INFANT FORMULA MARKETING POLICY MEMO

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Formula Standards

The Infant Formula Act of 1980 authorized the Food and Drug Administration (FDA) to assure quality control of infant formulas. The FDA, however, does not approve infant formulas before they can be marketed. All formulas marketed in the United States must meet federal nutrient requirements. Infant formula manufacturers are required to register with FDA and provide the agency with a notification prior to marketing a new formula.

The FDA has published a rule in 2014 that sets standards for manufacturers of infant formula and requires manufacturers to have been compliant by September 8, 2014. Under the final rule, standards include: 1) current good manufacturing practices specifically designed for infant formula, including required testing for Salmonella and Cronobacter; 2) a requirement that manufacturers demonstrate that the infant formulas they produce support normal physical growth; 3) a requirement that infant formulas be tested for nutrient content in the final product stage, before entering the market, and at the end of the products’ shelf life.¹

International and Federal Support for Restricting Formula Marketing

International

The negative association between the marketing of breast-milk substitutes and breastfeeding rates was the basis of the World Health Organization’s International Code of Marketing of Breast-milk Substitutes (the Code). Developed with infant formula manufacturers, the Code is a nonbinding public health recommendation prohibiting the unethical marketing of formula, including the promotion of formula as superior to breast milk, and the advertising and/or provision of free samples to pregnant women, new mothers, and health facilities.²

The Code entrusts governments to regulate what information, education, and equipment women, health care providers, and others in their countries receive on breastfeeding and formula, and there is no mechanism for international enforcement. It is voluntary in the United States and virtually no legal action has been taken on it.³

Federal, State, and Local Initiatives

The Surgeon General has also flagged the risks of formula marketing. In the 2011 Call to Action to Support Breastfeeding, the Surgeon General emphasized that we “must ensure that health care clinicians do not serve as advertisers for infant formula” in order to avoid undermining breastfeeding.⁴
HIPAA rules directly recognize formula bag distribution as a form of marketing, which normally requires that the covered entity (e.g., a hospital) first obtain an individual’s “authorization.” However, discharge bags do not actually require authorization because they fall under the exception of marketing in the form of a face-to-face communication made by a covered entity to an individual, or a promotional gift of nominal value provided by the covered entity.\(^5\)

There are some additional restrictions at the state and local level. Several jurisdictions have developed voluntary programs which hospitals undertake to eliminate the provision of non-medically indicated infant formula from their maternity and infant care protocols. This includes leaving infant formula out of the going-home packages given to breastfeeding mothers. Massachusetts, Rhode Island, Portland, Oregon, and New York City have all adopted voluntary programs that effectively eliminate infant formula marketing in birthing hospitals. Half of the hospitals in Oklahoma have done the same. These sorts of voluntary programs have proven quite effective and may serve as models for measures that local government may wish to take.

In 2012, for example, New York City implemented a voluntary “Latch On NYC” initiative in which hospitals may make a voluntary commitment to stop supplementing breastfeeding infants with formula, unless medically indicated or at the mother’s specific request. Under the initiative, hospitals would also pledge to end the distribution of promotional formula and materials during the hospital stay and at discharge.

**Professional Organizations**

Many doctors belong to professional organizations that also provide standards on similar issues as the Code. For example, in 2010, the Council of Medical Specialty Societies (CMSS), which represents 32 leading medical professional societies, including the American Academy of Pediatrics, adopted its own Code for Interactions with Companies. This code, which was revised in 2011, provides guidance for appropriate interactions with for-profit companies in the health care sector to ensure that interactions benefit patients and lead to improved care.

The CMSS code ensures that interactions with companies, such as manufacturers of breast-milk substitutes, meet high ethical standards. These standards may include disclosing any company sponsorship or support to CMSS members and the public and not accepting company sponsorship of items or programs unless they are aligned with the CMSS’s strategic plan and mission.\(^6\)

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<th>Policies and Practices that Support Restricting Formula Marketing</th>
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<td>• <em>Health care provider guidelines</em>: Guidelines for how public health clinics and facilities can display and distribute materials can influence health care providers to implement practices that curtail formula advertising to maximize breastfeeding initiation, duration, and exclusivity.</td>
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- **Targeted advocacy:** To continue momentum for best practices, those highest ranked U.S. News hospitals that have not banned formula company sponsored discharged bags should be pressured to do so.
- **Local policies:** Individual healthcare facilities should adopt policies modeled after the Code and train staff on how to implement the policies.

**Encourage Baby-Friendly facilities:** Birth facilities that have achieved a Baby-Friendly designation typically experience an increase in breastfeeding rates. This global program was launched by the WHO and the United Nations Children’s Fund (UNICEF) in 1991 to encourage and recognize hospitals and birthing centers that offer an optimal level of care for infant feeding and mother/baby bonding. To be designated as Baby-Friendly under the Baby-Friendly Hospital Initiative (BFHI), a facility must train its staff on the topics covered in the WHO course entitled “Section 3: Breastfeeding Promotion and Support in a Baby-friendly Hospital.”
- **Medicaid-funded hospitals:** Congress should urge the Department of Health and Human Services to require that all Medicaid-funded maternity hospitals achieve the Baby-Friendly designation.

- **Materials without marketing:** Government and health care providers should provide educational materials that do not deter breastfeeding initiation, duration, and exclusivity to the offices of pediatricians, family practitioners, obstetrician-gynecologists, and nurse-midwives; and to public health clinics and facilities.
- **Local professional associations:** Local associations of health care professionals (such as pediatricians, family practitioners, OB/GYNs, and nurse-midwives) should be targeted to encourage the use of informational or educational materials that do not deter breastfeeding initiation, duration, and exclusivity.
- **Local initiatives:** Like New York City, localities should develop initiatives to require or encourage hospitals to end infant formula marketing. They should adopt rules requiring that hospitals adopt model policies and follow best practices for breastfeeding, including eliminating formula marketing.
- **Follow-on products:** Regulators should ban or restrict follow-on or toddler formulas. These products are sold for ages six months to two years, and are not nutritionally complete nor subject to the same regulations as infant formula. Critics find these have been introduced to circumvent the regulations regarding infant formula and have resulted in confusing advertising.
- **Improve WIC:** WIC’s dependence on formula rebates and its large market share of all formula purchases should be analyzed and improved.
  - Congress should formulate a multi-pronged policy and regulatory strategy to encourage breastfeeding, review industry practices and ingredients, and protect the 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.
• **Enforce WIC marketing restrictions**: Pursue formula manufacturers who violate the USDA’s Food and Nutrition Service restrictions by using the trademarked WIC acronym in their printed materials. The GAO recommended that the Secretary of Agriculture educate all states about FNS’ policy restricting the use of the WIC acronym and logo and ensure that all state formula contracts include provisions restricting the use of these trademarks in infant formula advertisements.8

• **Evolving marketing**: Decision-makers should review the effects of and regulate new and evolving channels of direct-to-consumer marketing, such as social media.

• **FDA approval**: Congress should require the FDA to create and enforce more stringent approval criteria for both the safety and the efficacy of ingredients and health claims new to infant formula.
Works Cited


3. Country implementation of the international code of marketing of breast-milk substitutes.


8. GAO. BREASTFEEDING Some Strategies Used to Market Infant Formula May Discourage Breastfeeding; State Contracts Should Better Protect against Misuse of WIC Name. 2006;(February).