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WIC FOOD PACKAGE SHOULD BE BASED ON SCIENCE: Foods with New Functional Ingredients Should Be Provided Only If They Deliver Health or Nutritional Benefits

By Zoë Neuberger

Several foods offered through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) are now sold in higher-priced versions containing “functional ingredients” that manufacturers claim confer health and developmental benefits. While the Food and Drug Administration (FDA) ensures that these ingredients are *safe*, neither the FDA nor the Department of Agriculture (USDA) assesses whether they are *beneficial*. Moreover, WIC has no mechanism for considering scientific evidence when deciding whether to purchase foods with these ingredients — using taxpayer funds — for millions of low-income women and very young children. To fill this void, Congress should include a provision in pending WIC reauthorization legislation directing USDA, which operates the WIC program, to get expert advice from the independent Institute of Medicine before deciding whether to offer more costly products with functional ingredients.

WIC provides healthy foods, nutrition education, and health care referrals to more than 9 million low-income women and young children. The program, which is fully federally funded, has long enjoyed widespread bipartisan support because it delivers carefully tailored benefits to vulnerable individuals in a cost-effective manner. A large body of research has consistently found that WIC contributes to healthier births, more nutritious diets, and better health.¹

One reason WIC is so effective is that it offers a limited number of nutritious foods that are carefully selected to fill gaps in the diets of the low-income women and young children it serves. Those foods are consistent with and reinforce the nutrition education the program provides. Recently, after a rigorous review of the key nutrients lacking in WIC participants’ diets, USDA updated the foods offered through WIC to reflect the latest nutrition science and public health concerns.

Since that revision was undertaken, however, manufacturers of several of the foods WIC offers — including infant formula, baby food, infant cereal, eggs, and juice — have begun selling these foods with “functional ingredients,” which the companies market as conferring health or developmental benefits (such as improving brain and eye development or strengthening immunity). Foods with

¹ See Dorothy Rosenbaum and Zoë Neuberger, “Food and Nutrition Programs: Reducing Hunger, Bolstering Nutrition,” Center on Budget and Policy Priorities, Revised August 17, 2005, <http://www.cbpp.org/files/7-19-05fa.pdf>.

these ingredients generally cost more — sometimes much more — than comparable products without them.

There is no mechanism within the national WIC program that requires USDA to review the research evidence on the claimed benefits of these functional ingredients or to base decisions about whether to offer foods containing such ingredients on their benefits and the specific needs of WIC participants. Currently, instead, infant formula manufacturers themselves decide whether WIC offers infant formulas with new functional ingredients, while state WIC programs decide whether WIC should offer other foods with such ingredients.

If decisions continue to be made in this manner, WIC may fail to provide beneficial products to participants or, conversely, may squander taxpayer funds on products containing unproven ingredients. Moreover, if the program, which operates with limited funding, offers more costly food products regardless of their value to participants, this will likely displace more valuable foods that WIC could provide, such as more fresh fruits and vegetables, result in WIC having insufficient funds at some point to serve all eligible women, infants, and children who apply, or squeeze funding for other important programs.

As pressure mounts to limit federal discretionary spending, it is critical to ensure that WIC not spend funds on foods with functional ingredients that do not deliver clinically significant benefits. WIC spent approximately \$850 million on infant formula last year, and a recent USDA study found that more than ten percent of that spending (\$91 million annually) is attributable to higher-priced formulas with functional ingredients.² Under current law, the additional cost to WIC of providing foods with these ingredients is likely to grow substantially as such foods proliferate.

WIC reauthorization legislation pending in Congress provides a timely opportunity to address this issue. The legislation could direct USDA to contract with the Institute of Medicine (which is one of the National Academies, along with the National Academy of Sciences) to review specific foods with functional ingredients and make recommendations to USDA about whether offering such a food through WIC is likely to yield clinical benefits. USDA would then determine whether paying higher prices to offer foods with such an ingredient would benefit participants.

The reauthorization bill that the Senate Agriculture Committee unanimously approved last month includes a common-sense provision that would mark an important step toward establishing such a science-based decision-making mechanism. The provision clarifies that USDA has the authority to disallow foods with specific ingredients based on an assessment of the health or developmental benefits to participants of those ingredients as compared to their cost.

Manufacturers of infant formula and other foods are opposing such a provision. In essence, opposition amounts to insisting that WIC spend extra taxpayer funds on ingredients *without considering* whether they provide health or development benefits. This position is not responsible. Nothing should stand in the way of USDA getting expert scientific advice when making decisions about which foods to offer, financed with taxpayer dollars, to millions of low-income women, infants, and young children.

² See Victor Oliveira, Elizabeth Frazão, and David Smallwood, “Rising Infant formula Costs to the WIC Program: Recent Trends in Rebates and Wholesale Prices,” ERR-93, USDA, Economic Research Service, February 2010, pp.iii-iv, <http://www.ers.usda.gov/Publications/ERR93/ERR93.pdf>.

Background

WIC serves pregnant and postpartum women as well as children through age 4. Currently, just over 9 million participants are served each month. Applicants must have income below 185 percent of the poverty line or be covered by Medicaid to qualify. More than two million infants and nearly five million children aged 1 through 4 participate in WIC.

WIC offers three key benefits. Participants receive referrals to health care and other social services as needed, nutrition education and counseling so that they can improve their diets and health habits, and specific foods designed to fill gaps in their diets and reinforce the nutrition education WIC provides. Participants are given a voucher that they take to an authorized grocery store to purchase some combination of about a dozen foods (which make up what are referred to as the “WIC food packages”). WIC then reimburses the store for the retail price of the foods obtained.

As USDA has explained:

WIC was never intended to be a primary source of food, nor of general food assistance. Rather, WIC food benefits are scientifically-based and intended to address the supplemental nutritional needs of a specific population — low-income pregnant, breastfeeding, non-breastfeeding postpartum women, infants, and children up to five years of age who are at nutritional risk. . . . The ability of the WIC food packages to reinforce nutrition education messages provided to participants is critical to affecting the dietary quality and habits of infants, children, and mothers served by WIC.³

WIC is fully federally funded through the annual appropriations process. The program received \$7.3 billion for fiscal year 2010. WIC is not an entitlement program, so there is no guarantee that all eligible women, infants, and children will be served. But since 1997 there has been a strong bipartisan commitment by each Congress and Administration to provide enough funding so that no eligible applicants are turned away. If the cost of the foods provided by WIC increases (such as when dairy prices spiked in 2007 and 2008), or if the program purchases higher-priced versions of foods with functional ingredients, Congress needs to appropriate more funds to avoid turning away eligible applicants.

Decisions on New Functional Ingredients Are Not Based on Science

The foods WIC offers are meant to supplement participants’ typical diets to meet their nutritional needs, based on the most recent nutrition science, public health concerns, and cultural eating patterns. More than a decade ago, it became clear that the foods offered through WIC, which had not been comprehensively revised and updated since 1980, were not consistent with current dietary recommendations. For example, most participants received no whole grains, fruits, or vegetables. However, opposition from food manufacturers blocked USDA’s initial efforts to update the WIC food package.

³ Preamble to Interim rule, Special Supplemental Nutrition Program for Women, Infants, and Children, Revisions in the WIC Food Packages, 72 Fed. Reg. 68966 (December 6, 2007), <http://www.fns.usda.gov/wic/regspublished/wicfoodpkginterimrulepdf.pdf>.

To break the impasse on updating the food package, USDA contracted with the Institute of Medicine (IOM), a non-profit, non-governmental organization that is one of the National Academies, to review the supplemental nutrition needs of the population WIC serves and recommend how to improve the WIC food package in a cost-neutral manner. Those recommendations were ultimately adopted as program regulations that were implemented by October 1, 2009. WIC now offers smaller, more appropriate quantities of dairy products, juice, and infant formula than it used to, and offers more whole grains, fruits and vegetables, and baby foods. Because the process for identifying the changes was both independent and science-based, there has been widespread support for the changes.

At the time that USDA commissioned the IOM recommendations, however, the new functional ingredients that have since proliferated had just entered the market. The IOM was not asked to consider this issue, and its recommendations did not address whether products with or without these ingredients should be offered. The remainder of this section explains how decisions are made about whether to offer such products under current laws and program regulations.

State WIC Programs Decide Whether to Offer Foods with New Ingredients

The WIC food package rules implemented in 2009 do not specify whether states are to offer foods with or without functional ingredients; thus, for all foods other than infant formula, state WIC programs decide. A review of published state food lists indicates that currently states are generally not offering baby foods, infant cereal, or eggs with new functional ingredients.⁴

State WIC programs are ill-equipped to make decisions about whether to offer foods in the WIC package that include such ingredients. They do not have scientific advisory panels at their disposal with relevant experts in nutrition and medical research, and it would be wasteful and duplicative for each state to develop such capacity. State WIC programs also are subject to lobbying by food manufacturers and political pressure from the elected officials that manufacturers enlist as supporters. Moreover, if a state decides to offer foods with functional ingredients, the federal government must cover all of the additional cost because WIC is fully federally funded.⁵

It is neither logical nor responsible to put state WIC directors in the position of deciding whether to offer products with functional ingredients without the benefit of scientific evidence on which to base the decision. If an ingredient confers clinically significant benefits, WIC participants in states that fail to offer it could be denied that benefit. Conversely, if an ingredient increases a product's cost but does *not* confer clinically significant benefits, taxpayer funds could be wasted.

⁴ The Center on Budget and Policy Priorities reviewed the materials published on the web by each state's WIC program explaining which foods participants may purchase. The review was conducted in March, April, and May of 2010.

⁵ A few states add their own funds to provide extra services through WIC, but states are not required to contribute any funding and the vast majority do not.

What Is a Functional Food or Ingredient?

A functional food or ingredient is one that is purported to offer health benefits beyond basic nutrition. There is no legal definition of functional foods or ingredients, and USDA and the FDA regulate them no differently than other foods. In this paper, the term *functional ingredients* refers to substances purported to improve bodily functioning that are added to traditional foods through a manufacturing or other process.

Infant formula purchased through WIC now routinely contains docosahexaenoic acid (DHA), arachidonic acid (ARA), prebiotics, probiotics, lutein, lycopene, and/or betacarotene. Examples of other foods offered through WIC that are now sold in versions containing functional ingredients include: baby food with DHA, infant cereal with DHA, eggs with DHA, juice with DHA or zinc and prebiotic fiber, and whole-grain bread with DHA.

Infant Formula Manufacturers Decide Which Formulas WIC Offers

This issue is especially salient with regard to infant formula, the sole or a primary source of nourishment for infants who are not breastfed. WIC purchases more than half of all infant formula sold in this country. But under current law governing the WIC program, infant formula manufacturers — not WIC — decide whether to offer formulas with new functional ingredients.

While WIC purchases formula at a substantial discount, the program spent approximately \$850 million on infant formula in fiscal year 2009.⁶ WIC uses a competitive bidding process under which manufacturers offer discounts (in the form of rebates) to a state WIC program in exchange for being the sole formula provider to WIC participants in the state. Such contracts are valuable to manufacturers in part because they confer a marketing advantage; the WIC brand of formula is well-stocked and generally gets prominent shelf placement in grocery stores, which may attract non-WIC customers who pay full price.

In 2002 and 2003, infant formula manufacturers began offering in the United States more expensive formulas with new functional ingredients — docosahexaenoic acid (DHA) and arachidonic acid (ARA). There is currently no scientific consensus that adding these ingredients to infant formula offers benefits for healthy, full-term infants. Manufacturers nevertheless claim these ingredients provide developmental benefits and market them accordingly.

When the formula products containing these ingredients were introduced, USDA left it to each state to decide whether to offer them. According to the National WIC Association, formula manufacturers heavily lobbied state WIC programs and elected officials — which lacked comprehensive evidence to use to assess the manufacturers' claims — and eventually limited the availability of formula without DHA and ARA. Under pressure to offer the formulas with these

⁶ Center on Budget and Policy Priorities estimate based on USDA data for fiscal year 2005 contained in “WIC Food Package Costs and Rebates Summary: Fiscal Year 2005,” USDA, Food and Nutrition Service, September 2007, Table 4, <http://www.fns.usda.gov/ora/WICFoodCosts/FY2005/FY2005.pdf>.

ingredients, most states soon began to offer them.⁷ The federal government covered the additional cost: when they were introduced, the wholesale prices for these formulas were 7 percent to 30 percent higher than prices for the previously standard formulas, depending on the brand.

As a result of a provision Congress added in the 2004 WIC reauthorization legislation, when state WIC programs solicit bids for infant formula they may not require formula manufacturers either to include or to omit any specific ingredients in their formula (beyond USDA's basic requirements for formula).⁸ Once this provision became law, state WIC programs began receiving bids only for the more expensive formulas with DHA and ARA. Today, the formula that WIC offers in every state includes these ingredients. Formulas with these ingredients have saturated the broader consumer market as well, despite the fact that neither USDA nor the FDA have assessed the benefits of adding DHA and ARA.

Looking forward, the issue is not DHA or ARA—whose widespread use now makes their continued inclusion in WIC infant formula products a given—but the growing array of *additional* functional ingredients, such as prebiotics, probiotics, lutein, lycopene, and betacarotene. Formulas with these ingredients have entered the market, and infant formula manufacturers are beginning to bid with these products as states' current WIC infant formula contracts expire and new bids are solicited. As manufacturers continue to develop and offer bids on new formula products with even more functional ingredients, state WIC programs will have no choice but to offer them, even if they have not been proven beneficial.⁹ The federal government will have to pay the added cost.¹⁰

A recent study by USDA's Economic Research Service (ERS) found that state WIC programs are spending \$127 million more each year in federal funds for infant formula under their *current* contracts with infant formula companies — for formula products with DHA and ARA — than states would have paid under their *previous* contracts, after adjusting for inflation.¹¹ ERS attributed \$91 million of the increase (72 percent) to increases in the price of infant formula beyond the increases needed to keep pace with inflation (the remainder of the \$127 million increase reflects other factors).¹² Thus, WIC appears to be spending more than \$90 million extra annually — or more than 10 percent of its total spending on infant formula — to provide formulas with ingredients that neither USDA nor the FDA has assessed with regard to their benefits. Costs are likely to rise higher in the future if manufacturers add more ingredients to formula products and increase prices further.

⁷ A contemporaneous survey conducted by the National WIC Association and the Center on Budget and Policy Priorities found that by the summer of 2003, 60 percent of states had fully approved the use of formula with DHA and ARA and another 30 percent of states had approved the use of these formulas in certain situations.

⁸ See 42 U.S.C. § 1786(b)(22).

⁹ The federal government maintains a registry of clinical trials. A list of current studies involving infant formula, some of which involve new functional ingredients, can be found at:

http://clinicaltrials.gov/ct2/results?flds=Xh&flds=a&flds=b&flds=c&term=infant+formula&show_flds=Y.

¹⁰ The WIC program pays, with federal funds, the discounted wholesale price for infant formula plus any retail markup.

¹¹ See Victor Oliveira, Elizabeth Frazão, and David Smallwood, "Rising Infant formula Costs to the WIC Program: Recent Trends in Rebates and Wholesale Prices," ERR-93, USDA, Economic Research Service, February 2010, pp.iii-iv, <http://www.ers.usda.gov/Publications/ERR93/ERR93.pdf>.

¹² See *Ibid.*

Arguably, USDA has the authority under current law to require or prohibit the inclusion of specific ingredients in formula offered through WIC, but the only such requirements USDA has instituted are that infant formula companies comply with FDA standards for infant formula and that the formula products include iron. USDA has not indicated whether it interprets the Child Nutrition Act of 1966, which governs WIC, as conferring this authority.¹³ USDA has not exercised such authority with regard to any of the functional ingredients added to infant formula since 2002.

As noted above, states may not specify in their bid solicitations that the infant formula products being offered through the competitive bidding process contain (or not contain) a specific ingredient. State WIC programs must offer the specific formula for which the winning bid is received.

The practical result of these two factors — the lack of clarity about USDA’s authority with regard to new functional ingredients and the prohibition on state WIC programs with regard to bid specifications in this area — is that the infant formula manufacturers determine which formulas state WIC programs offer. A change in law is needed to clarify that USDA is permitted to require or prohibit functional ingredients in infant formula based on the scientific evidence related to their benefits and to provide an expeditious mechanism for USDA to secure scientific advice on this matter.

The FDA Is Not the Appropriate Body to Make Decisions about Functional Ingredients in WIC Foods

Some industry opponents of including such a provision in WIC reauthorization legislation have argued that no mechanism should be put in place for the WIC program to assess the benefits conferred by functional ingredients because such an assessment falls within the purview of the Food and Drug Administration (FDA). This argument is incorrect for three important reasons, detailed below. First, the FDA considers only the safety of new ingredients and has no authority to consider directly whether new ingredients offer the promised benefits. Second, FDA oversight of the kind of marketing claims being made about new functional ingredients is quite limited. Third, decisions about the foods WIC offers are made by USDA, not the FDA.

- **The FDA considers only the safety of new ingredients.** The FDA is charged with ensuring the safety of food.¹⁴ It monitors the safety of ingredients under the food additive and the GRAS (Generally Recognized as Safe) provisions of the Federal Food, Drug, and Cosmetic Act.¹⁵ These provisions “are intended to ensure the safety . . . not the efficacy, of the proposed ingredient.”¹⁶

¹³ See 42 U.S.C. § 1771 et seq.

¹⁴ The safety of meat and poultry is overseen by USDA.

¹⁵ See 21 U.S.C. § 301 et seq.

¹⁶ “Infant Formula: Evaluating the Safety of New Ingredients,” Institute of Medicine of the National Academies, 2004, p. 3, <http://www.iom.edu/Reports/2004/Infant-Formula-Evaluating-the-Safety-of-New-Ingredients.aspx>.

What Does the Research Show About the Benefits of DHA and ARA in Infant Formula?

The research evidence regarding the benefits for full-term infants of the fatty acids docosahexaenoic acid (DHA) and arachidonic acid (ARA), also known as long-chain polyunsaturated fatty acids, (LCPUFAs or LCPs), is inconclusive.^a

In 2007, the Cochrane Collaboration, a respected independent research organization, examined the most reliable studies to assess whether adding these fatty acids to formula is safe and beneficial for full-term infants. (Some benefits have been shown for pre-term infants.) It concluded that the studies have not shown beneficial effects on the physical, visual, or neurodevelopmental outcomes of full-term infants and that “supplementation of milk formula with LCPUFA to improve the physical, neurodevelopmental or visual outcomes of infants born at term can not be recommended based on the current evidence.”^b

A peer-reviewed paper commissioned by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) considered analyses of the data from randomized controlled trials; it reached a similar conclusion that the data “do not demonstrate a clear and consistent benefit of supplementing formula with LCPs on visual acuity, neuro-developmental outcomes and physical growth in term infants.”^c Nonetheless, the interim recommendation of the FAO and WHO is that all infants should receive quantities of DHA and ARA in their diets that are comparable to the quantities found in breastmilk.^d For fully formula-fed infants, presumably infant formula would be the source of DHA and ARA.

The process that the FAO and WHO undertook to reach this conclusion is an example of the kind of rigorous, science-based procedure for reviewing complex and sometimes contradictory research evidence that should be used in making decisions for the WIC program. Analyses such as these would presumably be taken into consideration in making WIC decisions.

The legislative proposal described in this paper is not aimed at DHA and ARA. In fact, because infant formula with these ingredients dominates the market, it is highly unlikely that USDA would choose to review the benefits associated with formulas with these ingredients. But it is instructive to consider the research on formula with these ingredients to illustrate that findings may not be consistent and that experts should assess the full range of evidence. Moreover, the universal presence of DHA and ARA in infant formula in the United States demonstrates that an ingredient can saturate the market even in the absence of a scientific consensus with regard to its benefits.

^a The FDA includes the following question and answer in a portion of its website geared toward consumers: “What is the evidence that addition of DHA and ARA to infant formulas is beneficial? The scientific evidence is mixed. Some studies in infants suggest that including these fatty acids in infant formulas may have positive effects on visual function and neural development over the short term. Other studies in infants do not confirm these benefits. There are no currently available published reports from clinical studies that address whether any long-term beneficial effects exist. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.” See <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/InfantFormula/ConsumerInformationAboutInfantFormula/ucm108560.htm> (accessed April 22, 2010).

^b Karen Simmer, Sanjay Patole, and Shripada C. Rao, “Longchain Polyunsaturated Fatty Acid Supplementation in Infants Born at Term,” Cochrane Database of Systematic Reviews, 2008, Issue 4, summary available at <http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD000376/frame.html>.

^c Ricardo Uauy and Alan Dangour, “Fat and Fatty Acid Requirements and Recommendations for Infants of 0-2 Years and Children of 2-18 Years,” *Annals of Nutrition and Metabolism* (September 2009), p. 87, <http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowPDF&ArtikelNr=228997&Ausgabe=250361&ProduktNr=223977&filename=228997.pdf>. The paper finds some benefits of DHA supplementation for infants with certain metabolic diseases. The paper also discusses findings related to *children*, stating, “Beyond infancy, evidence linking EFA [essential fatty acids] and LCPs with neurological benefits is limited to special population groups with very low dietary intakes of EPA [eicosapentaenoic acid] and DHA, such as children with phenylketonuria” and “There is currently insufficient evidence to identify an effect of LCPs on learning, education, or performance of school-age children in industrialized countries.” *Ibid.*, p. 87 and p. 88.

^d See “Interim Summary of Conclusions and Dietary Recommendations on Total Fat & Fatty Acids,” Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition, November 10-14, 2008, http://www.who.int/nutrition/topics/FFA_summary_rec_conclusion.pdf.

Infant formula is regulated as a food, and the general rules regarding foods apply. Because it is the sole or a primary source of nutrition for infants during a period of critical development, some additional requirements apply when a new or reformulated infant formula is brought to market. Infant formula manufacturers are required to notify the FDA 90 days before marketing a new or reformulated product; they must provide assurances that the formula meets all nutrient requirements, satisfies identified quality factors (such as the ability to support normal physical growth), and is processed in compliance with good manufacturing practices.¹⁷ If the FDA has concerns about the safety of the product, it may raise them during this period.

Manufacturers are not required to provide any information about the benefits associated with new ingredients, but may choose to do so. To the extent that the FDA considers this additional information, it is only in the context of the product's safety. Although not required to wait beyond the 90 days, infant formula manufacturers typically do not market a new product until they receive a letter from the FDA indicating that the FDA has no further concerns about the safety of the new or reformulated product.

Throughout this process, the FDA does not have the authority to consider whether new ingredients produce the claimed benefits. For infant formula as well as other foods, *the FDA does not review the benefits associated with new ingredients.*

- **The FDA exercises very limited oversight of the typical claims made for functional ingredients.** FDA's current statutory authority strictly regulates statements on food labels related to disease prevention (known as "health" claims): a company cannot make such a claim unless there is significant scientific agreement in support of the claim and the claim has been approved by the FDA.^{18,19} In contrast, if a claim relates to the structure or function of the body (known as a "structure/function" claim), there is *no statutory standard* regarding the scientific evidence a company must have to support the claim. Moreover, the FDA has not provided guidance to manufacturers regarding the nature and extent of scientific substantiation they need to support structure/function claims for conventional foods (as opposed to dietary supplements).²⁰ The FDA does not have to approve the claim before it can be made publicly, nor are manufacturers required to provide any research findings to the FDA.²¹

For example, when a container of baby food with DHA states, "DHA & Choline helps support

¹⁷ See "Guidance for Industry--Frequently Asked Questions about FDA's Regulation of Infant Formula," U.S. Department of Health and Human Services, FDA, March 1, 2006, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm>.

¹⁸ See Bruce Silverglade and Ilene Ringel Heller, "Food Labeling Chaos—The case for reform," Center for Science in the Public Interest, March 2010, pp. VI-1 - VI-4, http://cspinet.org/new/pdf/food_labeling_chaos_report.pdf.

¹⁹ The Federal Trade Commission (FTC) enforces consumer protection laws regarding the claims made in advertising materials for foods. The FTC must apply a different statutory standard than the FDA and sometimes allows a claim that is not allowed on a food label. See "Food Safety, Improvements Needed in Overseeing the Safety of Dietary Supplements and 'Functional Foods,'" General Accounting Office, July 2000, pp. 12 and 18.

²⁰ The Government Accountability Office (GAO) recommended that the FDA issue such guidance but to date the FDA has not done so. See *Ibid.*, pp. 18, 19, and 27.

²¹ See *Ibid.*, pp. 20-21.

brain and eye development,” the FDA has not approved that claim nor set a standard for the level of scientific evidence the company must be able to demonstrate to support it.²²

In the last few years, food manufacturers have increasingly used structure/function claims.²³ Studies have shown, however, that consumers do not distinguish between claims related to the structure or function of the body (for example, “helps maintain a healthy heart”) and claims related to disease prevention (for example, “may help reduce the risk of heart disease”).²⁴

The FDA has no *administrative* process to review, correct, or sanction a misleading structure/function claim. If the agency has concerns about a marketing claim, it may issue a warning letter to the manufacturer explaining the violation and indicating that the FDA may take *legal* action. To stop the use of a claim, the FDA would have to convince a court that the claim is demonstrably false or misleading.²⁵ The FDA apparently has never issued a warning letter charging that a structure/function claim for a conventional food is misleading. In early 2010, the FDA issued a batch of 17 warning letters to food manufacturers about marketing claims, which was perceived as an indication that the agency intends to conduct more aggressive oversight. But none of those letters challenged structure/function claims.²⁶

In addition, no special rules apply to marketing claims made about infant formula. Infant formula labels and advertising contain numerous structure/function claims.²⁷ To date, the FDA has not issued any warning letters related to structure/function claims made regarding infant formula and has not pursued any court intervention.

Because neither scientific substantiation nor FDA approval is required for structure/function claims, the fact that a claim appears on a food label does not mean that the FDA has considered the scientific support for the claimed benefits. Unlike dietary supplements, however, food and infant formula labels with structure/function claims are not required to include a disclaimer stating that the FDA has not evaluated the claim.²⁸

²² This statement appears on Gerber’s Apple Blackberry baby food. A similar statement is on Gerber’s web site at http://www.gerber.com/AllStages/Products/2nd_Foods_Dinners_with_DHA.aspx?PLineId=a6ee80e5-1538-4112-8b2a-3dc83a3347eb&PCatId=00ac068d-a9cf-484e-b9ea-9e22f2e25049 (accessed April 28, 2010).

²³ See Bruce Silverglade and Ilene Ringel Heller, “Food Labeling Chaos—The case for reform,” Center for Science in the Public Interest, March 2010, p. VI-2, http://cspinet.org/new/pdf/food_labeling_chaos_report.pdf.

²⁴ See *Ibid.*, pp. VI-1 - VI-4, http://cspinet.org/new/pdf/food_labeling_chaos_report.pdf.

²⁵ See “Food Safety, Improvements Needed in Overseeing the Safety of Dietary Supplements and ‘Functional Foods,’” General Accounting Office, July 2000, pp. 19-21.

²⁶ See FDA’s summary of these letters at <http://www.fda.gov/Food/LabelingNutrition/ucm202784.htm>. See also William Neuman, “F.D.A. Cracks Down on Nestlé and Others Over Health Claims on Labels,” *New York Times*, March 3, 2010, <http://www.nytimes.com/2010/03/04/business/04food.html>.

²⁷ See examples in the *Infant Formula Companies’ Opposition to Science-Based System Is Not Responsible* section of this report.

²⁸ A dietary supplement with a structure/function claim on the label must also state, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” 21 U.S.C. § 343(r)(6).

- **The FDA has no authority over WIC.** The FDA plays no role in the WIC program, which is overseen by USDA. The foods WIC offers are selected by USDA because they contain nutrients lacking in the diets of the low-income women and young children who participate and because they promote the health of these populations, as indicated by nutrition science, public health concerns, and cultural eating patterns.²⁹

WIC Reauthorization Should Establish a Science-Based Process for Decision-Making

The current system leaves to infant formula manufacturers all decisions about whether WIC should offer *formulas* with new functional ingredients, and it leaves to state WIC programs all questions about whether WIC should offer *other foods* with such ingredients. This approach is unsound. It allows babies to be denied the benefits of products that confer health or developmental advantages, and tax dollars to be wasted on products that confer no such advantages.

The pending reauthorization of the WIC program offers an opportunity to establish a science-based process for making these decisions. That process could be designed as follows. USDA would be required to enter into a contract with the Institute of Medicine (IOM) to develop a framework to evaluate new functional ingredients generally. The framework could address issues such as the kind of clinical studies to consider and how much scientific substantiation is needed to determine that a food with a functional ingredient offers clinically significant benefits that address the needs of WIC participants.

At the request of USDA, the IOM would then apply that framework to specific foods with functional ingredients and make recommendations to USDA about whether offering a food with a functional ingredient through WIC is likely to yield clinically significant benefits to WIC participants. USDA would have the authority, based on those recommendations, to require WIC to offer — or bar WIC from offering — a product with a specific functional ingredient. If an ingredient offered a clinically significant benefit that could also be achieved by making another change in the food package, USDA would decide which approach was the best way to strengthen the food package.

USDA would also be required to bar bids on infant formula products currently under review so that states would not be put in the position of entering into a contract to offer a product that might be disallowed. To benefit all consumers, USDA would also be required to make the IOM findings available to the general public in a comprehensible format.³⁰

This approach would leave all the decisions about WIC to USDA, while ensuring that the Department has sound scientific information to draw upon in making those decisions. This process would not affect the FDA's authority or duplicate FDA efforts, since as noted above, the FDA considers only the safety of new functional ingredients, not their possible benefits. Moreover, the IOM would be looking not at marketing *claims* but rather the actual *benefits* associated with a specific

²⁹ See 42 U.S.C. § 1786(b)(14).

³⁰ MyPyramid for Pregnancy and Breastfeeding offers an example of USDA making complicated research findings available to the public in a comprehensible format. See http://www.mypyramid.gov/mypyramidmoms/pregnancy_nutrition_needs.html.

ingredient (such as whether additional calcium in juice confers benefits, regardless of any claims made on the food label or in advertisements). Nonetheless, if the FDA's authority or oversight activities were to expand in the future and it began assessing the benefits associated with an infant formula product or other food containing a functional ingredient, it would be expected to make its findings available to the IOM and USDA to facilitate the scientific review process.

To be sure, this new process likely would redirect some lobbying by some food manufacturers on the WIC food package from the 50 states and tribal WIC programs to USDA and would require USDA, rather than the manufacturers, to make certain decisions about the ingredients in the infant formula and other foods WIC offers. These responsibilities would increase USDA's workload to some extent, so the Department would need appropriate resources to effectively implement the new provisions. Making science-based decisions about the foods WIC offers is an appropriate role for the administrator of a federal program, and USDA has a responsibility both to the millions of low-income women and young children who rely on WIC and to U.S. taxpayers to take on that role.

The WIC reauthorization bill that the Senate Agriculture Committee unanimously approved on March 24 includes an important provision to begin addressing this issue.³¹ The statutory language is broadly written to clarify USDA's authority to require or disallow food products with functional ingredients, based on an evaluation of the health or developmental benefits to participants relative to the cost of the product. While the statute does not require USDA to contract with the IOM or another independent body to assess the scientific evidence on health and developmental benefits, USDA does not have the capacity or expertise to conduct such an assessment and thus would likely turn to the IOM, with which USDA has a history of working on nutritional issues. For example, although not required by Congress to do so, USDA sought the IOM's advice when revising the WIC food packages and, more recently, with regard to updating school meal requirements to reflect the latest nutrition science.³²

Infant Formula Companies' Opposition to Science-Based System Is Not Responsible

While infant formula manufacturers offer WIC substantial discounts through WIC's competitive bidding system, they have a history of opposing cost-containment measures in the WIC program. In the late 1980s, when states experimented with competitive bidding and demonstrated that it produced significant savings, manufacturers sought to persuade many states not to adopt it and opposed instituting a federal requirement that states use competitive bidding.³³ Nevertheless, Congress enacted legislation with bipartisan support in 1989 requiring use of competitive bidding in

³¹ See section 353 of the Healthy, Hunger-Free Kids Act of 2010 (S.3307), <http://ag.senate.gov/Legislation/FULLCNB10.pdf>.

³² See "WIC Food Packages: Time for a Change," Institute of Medicine of the National Academies, April 2005, [http://www.fns.usda.gov/ora/menu/Published/WIC/FILES/Time4AChange\(mainrpt\).pdf](http://www.fns.usda.gov/ora/menu/Published/WIC/FILES/Time4AChange(mainrpt).pdf), and "School Meals: Building Blocks for Healthy Children," Institute of Medicine of the National Academies, October 20, 2010, <http://www.iom.edu/Reports/2009/School-Meals-Building-Blocks-for-Healthy-Children.aspx>.

³³ For a discussion of cost-containment efforts in the late 1980s, see Stefan Harvey, Robert Greenstein, and Scott Barancik, "Saving to Serve More: Ways to Reduce WIC Infant Formula Costs," Center on Budget and Policy Priorities, 1988.

all states.³⁴ That system is now reducing federal WIC costs by approximately \$2 billion annually; had it not been put in place, either Congress would have to provide an additional \$2 billion annually in taxpayer funds for WIC or more than two million eligible low-income women and very young children would not be able to receive WIC benefits.

Once the competitive bidding system was in place, concerns grew that infant formula manufacturers were engaging in anti-competitive practices.³⁵ The Senate Subcommittee on Antitrust, Monopolies, and Business Rights conducted a hearing in 1990 on potentially abusive behavior by infant formula manufacturers in response to WIC bid solicitations, and the Federal Trade Commission (FTC) launched an investigation.³⁶ In 1992, the FTC brought charges against the three largest domestic manufacturers alleging bid-rigging in connection with a state WIC contract.³⁷

In addition, in the early years of the last decade, in conjunction with WIC's last reauthorization, an infant formula manufacturer promoted a legislative proposal to try to start moving WIC away from its current competitive bidding practices. Congress rejected the proposal because it likely would have raised WIC costs substantially.

Consistent with such past efforts, the infant formula manufacturers that currently bid on WIC contracts — Mead Johnson & Company, Abbott Laboratories, and Nestlé — are now opposing the provision in the pending Senate bill that would bring science to bear on WIC's choice of food products to offer. Their opposition amounts to insisting that WIC spend extra taxpayer funds on products with functional ingredients without considering whether scientific evidence demonstrates that the products have health or developmental benefits.

Each of these manufacturers asserts publicly that science backs up its products. Mead Johnson's website states, "We go beyond just stating health benefits, we prove them" and "Enfamil Premium has Triple Health Guard. It's a clinically proven formula to promote growth, to improve brain and eye development, and to support the immune system too."³⁸ Footnotes elaborate on study findings.

³⁴ See discussion of the competitive bidding system on page 5. For a discussion of the development of competitive bidding leading to the 1989 requirement, see Victor Oliveira, Mark Prell, David Smallwood, and Elizabeth Frazão, "WIC and the Retail Price of Infant Formula," Economic Research Service, USDA, May, 2004, Appendix A, <http://www.ers.usda.gov/Publications/FANRR39-1/>.

³⁵ See Joseph Tiang-Yau Liu, "Strength in Numbers—Multi-State Cost-Containment in the WIC Program," Center on Budget and Policy Priorities, July 1991, Chapter III.

³⁶ See Victor Oliveira, Mark Prell, David Smallwood, and Elizabeth Frazão, "WIC and the Retail Price of Infant Formula," Economic Research Service, USDA, May, 2004, Appendix A, <http://www.ers.usda.gov/Publications/FANRR39-1/>.

³⁷ See *Ibid.* Two of the manufacturers (Mead Johnson & Company and American Home Products, parent company of Wyeth-Ayerst Laboratories) settled the charges by providing millions of pounds of free infant formula to the WIC program. See FTC press release announcing the settlement at <http://www.ftc.gov/opa/2004/05/med-ahp24.htm>. A federal court ruled in favor of the third manufacturer, Abbott Laboratories. See 853 Federal Supplement 526, May 27, 1994.

³⁸ See http://www.enfamil.com/app/iwp/enfamil/productDetail.do?dm=enf&id=/Consumer_Home2/Enf_Products/ForInfants/EnfamilPremium&iwpst=B2C&ls=0&csred=1&r=3449315695 (accessed April 21, 2010).

Abbott Laboratories' website states, "Your baby's gut relies on millions of 'good bacteria' to support digestive health. Recent clinical research suggests that special carbohydrates (prebiotics) found in breast milk and Similac Advance EarlyShield can help stimulate the growth of these beneficial bacteria, which helps support the immune system."³⁹ Likewise, Nestlé's website states, "Good Start milk-based formulas have levels of DHA & ARA that are recommended by experts and similar to levels shown in studies to support babies' brain and eye development."⁴⁰

If research shows that functional ingredients in infant formulas confer clinically significant benefits that address the needs of WIC participants, then infant formula manufacturers should have nothing to fear from science-based WIC decisions.

Conclusion

The WIC program's reputation as a cost-effective program that delivers critical benefits to a vulnerable population rests in large measure on the careful tailoring of the foods the program provides to low-income women and very young children. USDA recently updated the WIC food packages based on a rigorous, science-based review by the Institute of Medicine. That review, however, did not consider a recent trend in which several of the foods WIC provides are now offered in more expensive versions with new functional ingredients.

Currently, decisions over whether WIC should offer the more expensive products with additional ingredients are made without regard to whether scientific research demonstrates that products with these ingredients are beneficial or whether the benefits are provided most effectively through these products. For all foods except for infant formula, these decisions are left to state WIC programs, which generally lack the capacity to thoroughly review the scientific evidence. For formula, these decisions are left to the manufacturers themselves.

If these functional ingredients confer clinically significant benefits that address the needs of WIC participants and are best provided through the foods into which they are being introduced, then WIC has an obligation to ensure that low-income families get these products, even if that raises program costs. But in the absence of convincing scientific evidence, WIC has an obligation to ensure that the products it offers are consistent with the education it provides to participants about using their limited resources to purchase foods that offer sound nutritional value.

As pressure builds on policymakers to slow the growth in discretionary spending, it is important to ensure that taxpayer funds are spent wisely in WIC and are used to purchase more costly items only if scientific evidence shows that they benefit participants.

³⁹ See <http://similac.com/feeding-nutrition/baby-immune-system-digestive-health> (accessed April 21, 2010).

⁴⁰ See http://www.gerber.com/AllStages/Products/Good_Start_DHA_ARA_Formula.aspx?PLineId=cc27fb48-a094-4015-b29c-f8d861415f88&PCatId=06a3314b-3aca-47e4-b79e-089e5c09efc3 (accessed April 21, 2010).