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U.S. Department of Agriculture
U.S. Department of Health and Human Services

Re: Development of the 2020-2025 Dietary Guidelines for Americans.

As a nutritional scientist long involved in feeding infants and young children, I very much appreciate the opportunity to provide comments on the Dietary Guidelines under development. I have been a member of the American Society for Nutrition, originally the American Institute of Nutrition, for the past 47 years. I worked in research and development and also general management in the infant and toddler food industry from 1965 until retiring in 1999. Currently I consult in nutrition and food processing, especially of organic foods. In 1992 I was appointed to a three-year term on the inaugural National Organic Standards Board, an advisory board to the U. S. Secretary of Agriculture. My academic affiliation since 2000 is as an Adjunct Professor in the Department of Food, Bioprocessing and Nutrition Sciences at North Carolina State University.

I had three major responsibilities during the sixteen years 1983 to 1999 that I worked in the baby food industry: to improve baby food quality, especially nutritional quality (we were the first major producer to eliminate chemically modified starch from the entire line and to remove added sugar from fruit products); to manage regulatory affairs; and to provide scientific and pediatric nutritional information for a consumer hotline fielding up to 180,000 phone calls a year from the mothers (mostly) of infants and young children. I served on the Technical Advisory Group (TAG) to the Committee on Nutrition of the American Academy of Pediatrics from 1984 until the TAG was disbanded in 1995.

I do not currently consult for any infant formula or baby food manufacturer and have not done so in the past five years. My comments reflect only my personal and professional perspective and learning over the past 50+ years.

Extending the Dietary Guidelines for Americans to dictate infant feeding practices during the first two years of life must be done cautiously. Fifty to sixty years ago a common pediatric recommendation was to feed pasteurized cow's milk to young infants who were not breast-fed. It took years to recognize the resulting high prevalence of iron deficiency, with and without anemia, and to end this inappropriate practice. Introducing complementary foods as early as the first month of life, a common occurrence fifty years ago, had its negative consequences. However, delaying the introduction beyond six months of age can have different unforeseen consequences.

Recommended duration of exclusive human milk or infant formula feeding

The current emphasis on breast feeding, with infant formula as the only appropriate substitute for human milk is appropriate. However, since exclusive breast-feeding for the first six months or longer by mothers with diabetes during pregnancy significantly reduces the risk of childhood obesity in their infants (Crume, Ogden, Daniels, et al., 2011; Crume, Ogden, Maligie, et al., 2011; Crume et al., 2012), feeding infant formula to these infants in the first six months should be actively discouraged and exclusive breastfeeding should be strongly encouraged.

A frequent question that new mothers ask their pediatrician and that they also ask on a baby food manufacturer's hotline is: "when can I start feeding solid foods?" The authoritative source is the "Pediatric Nutrition Handbook" (PNH) published by the American Academy of Pediatrics (AAP). This AAP has taken two paths to answer to this question, an older one based on infant development and a recent one more focused on the benefits of exclusive breast feeding. The developmental aspects are succinctly discussed in the second edition of PNH (page 29), where it talks to the loss of the extrusion reflex and the ability to swallow non-liquid foods by 4 to 5 months of age, and the infant's behavior indicating his or her interest in complementary foods by 5 to 6 months of age. In the PNH sixth edition (page 31), the AAP recommends exclusive breast feeding for a minimum of 4 months but preferably for 6 months and continued breastfeeding at least through the first 12 months of age.

Observational studies confirm that introducing complementary foods prior to four months of age is inappropriate. Among formula-fed infants, introduction of solid foods before 4 months was associated with a six-fold increase in odds of obesity at age 3 years (Huh, Rifas-Shiman, Taveras, Oken, & Gillman, 2011).

The one-month difference between the WIC operational definition of the "pre-complementary food infant" (birth through five months) and the AAP recommendation (birth through four months) may have a long-term health outcome of reduced appetite for vegetables throughout the lifespan. An important dietary guideline for American children and adults is to consume more vegetables. In the second half of the first year of life and in the second year of life, toddlers can become "picky eaters." A major reason why is that the toddler is unfamiliar with a new food: "I don't like it. I never tried it" (Birch & Marlin, 1982). To avoid this issue, it is important for infants to "learn" a variety of foods during their 'taste test window'. Delaying the introduction of complementary foods beyond the period when the infant is developmentally ready for them may cause "picky eating." Beginning complementary foods at four months versus six months had no effect on the food preferences of low-income Honduran children in the second six months of life, with one important exception: infants beginning complementary foods at 4 months consumed more vegetables at 9 months of age (Cohen, Rivera, Canahuati, Brown, & Dewey, 1995).

The AAP recommendation for the introduction of complementary foods stresses the need to introduce one single-ingredient new food at a time and not to introduce other new foods for 3 to 5 days in order to observe for possible allergic reactions. Consequently, this is a very slow process: no more than two new foods a week. Moreover, mothers are guided by the facial reactions of their infant. Foods that taste sweet, both fruits like apples, pears, and bananas, and vegetables like sweet potatoes, squash, and peas (if picked early), generate a smile! Several vegetables, however, like green beans or carrots, have a bitterness that elicits a frown. It takes several exposures – as many as ten – to teach an infant that he or she likes green beans (Sullivan and Birch 1994). If started too late, familiarity with certain vegetables may never happen! Appropriately, the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Committee on Nutrition specifically recommends that Infants should be offered foods with a variety of flavors and textures including bitter tasting green vegetables (Fewtrell et al., 2017). Perhaps we should adapt the French approach to complementary feeding, as providing the foundation of taste ("donner les bases du gout"), to adapt to the family's diet by educating the palate with a variety of different foods, which is considered important for children's later eating habits (Schwartz et al., 2013).

Breast-fed infants are more likely to enjoy vegetables with some bitterness if their mother has consumed this food during pregnancy or lactation (Hetherington et al., 2015; Mennella, Daniels, & Reiter, 2017; Mennella, Jagnow, & Beauchamp, 2001). This may justify a mention in the dietary guidelines for pregnancy and lactation that consuming a wide variety of vegetables during these periods may improve the infant's acceptance of vegetables.

The USDA regulations for the WIC package for infants at 7CFR246.9 (e)(1) and (e)(9) describe several food packages for infants less than 6 months old of age (i.e., "infants birth through 5 months" thus infants aged less than 153 days of age). None of these packages have any complementary foods. Consequently, the WIC package is inconsistent with the AAP position that introduction of solid foods at 4 months of age (in the fifth month of life) is permissible. When the infant shows an interest in complementary foods, he or she should be fed them. Infants economically dependent on the WIC food package should not be deprived of this choice.

Dietary supplements for infants - Iron

Full-term infants born to healthy mothers have an iron endowment that lasts four to six months as the infant "bleeds into his or her growing blood volume," so the Adequate Intake (AI) of iron in the first six months of life is only 0.27 mg/day (IOM (Institute of Medicine), 2001), an amount provided by human milk which contains about 0.35 to 0.5 mg/L. The iron in human milk is very bioavailable.

During the second six months of life, the Estimated Average Requirement (EAR) is DRI of iron is 6.9 mg/day and the Recommended Dietary Allowance (RDA) is 11 mg/day, forty times greater than the AI for the first six months. Given the iron content of most American iron-fortified infant formulas (1.9 mg/100kcal) and its caloric density (67 kcal/100 mL), consuming 540 mL of this formula provides the EAR of 6.9 mg/day of iron along with 360 kcal. The Estimated Energy Requirement EER) at ages 6 to 12 months is 645 to 844 kcal/day for boys and 593 to 764 kcal for girls (IOM (Institute of Medicine), 2005), so the amount of iron fortified formula required to satisfy the need for iron "leaves room" for the infant to learn the taste and texture of the foods consumed by the family.

The traditional complementary food for providing iron to American infants is iron-fortified infant cereal, which can be started in the fifth month of life (at four months of age). Iron-fortified infant cereal is provided in the WIC package for older infants starting only in the sixth month of life [7CFR246.10], when the infant is five months of age.

The usual iron source in these cereals is electrolytically reduced iron of small particle size ("electrolytic iron"). We have shown that ascorbic acid-containing infant cereals made with either electrolytic iron or ferrous fumarate are equally efficacious for maintaining iron status in breast-fed older infants (Ziegler, Fomon, Nelson, Jeter, & Theuer, 2011).

Another food that provides bioavailable iron is red meat (Engelmann, Sandstrom, & Michaelsen, 1998; Krebs, 2007; Krebs et al., 2006; Tang, Sheng, Krebs, & Hambidge, 2014). Note that poultry meat does not have the same hematological effect (Moshe et al., 2013). Red meat-containing complementary foods are available in the United States. The USDA/FSIS Food Standards and Labeling Policy Book establishes the standards for meat- and poultry-containing baby foods. (Non-poultry (red) meat is expressed on a raw basis; poultry is expressed on a cooked basis. The cooked yield of raw meat is about 70%.

- Meat and Broth - At least 61 percent raw meat.
- Poultry with Broth - At least 43 percent cooked poultry meat, skin, and giblets.

- High Meat Dinner: At least 26 percent raw meat.
- High Meat Poultry Dinner - At least 18.75 percent cooked poultry meat, skin, fat and giblets.
- Vegetable with Meat - At least 8 percent raw meat.
- Poultry and Rice - At least 5 percent cooked deboned poultry meat [equal to 7% to 8% raw].

Red meat-containing baby foods provide bioavailable iron, especially a “Meat and Broth” (pureed meat) product (Dewey, 2001). In the United States, the “Vegetable with Meat” and “Poultry with Rice” type baby foods, both of which contain 7% or 8% raw ‘meat,’ are most popular because baby foods containing the higher ‘meat’ contents have unique flavors, an arguably strange aroma, and a higher cost. In Germany, where meat-containing complementary foods are relied upon to satisfy the breast-feeding infant’s need for iron to a greater degree than in the U.S., complementary foods with 8% red meat were found to be inferior for maintaining iron status in older breast-feeding infants compared to complementary foods containing 12% meat foods (Dube, Schwartz, Mueller, Kalhoff, & Kersting, 2010).

Krebs (Krebs, 2014; Krebs et al., 2006) pointed out that meat products provide zinc as well as iron. Older breastfed infants depend upon complementary food choices to meet their requirements for both of these two critical micronutrients. Zinc requirements for older breastfed-only infants are unlikely to be met without the regular consumption of either meats or zinc-fortified foods (Krebs et al., 2013).

The current WIC food packages for infants from birth through five months provide iron-fortified infant formula for those infants not completely breast feeding, even though the infant has his or her birthright iron endowment which should suffice for most or all of this period. The bioavailability of the iron in iron-fortified soy-based infant formulas (Theuer, Kemmerer, Martin, Zoumas, & Sarett, 1971) and milk-based infant formulas (Theuer, Martin, Wallander, & Sarett, 1973) is high. Although AAP “sees no role for the use of low-iron formulas in infant feeding and recommends that all formulas fed to infants be iron-fortified” (PNH 6th Ed., p. 71), recent research suggests that the level of iron in iron-fortified infant formulas sold in the United States may be excessive (Lonnerdal, 2017), especially in the first six months of life. Deoni et al. (Deoni, Dean, Joelson, O'Regan, & Schneider, 2017) found significantly improved overall myelination in breastfed children accompanied by increased general, verbal, and non-verbal cognitive abilities compared to children who were exclusively formula-fed. These differences were found to persist into childhood even with groups matched for important socioeconomic and demographic factors. They also reported significant developmental differences depending on formula composition received and that the iron level in infant formula was significantly associated with early myelination trajectories.

The current FDA requirement [21CFR107.100(a)] for an infant formula labeled “with iron” is not more than 3 milligrams of iron per 100 kilocalories. An infant formula not labeled as “with iron” must contain not less than 0.15 milligrams of iron per 100 kilocalories, which is about twice the level of iron in breast milk. Most iron-fortified infant formulas in the United States currently contain iron at 12 mg/qt., or 1.9 mg/100 kcal. Historically, some U.S. infant formulas with iron contained 8 mg/qt., equivalent to 1.25 mg/100kcal. In Europe, the ESPGHAN Committee on Nutrition recommends an iron fortification range of 4 to 8 mg/L, equivalent to 0.6 to 1.2 mg/100 kcal (Domellof et al., 2014).

The FAO/WHO Codex Alimentarius Commission international standard for any infant formula requires a minimum iron content of 0.45 mg/100 kcal, equivalent to 3 mg/L, and leaves the maximum to be set by national authorities.

USDA and HHS (specifically FDA) may wish to ask the Committee on Nutrition of the AAP to review the upper limit of iron in iron-fortified infant formula.

USDA/FSIS may wish to review the current standards for the minimum meat and poultry contents of baby foods.

As a final comment on supplementary iron for infants, be aware that the term “supplement” in normal conversation is considered by many people to be synonymous with the term “nutritional supplement,” which connotes a pharmaceutical dosage form of a vitamin or mineral. Relevant to the micronutrient iron, ferrous sulfate drops have been used as an infant supplement for over half a century to prevent anemia and to treat iron deficiency. In fact, the U.S. Pharmacopeia has a standard Ferrous Sulfate Syrup formulation that provides 7.5 to 8.5 mg of iron per milliliter. However, iron supplements are one of the most common causes of childhood poisoning. Packages of all preparations that contain iron for use as dietary supplements or for therapeutic purposes must prominently and conspicuously display this warning: "**WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.**" I urge those creating the 2020-2025 Dietary Guidelines not to mention the term “iron supplements” in the guidelines. Iron-fortified formula and iron-containing complementary foods, such as iron-fortified infant cereals and pureed red meat compositions (if the meat level is high enough), are appropriate weaning foods that provide available iron to infants and toddlers.

Beverages (cow’s milk, water, 100% fruit juice, sugar-sweetened beverages, milk alternatives)

Beverages for infants – “milk”

The AAP recommendation for the “milk” fed in the first year of life is clear: only breast milk or infant formula are appropriate: “Withhold cow milk and other ‘milks’ not specifically formulated for infants during the first year of life” (PNH 6th Ed. P. 132). The PNH cites usage rates for cows’ milk of as high as 20% at 9 to 11 months of age and almost 1.7% of these older infants consumed ‘soy milk’ based on 2002 feeding survey data.

Beverages for the second year of life – “milk”

The AAP recommendation for the “milk” fed in the second year of life is equally clear. The AAP states (PNH, 6th Ed., p.132): “. . . when cow milk is introduced at 1 year of age, only whole cow milk, not reduced fat alternatives, should be offered” and warns that “. . . data from the FITS show that approximately one quarter of the cow milk served to infants and toddlers was reduced fat.” Grimes et al. (Grimes, Szymlek-Gay, & Nicklas, 2017) analyzed the data of 2740 toddlers 12 to 24 months of age in the 2005-2012 NHANES population and found that the most commonly consumed beverage, consumed by 83.6% of these children, was plain milk: 63% used whole milk and 25% used partially or totally skimmed milk.

The WIC regulations at 7CFR246.10(e)(10) Table 2, footnote 7 state: “Whole milk is the standard milk for issuance to 1-year-old children (12 through 23 months).” However, the regulation continues: “At State agency option, fat-reduced milks may be issued to 1-year-old children for whom overweight or obesity is a concern. The need for fat-reduced milks for 1-year-old children must be based on an individual nutritional assessment and consultation with the child's health care provider if necessary, as established by State agency policy.” This exception is consistent with the AAP statement: “for children between 12 months and 2 years of age, low-fat dairy products should be considered for children with a body mass index (BMI) at the 85th percentile or greater or a family history of obesity." Unfortunately, this is an inappropriate exception in my judgment, which I document below.

Beverages for two-year-olds and older – "milk"

The most recent edition (2015-2020) of the Dietary Guidelines for Americans includes a "Key Recommendation" that "A healthy eating pattern includes . . . Fat-free or low-fat dairy, including milk, yogurt, cheese, and/or fortified soy beverages." This recommendation has great influence on medical recommendations and Federal food policy. For example, in a recent recommendation, the American Academy of Pediatrics provides a "Sample Menu for a Two-Year-Old" and discusses "Milk and milk products." "Milk, yogurt, cheese, and other milk products supply calcium for building and maintaining strong bones and teeth and protecting bones from osteoporosis. Children need 2 to 3 servings per day. Children ages 1 to 2 need whole milk. After age 2, children should gradually increase the proportion of low-fat foods in their diets."

The AAP recommendation for the "milk" fed in subsequent years parallels the diktat of the U.S. Dietary Guidelines: "help children 2 to 8 years consume 2 cups per day of fat-free or low-fat milk or equivalent milk produc3ts and help children 9 years of age and older consume 3 cups a day." The WIC regulation at 7CFR246.10(e)(10) Table 2, footnote 7 states: "Lowfat (1%) or nonfat milks are the standard milk for issuance to children ≥24 months of age and women. Reduced fat (2%) milk is authorized only for participants with certain conditions, including but not limited to, underweight and maternal weight loss during pregnancy. The need for reduced fat (2%) milk for children ≥24 months of age (Food Package IV) and women (Food Packages V-VII) must be based on an individual nutritional assessment as established by State agency policy."

The reason given in support of feeding fat-free and low-fat milk to children is to promote health and to reduce the risk of major chronic diseases, including obesity. Indeed, reduced fat milk does play a role in overweight and obesity among children . . . by making it more likely! Recent research documents that children consuming reduced fat milks are MORE likely to be overweight or obese and to become overweight or obese.

Fortunately, despite the "Dietary Guidelines for Americans," most parents do not feed their young children low-fat or no-fat milk. Scharf et al (Scharf, Demmer, & DeBoer, 2013) found that the majority of young children drank whole or 2% milk (87% at 2 years, 79.3% at 4 years). O'Connor et al. (O'Connor, Yang, & Nicklas, 2006) studied preschool children and found that 83% of children drank milk, with whole milk being consumed by 46.5% of the children, and only 3.1% and 5.5% of the children consuming skim milk and 1% milk, respectively. Preschool children consumed a mean total beverage volume of 26.93 oz. per day, which included 12.32 oz. of milk.

Unfortunately, once children go to school or to a daycare setting that must comply with Federal rules, parents lose control over the beverage consumed by their children. The USDA Child Care Meal Pattern requires that "Milk served must be low-fat (1%) or non-fat (skim) for children ages 2 years and older and adults." Only low-fat milk and no-fat milk (and recently sugar-sweetened chocolate-flavored skim milk) are permitted in the School Lunch Program.

The “Dietary Guidelines for Americans,” which are intended to protect Americans from chronic diseases related to obesity, are misguided! The notion that milk with more fat makes kids have more fat is wrong.

O’Connor et al. (O'Connor et al., 2006) reported no clinically significant association between the types of milk (percentage of fat) consumed and weight status in preschool-aged children. More recent research strongly suggests that whole milk actually is superior to non-fat and low fat (1% fat) milk for avoiding obesity in children, an important cardiovascular benefit of superior childhood nutrition. Barba et al. (2005) found that milk consumption was significantly and inversely associated with Body Mass Index (BMI, a measure of obesity) z score (t=-2.791, P=0.005) in young school-age children consuming whole milk (more whole milk, less obese), when controlling for age and the frequency of consumption of various foods. However, the association between more milk and less obesity was no longer significant (P=0.21) when children consuming skimmed milk were included in the analysis.

Milk provides calcium and virtually all cows’ milk sold in the United States is fortified with Vitamin D3. Vanderhout et al. (Vanderhout, Birken, Parkin, Lebovic, Chen, O’Connor, et al., 2016) found that healthy young Canadian children 12 to 72 months of age who consumed vitamin D fortified whole milk had higher vitamin D stores and also lower BMI than children who consumed vitamin D fortified reduced-fat milks. Scharf et al. (Scharf et al., 2013) found that, in comparison to 2- and 4-year-old children drinking 2% or whole milk, those drinking 1% fat or skim milk had an increased adjusted odds ratio (OR) of being overweight (age 2 OR=1.64, p<0.0001; age 4 OR=1.63, p<0.0001) or obese (age 2 OR=1.57, p<0.01; age 4 OR=1.64, p<0.0001). Huh et al. (Huh, Rifas-Shiman, Rich-Edwards, Taveras, & Gillman, 2010) found that a higher intake of whole milk at age 2, but not reduced-fat milk, was associated with a slightly lower BMI z score (-0.09 unit per daily serving [95% confidence interval: -0.16 to -0.01]) at age 3 years. Berkey et al. (Berkey, Rockett, Willett, & Colditz, 2005) found that milk fat consumption was not associated with weight changes in adolescents, but they did find that higher consumption of 1% milk (boys) or skim milk (girls) was linked to greater BMI increase. Among British children in the Avon Longitudinal Study of Parents and Children, those in the highest quartile of dairy fat intake at age 10 had lower risk of excess total body fat mass at age 13 and lower gains in BMI (Bigornia et al., 2014).

Commenting on the Vanderhout study, Rolland-Cachera et al. (Marie Françoise Rolland-Cachera, Briend, & Michaelsen, 2017) noted that inverse associations between fat intake and later overweight have been reported previously. In a 2-decade-long follow-up study (M. F. Rolland-Cachera et al., 2013), a low fat intake at the age of 2 y was associated with high fat mass and leptin concentrations at 20 y, suggesting that fat restriction in early life may have activated adaptive mechanisms to store energy, thus increasing the susceptibility to later overweight, metabolic diseases, and leptin resistance. Likewise, a negative association between fat intake and BMI was reported in subjects followed from the age of 2-18 y in the DONALD (DOrtmund Nutritional and Anthropometric Longitudinally Designed Study) longitudinal study (Alexy, Sichert-Hellert, Kersting, & Schultze-Pawlitschko, 2004). Also, a recent study showed that the benefits of breastfeeding on reducing the risk of obesity could be related to the high fat content of breast milk: the fat percentage in breast milk was inversely correlated to 3- to 12-mo gains in weight, BMI, and adiposity (Prentice et al., 2016). These results are consistent with reviews of the literature that reported either no deleterious effect or even favorable effects of high fat consumption in adults (Kratz, Baars, & Guyenet, 2013) and that even a relatively high-fat diet in young children does not seem to lead to later unfavorable health conditions (Agostoni & Caroli, 2012).

It can be argued that a correlation of reduced-fat milk consumption and increased BMI is not necessarily causal and that even if it is causal, it is not obvious which is the cause and which is the effect. Some have suggested that any causality may not be that reduced-fat milk causes a higher BMI, but that parents may be implementing the pediatric recommendation to provide low-fat milk to their children for whom obesity is a concern. However, it is significant that Scharf et al. (Scharf et al., 2013) found in longitudinal analysis, that children drinking 1% fat or non-fat milk at both 2 and 4 years were more likely to become overweight or obese between these time points (adjusted OR=1.57, $p<0.05$).

In a follow-up study, Beck et al. (Beck, Heyman, Chao, & Wojcicki, 2017) tested the theory that consumption of non- or low-fat dairy products lowers the risk of childhood obesity. Twenty-four-hour recall data for 145 Mexican American children, of whom 17% were severely obese, were analyzed to determine participants' consumption of whole milk, 2% milk, and 1% milk. Milk consumption data were used to calculate grams of milk fat consumed. Severely obese children had a lower mean intake of milk fat (5.3 g vs. 8.9 g) and fewer drank any milk (79% versus 95%) than children who were not severely obese.

Whole cows' milk provides children with an additional nutritional advantage because the fat facilitates the absorption of fat-soluble vitamins. The "Dietary Guidelines for Americans" are intended to protect Americans from chronic diseases such as osteoporosis and cardiovascular disease. Vitamins D and K, two fat-soluble vitamins, and the mineral calcium are directly involved in both osteoporosis and cardiovascular disease.

Karpinski et al (2017) reviewed the beneficial role of vitamin K, particularly vitamin K2 as menaquinone-7 (MK-7), in bone and cardiovascular health, particularly as it relates to subclinical insufficiency of vitamins D and K in otherwise healthy pediatric populations with low-energy bone fractures. It is well-established that children who do not drink milk are shorter and have more low-energy bone fractures than milk-drinking children (Goulding 2004; Rockell 2005).

As noted above, Vanderhout et al. (Vanderhout, Birken, Parkin, Lebovic, Chen, O'Connor, et al., 2016) found that children consuming full-fat milk had higher vitamin D stores than children consuming reduced fat milks, despite both types of milk being vitamin D fortified. They suggested that absorption of a fat-soluble vitamin depends upon the total amount of fat it is dissolved in. Vanderhout et al. (Vanderhout, Birken, Parkin, Lebovic, Chen, O'Connor, et al., 2016) further demonstrated that children over 2 years of age who drank 1% milk needed 2.46 cups (95% confidence interval (CI) 2.38-2.54) of milk to have a 25(OH)D concentration similar to that of children who drank 1 cup of homogenized full-fat milk (3.25% fat). Children who consumed 1% milk had 2.05 (95% CI 1.73-2.42) times higher odds of having a 25(OH)D concentration <50 nmol/L compared with children who consumed whole milk.

In contrast to vitamin D, vitamin K is not added to milk so the concentration of this fat-soluble vitamin in milk is directly related to the fat level. Fu et al. (Fu et al., 2017) analyzed U.S. milk samples and found mean total vitamin K contents of full-fat milk, 2%-fat milk, 1%-fat milk, and fat-free milk to be 38.2 ± 2.7, 19.5 ± 2.4, 13.0 ± 0.6, and 5.2 ± 0.9 mg/100 g, respectively. Full-fat milk was the only type that contained K1 (phylloquinone); all milks contained K2 (menaquinones), principally subtypes MK-9 and MK-11. Adequate Intakes (AI) of vitamin K established for children and adolescents (IOM 2001) are 30 mcg/d for children 1-3 y, 55 mcg/d for children 4-8 y, 60 mcg/d for boys and girls 9 to13 y, and 75 mcg/d for adolescents 14 to 18 y. An eight- ounce serving of whole milk provides 90 mcg of vitamin K2, compared to only about 13 mcg per serving of fat-free milk.

Vitamin K dependent proteins have been demonstrated to inhibit vascular calcification and thus maintain arterial elasticity (Theuwissen et al., 2012). Douthit et al. (Douthit et al., 2017) found that the prevalence of left ventricular (LV) hypertrophy in adolescents progressively decreased across tertiles of phylloquinone intake ($P < 0.01$). The adjusted Odds Ratio (OR) for LV hypertrophy was 3.3 (95% CI: 1.2, 7.4) for those in the lowest phylloquinone intake tertile. Cardiac function and structure variables were most favorable at higher phylloquinone intakes.

Adults receiving vitamin K supplementation during a 3-year period maintained vascular elasticity of the common carotid artery, whereas a control group experienced a 12% loss of arterial elasticity (Braam et al., 2004). Geleijnse et al. (Geleijnse et al., 2004) investigated whether dietary intake of phylloquinone (vitamin K-1) and menaquinones (vitamin K-2) were related to aortic calcification and coronary heart disease (CHD) in the population-based Rotterdam Study. The analysis included 4807 subjects with dietary data and no history of myocardial infarction at baseline (1990-1993) who were followed until January 1, 2000. The relative risk (RR) of CHD mortality was reduced in the mid and upper tertiles of dietary menaquinones compared to the lower tertile [RR = 0.73 (95% CI: 0.45, 1.17) and 0.43 (0.24, 0.77), respectively]. Intake of menaquinones was also inversely related to all-cause mortality [RR = 0.91 (0.75, 1.09) and 0.74 (0.59, 0.92), respectively] and severe aortic calcification [odds ratio of 0.71 (0.50, 1.00) and 0.48 (0.32, 0.71), respectively]. Vitamin K1 (phylloquinone) intake was not related to any of these outcomes.

Gast et al. (Gast et al., 2009) followed 16,057 Dutch women, enrolled between 1993 and 1997 and aged 49-70 years, who were free of cardiovascular diseases at baseline. Intake of vitamin K and other nutrients was estimated with a food frequency questionnaire. Multivariate Cox proportional hazards models were used to analyze the data. After a follow-up of 8.1 ± 1.6 years, they identified 480 incident cases of coronary heart disease. Mean intake of vitamin K1 (phytonadione) was 212 ± 100 mcg/d and mean intake of vitamin K2 (menaquinones) was 29 ± 13 mcg/d. They observed an inverse association between intake of vitamin K2 and risk of Coronary Heart Disease (CHD) with a Hazard Ratio of 0.91 [95% CI 0.85-1.00] per 10 mcg/d vitamin K2 intake. This association was mainly due to vitamin K2 subtypes MK-7, MK-8 and MK-9. Vitamin K1 intake was not significantly related to CHD. Knapen et al. (Knapen et al., 2015) provided MK-7 supplements or placebo to healthy postmenopausal women for 3 y and found that MK-7 reduced arterial stiffness, especially in women who had high arterial stiffness at the outset of the study.

Using the 2005-2012 NHANES database to determine the most commonly consumed beverages by toddlers 12-24 months, Grimes et al. (Grimes et al., 2017) identified plain milk (83.6% of children consuming; 63% whole milk and 25% partially or totally skimmed)), water (68.6%), 100% fruit juice (51.8%) and sweetened beverages (31.2%). Non-Hispanic black and Mexican-American children were more likely to consume sweetened beverages and 100% fruit juice than Non-Hispanic white children. Children from lower income households were more likely to consume sweetened beverages and 100% fruit juice than children from higher income households. As noted above, higher milk fat consumption is associated with lower odds of severe obesity among Latino preschoolers (Beck et al., 2017).

Childhood and adolescence are periods of growth and increase in lean body mass. Protein in whole milk has increased utilization of available amino acids for protein synthesis than the same amount of protein provided as fat-free milk (Elliot, Cree, Sanford, Wolfe, & Tipton, 2006).

The most critical question is whether the provision of low-fat and non-fat milk and the prohibition of whole milk in every Federally funded child feeding program has reduced obesity and cardiovascular disease among American children and adolescents. Based on NHANES surveys, the answer is NO. An international survey of overweight and obesity among youths 10 to 16 years found that the two countries with the highest prevalence of overweight (85th to 95th percentile) and obese (≥ 95th percentile) youth were Malta (17.5% and 7.9%) and the United States (18.3% and 6.8%) (Janssen et al., 2005).

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations of a nationally representative sample. The sponsoring U.S. federal agency is the National Center for Health Statistics in the Centers for Disease Control and Prevention ("CDC"). Based on NHANES data collected from 2- to 17-year-olds in four examinations (1971-1974 through 1999-2002), black children experienced much larger secular increases in BMI, weight, and height than did white children. Over the 30-year period, the prevalence of overweight increased approximately 3-fold (4% to 13%) among 6- to 11-year-old white children but 5-fold (4% to 20%) among black children. In most sex-age groups, Mexican-American children experienced increases in BMI and overweight that were between those experienced by blacks and whites. Race/ethnicity differences were less marked among 2- to 5-year-olds. In this age group, white children experienced the largest increase in overweight (from 4% to 9%). In 1999-2002, the prevalence of extreme BMI levels (> or =99th percentile) reached 6% to 7% among black girls and Mexican-American boys (Freedman, Khan, Serdula, Ogden, & Dietz, 2006).

Ogden (Ogden, Flegal, Carroll, & Johnson, 2002) compared the prevalence of overweight and obesity among a national sample of 4722 children from birth through 19 years of age in NHANES 1999-2000 with the prevalence found in NHANES III (1988-1994). Obesity among those aged 2 through 19 years was defined as a sex-specific body mass index (BMI) for age at or above the 95th percentile. The prevalence of obesity in 1999-2000 was 15.5% among 12- through 19-year-olds, 15.3% among 6- through 11-year-olds, and 10.4% among 2- through 5-year-olds, compared with 10.5%, 11.3%, and 7.2%, respectively, in 1988-1994 (NHANES III). Ogden et al. (Ogden et al., 2006)) reported that, in 2003-2004, 17.1% of US children and adolescents were overweight. Tests for trend were significant for male and female children and adolescents, indicating an increase in the prevalence of overweight in female children and adolescents from 13.8% in 1999-2000 to 16.0% in 2003-2004 and an increase in the prevalence of overweight in male children and adolescents from 14.0% to 18.2%. Ogden et al. (Ogden, Carroll, & Flegal, 2008) reported that the prevalence of high BMI for age among children and adolescents showed no significant changes between 2003-2004 and 2005-2006 and concluded that there were no significant trends between 1999 and 2006.

Flegal et al. (Flegal, Ogden, & Carroll, 2004) described the trends in overweight and obesity occurring in the Mexican-American population in the United States between 1982 and 2002. The prevalence of overweight (BMI ≥ 85th percentile) in children and adolescents 6 to 19 years of age essentially doubled in this twenty-year period to 40%, with 22% meeting the criterion of obese (BMI ≥ 95th percentile). The prevalence of obesity among non-Hispanic black and Mexican-American adolescents increased more than 10 percentage points between 1988-1994 and 1999-2000 (Ogden et al., 2002).

Overweight and obesity in children are major risk factors for undesirable blood lipid levels. Desirable blood lipid levels are low total cholesterol, high high-density lipoprotein (HDL) cholesterol, low non-HDL cholesterol, and low triglycerides. The 2011-2014 NHANES survey found that overweight and especially obese children and adolescents had a much greater prevalence of undesirable blood cholesterol levels (Nguyen, Kit, & Carroll, 2015):

- The prevalence of high total cholesterol was greater in children and adolescents with obesity (11.6%) than in those of normal weight (6.3%) and in those who were overweight (6.9%).
- The prevalence of low HDL cholesterol increased with increased body mass index (BMI). The prevalence of low HDL cholesterol among children and adolescents with obesity (33.2%) was almost five times higher than for children and adolescents of normal weight (6.8%) and over twice as high as the prevalence among children and adolescents who were overweight (14.8%).
- High non-HDL cholesterol prevalence increased with increased BMI, and the prevalence among children and adolescents with obesity (16.7%) was almost three times higher than those of normal weight (5.7%) and about 80% higher than those who were overweight (9.7%).

Body Mass Index (BMI) is calculated as weight in kilograms divided by height in meters squared, rounded to one decimal place. The age- and sex-specific percentiles of the 2000 CDC growth charts were used to categorize BMI. BMI percentiles were categorized as follows: at or above 5th to less than 85th (normal weight), at or above 85th to less than 95th (overweight), and at or above 95th (obese). High non-HDL cholesterol was defined as serum non-HDL cholesterol at or above 145 mg/dl., high total cholesterol was defined as serum total cholesterol at or above 200 mg/dl, and low HDL cholesterol was defined as serum HDL cholesterol less than 40 mg/dl (Expert Panel on Integrated Guidelines for Cardiovascular, Risk Reduction in, Adolescents, National Heart, & Blood, 2011).

Beverages for infants, and young children – plant (“non-cow) milks

In the past two decades, plant-based ‘milks’ have become popular, including ‘rice milk’ and ‘almond milk’ as well as ‘soy milk.’ Although many parents choose these non-cow milk beverages because of perceived health benefits, they are nutritionally inadequate. Milk alternative beverages expose infants to severe nutritional deficiencies. Serious complications can occur. Early, exclusive, and extended use is particularly risky (Keller, Shuker, Heimall, & Cianferoni, 2012; Le Louer et al., 2014; Vitoria, 2017). These ‘milks’ contain less protein and less fat than cow milk. Morency et al. (Morency et al., 2017) used a cross-sectional approach to demonstrate a dose-dependent association between higher non-cow milk consumption and lower height in 5034 children 24 to 72 months of age.

Beverages for infants, and young children – 100% fruit juice

AAP recommends that 100% juice should not be introduced before 6 months of age, should not be given in containers that encouraged extended contact with emerging teeth, and should not be given at bedtime. AAP recommends an upper limit of 4 to 6 fl.oz. of 100% fruit juice for children 1 to 6 years of age. The nutritional rationale for inclusion of the AAP-recommended amount of 100% fruit juice in the WIC package for older infants (Kleinman & Nicklas, 2017) includes the report of Vargas et al., who found that consumption of 100 percent fruit juice is not associated with early childhood dental caries (Vargas et al., 2014), and a review of twenty-two studies on weight status that provides evidence that did not support an association between 100% fruit juice consumption and weight/adiposity in children after controlling for energy intake and also provides limited evidence from eight studies that suggests that children consuming 100% fruit juice have higher intake and adequacy of dietary fiber, vitamin C, magnesium, and potassium (Crowe-White et al., 2016).

Some popular fruit juices contain the non-digestible sugar alcohol sorbitol (2 g/100mL in pear juice and 0.5 g/100mL in apple juice), most 100% fruit juices are hypertonic solutions, and these juices can cause gastrointestinal symptoms in some 1- to 2-year-old children with chronic nonspecific diarrhea (Hyams, Etienne, Leichtner, & Theuer, 1988), especially when fed in amounts greater than recommended by AAP.

Beverages for infants, and young children – sugar-sweetened beverages

Sugar-sweetened beverages displace whole milk in the diet of children, and these are known to encourage obesity (Harrington, 2008; Malik, Schulze, & Hu, 2006). Beck et al. (Beck, Tschann, Butte, Penilla, & Greenspan, 2014)) studied the association of beverage consumption with obesity in Mexican American children (n 319) aged 8-10 years, 20% of whom were overweight (≥ 85th and <95th percentiles of reference BMI) and 31% of whom were obese (≥ 95th percentile). Consuming more servings of sugar-sweetened soft drinks ("soda") was associated with increased odds of obesity (OR = 1.29; P < 0.001). Consumption of sugar-sweetened beverages is associated with increased BMI in pre-school children ((DeBoer, Scharf, & Demmer, 2013; Dubois, Farmer, Girard, & Peterson, 2007) and 10- to 13-year-olds (Bigornia et al., 2015).

Flavored milk is a sugar-sweetened beverage. Flavored milk recently was included by Congress in Federal child feeding programs. Studies in Australia (Fayet, Ridges, Wright, & Petocz, 2013) and the United States (Murphy, Douglass, Johnson, & Spence, 2008) found no effect of flavored milk on obesity but a very positive effect on calcium and other mineral intakes compared to non-milk drinkers. In contrast, a study in England found flavored milk consumption to be associated with less favorable BMI changes (Noel, Ness, Northstone, Emmett, & Newby, 2013).

Adults, ages 19-64 years old and Older adults, ages 65 years and older

Dietary patterns to promote health, prevent disease, and meet nutrient needs

Directly responding to the question "What is the relationship between specific dietary patterns (Dietary Guidelines-related, Mediterranean-style, Dietary Approaches to Stop Hypertension (DASH), vegetarian/vegan, and low-carbohydrate diets) consumed during adulthood and 1) body weight or obesity; 2) risk of cardiovascular disease; 3) risk of type 2 diabetes; and 4) risk of certain types of cancer?" ignores a critical aspect of these diets – a requirement for low-fat and non-fat dairy products – which eliminates consideration of some full-fat dairy products with documented positive effects on body weight and obesity, hypertension and risk of cardiovascular disease and type 2 diabetes.

The past and current Dietary Guidelines insist on low-fat and no-fat dairy, but the American public is becoming aware of the positive nutritional and health effects of full-fat "whole milk" yogurt and other dairy products from articles in the general media. For example, the October 28, 2016 issue of U.S. News and World Report[1] has an extensive article entitled "5 Reasons to Start Eating Full-Fat Dairy, According to Science." The five reasons they list read as follows:

> "1. Easier Weight Loss
>
> "Let's repeat: Fat does not make you fat. No, not even dairy fat. For instance, a 2013 review published in the European Journal of Nutrition found that people who eat full-fat dairy tend to be leaner than those who opt for low-fat versions. And in a 2016-released long-term study of 18,438 middle-aged women, consumption of high-fat dairy, but not low-fat dairy, was associated with reduced likelihood of becoming overweight through the years.
>
> "That may be because fat is an incredibly satiating nutrient, filling you up, slowing down the release of sugars into your bloodstream and helping to prevent overeating, explains Brian Quebbemann, a bariatric surgeon with the Chapman Medical Center in California and president of The N.E.W. Program. "By eating the full-fat form of dairy products, you might actually eat fewer calories throughout the day than you would otherwise," he says.
>
> "2. A Lower Risk of Diabetes
>
> "While maintaining a healthy weight can certainly help lower your risk of developing Type 2 diabetes, research suggest that, all scales being equal, dairy fat may still improve metabolic health. After all, one 15-year study from Tufts University researchers found that, compared to people who eat the least dietary fat, people who eat the most have a 46 percent lower risk of developing Type 2 diabetes.
>
> "One reason: "When someone eats full-fat dairy versus low-fat dairy, the fat will actually delay the absorption of the milk's sugar," says NYC registered dietitian and certified diabetes educator Laura Cipullo, author of "Women's Health Body Clock Diet." As a result, blood sugar rises more slowly over a longer period of time. Consequently, insulin follows this same pattern. Less circulating insulin means less risk for the development of insulin resistance and diabetes." Meanwhile, the study suggests that specific fatty acids contained in dairy, such as pentadecanoic acid and heptadecanoic acid (two odd-carbon fatty acids) may play special roles in risk reduction.
>
> "3. A Happier Heart
>
> "Yes, cheese can be part of a heart-healthy diet! Research published this year (2016) in The American Journal of Clinical Nutrition found that consumption of full-fat cheese raises healthy HDL cholesterol levels, which are associated with a decreased risk of heart disease, better than does consumption of low-fat varieties.
>
> "The study builds on a 2014 review published in Current Nutrition Reports, which concluded that fat from milk, cheese and yogurt does not contribute to the development of coronary artery disease. While researchers are still trying to tease out why, Cipullo notes that dairy contains more than 400 unique types of fatty acids, some of which are believed to have anti-inflammatory effects in the body.
>
> "4. A Calmer Digestive Tract

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[1] https://health.usnews.com/wellness/food/articles/2016-10-28/5-reasons-to-start-eating-full-fat-dairy-according-to-science . Accessed March 9, 2018

> “Whole milk and yogurt could also reduce belly bloat. "Full-fat dairy is lower in lactose, making it easier for individuals with lactose intolerance to digest compared to low-fat or no-fat dairy," Cipullo explains.
>
> “Meanwhile, one specific fatty acid contained in dairy, called butyric acid, is known to aid in gastrointestinal health and, according to a 2013 review from Polish researchers, may actually hold promise in the treatment of irritable bowel syndrome by supplying the bowels with cellular energy and promoting healthy gut bacteria.
>
> “5. Lower Sugar Intake
>
> “When people reduce the amount of fat they eat, they tend to increase their intake of refined carbohydrates and sugar, the driving forces behind the bulk of our nation's chronic health problems, says Dr. Kevin Campbell, a board-certified internal medicine and cardiac specialist based in North Carolina. In fact, newly discovered documents published in JAMA Internal Medicine show that decades ago, the sugar industry paid scientists to downplay the effects of sugar and put the blame on saturated fat (like that in dairy).
>
> “Currently, 3 out of every 4 Americans eat too much added sugar, with 90 percent of it coming from ultra-processed foods – like that ice cream in your freezer. And, while we aren't promoting ice cream as a health food (everything in moderation!), it's worth noting that full-fat tubs tend to contain less sugar than do their low-fat counterparts. Why? When food manufacturers remove fat from foods (like dairy fat from ice cream), they add in extra sugar to keep you hooked, Cipullo says. Again, full-fat dairy for the win.”

Clinical documentation of positive effects of full-fat (“whole milk”) yogurt, full-fat fermented milk, and other full-fat dairy products continue to appear. Here are some recent examples:

Regular (full-fat) yogurt intake was inversely associated with CVD risk (myocardial infarction and stroke) among hypertensive participants in the (female) Nurses’ Health Study (NHS) and male Health Professionals Follow-Up Study (HPFS) (Buendia et al., 2018).

“The evidence for a dairy matrix effect was presented and discussed by an expert panel at a closed workshop, and the following consensus was reached: 1) Current evidence does not support a positive association between intake of dairy products and risk of cardiovascular disease (i.e., stroke and coronary heart disease) and type 2 diabetes. In contrast, fermented dairy products, such as cheese and yogurt, generally show inverse associations. 2) Intervention studies have indicated that the metabolic effects of whole dairy may be different than those of single dairy constituents when considering the effects on body weight, cardiometabolic disease risk, and bone health. 3) Different dairy products seem to be distinctly linked to health effects and disease risk markers. 4) Different dairy structures and common processing methods may enhance interactions between nutrients in the dairy matrix, which may modify the metabolic effects of dairy consumption. 5) In conclusion, the nutritional values of dairy products should not be considered equivalent to their nutrient contents but, rather, be considered on the basis of the biofunctionality of the nutrients within dairy food structures.” (Thorning et al., 2017)

A study involving the Danish Diet, Cancer and Health cohort (54,277 men and women aged 50-64 years) found that low-fat yogurt products in place of whole-fat yogurt products were associated with a higher rate of type 2 diabetes (hazard ratio (HR) 1.17; 95 % CI 1.06, 1.29) per serving per day substituted.

Whole-fat yogurt products in place of low-fat milk, whole-fat milk or buttermilk were associated with a lower rate of type 2 diabetes. (Ibsen et al., 2017)

In a cohort of community dwelling older adults (>60 years), greater yogurt consumption was associated with increased bone mineral density and better physical function. (Laird et al., 2017)

A daily intake of ≥200 g of yogurt was significantly associated with a lower risk of CVD in a systematic review and meta-analysis of nine prospective cohort articles involving a total of 291,236 participants. (Wu & Sun, 2017)

In a Mediterranean trial focused on dietary fat interventions, baseline intake of saturated and animal fat was not associated with T2D incidence, but the yearly updated intake of saturated and animal fat was associated with a higher risk of T2D. Cheese and butter intake was associated with a higher risk of T2D, whereas whole-fat yogurt intake was associated with a lower risk of T2D. (Guasch-Ferre et al., 2017)

"We found that 13 prospective studies evaluated the association between yogurt intake and type 2 diabetes, most of which showed an inverse association between the frequency of yogurt consumption and the risk of diabetes. In addition to the scientific evidence accumulated from individual prospective studies, several meta-analyses have shown that yogurt consumption has a potential role in diabetes prevention. The most recent analysis shows a 14% lower risk of type 2 diabetes when yogurt consumption was 80-125 g/d compared with no yogurt consumption. The intake of fermented dairy products, especially yogurt, has been inversely associated with variables of glucose metabolism." (Salas-Salvado, Guasch-Ferre, Diaz-Lopez, & Babio, 2017).

"Dietary Guidelines for Americans" that call for behavior contradicted by public awareness that is founded on the latest science, will not guide many Americans in the right dietary direction.

Conclusion

As I mentioned initially, for many years I was responsible for regulatory compliance in a baby food company. In that role, I visited with regulators of advertising at the Federal Trade Commission and regulators of food labeling at the Food and Drug Administration. Foods for babies and young children is a very sensitive food category with heightened regulatory scrutiny. This experience showed the value of setting a high standard and asking tough questions to ensure that our label claims and advertising claims were truthful and not misleading.

After searching the literature for research on health outcomes related to the foods discussed above in the context of the existing Dietary Guidelines, I conclude that many of the actual and implied claims for low-fat and non-fat dairy foods currently made in the Dietary Guidelines would be judged false and misleading if made by a food manufacturer. For example, petitioning FDA for an unqualified health claim or a qualified health claim that substituting a low-fat or non-fat dairy product for whole milk reduces the risk of obesity or cardiovascular disease for children would have zero chance of success because the clinical evidence cited in this comment documents that the opposite is true.

I believe that my perspective would be an asset on the advisory panel in the creation of the 2020-2025 Dietary Guidelines for Americans.

Sincerely,

Richard C Theuer, Ph.D.

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