High School Associations,^x and numerous scientists, clinicians, and public health professionals.^{xi}

^{vi} The FDA Deputy Commissioner in 2013 stated, “Our concern is about caffeine appearing in a range of new products, including ones that may be attractive and readily available to children and adolescents, without careful consideration of their cumulative impact ... Meanwhile, ‘energy drinks’ with caffeine are being aggressively marketed, including to young people. An instant oatmeal on the market boasts that one serving has as much caffeine as a cup of coffee, and then there are similar products ... The proliferation of these products in the marketplace is very disturbing to us.” Food and Drug Administration. Caffeine and kids: FDA takes a closer look. May 3, 2013. Available at

<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm350570.htm>.

^{vii} “Consumption of energy drinks is a rising public health problem because medical and behavioral consequences can result from excessive caffeine intake. A growing body of scientific evidence documents harmful health effects of energy drinks, particularly for children, adolescents, and young adults.” From Substance Abuse and Mental Health Services Administration (SAMHSA). *The Dawn Report: Update on Emergency Department Visits Involving Energy Drinks: A Continuing Public Health Concern*. January 10, 2013. Available online. <http://www.samhsa.gov/data/2k13/DAWN126/sr126-energy-drinks-use.pdf>.

^{viii} The Institute of Medicine recommends that school foods and beverages be caffeine-free, with the exception of trace amounts of naturally occurring caffeine-related substances. This is a Tier 1 recommended standard for all students and a Tier 2 recommended standard for high school students after school. (Institute of Medicine. *Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth*. Washington, D.C.: National Academies Press, 2007.)

^{ix} The Academy states, “energy drinks pose potential health risks primarily because of stimulant content; therefore, they are not appropriate for children and adolescents and should never be consumed,” and “In general, caffeine-containing beverages, including soda, should be avoided.” See *Pediatrics* 2011, 127(6):1182-1189 at <http://pediatrics.aappublications.org/content/pediatrics/early/2011/05/25/peds.2011-0965.full.pdf> and “Kids should not consume energy drinks, and rarely need sports drinks, says AAP”, 2011, at <http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Kids-Should-Not-Consume-Energy-Drinks,-and-Rarely-Need-Sports-Drinks,-Says-AAP.aspx>.

^x In its *Position Statement and Recommendations for the Use of Energy Drinks by Young Athletes* (NFHS, 2014), available at <http://www.nfhs.org/media/1014749/nfhs-smac-position-statement-for-use-of-energy-drinks-october-2014.pdf>, the Committee “strongly recommends that energy drinks should not be used for hydration prior to, during, or after physical activity.”

^{xi} A letter signed by 18 scientists, clinicians, and public health professionals studying and conducting research on caffeine and energy drinks concludes “that there is neither sufficient evidence of safety nor a consensus of scientific opinion to conclude that the high levels of added caffeine in energy drinks are safe under the conditions of their intended use...To the contrary, the best available scientific evidence demonstrates a robust correlation between the caffeine levels in energy drinks and adverse health and safety consequences,

b. Artificial (synthetic) food dyes^{xii}

Dyes have no nutritional or public health benefit—they are added for aesthetic purposes and are often used to make unhealthy foods more appealing, particularly to children. For example, Tropicana Twister Cherry Berry Blast, despite its name and a label showing images of cherries and berries, has no cherry or berry juice. Much of its dark red color comes from Red 40, and there is more high fructose corn syrup than even apple and grape juice concentrate. Furthermore, the Food and Drug Administration reported in 2011 that synthetic dyes are associated with adverse behaviors in some susceptible children with Attention Deficit/Hyperactivity Disorder or other problem behaviors⁵⁹ and possibly in other susceptible children from the general population.⁶⁰ At the time, the FDA concluded that the evidence was not sufficient to establish a causal relationship between exposure to synthetic food dyes and hyperactivity in the general population.⁶¹ Since 2011, eight additional reviews of the evidence, including two meta-analyses, concluded that excluding food dyes—or a diet that eliminates dyed foods and certain other foods and ingredients—reduces adverse behavior in some children.^{62,63,64,65,66,67,68,69} The American Psychiatric Association states in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) that "a minority of cases [of Attention-Deficit/Hyperactivity Disorder] may be related to reactions to aspects of diet,"⁷⁰ and cites two of these reviews.^{71,72} Throughout the European Union, a warning notice—"may have an adverse effect on activity and attention in children"—is required on foods that contain certain dyes, including the three most widely used food dyes in the United States.⁷³ Yet many Americans are unaware that synthetic food dyes can trigger adverse behavioral reactions in certain individuals.

The FDA estimates that all American children ages 2 to 5 and teenage boys ages 13 to 18^{xiii} consume foods and beverages dyed with Red 40, Yellow 5, Yellow 6, and Blue 1.⁷⁴ One study found that more than 90 percent of child-oriented candies, fruit-flavored snacks, and drink mixes and powders are artificially colored.⁷⁵

V. Pregnancy and Lactation

The DGAC should consider the following additional topic for pregnant and postpartum women.

a. Avoiding or Reducing Exposures of Concern

Pregnancy is an especially critical time for pregnant women to avoid or reduce dietary exposures of concern, such as alcohol, caffeine, lead, listeria, and others, and the DGAC

particularly among children, adolescents, and young adults." Arria, A et al. Letter to The Honorable Margaret A. Hamburg, MD, Commissioner, Food and Drug Administration, Re: The Use of Caffeine in Energy Drinks, March 19, 2013. Available at: <http://www.sfcityattorney.org/wp-content/uploads/2015/07/Herrera-Scientists-letter-to-the-FDA-re-caffeinated-drinks.pdf>.

^{xii} Refers to FD&C color additives, including Blue 1, Blue 2, Green 3, Red 3, Red 40, Yellow 5, Yellow 6.

^{xiii} Other age and sex groups were not studied.

should provide specific, practical advice to assist pregnant women to do that, as noted above.

For example, caffeine poses a risk of adverse pregnancy outcomes including spontaneous abortion, stillbirth, preterm delivery, as well as childhood leukemia. This evidence does not support the common advice that up to 200 mg of caffeine per day is safe for pregnant women. Doses as low as 100 mg per day have been associated with a 14 percent increase in risk of miscarriage, a 19 percent increase in the risk of stillbirth, and increased risks of small-for-gestational-age fetuses and low birth weight.⁷⁶ Furthermore, there is compelling evidence linking maternal coffee consumption during pregnancy and childhood acute leukemia, which has not received much attention.⁷⁷

VI. Adults

While we are pleased that the Guidelines will offer recommendations to a broader, more diverse population through the lifespan approach, the proposed age groups and topics fail to address issues in all relevant life stages. Therefore, sodium, whole grains, fruits and vegetables, alcohol, dietary cholesterol, saturated fats, added sugars and beverages, and dietary exposures should be considered for all age groups aged two and older, as addressed in Section II above.

Furthermore, the Guidelines should consider recommendations on powdered or concentrated liquid caffeine, as well as energy drinks and energy shots, especially for young adults for whom these products particularly appeal due to their positioning as athletic performance enhancers. As noted previously, adverse effects, including deaths, have been associated with the use of these products.

VII. Older Adults

Several questions proposed by USDA and HHS create an arbitrary distinction between adults ages 19–64 and adults aged 65 and older. In fact, most of evidence concerning diet and risk of disease applies to both age groups. Rather than review the evidence for the two age groups separately, the DGAC should consider the evidence for all adults for most outcomes. The DGAC could conduct a separate review for older adults for problems that do not occur as frequently at younger ages, such as impaired dentition and reduced muscle strength. An estimated 15 percent of men and 22 percent of women aged 80 or older—but only 2 percent of men and women aged 60 to 79—have “weak muscle strength.”⁷⁸ As noted above, DSM-5 states that caffeine intoxication can occur with low doses (e.g., 200 mg) in the elderly.⁷⁹

VIII. Conclusion

Thank you for the opportunity to provide comments on the proposed topics for the 2020 *Dietary Guidelines for Americans*. In summary, we appreciate the lifespan approach and the addition of guidance for pregnant women, infants, children and adolescents, adults,

and older adults. We also support opportunities to make the DGA process more transparent.

We strongly encourage the Agencies to consider adding to and amending several of the proposed topics to better serve Americans with more complete nutrition advice.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bonnie Liebman". The signature is fluid and cursive, with a large initial "B" and a long horizontal stroke at the end.

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Director of Nutrition
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A handwritten signature in black ink, appearing to read "Lisa Y. Lefferts". The signature is cursive, with a large initial "L" and a long horizontal stroke at the end.

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A handwritten signature in black ink, appearing to read "Angela Amico". The signature is cursive, with a large initial "A" and a long horizontal stroke at the end.

Angela Amico, MPH
Policy Associate
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- ¹ Fryar CD, Carroll MD, Ogden CL. Prevalence of overweight, obesity, and extreme obesity among adults aged 20 and over. *National Center for Health Statistics*. 2016 July. Available at https://www.cdc.gov/nchs/data/hestat/obesity_adult_13_14/obesity_adult_13_14.htm.
- ² Fryar CD, Carroll MD, Ogden. Prevalence of overweight and obesity among children and adolescents aged 2–19: United States, 1963–1965 through 2013–2014. *National Center for Health Statistics*. 2016 July. Available at https://www.cdc.gov/nchs/data/hestat/obesity_child_13_14/obesity_child_13_14.htm.
- ³ Centers for Disease Control and Prevention. A Snapshot: Diabetes in the United States. 2017 November. Available at <https://www.cdc.gov/diabetes/library/socialMedia/infographics.html>.
- ⁴ Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2017 Nov 7. pii: S0735-1097(17)41519-1. doi: 10.1016/j.jacc.2017.11.006.
- ⁵ Centers for Disease Control and Prevention. Cancers associated with overweight and obesity make up 40 percent of cancers diagnosed in the United States. 2017 October. Available at <https://www.cdc.gov/media/releases/2017/p1003-vs-cancer-obesity.html>.
- ⁶ Centers for Disease Control and Prevention. National Diabetes Statistics Report. 2017. Available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.
- ⁷ Benjamin EJ, Virani SS, Callaway CW, et al. American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2018 Update: A Report from the American Heart Association. *Circulation*. 2018 Mar 20;137(12):e67-e492. doi: 10.1161/CIR.0000000000000558.
- ⁸ Centers for Disease Control and Prevention, National Center for Health Statistics. National Health and Nutrition Examination Survey, 2005–2008. Osteoporosis or Low Bone Mass at the Femur Neck or Lumbar Spine in Older Adults: United States, 2005–2008. NCHS Data Brief No. 93, April 2012.
- ⁹ American Heart Association. High blood pressure redefined for first time in 14 years: 130 is the new high. 2017 November. Available at <https://newsroom.heart.org/news/high-blood-pressure-redefined-for-first-time-in-14-years-130-is-the-new-high>.
- ¹⁰ Cogswell ME, Loria CM, Terry AL, et al. Estimated 24-hour urinary sodium and potassium excretion in U.S. adults. *JAMA*. 2018 Mar 7; doi: 10.1001/jama.2018.1156.
- ¹¹ Cogswell ME, Mugavero K, Bowman BA, Frieden TR. Dietary sodium and cardiovascular disease risk—measurement matters. *N Engl J Med*. 2016 Aug 11;375(6):580-6. doi: 10.1056/NEJMs1607161.
- ¹² U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition, Page 48 December 2015. Available at <https://health.gov/dietaryguidelines/2015/guidelines/>.
- ¹³ Aune D, Keum N, Giovannucci E, et al. Whole grain consumption and risk of cardiovascular disease, cancer, and all cause and cause specific mortality: systematic review and dose-response meta-analysis of prospective studies. *BMJ*. 2016 Jun 14;353:i2716. doi: 10.1136/bmj.i2716.
- ¹⁴ Aune D, Giovannucci E, Boffetta P, et al. Fruit and vegetable intake and the risk of cardiovascular disease, total cancer and all-cause mortality—a systematic review and dose-response meta-analysis of prospective studies. *Int J Epidemiol*. 2017 Jun 1;46(3):1029-1056. doi: 10.1093/ije/dyw319.
- ¹⁵ National Institutes of Health, National Cancer Institute. Alcohol and Cancer Risk. 2013 June. Available at <https://www.cancer.gov/about-cancer/causes-prevention/risk/alcohol/alcohol-fact-sheet>.
- ¹⁶ Scientists' Comment on Dietary Cholesterol to the Secretaries of the U.S. Department of Health and Human Services & the U.S. Department of Agriculture. May 8, 2015. Available at <https://cspinet.org/new/Dietary%20Cholesterol%20-%20Comment%20to%20DGA%205-8-15.pdf>.
- ¹⁷ International Agency for Research on Cancer. World Health Organization IARC Monographs evaluate consumption of red meat and processed meat. 26 October 2015. Available at https://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr240_E.pdf.

-
- ¹⁸ The President's Cancer Panel. Reducing environmental cancer risk: What we can do now. P. 13. April 2010. Available at https://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.
- ¹⁹ International Agency for Research on Cancer, *op. cit.*
- ²⁰ Bouvard V, Loomis D, Guyton KZ, et al. International Agency for Research on Cancer Monograph Working Group. Carcinogenicity of consumption of red and processed meat. *Lancet Oncol*. 2015 Dec;16(16):1599-600.
- ²¹ Centers for Disease Control and Prevention. Salmonella: Questions and Answers. 2015. Available at <https://www.cdc.gov/salmonella/general/index.html>.
- ²² Sacks FM, Lichtenstein AH, Wu JHY, et al; American Heart Association. Dietary Fats and Cardiovascular Disease: A Presidential Advisory from the American Heart Association. *Circulation*. 2017 Jul 18;136(3):e1-e23. doi: 10.1161/CIR.0000000000000510.
- ²³ Siri-Tarino PW, Sun Q, Hu FB, Krauss RM. Meta-analysis of prospective cohort studies evaluating the association of saturated fat with cardiovascular disease. *Am J Clin Nutr*. 2010;91:535-546. doi: 10.3945/ajcn.2009.27725.
- ²⁴ Chowdhury R, Warnakula S, Kunutsor S, Crowe F, Ward HA, Johnson L, Franco OH, Butterworth AS, Forouhi NG, Thompson SG, Khaw KT, Mozaffarian D, Danesh J, Di Angelantonio E. Association of dietary, circulating, and supplement fatty acids with coronary risk: a systematic review and meta-analysis [published correction appears in *Arch Intern Med*. 2014;160:658]. *Ann Intern Med*. 2014;160:398-406. doi: 10.7326/M13-1788.
- ²⁵ Jakobsen MU, O'Reilly EJ, Heitmann BL, Pereira MA, Bälter K, Fraser GE, Goldbourt U, Hallmans G, Knekt P, Liu S, Pietinen P, Spiegelman D, Stevens J, Virtamo J, Willett WC, Ascherio A. Major types of dietary fat and risk of coronary heart disease: a pooled analysis of 11 cohort studies. *Am J Clin Nutr*. 2009;89:1425-1432. doi: 10.3945/ajcn.2008.27124.
- ²⁶ Li Y, Hruby A, Bernstein AM, Ley SH, Wang DD, Chiuve SE, Sampson L, Rexrode KM, Rimm EB, Willett WC, Hu FB. Saturated fats compared with unsaturated fats and sources of carbohydrates in relation to risk of coronary heart disease: a prospective cohort study. *J Am Coll Cardiol*. 2015;66:1538-1548. doi: 10.1016/j.jacc.2015.07.055.
- ²⁷ Hooper L, Martin N, Abdelhamid A, Davey Smith G. [Reduction in saturated fat intake for cardiovascular disease](#). *Cochrane Database Syst Rev*. 2015 Jun 10;(6):CD011737. doi: 10.1002/14651858.CD011737.
- ²⁸ Hooper L, Martin N, Abdelhamid A. [Cochrane corner: what are the effects of reducing saturated fat intake on cardiovascular disease and mortality?](#) *Heart*. 2015 Dec;101(24):1938-40. doi: 10.1136/heartjnl-2015-308521.
- ²⁹ Core trials "compared high saturated with high polyunsaturated fat intake; did not include *trans* unsaturated fat as a major component; controlled the dietary intake of the intervention and control groups; had at least 2 years of sustained intake of the assigned diets; proved adherence by objective biomarkers such as serum cholesterol or blood or tissue levels of polyunsaturated fatty acids; and collected and validated information on cardiovascular or coronary disease events."
- ³⁰ A meta-analysis by Chowdhury et al erroneously concluded that replacing saturated fats with polyunsaturated fats does not lower the risk of CHD because the authors included such a study, the Sydney Diet Heart Study. As the Chowdhury et al appendix notes, when the SDHS is removed from the meta-analysis, replacing saturated fats with polyunsaturated fats lowers the risk of heart disease by roughly 20 percent]. Chowdhury R, Warnakula S, Kunutsor S, Crowe F, Ward HA, Johnson L, Franco OH, Butterworth AS, Forouhi NG, Thompson SG, Khaw KT, Mozaffarian D, Danesh J, Di Angelantonio E. Association of dietary, circulating, and supplement fatty acids with coronary risk: a systematic review and meta-analysis. *Ann Intern Med*. 2014 Mar 18;160(6):398-406. doi: 10.7326/M13-1788. Review. Erratum in: *Ann Intern Med*. 2014 May 6;160(9):658. Willett WC, Stampfer MJ, Sacks FM. [Association of dietary, circulating, and supplement fatty acids with coronary risk](#). *Ann Intern Med*. 2014 Sep 16;161(6):453. doi: 10.7326/L14-5018. Liebman BF, Katan MB, Jacobson MF. Association of dietary, circulating, and supplement fatty acids with coronary risk. *Ann Intern Med*. 2014 Sep 16;161(6):454-5. doi: 10.7326/L14-5018-4.
- ³¹ Eckel RH, Jakicic JM, Ard JD, de Jesus JM, Houston Miller N, Hubbard VS, Lee IM, Lichtenstein AH, Loria CM, Millen BE, Nonas CA, Sacks FM, Smith SC Jr, Svetkey LP, Wadden TA, Yanovski SZ; **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. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2960-84. doi: 10.1016/j.jacc.2013.11.003

³² Van Horn L, Carson JA, Appel LJ, Burke LE, Economos C, Karmally W, Lancaster K, Lichtenstein AH, Johnson RK, Thomas RJ, Vos M, Wylie-Rosett J, Kris-Etherton P; American Heart Association Nutrition Committee of the Council on Lifestyle and Cardiometabolic Health; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; and Stroke Council. Recommended Dietary Pattern to Achieve Adherence to the American Heart Association/American College of Cardiology (AHA/ACC) Guidelines: A Scientific Statement from the American Heart Association. Circulation. 2016 Nov 29;134(22):e505-e529.

³³ Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report. Pediatrics 2011;128;S213. DOI: 10.1542/peds.2009-2107C

³⁴ Samuel S. Gidding, MD, Chair; Barbara A. Dennison, MD, Cochair; Leann L. Birch, PhD; Stephen R. Daniels, MD, PhD; Matthew W. Gilman, MD; Alice H. Lichtenstein, DSc; Karyl Thomas Rattay, MD; Julia Steinberger, MD; Nicolas Stettler, MD; Linda Van Horn, PhD, RD. Dietary Recommendations for Children and Adolescents A Guide for Practitioners Consensus Statement From the American Heart Association. Circulation. 2005; 112:2061-2075.

³⁵ MacKay H, Heindel JJ, Ross MG, Waterland RA. Meeting summary: the inaugural meeting of the US DOHaD society. *Environ Epigenet* 2017; 3(1):dvw026. doi: 10.1093/eep/dvw026. eCollection 2017 Jan;..

³⁶ Mitro SD, Johnson T, Zota AR. Cumulative chemical exposures during pregnancy and early development. *Curr Environ Health Rep* 2015;2(4):367-78. doi: 10.1007/s40572-015-0064-x

³⁷ Heindel JJ and Vandenberg LN. Developmental origins of health and disease: a paradigm for understanding disease etiology and prevention. *Curr Opin Pediatr*. 2015; 27(2):248-53. . doi: 10.1097/MOP.0000000000000191.

³⁸The American College of Obstetricians and Gynecologists. Committee opinion 575, exposure to toxic environmental agents. 2013 October. Available at <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Exposure-to-Toxic-Environmental-Agents>.

³⁹ Nicole W. Advocates for children's health: Working together to reduce harmful environmental exposures. *Environ Health Perspect*. 2018;126(1):012001-7. doi:10.1289/EHP2423.

⁴⁰ The President's Cancer Panel. Reducing environmental cancer risk: What we can do now. April 2010. Available at https://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.

⁴¹ Centers for Disease Control and Prevention. Lead. 2017. Available at <https://www.cdc.gov/nceh/lead/>.

⁴² Centers for Disease Control and Prevention. Alcohol use in pregnancy. 2016. Available at <https://www.cdc.gov/ncbddd/fasd/alcohol-use.html>.

⁴³ Lanphear BP, Dietrich K, Auinger P, Cox C. Cognitive Deficits Associated with Blood Lead Concentrations <10 ug/dL in US children and adolescents. *Public Health Rep*. 2000;115(6):521-9.

⁴⁴ 21 CFR 81.10(u).

⁴⁵ McLaughlin, P. (April 22, 1990). Seeing Red Dye No. 3. Chicago Tribune. Chicago: 5.

⁴⁶ US Department of Health and Human Services, Public Health Service, National Toxicology Program. Report on Carcinogens. Fourteenth Edition, 2016. <https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html>.

⁴⁷ The President's Cancer Panel, *op. cit*.

⁴⁸ Neal-Kluever A, Aungst J, Gu Y et al. Infant toxicology: State of the science and considerations in evaluation of safety. *Food Chem Toxicol*. 2014; 70:68-83. doi: 10.1016/j.fct.2014.05.003.

⁴⁹ Centers for Disease Control and Prevention. Learn about Cronobacter infection. Available at <https://www.cdc.gov/features/cronobacter/index.html>.

⁵⁰ US Department of Health and Human Services, Public Health Service, National Toxicology Program. Report on Carcinogens. Fourteenth Edition, 2016. <https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html>.

⁵¹ Environmental Defense Fund. Lead in food: A hidden health threat. 2017. Available at <https://www.edf.org/health/lead-food-hidden-health-threat>.

⁵² Healthy Babies Bright Futures. Arsenic in 9 Brands of Infant Cereal. December 2017. http://www.healthybabycereals.org/sites/default/files/2017-12/HBBF_ArsenicInInfantCerealReport.pdf

-
- ⁵³ The Diagnostic and Statistical Manual of Mental Disorders, § 305.90 (Am. Psychiatric Ass'n 5th ed.) (2013).
- ⁵⁴ 21 CFR 81.10(u).
- ⁵⁵ Statista. U.S. Energy Drinks – Statistics & Facts. Accessed March 22, 2018. Available at <https://www.statista.com/topics/1687/energy-drinks/>.
- ⁵⁶ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. The Dawn Report: Update on Emergency Department Visits Involving Energy Drinks: A Continuing Public Health Concern. 2013. Available at <https://archive.samhsa.gov/data/2k13/DAWN126/sr126-energy-drinks-use.pdf>.
- ⁵⁷ Center for Science in the Public Interest. Caffeine Chart. Available at http://www.cspinet.org/new/cafchart.htm#table_coffee.
- ⁵⁸ U.S. Food and Drug Administration, Pure Powdered Caffeine, <https://www.fda.gov/food/dietarysupplements/productsingredients/ucm460095.htm>.
- ⁵⁹ U.S. Food and Drug Administration Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children. 2011. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM248549.pdf>.
- ⁶⁰ Cheeseman MA. Artificial Food Color Additives and Child Behavior. *Environ Health Perspect.* 2012 ;120 (1): A15-A16.
- ⁶¹ U.S. Food and Drug Administration Background Document for the Food Advisory Committee, *op. cit.*
- ⁶² Stevens LJ, Kuczek T, Burgess JR, et al. Dietary sensitivities and ADHD symptoms: thirty-five years of research. *Clin Pediatr (Phila)*. 2011;50(4):279-93. doi: 10.1177/0009922810384728.
- ⁶³ Nigg JT, Lewis I, Ediinger T, et al. Meta-analysis of attention-deficit/hyperactivity disorder or attention-deficit/hyperactivity disorder symptoms, restriction diet, and synthetic food color additives. *J Am Acad Child Adolesc Psychiatry.* 2012; 51(1):86-97.e8. doi: 10.1016/j.jaac.2011.10.015
- ⁶⁴ Arnold LE, Lofthouse N, Hurt E. Artificial food colors and attention-deficit/hyperactivity symptoms: Conclusions to dye for. *Neurotherapeutics.* 2012 (Jul);9(3):599-609. doi: 10.1007/s13311-012-0133-x.
- ⁶⁵ Sonuga-Barke EJ, Brandeis D, Cortese S, et al. Nonpharmacological interventions for ADHD: systematic review and meta-analyses of randomized controlled trials of dietary and psychological treatments. *Am J Psychiatry.* 2013; 170(3):275–89. doi: 10.1176/appi.ajp.2012.12070991.
- ⁶⁶ Arnold LE, Hurt E, Lofthouse N. Attention-deficit/hyperactivity disorder: dietary and nutritional treatments. *Child Adolesc Psychiatr Clin N Am.* 2013; 22(3): 381–402, v. doi: 10.1016/j.chc.2013.03.001.
- ⁶⁷ Stevenson J, Buitelaar J, Cortese S, et al. Research Review: The role of diet in the treatment of attention-deficit/hyperactivity disorder – an appraisal of the evidence on efficacy and recommendations on the design of future studies. *J Child Psychol Psychiatry.* 2014;55(5):416-27. doi:10.1111/jcpp.12215.
- ⁶⁸ Faraone SV, Antshel KM. Towards an evidence-based taxonomy of nonpharmacologic treatments for ADHD. *Child Adolescent Psychiatr Clin N Am.* 2014; 23(4):965–972. doi: 10.1016/j.chc.2014.06.003.
- ⁶⁹ Nigg, JT, Holton, K. Restriction and elimination diets in ADHD treatment. *Child Adolesc Psychiatr Clin N Am.* 2014 Oct;23(4):936-53. doi: 10.1016/j.chc.2014.05.010.
- ⁷⁰ American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders: DSM-5. American Psychiatric Association. 2013.
- ⁷¹ Nigg JT, Lewis I, Ediinger T, et al, *op. cit.*
- ⁷² Stevens LJ, Kuczek T, Burgess JR at al. Dietary sensitivities and ADHD symptoms: thirty-five years of research. *Clin Pediatr.* 2011;50(4):279-93. doi: 10.1177/0009922810384728.
- European Union. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF>.
- ⁷⁴ Doull DL, Folmer DE, Lee HS, Carberry SW. Exposure estimate for FD&C color additives for the U.S. population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* 2016;33(5):782-97. doi: 10.1080/19440049.2016.1179536.
- ⁷⁵ Batada A, Jacobson MF. Prevalence of artificial food colors in grocery store products marketed to children. *Clin Pediatr (Phila)* 2016;55(12): 1113-9. doi: 10.1177/0009922816651621.

-
- ⁷⁶ Greenwood DC, Thatcher NJ, Ye J et al. Caffeine intake during pregnancy and adverse birth outcomes: a systematic review and dose–response meta-analysis. *Eur J Epidemiol.* 29(10):725 - 734. doi: 10.1007/s10654-014-9944-x.
- ⁷⁷ Cheng J, Hong S, Zhu R et al. Maternal coffee consumption during pregnancy and risk of childhood acute leukemia: a metaanalysis. *Am J Obstet Gynecol.* 2014 Feb;210(2):151.e1-151.e10. doi: 10.1016/j.ajog.2013.09.026
- ⁷⁸ Looker AC, Wang CY. Prevalence of reduced muscle strength in older U.S. adults: United States, 2011–2012. *NCHS Data Brief.* 2015;(179):1-8.3
- ⁷⁹ The Diagnostic and Statistical Manual of Mental Disorders, § 305.90 (Am. Psychiatric Association 5th ed.) (2013).