VIEWPOINT

Marketing Claims for Infant Formula
The Need for Evidence

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The market for infant formulas has become increasingly competitive over the past decade. Ingredients that manufacturers once included only in specialized formulas are now added to nearly all formulas. These ingredients come with marketing claims, such as "fosters cognitive development" and "supports digestive health."

It is time to ask whether there are data to support these claims. On September 9, 2016, the US Food and Drug Administration (FDA) issued its first draft guidance on this topic, which outlines the quality of evidence that formula manufacturers should have to substantiate these claims, including randomized trials.[1] The evidence currently available to the public does not meet these standards. For many claims there is no evidence available to the public, and when the results of randomized trials are made public, we learn that they are limited by small sample sizes, poor follow-up, and provide unpersuasive results.[2] It is also important to understand how these claims may affect breastfeeding and public health budgets, and to consider regulatory approaches that might produce better publicly available evidence.

The story of long-chain polyunsaturated fatty acids (LCPUFAs, eg, docosahexaenoic acid [DHA] and arachidonic acid [ARA]) highlights how claims that are unsubstantiated in the literature are used in infant formula marketing. Long-chain polyunsaturated fatty acids are found in high levels in breast milk in comparison with unfortified standard formula, and some researchers have hypothesized that this may explain evidence of better cognitive outcomes in breastfed infants. Most manufacturers now add LCPUFAs to their formulas and make such claims as "supports brain development." However, a 2011 Cochrane review examining 15 studies assessing the benefits of LCPUFAs, including 11 tracking neurodevelopmental outcomes, did not find any benefit to supplementation.[2]

Long-chain polyunsaturated fatty acids are not the only formula ingredient marketed using these types of claims. Low-lactose formulas ("sensitive") and those containing prebiotics ("supports immune system") are marketed to consumers despite a lack of scientific consensus regarding their benefits.[3] One recent study found that more than half of the 22 infant formula products reviewed were marketed with claims; none were backed by publicly available scientific evidence. The authors suggested "the purpose of these messages is to widen the use of modified formulas largely in the absence of evidence."[4]

The lack of available evidence is related to the regulatory structure for infant formula. These claims are classified by the FDA as structure/function claims (characterizing the relationship between an ingredient and the structure/function of the body without referencing disease, eg, probiotics support digestive health) as opposed to health claims (describing the relationship of an ingredient to a disease, eg, adequate calcium reduces the risk of osteoporosis).[1] Under the Federal Food, Drug, and Cosmetic Act, structure/function claims do not require prior authorization by the FDA and are subject to a lower standard of evidence than health claims. Companies are required to have on hand data to substantiate structure/function claims, but there is no obligation to share the data with the FDA or the public.

There are several consequences to the inadequately supported claims used in infant formula marketing.

First, the claims may confuse parents into thinking these formulas are equivalent or superior to breastfeeding. In an effort to promote breastfeeding, the World Health Organization's International Code of Marketing of Breast-Milk Substitutes prohibits direct-to-consumer advertising of infant formula and discourages the use of marketing claims on packaging.[3] Unlike many other developed nations, the United States does not adhere to this code.

Second, these unsubstantiated formula additives increase costs for families. In the early 2000s, when LCPUFAs were introduced into the mainstream formula market, wholesale formula prices increased by 7% to 30% in comparison with standard formulas.[5] With formula prices inflated by this magnitude, a family might spend an extra $400 per year on formula as a result of these ingredients.

Third, the claims reduce the reach of critical federal nutrition programs. The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is the single largest purchaser of infant formula in the United States, serving more than half of all infants. WIC is a discretionary federal grant program where states are awarded funds to provide nutritional support to low-income families. The number of infants served is limited by each state's WIC budget and the cost of formula. Approximately 30% of infants and children eligible for WIC do not participate due in part to insufficient resources.[6] The US Department of Agriculture (USDA) estimated that more than $91 million of the approximately $850 million spent on infant formula by WIC was attributable to the higher price because of ingredients bearing these claims.[6]

The FDA's recent draft guidance recommends high standards for studies on the effectiveness of infant formula ingredients. If adopted by the agency, companies would be expected to conduct randomized clinical studies of sufficient size to demonstrate a meaningful clinical outcome.

However, the FDA lacks the authority to enforce the new guidance even assuming it is finalized. Under the law, the FDA cannot require submission of substantiating data or insist that such data be made available to the public.

One option is to change the law and require premarket approval by the FDA of any structure/function claim made for an infant formula. Unfortunately, it is unlikely that Congress would pass such a law at this time.

An alternative to a statutory change would be a voluntary process. Together, the FDA and WIC could establish a program that would encourage formula manufacturers to voluntarily submit the recommended data that substantiate structure/function claims for review. This voluntary program would be modeled on a notification procedure by which the FDA currently vets the safety of most food ingredients, called the GRAS procedure.

GRAS stands for generally recognized as safe. Under the Federal Food, Drug, and Cosmetic Act, companies need not obtain approval by the FDA prior to adding an ingredient to a food if such an ingredient is generally recognized as safe (under its specific intended conditions of use, by qualified experts). In 1997, the FDA established a procedure whereby companies can voluntarily submit evidence attempting to demonstrate the GRAS status of a particular ingredient. If the FDA has no reason to question this conclusion, the agency responds with a letter, known as a "good day" letter, explaining that the agency does not challenge the company's GRAS finding.[7] This process allows for more information to reach the FDA and the public; GRAS notices and almost all information submitted with them are available via FDA postings on the web or via Freedom of Information Act requests.

An extension of this voluntary FDA safety program could be introduced to address formula ingredient effectiveness. WIC purchasing power could be used to encourage manufacturer participation. Here's how such a process would work: Formula manufacturers would submit evidence substantiating their claims to the FDA. If the FDA did not have any reason to question the submitter's conclusion that the claim is substantiated, the agency would provide a "good day" letter to the manufacturer. Through the USDA, WIC would support this effort by agreeing, after a phase-in period, that it would only purchase formulas with claims supported by such a letter.

Infant formula marketing claims are leading to confusion among consumers and increased costs. Families and governmental agencies deserve a higher standard of evidence. Establishing this voluntary program at the FDA would help WIC to maximize each dollar spent on supplemental nutrition and would bring order to the chaos of infant formula marketing.

ARTICLE INFORMATION

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