


A Critical Review of the Marketing Claims of Infant Formula Products in the United States

Clinical Pediatrics
1–6
© The Author(s) 2015
Reprints and permissions:
sagepub.com/journalsPermissions.nav
DOI: 10.1177/0009922815589913
cpj.sagepub.com


Peter F. Belamarich, MD¹, Risa E. Bochner, MD¹,
and Andrew D. Racine, MD, PhD¹

Abstract

A highly competitive infant formula market has resulted in direct-to-consumer marketing intended to promote the sale of modified formulas that claim to ameliorate common infant feeding problems. The claims associated with these marketing campaigns are not evaluated with reference to clinical evidence by the Food and Drug Administration. We aimed to describe the language of claims made on formula labels and compare it with the evidence in systematic reviews. Of the 22 product labels we identified, 13 product labels included claims about colic and gastrointestinal symptoms. There is insufficient evidence to support the claims that removing or reducing lactose, using hydrolyzed or soy protein or adding pre-/probiotics to formula benefits infants with fussiness, gas, or colic yet claims like “soy for fussiness and gas” encourage parents who perceive their infants to be fussy to purchase modified formula. Increased regulation of infant formula claims is warranted.

Keywords

advertising as a topic, infant formula, breastfeeding, breast milk, colic, Food and Drug Administration, WIC program

Introduction

The sale of infant formula products in the United States is a highly competitive multibillion dollar industry. One response to the intense competition within this market has been the attempt to create product differentiation by offering specialized infant formulas targeted at specific portions of the market. This has led to a corresponding increase in marketing claims on infant formula product labels. The regulation of the claims that formula companies make with respect to their products occupies a special niche in the regulatory affairs of the Food and Drug Administration (FDA).¹ The degree of FDA regulatory oversight of a product varies based on the type of statement being made (Table 1) and by the substance classification (ie, conventional food, dietary supplement, medication). Since infant formulas are classified as conventional foods and the claims on product labels are not considered health claims, they are not subject to premarketing approval by the FDA, and they do not require disclaimer statements describing the level of scientific evidence underlying them. They must only meet the general statutory requirement that they are “truthful and not misleading.”¹

The regulatory environment surrounding the manufacture and marketing of infant formulas and the recent rise in development of specialized infant formulas is the subject of a recently published commentary piece by Dr Steven A. Abrams titled, “Is it time to put a moratorium on new infant formulas that are not adequately investigated?”⁴ Abrams concludes that the manufacture and sale of specialized infant formulas with small compositional changes such as reduced lactose or the addition of probiotics is not evidence based and has little if any benefit to infants, parents, or pediatricians. He proposes a moratorium on new infant formula manufacture until the evidence base is expanded or, alternatively, there is an increase in regulation. We agree with the sentiments expressed by Abrams and share his concerns. Our article complements Abrams’ analysis by focusing on the

¹Children’s Hospital at Montefiore, Albert Einstein College of Medicine, Bronx, NY, USA

Corresponding Author:

Peter F. Belamarich, Children’s Hospital at Montefiore, Albert Einstein College of Medicine, Comprehensive Family Care Center, 1621 Eastchester Road, Bronx, NY, 10460, USA.
Email: pbelamar@montefiore.org

Table 1. Food and Drug Administration (FDA) Classification of Nutrition-Related Claims.

Type of Statement	Health Claim	Qualified Health Claim	Structure Function Claim	Nutrient Content Claim
Definition	Claims that characterize the relationship of any substance to a disease or health-related condition ¹	Claims that use qualifying language in the form of disclaimer statements to characterize the strength of scientific evidence in support of the claims ¹	Claims that describe the relationship between a substance and the structure or function of the body without referencing disease ¹	Claims that characterize the level of a nutrient in the food ¹
Example	"Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease" ²	"Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive." ¹	"Probiotic LGG to support digestive health" ^{1,3}	"Lactose-free" ^{1,3}
Regulation	Preapproval by FDA ¹	Preapproval by FDA ¹	No preapproval by FDA ¹	No preapproval by FDA ¹
Level of evidence	Significant Scientific Agreement (SSA) Standard ¹	Science supporting the claim does not meet SSA and must be "qualified" with a disclaimer so as to not be misleading ¹	Must be truthful and not misleading ¹	Must abide by published FDA guidelines ¹

specific claims being made on infant formula product labels. We sought to identify and classify commercially produced term infant formulas, catalogue the clinical benefits they claim to produce and then subject the language of the claims to a critical analysis in which we impute their meaning and compare them to specific evidence in systematic reviews. Because the majority of infant formula marketing claims are directed to the treatment of colic and gastrointestinal (GI) symptoms we limited our investigation to claims surrounding infantile colic, crying, or perceived GI distress.

Methods

Identifying Formula Products

We identified formulas for inclusion in our analysis by reviewing the websites of the 3 top formula manufacturers in the United States: Meade Johnson Nutrition,³ Abbott Nutrition,⁵ and Gerber.⁶ We restricted our analysis of the claims to the printed labels on the formula products as this was the most universally accessible placement to the broadest cross-section of consumers. We excluded preterm and next step (toddler) formulas from our analyses. Generic or store brand formulas were also excluded because the generic formulas offer a lower

cost alternative to formula by avoiding the cost associated with marketing.

Formula Composition

Data on formula composition were gathered from inspections of formula product labels and by accessing information from the manufacturers' websites.

Claims on Infant Formula Labels

The text on the cans was extracted from the labels verbatim and then entered into a spreadsheet. For the claims directed at the treatment of colic and GI symptoms, we grouped them by associated formula modification for comparison to the existing evidence. Additionally, we critically analyzed the wording used and attempted to impute their direct and implied meanings.

Evidence for the Claims

The evidence basis for the claims was sought in the 2 most authoritative sources of systematic reviews: *Clinical Evidence*⁷ and Cochrane Reviews,⁸ in the Handbook and Policy Statements of the American Academy of Pediatrics' (AAP) Committee on Nutrition⁹

Table 2. Formula Name, Modification, and Claim.

	Formula Brand Name	Formula Modification	Claims
1	Nutramigen with Enflora LGG North America ³	Amino acids, reduced lactose, probiotic	Fast management of colic
2	Nutramigen ³	Amino acids, reduced lactose	Fast management of colic
3	Enfamil Gentlease USA ³	Whey hydrolysate, reduced lactose	For Fussiness, gas and crying. Helps reduce fussiness, gas, and crying within 24 hours. Easy to digest protein
4	Enfamil Reguline ³	Whey hydrolysate, prebiotic	Easy to digest gentle protein
5	Enfamil ProSobee ³	Soy protein, reduced lactose	Soy for fussiness and gas reduces fussiness and gas
6	Similac Sensitive ⁵	Reduced lactose	For fussiness and gas due to lactose sensitivity. Complete nutrition for sensitive tummies
7	Similac Total Comfort ⁵	Whey hydrolysate, reduced lactose	For discomfort due to persistent feeding issues. Partially broken down protein for easy digestion
8	Similac Soy Isomil ⁵	Soy protein, reduced lactose	For fussiness and gas
9	Similac Expert Care Alimentum ⁵	Casein hydrolysate, reduced lactose	For food allergies and colic due to protein sensitivity
10	GERBER GOOD START Gentle ⁶	Whey hydrolysate	Comfort proteins advantage. Easy to digest
11	GERBER GOOD START Soothe ⁶	Whey hydrolysate, reduced lactose, probiotic	Comfort proteins advantage. Easy to digest For excessive crying, colic, and fussiness
12	GERBER GOOD START Soy ⁶	Soy protein, reduced lactose	Easy to digest. For sensitive tummy
13	GERBER GOOD START Gentle for supplementing ⁶	Whey hydrolysate, probiotic	Gentle nutrition for when breastfeeding moms supplement comfort proteins advantage

and, if not assessed in these sources, in the latest systematic reviews. We sought evidence of effectiveness of the following formula modifications on infantile colic, crying, or perceived GI distress: casein and whey protein hydrolysates, removal or reduction of lactose, soy-based formula, and addition of prebiotics or probiotics.

Results

Products and Claims

We identified 22 infant formulas for term infants listed on the websites of the top 3 US formula manufacturers.^{3,5,6} Of the 22 infant formulas, we identified 13 that made claims directed at the treatment of colic and GI symptoms on their product labels. All 13 contained at least 1 formula modification that distinguished them from routine milk-based, lactose-containing infant formula. Ten of the 13 were lactose-free or reduced, 7 contained partially hydrolyzed whey or casein protein, 2 contained fully hydrolyzed protein, 4 contained pre-/probiotics, and 3 were soy protein based. These formulas are presented along with formula modifications, and claims related to the treatment of colic and GI symptoms in Table 2.

Analysis of Language of Claims

We identified 13 unique claims directed at colic or GI symptoms (see Table 2). Statements like “soy for fussiness

and gas” imply that parents with fussy and gassy infants should feed them soy protein in order to improve their symptoms. The claim, “for fussiness and gas due to lactose sensitivity” avoids the use of the term “lactose intolerance” that might invite more careful scrutiny of the claim as treatment for a disease. Many claims used phrases like “comfort proteins,” “gentle . . . for sensitive tummies,” and “easy to digest.” Parents are invited to think that fussy babies may be experiencing digestive discomforts—it makes sense to employ *comfort protein*. Similar messages are implied by formula names like Enfamil “*Gentlease*,” Similac “*Sensitive*” and “*Total Comfort*,” and GERBER GOOD START “*Gentle*” and “*Soothe*.”

Review of Evidence for the Claims

In 2010, *Clinical Evidence* published a systematic review of treatments of infantile colic that exhaustively compiled, critically reviewed, and synthesized the available evidence from trials of the following formula modifications: protein hydrolysates, lactose-reduced feedings, and soy formula.¹⁰ The Cochrane Library has not yet published a Cochrane Review on any formula modifications and infantile colic.⁸ The AAP’s Committee on Nutrition Handbook includes commentary on the evidence behind soy protein-based formula but not the other formula modifications.⁹ In 2013, Sung et al¹¹ systematically reviewed the evidence from trials of oral probiotics to prevent or treat infantile colic.

Regarding the value of casein hydrolysates, the Clinical Evidence review included a study of 122 infants enrolled in a trial of casein hydrolysate milk (or hypoallergenic diet for breastfeeding mothers) versus standard cow's milk formula or control diets for breastfeeding mothers.¹² Based on the results of this study the review concluded that there was "insufficient evidence of an effect."

For whey hydrolysate formulas the review focused on a double blind randomized controlled trial of 43 infants fed a whey hydrolysate formula versus standard formula.¹³ Infants fed whey hydrolysate cried less and this result was statistically significant. However, unblinding of four parents who fed hydrolysate and a wide confidence interval around the effect led the reviewer to conclude that the available evidence was of "low quality."

The Clinical Evidence review identified 2 studies of the effect of soy-based formulas on infant colic of which one was too small, and the other suffered from methodological weaknesses.^{14,15} Regarding soy formula, the review concluded that there was "no direct information." The AAP Committee on Nutrition also concluded that soy protein-based formula is "not recommended for the prevention of colic or allergy."⁹

Clinical Evidence also reviewed low-lactose milks for colic. After excluding trials that were too small, the review focused on a randomized controlled trial of 53 infants that found a nonsignificant difference in crying time.¹⁶

Regarding the use of oral probiotics to prevent or treat excessive infant crying, Sung et al¹¹ identified 12 randomized controlled trials of 1825 infants that compared oral probiotics to placebo or no treatment. They concluded that in exclusively breastfed infants, *Lactobacillus reuteri* may be effective in treating excessive crying. However, "there is still insufficient evidence" for probiotic use in formula fed infants to manage colic and crying."¹¹

Discussion

We have documented the multiplicity of modified formula products and associated claims that parents face when attempting to choose a formula for their infant. Our review of the evidence for these claims demonstrates a distinct paucity of evidence for the claims as written. We have documented that these claims encourage those parents who perceive their infants to be fussy, gassy, or colicky to purchase lactose-reduced, protein hydrolysate, soy, or pre-/probiotic containing formulas as a remedy, contrary to the currently available research as summarized by the highest quality systematic reviews.

Infant formula companies are under increased pressure to differentiate their products in a highly competitive market. Most likely as a result of the strict and lengthy application process for approval of health and qualified health claims, formula companies are placing claims on their products that use language to *imply* product-disease relationships without making direct health claims that would be subject to premarket approval by the FDA. As of January 2013, only 18 health claims and 19 qualified health claims have been approved for use on food labels by the FDA.¹ The small number of approved health and qualified health claims highlights the difficulties companies face in meeting the requirements necessary to substantiate health claims.

Consumers rely on the information on food labels to help them make healthy food choices for themselves, and in this case, their infants. It has been shown that consumers have difficulty distinguishing between health claims that are supported by significant scientific agreement and other claims on food labels that have lower levels of scientific support.² Likewise, consumers are just as likely to purchase a product with a structure function claim that does not require FDA preapproval as they are a product with a health claim.² When claims are misleading or not substantiated by the scientific evidence, consumers' efforts to make informed decisions about their food choices are undermined.

Our analysis of claims made by infant formula marketing suggests that the purpose of these messages is to widen the use of modified formulas largely in the absence of evidence. The manufacturers employ a variety of rhetorical strategies to achieve this aim. When applied to medications and tests this phenomenon has been referred to as "indication creep."¹⁷ First parents face both prescriptive claims (for "fussiness" and "gas") that lack a basis in clinical evidence and more ambiguous descriptions such as "comfort proteins" and "easy to digest" that imply a benefit or an indication while eluding the scrutiny that would be applied to direct health claims. A second approach involves an appeal to commonly held misperceptions. While "lactose free" is neither a direct nor an indirect claim it is clear that formula companies use this descriptor to successfully market lactose free formula by exploiting a mistaken health belief regarding the prevalence of lactose intolerance in infants. Significant lactose intolerance is very unusual in otherwise healthy infants.¹⁸ A third technique makes use of qualification that a layperson could not possibly be expected to appreciate that nonetheless invites a form of "indication creep" by generalization from the particular to the general. An example of this is, "for colic due to cow's milk protein allergy." While individual infants with incipient cow's milk protein sensitivity could have symptoms

attributable to “colic,” colic exists in the absence of identifiable GI pathology. Thus claims about hydrolysates for “colic due to . . .” invite the phenomenon of “indication creep’ from the symptoms of cow’ milk protein intolerance to colic and fussiness in general.

While we acknowledge that all the products we have reviewed are safe and have met the stringent requirements of the Infant Formula Act¹⁹ our concerns are focused on the claims. One concern is that successful marketing of formula may compete with the initiation or duration of breastfeeding.²⁰ This concern forms the motivation for the World Health Organization international code on marketing breast milk substitutes.²¹ The health and economic benefits of breastfeeding are well established.^{22,23} While we do not currently present evidence to substantiate this concern, this is something that should be addressed with further research. A second concern is the economic cost associated with the purchase of modified formulas as opposed to routine formula. A 6-pack of ready-to-use 8-oz bottles of standard Similac formula costs \$11.99 at Babies “R” Us. A comparable purchase of Similac Isomil costs \$12.99 and Similac Expert Care Alimentum costs \$17.99.²⁴ These costs can add up overtime and may be an unnecessary financial burden on parents. Our third concern is related to labeling infants who manifest varying degrees of normal infant crying with medical conditions such as lactose intolerance that they may not have.²⁵ An additional concern is the effect of marketing specialized formulas on the Supplemental Nutrition Program for Women Infants and Children (the WIC program). The WIC program purchases more than 50% of the infant formula in the United States.²⁶ WIC recipients can receive nonroutine formulas with a written prescription from a physician. While pediatricians are required by WIC to prescribe modified formula when medically indicated, it can be both difficult and time consuming for pediatricians to convince the parents of fussy but otherwise normal infants who have seen these claims that the answer to their child’s problem is not a diagnosis requiring a specialized formula.

Our concerns with the power of marketing claims are not unique to the United States. In Australia, Kemp²⁷ noted geographic disparities in the use of highly specialized formula inconsistent with evidence-based practice that was attributed to the marketing efforts of the formula company and The French Pediatric Society’s Committee on Nutrition has also noted the power of formula marketing to undermine the scientific and evidence-based use of infant formula products.²⁸

This descriptive study has certain limitations. We have not examined longitudinal evidence documenting the growth of sales subsequent to the appearance of these claims to fully substantiate that the marketing

messages work to sell modified formula in the way that we hypothesize. Nor do we have the counterfactual to confirm the inference that these claims dissuade mothers from initiating or continuing breastfeeding. Finally, our analysis of these claims is somewhat interpretive. Despite these limitations, based on our synthesis of the evidence we believe that infants, parents, and pediatricians in the United States would be well served by a rigorous review by the federal government of the current statements and claims made by the manufacturers of infant formula.

Author Contributions

PFB had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. PFB conceived of and designed the study. PFB and REB collected, analyzed, and interpreted the data. PFB, REB, and ADR prepared the manuscript for publication.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

1. US Food and Drug Administration. *Food Labeling Guide*. Silver Spring, MD: US Food and Drug Administration; 1994. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>. Accessed May 29, 2014.
2. US Government Accountability Office. *Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers From False or Misleading Claims*. Washington, DC: US Government Accountability Office; January 2011.
3. Enfamil. <http://www.enfamil.com/products>. Accessed December 28, 2014.
4. Abrams SA. Is it time to put a moratorium on new infant formulas that are not adequately investigated? *J Pediatr*. 2015;166:756-760.
5. Similac. <https://similac.com/baby-formula>. Accessed December 28, 2014.
6. Gerber. <http://www.gerber.com/products/formula>. Accessed December 28, 2014.
7. *BMJ Clinical Evidence*. <http://www.clinicalevidence.com>. Accessed March 11, 2015.
8. Cochrane Library. <http://www.thecochranelibrary.com>. Accessed March 11, 2015.
9. Formula Feeding of Term Infants. Kleinman RE, ed. *American Academy of Pediatrics Pediatric Nutrition Handbook*. 7th edition, Elk Grove Village, IL: American Academy of Pediatrics; 2013.

10. Lucassen P. Colic in infants. *BMJ Clinical Evidence*. Published February 5, 2010. <http://www.clinicalevidence.com>. Accessed March 11, 2015.
11. Sung V, Collett S, de Gooyer T, Hiscock H, Tang M, Wake M. Probiotics to prevent or treat excessive infant crying: systematic review and meta-analysis. *JAMA Pediatr*. 2013;167:1150-1157.
12. Hill DJ, Hudson IL, Sheffield LJ, Shelton MJ, Menahem S, Hosking CS. A low allergen diet is a significant intervention in infantile colic: results of a community-based study. *J Allergy Clin Immunol*. 1995;96(6 pt 1):886-892.
13. Lucassen PL, Assendelft WJ, Gubbels JW, van Eijk JT, Douwes AC. Infantile colic: crying time reduction with a whey hydrolysate: a double blind, randomized, placebo-controlled trial. *Pediatrics*. 2000;106:1349-1354.
14. Campbell JP. Dietary treatment of infantile colic: a double-blind study. *J R Coll Gen Pract*. 1989;39(318):11-14.
15. Lothe L, Lindberg T, Jakobsson I. Cow's milk formula as a cause of infantile colic: a double-blind study. *Pediatrics*. 1982;70:7-10.
16. Kanabar D, Randhawa M, Clayton P. Improvement of symptoms in infant colic following reduction of lactose load with lactase. *J Hum Nutr Diet*. 2001;14:359-363.
17. Hébert PC, Stanbrook M. Indication creep: physician beware. *CMAJ*. 2007;177:697, 699.
18. Heyman MB, for the Committee on Nutrition. Lactose intolerance in infants, children, and adolescents. *Pediatrics*. 2006;118:1279-1286.
19. Federal Food Drug and Cosmetic Act Amendment relating to infant formula. 99th Congress, 2nd Session. *Congressional Record*. 1986;132(130):S14042-S14047.
20. Kaplan DL, Graff KM. Marketing breastfeeding—reversing corporate influence on infant feeding practices. *J Urban Health*. 2008;85:486-504.
21. World Health Organization. *International Code of Marketing of Breast Milk Substitutes*. Geneva, Switzerland: World Health Organization; 1981. http://www.who.int/nutrition/publications/code_english.pdf. Accessed May 29, 2014.
22. Ip S, Chung S, Raman G, Trikalinos TA, Lau J. A summary of the Agency for Healthcare Research and Quality's evidence report on breastfeeding in developed countries. *Breastfeed Med*. 2009;4(suppl 1):S17-S30.
23. Bartick M, Reinhold A. The burden of suboptimal breastfeeding in the United States. *Pediatrics*. 2010;125:e1048-e1056.
24. Babies "R" Us. Similac. <http://www.toysrus.com/family/index.jsp?categoryId=3856967&sr=1&origkw=similac>. Accessed March 11, 2015.
25. Armstrong K, Previterra N, Mccallum R. Medicalizing normality? Management of irritability in babies. *J Paediatr Child Health*. 2000;36:301-305.
26. Oliveira V, Frazão E, Smallwood D. *Rising Infant Formula Costs to the WIC Program: Recent Trends in Rebates and Wholesale Prices* (ERR-93.) Washington, DC: Department of Agriculture, Economic Research Service; 2010.
27. Kemp A. Hypoallergenic formula prescribing practices in Australia. *J Paediatr Child Health*. 2006;42:191-195.
28. Comité de nutrition de la Société française de pédiatrie. Infant formulae and follow-on formulae: an evidence-based dietetic approach is necessary for marketing and communication. *Arch Pediatr*. 2007;14:319-321.