Concerns About Infant Formula Marketing and Additives

Congressional Action Needed to Limit Marketing and Strengthen Regulation of Formula Additives

Troubling pricing trends and marketing practices in the infant formula industry continue to threaten basic public health, and could have a major impact on the WIC Program's ability to serve all eligible applicants. It is critically important for Congress and the Administration to understand clearly the effect of these trends on the WIC program (as well as on all consumers), and then formulate a multi-pronged policy and regulatory strategy to address them.

Infant Formula Competes with Breastmilk

Infant formula companies battle for market share against a unique product: breast milk, a living food that contains hundreds of active biological substances that cannot be manufactured and are not present in infant formula. As breastfeeding rates have slowly and steadily increased, particularly among low-income women, the formula industry has grown more aggressive in its attempt to regain market share, particularly by pushing formula supplementation (i.e., combining breastfeeding and formula feeding).[1]

Because breast milk provides infants with all the nutrients they need as well as elements that promote growth and a healthy immune system, breastfeeding can reduce children's risk for infections and chronic diseases such as diabetes and asthma. Breastfeeding has also been shown to lower the mother's risk for diabetes and for breast and ovarian cancers. More recent research shows that breastfeeding also plays a foundational role in preventing childhood obesity and improving cognitive development. A recent comprehensive government analysis of hundreds of studies showed that breastfeeding consistently reduced risks for overweight and obesity. The greatest protection is seen when breastfeeding is exclusive (no formula or solid foods given the infant) and continues for more than three months.[2,3,4]

Thanks in large part to the WIC Program's efforts, breastfeeding *initiation* rates among low-income women have increased in the last decade. However, *exclusive* breastfeeding rates remain much lower and are virtually unchanged — indicating widespread supplementation of breast milk with formula.[5] Duration of breastfeeding beyond the first few months is also rare in the WIC population: in California, only about 18% of WIC mothers are still breastfeeding after the first three months.[6] Using formula undermines breastfeeding because it interferes with a mother's ability to establish her milk supply.

Aggressive Marketing Undermines Breastfeeding – Particularly in WIC

In 1994, the United States signed on to a nonbinding International Code for Marketing of Breastmilk Substitutes of the World Health Organization, which prohibits direct marketing of infant formula to mothers and health care providers.[7] However, there are increasing reports that U.S. formula companies are violating this WHO Code through a number of means: routine and widespread direct marketing, including saturation advertising to mothers with billboards and magazine ads; detail marketing to healthcare providers; and provision of free formula to new and expectant mothers via discount coupons, direct free shipments of formula, and hospital discharge packs.[1] A 2006 GAO report documented marketing practices and how much formula manufacturers spend on them.[8]

As the U.S. birth rate levels off, growth in the domestic infant formula market is primarily being driven by price increases, not by the quantity of formula sold.[9] To maintain profitability, formula manufacturers have raised their prices by creating a dizzying array of new product lines and additives that come with attractive—though scientifically questionable—health claims. Examples of claims for more recent formulations tout relief for "fussy babies" or "gas." Although these products include FDA-approved "designer" ingredients, which have been "generally recognized as safe" as per FDA rules,[10] the direct health benefits of these additives have *not* been proven.

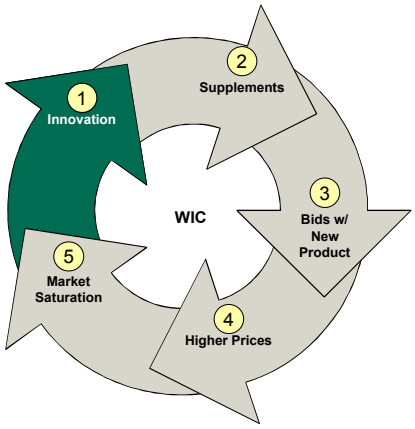
The most disturbing direct advertising for these more expensive "new" formulas subtly undermines the obvious and proven superiority of breastfeeding by positioning formula as more and more equivalent to breast milk, as demonstrated by the following text on a company website*: "Closer Than Ever to Breast Milk!...The first and only infant formula that has a unique blend of prebiotics, nucleotides, and antioxidants -- nutrients naturally found in breast milk. Plus, it has DHA and ARA, ingredients shown to help your baby's brain and eyes."*[11] WIC providers report that this kind of marketing is causing confusion among WIC participants using infant formula, who sometimes ask if WIC provides "the breast milk in a can."

Costly Additives Threaten WIC's Bottom Line

WIC is the nation's largest purchaser of formula, accounting for 60% of total sales. Under federal law, in order to contain costs, state WIC programs currently procure infant formula using a competitive bidding system, awarding a sole-source contract to the firm offering the lowest net price (wholesale price minus the rebate bid). The rebates are substantial, typically about 85% of the wholesale price, and they reduce WIC food costs by about $2 billion a year. Although the rebate system currently allows WIC to serve an additional 2 million participants, the increased price that the formula industry imposes on "new" products has begun to erode the savings that this procurement system has historically achieved.[12]

Infant formula manufacturers began introducing the DHA/ARA additives in 2003 and heavily marketed the new products as better for babies and "just like breast milk." Within a couple of years, these products had saturated the market, increasing the manufacturers' profits in both the WIC and non-WIC market. With all formula manufacturers wanting to increase profits by promoting DHA/ARA, each new contract since 2004 has been for formulas with these

ingredients. Moreover, WIC infant formula costs began to rise sharply starting around 2003, which coincides with the arrival of DHA/ARA.[13]



Thus, a troubling and costly cycle is beginning to affect WIC's bottom line, in which the "designer" formulas that carry higher wholesale (and retail) prices become the standard, increasing WIC costs and requiring Congress to appropriate more funds for WIC to pay for them. A study recently released by the Economic Research Service at USDA found that the WIC program is spending $127 million more annually for infant formula under the contracts that are currently in place than under previous contracts. ERS tagged most ($91 million or 72%) of this higher expenditure to higher formula prices, the rest to lower rebates.[14]

Formula Additives Are Ruled Safe, but Are They Effective?

While some benefits are evident for premature infants, the research evidence regarding the efficacy of DHA/ARA for full-term infants is inconclusive. In fact, a recent independent analysis of the most reliable studies concluded that the studies did *not* demonstrate beneficial effects on visual or brain development outcomes of full-term infants, and did *not* recommend that formula be supplemented with this additive.[15]

California WIC Association believes that these troubling trends and practices in the infant formula industry threaten the public's health and, unless policy changes are made, will continue to make it more expensive for the WIC Program to serve all eligible applicants and address the stark breastfeeding disparities found in low-income WIC mothers. Policymakers are urged to consider the recommendations listed below.

Recommendations

Congress and the Administration are urged to formulate a multi-pronged policy and regulatory strategy to encourage breastfeeding, review industry practices and ingredients, and protect the WIC Program from unnecessary expenditures.

Protect WIC Program from Unnecessary Expenditures

USDA should establish a science-based process for reviewing WIC formulas and other foods with additives, to determine whether a food with a particular additive confers appreciable health or developmental benefits should be offered by the WIC program.

With USDA support and approval, state WIC Programs should investigate and implement demonstration projects that test the feasibility of new methods for infant formula procurement and distribution while still meeting the federal infant formula cost-containment requirements.

Review Industry Practices and Ingredients

Congress should require the Federal Trade Commission to conduct a thorough review of industry expenditures, strategies, and public health impacts of direct and indirect marketing of infant formula to low-income women in the U.S.

Congress should hold hearings to follow up on FDA's implementation of the IOM infant formula safety recommendations and to examine the impact of formula additives and their marketing on breastfeeding.

Congress should require the FDA to commission the Institute of Medicine to review and assess standards for determining the efficacy of ingredients new to infant formula since 2000.

Congress should require the FDA to create and enforce more stringent approval criteria for both the safety and the efficacy of ingredients new to infant formula.

Encourage Breastfeeding

Congress should introduce a measure to reaffirm the United States' endorsement of the World Health Organization's International Code of Marketing of Breastmilk Substitutes, as well as the W.H.O. Global Strategy for Infant & Young Child Feeding.

Congress should urge the Department of Health and Human Services to require that all Medicaid-funded maternity hospitals achieve the Baby-Friendly designation.

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California WIC Association
1107 Ninth Street, Suite 625
Sacramento, CA 95814
916/448-2280 www.calwic.org