

## Consumer protection and self-regulation

**Preliminary review of consumer  
protection and self-regulation of infant  
formula marketing**

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Memo prepared for  
**Feeding infants and children:  
Is industry marketing undermining health?**

A cross-disciplinary meeting to identify research questions and  
explore opportunities for action

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## **Introduction**

This memo provides a preliminary overview of consumer protection policies that govern infant formula marketing and related self-regulation and international codes of conduct. The four major infant formula producers are Mead Johnson (Enfamil), Abbott Nutrition (Similac), Nestlé (Gerber), and PBM Nutritionals (Bright Beginnings and private label). Historically the industry has focused heavily on healthcare provider-directed marketing to reach new mothers. It now also seeks to engage women with an ever expanding range of direct-to-consumer marketing tactics that include traditional marketing on television, coupons, elaborate websites, rewards programs, infant feeding advice hotlines, YouTube videos, social media marketing on Facebook, Twitter and Instagram, and product packaging.<sup>1</sup> This marketing is structured to build a path-to-purchase: during pregnancy; at the doctor's office; at maternity clothing retailers; in the hospital; in the food retail environment; and at home when infant caregivers are making decisions to supplement with formula, wean and introduce solid foods.

The number of babies born each year is stable<sup>2</sup> and breastfeeding rates in the US are on the rise, which translates to projections of lower US infant formula sales.<sup>3</sup> In this mature market, formula companies must compete for market-share through the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) sole source contract process, product differentiation, marketing breast-feeding supplementation to shorten the length of exclusive breastfeeding, and the addition of supplements to increase price.<sup>4</sup> Infant formula marketing has spawned numerous disputes between formula companies via self-regulatory proceedings, private consumer litigation for false and deceptive marketing, and limited oversight by federal and state consumer protection regulators. In the memo, I discuss these actions and explore potential paths forward.

## **The FDA's Role**

The Food and Drug Administration (FDA) ensures that infant formula meets the nutritional needs of infants and is safe,<sup>5</sup> and conducts some infant formula consumer research.<sup>6</sup> For infant formula marketing, FDA requires pre-approval for certain health claims, but does not preapprove marketing claims called "structure/function claims" that "describe the relationship between a substance and the structure or function of the body without references to a specific disease" like "Probiotic LGG to support digestive

health.”<sup>7</sup> This has provided considerable latitude for marketing claims about common infant behaviors like colic, crying and stomach upset.<sup>8</sup>

On Sept 8, 2016, the FDA released a draft of a new “Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Guidance for Industry” for public comment.<sup>9</sup> This is the first time the FDA has issued guidance for a conventional food and is similar to its guidance for the dietary supplement industry.<sup>10</sup> FDA guidance is voluntary but signals to an industry how the agency interprets its regulatory authority. The following are key points from the proposed guidance:

- The FDA “intends to apply the ‘competent and reliable evidence’ standard for the substantiation of infant formula claims” consistent with its approach for the substantiation of dietary supplement claims.
- “[T]o...avoid the possibility of subjecting the [infant formula] product to regulation as a drug, a structure/function claim in the labeling of infant formula should derive from the product’s character as a food.”
- “[C]ompetent and reliable scientific evidence means evidence that includes findings from well-designed and controlled intervention studies in an appropriate population of U.S. infants (or infants with similar nutrition and general health status) using an appropriate formula matrix with and without the constituent of interest.”
- “[W]e recommend that the substantiation for [structure/function claims in infant formula labeling] rely on the results of infant feeding intervention studies that are randomized, double-blind, and parallel-controlled.”
- “[L]abeling claims that suggest that the product contains constituents found in breast milk or that the product is ‘closer’ to breast milk than other formulas...are not structure/function claims and are not addressed in this guidance.”<sup>11</sup>

This guidance signals to industry that the FDA plans to take a more active role in policing infant formula marketing and it is now subject to public comment before it is finalized.

## **Self-Regulation**

Industry self-regulation occurs when private firms together or individually police their own business conduct. Mead Johnson, Abbott and Nestlé actively participate in self-regulation through the Better Business Bureau’s National Advertising Division (NAD). This section will provide some historical context, discuss the shortcomings of current formula industry self-regulation and suggest opportunities to strengthen the NAD system to better protect consumers.

### ***Abuse of Self-Regulation by the Formula Industry***

Infant formula industry self-regulation has a checkered past that may complicate more robust voluntary marketing restrictions. Collaborative self-regulation must comply with antitrust laws that prohibit competitor collaborations that unlawfully restrain advertising or raise prices.<sup>12</sup> Up until the 1980's, Abbott and Mead Johnson had a duopoly and indirectly marketed to mothers via the healthcare sector. When Nestlé sought to enter the US market it planned to market its products directly to the public.<sup>13</sup> In response, Abbott and Mead, with the American Academy of Pediatrics (AAP), lobbied for restrictions on direct-to-consumer infant formula advertising “citing its negative impact on breastfeeding rates.”<sup>14</sup> Nestlé unsuccessfully sued Abbott, Mead and the AAP. Advertising restrictions remained until Abbott and Mead raised formula prices six-fold. A subsequent antitrust enforcement action for “price collusion, bid rigging, and conspiracy to prevent advertising” resulted in a \$230 million settlement.<sup>15</sup>

### ***The National Advertising Division***

The three major infant formula companies are members of the Better Business Bureau's National Advertising Division (NAD), and a search of NAD case reports from 2000-2016 found a total of 17 challenges brought by formula companies against one another.<sup>16</sup> PBM Nutritionals does not participate in NAD. This section will discuss NAD's lack of scientific expertise, its current breast milk comparison standard, and its role in healthcare sector marketing.

**The NAD Process:** NAD seeks to reduce “inaccurate and deceptive” national advertising.<sup>17</sup> NAD can initiate actions on its own and accepts consumer complaints.<sup>18</sup> National advertising includes direct-to-consumer advertising (e.g. television commercials, websites, coupons) and healthcare provider-directed marketing (e.g. medical detailing) that occurs on a national basis. NAD issues decisions in the form of case reports and adverse decisions can be appealed internally to the Better Business Bureau's National Advertising Review Board. The vast majority of NAD cases are brought by business competitors against each other.<sup>19</sup>

**NAD Is Not A Scientific Body:** The current, lax regulatory environment has essentially left it up to marketing executives to determine whether there is a scientific basis for complex infant formula marketing claims. NAD routinely makes determinations of the evidence base for infant formula health and ingredient claims. For example, a 2005 decision on Abbott's claim that its Similac Advance product “can help develop a baby's immune system” was decided by a National Advertising Review Board panel that consisted of a VP of Global Marketing for Goldman, Sachs & Co., the Director of Multi-Cultural Marketing for AstraZeneca Pharmaceuticals, and a Managing Partner for the marketing firm Deutsch, Inc.<sup>20</sup> Abbott complained the deliberations were compromised, not for lack of scientific expertise, but because one member missed the hearing, one only heard portions via telephone, and the other was extremely late.<sup>21</sup>

**NAD's Inconsistent Breast Milk Comparison Standard:** NAD has resolved a series of disputes involving infant formula comparisons to breast milk. Over time its standard for such comparisons has weakened. A 2000 NAD case report found that: "at the current time there is no scientific evidence that any infant formula is better than another in supporting infant growth and development."<sup>22</sup> This finding underpinned NAD's 2005 standard for breast milk comparisons that "[i]nfant formula advertising claims making comparisons to breast milk must be narrowly drawn and supported by competent and reliable scientific evidence."<sup>23</sup> In that case, the advertiser made numerous statements that its product was "like breast milk." Such a statement was deemed unsubstantiated by NAD.

NAD's current standard for breast milk comparisons has evolved to: "Claims of an infant formula's compositional similarity to breast milk can be supported so long as the claims are clearly compositional in nature and there is no implication that the compositional similarity gives rise to superior performance," and there is a "reasonable basis" for such claims.<sup>24</sup> Moreover, NAD currently applies a lesser standard when an advertiser "is simply touting its own product's similarity to breast milk."<sup>25</sup> According to NAD, advertising that pairs a breast milk comparison with a claim that the product is superior to a competitor's requires additional disclosures regarding the basis of the comparison to breast milk.<sup>26</sup>

Table 1 provides examples of NAD breast milk comparison findings. It is hard to see the difference in a consumer's take-away from a "closer than ever to breast milk" claim with or without a comparison to another product or the substantive difference between the terms "like" and "closer than" (Table 1). All convey to caregivers that the product is similar to breast milk and therefore good for babies. Using breast milk comparisons deceptively to tout infant formula should be barred with or without a comparison to a competitor's product.

**NAD Also Covers National Health Care Provider-Directed Advertising:** NAD self-regulation extends to healthcare provider-directed claims on nationally distributed printed or digital advertising.<sup>27</sup> For example, in 2008, NAD issued a case report for claims made on a national detailer stating that Enfamil LIPIL was superior to Similac for IQ.<sup>28</sup>

<b>Table 1: NAD Dispositions of Infant Formula Comparisons to Breast Milk</b>	
<b>ALLOWABLE CLAIMS</b>	<b>PROHIBITED CLAIMS</b>
<p>“Now Closer to Breast Milk than Ever*                      (*Reformulated to better match the average caloric density of breast milk.)” (2015)</p> <p>Despite scientific uncertainty, advertiser established a reasonable basis that reformulated 19 cal./fl. oz. formula was “closer to breast milk,” and did not compare the product to competitor’s products, but rather to the company’s own prior formulations.<sup>29</sup></p>	<p>“[C]loser than ever to breast milk” and “Closer to breast milk” when made in comparison to other infant formulas (2009)</p> <p>“...the advertiser’s claims...appear... next to the comparative chart of ‘advantages’ of EarlyShield versus other named competitors,...[T]hese claims give rise to the implied superior performance message (i.e., that the...similarity of the advertiser’s EarlyShield to breast milk offers superior performance as compared to other... infant formulas).”<sup>30</sup></p>
<p>“Closer than ever to breast milk” in conjunction with the advertiser’s claim that “Similac Advance EarlyShield has our unique blend of prebiotics, nucleotides, and Carotenoids” (2010)</p> <p>NAD found this to be “an entirely monadic claim in keeping with NAD’s findings and recommendations that NAD did not find to be problematic.”<sup>31</sup></p>	<p>Similac Advance® “can help develop” a baby’s immune system “like breast milk;”</p> <p>Similac Advance® results in “immune cell development like breast milk.” (2005)</p> <p>“NAD was particularly concerned about the use of the word ‘like.’...[O]ne reasonable takeaway is that the supplemented formula rises to the level of breast milk in terms of immune system development. Even though the disclaimer expressly explains otherwise...NAD recommended that Ross modify the claims to avoid any implication that Similac Advance is ‘like’ breast milk.”<sup>32</sup></p>

### ***Voluntary Marketing Pledges and Commitments***

The International Association of Infant Food Manufacturers (IFM) has an Infant Food Manufacturers' Commitment and Rules for Responsible Conduct (2014) and Nestlé has an international formula marketing policy.<sup>33</sup> These pledges only apply to lower income countries.<sup>34</sup>

### ***Non-Binding International Codes of Conduct***

Companies can choose to comply with international codes of conduct not formally adopted in countries where they do business. Article 5 of the World Health Organization's 1981 International Code of Marketing of Breast-Milk Substitutes ("WHO Code") states that "[t]here should be no advertising or other form of promotion to the general public of products within the scope of this Code."<sup>35</sup> It then specifies various forms of prohibited marketing tactics. The WHO Code has not been adopted in the US, and numerous violations have been documented.<sup>36</sup>

Even when not enforceable, international codes like the WHO Code can "help[] galvanize public support...and [provide] a tool that activists [can] use[] to rally others to support their cause."<sup>37</sup> For example, "activist groups still speak of corporate misbehavior in the realm of infant formula as 'violations' of [the WHO Code]."<sup>38</sup> The WHO Code also has been used in lawsuits against the infant formula industry. A recent complaint filed against Nestlé for marketing Gerber Good Start described the WHO Code's marketing restrictions and Nestlé's disingenuous support of an exclusive 6 months of breastfeeding recommendation on various company websites.<sup>39</sup>

### ***Future Directions for Self-Regulation***

Self-regulation has many shortcomings, but an effort to strengthen NAD may provide an initial path forward. Agencies like the Federal Trade Commission (FTC) are highly deferential to self-regulation, and industry resistance to a more robust NAD system could be used to demonstrate the need for formal regulation. The NAD process is vigorously used by the infant formula industry to protect against comparative advertising that may harm a competitor's bottom line. However, as evidenced by its illogical breast milk comparison standard, consumers have gotten lost in the NAD process. As a starting point to strengthen NAD, advocates could:

**Engage with NAD to revise its breast milk comparison standard to prohibit all breast milk comparisons**, or, at a minimum, universally apply the standard that "[i]nfant formula advertising claims making comparisons to breast milk must be narrowly drawn and supported by competent and reliable scientific evidence" regardless of whether or not the claim is comparative to a competing product.<sup>40</sup>

**Develop an infant formula-specific marketing code.** The BBB's Children's Advertising Review Unit uses guidelines for marketing to children, and its Children's Food and Beverage Initiative uses nutrition criteria for foods advertised to children. These systems are not perfect, but may serve as a model for infant formula self-regulation. A set of evidenced-based standards for

direct-to-consumer and healthcare sector marketing of infant formula for use by NAD could be valuable.

**Organize health care professionals to utilize NAD's consumer complaint system to challenge health care provider-directed advertising.** Concerned health care professionals could use the NAD consumer complaint system to challenge nationally distributed, inaccurate and deceptive materials. Such complaints could encompass arguments that business competitors are unlikely to raise, like how such marketing undermines evidence-based standards for promotion of breastfeeding. This would broaden NAD's current approach and provide a public platform to draw attention to marketing at odds with medical best practices.

**Insist that NAD follow FDA's standards for "competent and reliable scientific evidence."** Self-regulation, at a minimum, should result in private firms following current law. The FDA's proposed guidance for infant formula structure/function claims sets out a framework for analyzing the scientific basis for such claims. While NAD is not a scientific body, if it is going to evaluate structure/function claims it should comply with the FDA's guidance for evaluating such claims, including its proposed recommendation that "structure/function claims in infant formula labeling rely on the results of infant feeding intervention studies that are randomized, double-blind, and parallel-controlled."<sup>41</sup>

## **Consumer Protection**

The FTC regulates false, unfair and deceptive acts or practices in or affecting commerce through enforcement actions and rulemaking.<sup>42</sup> States have their own consumer protection acts enforceable by State Attorneys General, and, where authorized, local agencies (e.g. the New York City Department of Consumer Affairs). Consumer protection centers on the economic harm to consumers when they are misled into purchasing products they otherwise would not have purchased. Private plaintiffs can bring lawsuits under state consumer protection acts individually or as a class for false, deceptive, and, in some jurisdictions, unfair advertising. Consumer protection regulators also have subpoena authority and can demand substantiation of advertising claims. Due to the nuance of state consumer protection law, unless otherwise noted, this discussion will focus on FTC doctrine. This section will set out the basic FTC deception doctrine, discuss how WIC moms may fit into consumer protection actions, and discuss limitations and considerations for future action.



### **Deception**

In order to state a claim of deceptive advertising, the FTC must satisfy three elements: (1) a claim was made; (2) the claim is likely to mislead a reasonable consumer under the circumstances; and (3) the claim was material.<sup>43</sup> Deception is viewed as “especially attractive from a regulatory standpoint” because the FTC need not prove an injury to consumers since “the deception itself is...injurious, given that it involves a material issue affecting” consumer decision-making.<sup>44</sup> Thus, deception can be applied to “situations where advertisements are believed to contribute to consumer injury but the causal relationship is difficult to establish empirically.”<sup>45</sup>

For infant formula marketing, a “reasonable consumer” likely would be construed as a reasonable new mother. Claims about health and safety, and a product’s “price, purpose, quality and performance” are material to consumers.<sup>46</sup> Health-related claims must be substantiated by “competent and reliable scientific evidence.”<sup>47</sup> For example, Enfamil’s claim on social media that “Enfamil Gentlease has complete nutrition

that helps ease tiny tummy discomfort within 24 hours and is easy to digest” could be subject to a request for substantiation from the FTC or a State Attorney General. A similar claim by Abbott for Similac Total Comfort that “partially broken down protein[s]” help with “easy digestion” was subject to a demand for substantiation by the New York City Department of Consumer Affairs.<sup>48</sup>

Reasonable consumers are, however, expected to be able to discern “puffery” or exaggerated representations and to not take them seriously. For example, infant formula claims like “[a] baby’s first year is so important, so count on Similac for nutrition you can trust;” and “Moms can count on [Similac] for trusted nutrition and the formula that’s right for their babies” have been deemed puffery.<sup>49</sup>

### **Where Do WIC Moms Fit?**

Deception cases brought by private plaintiffs under state consumer protection acts must satisfy the additional element of a product purchase, and, in some states, actual reliance on the deceptive trade

### **Two Judicial Views of Infant Formula Marketing**

Judges initially determine whether a “reasonable consumer” could have been misled by allegedly deceptive advertising. In a 2015 hearing, one judge stated:

...I...think...that a lot of the advertising causes confusion with young mothers, or mothers who are in this dilemma of how to properly give nutrition to their babies. ...I’ve already made it clear I think breastfeeding is the way to go, but who cares what I think.

In a 2011 written opinion, a judge was highly skeptical:

Some...representations...are not even arguably misleading: Similac is the “# 1 brand fed in hospitals,” and contains “calcium for strong bones,” “nucleotides to help support the immune system,” “prebiotics to help promote digestive health,” “carotenoids naturally found in breast milk.”

In fact, there have been NAD disputes over all of the claims listed.

practice alleged. WIC moms are the largest consumer block of infant formula users, and are impacted by infant formula marketing.<sup>50</sup> Yet they do not purchase formula with their own funds and are subject to WIC restrictions on the type of formula they can obtain in stores. As a result, WIC moms do not have standing as potential private plaintiffs in deception actions under state consumer protection acts requiring a product purchase. It is up to federal, state and local consumer protection regulators, and potentially the private bar, to craft enforcement actions and cases that challenge deceptive marketing impacting WIC and non-WIC moms' infant feeding practices that may discourage initial intent to breastfeed and duration of exclusive breastfeeding. This would be a departure from the very narrowly tailored deception cases about distinct health claims that are designed to spur brand and product choice once women have already initiated formula. Such an approach would protect WIC and non-WIC moms alike from misleading information when they are developing their intent to breastfeed and navigating how long to exclusively breastfeed.

### ***Digital Marketing is Like Any Other Marketing, Only Different***

The FTC is apt to reiterate that it treats digital marketing like any other advertising that impacts interstate commerce: "Although digital media has expanded and changed the way marketers reach consumers, all advertisers, including digital advertisers, must comply with the same legal principles regarding deceptive conduct the Commission has long enforced."<sup>51</sup> In reality, digital marketing has resulted in a paradoxical situation where, contrary to the FTC's assertion that digital marketing is treated like any other marketing, the more complex a digital marketing campaign, the harder it is to successfully subject it to robust consumer protection action.

The FTC has revised and developed new FTC policy statements and guidance to address digital marketing like its Deceptively Formatted Advertisements (2015) (e.g. "native ads") policy statement, Search Engine Advertising Guidance (2013), and Dot Com Disclosures (2013) guidance.<sup>52</sup> These are primarily designed to protect consumers' privacy and require marketers to disclose when digital content, like a mommy blogger post paid for by a formula company, is sponsored by a commercial interest.

Nonetheless, the explosion of marketing techniques has greatly complicated enforcement actions against multi-faceted marketing campaigns that blend old and new media. For example, concerned about potentially deceptive infant formula marketing, the New York City Department of Consumer Affairs issued subpoenas to the major infant formula makers with a demand that they produce a wide range of documents about their marketing activities in NYC.<sup>53</sup> In order to capture the full extent of the Similac StrongMoms campaign, the Abbott subpoena covered traditional media and digital marketing, demanded substantiation of claims on product packaging, and requested disclosure of contacts between NYC consumers and Abbott's infant feeding hotline and online "feeding expert" help.<sup>54</sup> Abbott moved to quash

the subpoena arguing that it was overly broad, burdensome, and was not tied to a complaint of wrongdoing. A court agreed and quashed the subpoena.<sup>55</sup>

Multi-faceted digital marketing schemes also have complicated cases brought by the private bar. A pending consumer class action complaint alleging Nestlé misled consumers through its “overall marketing” campaign for its Gerber Good Start Protect products was initially dismissed because the complaint failed to allege that members of the class had been exposed to marketing for the product beyond product labels.<sup>56</sup>

### ***The Limits of Falsity and Deception: Nestlé’s Allergy Claims***

The ongoing saga of Nestlé’s allergy claims demonstrates the limits of consumer protection actions to swiftly deal with claims that may mislead caregivers even when they implicate issues of health and safety. In 1989, Nestlé agreed to pay a fine and remove “hypoallergenic” claims on its Good Start formula (then under the Carnation brand name) after consumer protection enforcement action was taken by State Attorneys General. Pediatricians groups were concerned the hypoallergenic claim could cause confusion about cow’s milk allergens and could “mislead many mothers into believing the formulas are allergen-free.”<sup>57</sup> In 2014, NAD issued a case report of a challenge against Nestlé for deceptive marketing of its Gerber Good Start formula’s ability to reduce the risk of allergies.<sup>58</sup> NAD ordered Nestlé to modify its allergy claims to make the lack of evidence for such claims clearer to consumers.<sup>59</sup> The same year, the FTC filed a federal lawsuit against Nestlé alleging false and deceptive claims for Gerber Good Start Gentle that mirrored the NAD case report.<sup>60</sup> The FTC alleged that Nestlé made false and deceptive claims that the product would help prevent babies from developing allergies and that it was the “1<sup>st</sup> and ONLY” infant formula to obtain FDA qualified health claim status for its allergy claims. In fact, the FDA denied two petitions for pre-approval of such claims.<sup>61</sup> The FTC case has yet to be resolved. There also is a pending class action making similar allegations of false and deceptive Gerber Good Start allergy-prevention claims.<sup>62</sup> Nonetheless, Nestlé continues to claim Good Start may reduce the risk of atopic dermatitis.<sup>63</sup>

### ***Considerations Moving Forward***

Piecemeal regulation of infant formula marketing via consumer protection enforcement actions and private lawsuits is a consequence of a larger regulatory failure. Yet, the infant formula industry is surely very concerned about its public image, and consumer protection may provide a useful approach to help denormalize infant formula marketing and subsequent use. The following are some considerations for advocates moving forward:

**Digital marketing is a bear, but worth the fight.** This preliminary analysis did not cover the range of possible technical violations of FTC digital marketing policies for consumer privacy and required disclosures. Such violations are worthwhile to pursue because they can draw attention to unscrupulous marketing. Company privacy policies also create private contracts and can form the

basis of deception claims if consumer information is abused. Privacy policy violations have been a useful way to draw attention to intrusive digital marketing. There is still much to be learned about digital infant formula marketing that may give rise to viable legal theories to challenge egregious infant formula marketing tactics.

**Continue to work with regulators to demand substantiation of claims for specially-formulated products.** In 2000, NAD issued a case report that clearly stated: “at the current time there is no scientific evidence that any infant formula is better than another in supporting infant growth and development.”<sup>64</sup> Fifteen years and 17 NAD cases later, the *Journal of Pediatrics* published an article suggesting a voluntary moratorium on novel infant formulas for use with healthy infants.<sup>65</sup> The article described consumer and pediatrician confusion from the rapid proliferation of formulas “specially formulated” for supplementation, newborns, low energy, lactose, and protein formulations, and fluctuating prebiotic and probiotic content.<sup>66</sup> A subsequent study of marketing claims about such products’ actual ability to reduce colic, crying and gastrointestinal upset found “a distinct paucity of evidence for the claims as written.”<sup>67</sup> The most recent failed attempt by NYC to demand substantiation for infant formula health claims was motivated in part by this research. Product differentiation may be reaching a critical stage. There are a number of pending private consumer class actions, and the FDA has proposed new and unprecedented guidance for substantiating structure/function claims for infant formula. Advocates can add urgency to the need for regulatory oversight by highlighting the failure of NAD self-regulation to adequately protect consumers from specialty formula marketing.

**Whenever possible, focus on the economic harm to families.** The consumer protection legal framework is, at its core, designed to address unlawful trade practices that cost consumers money. Advocates should be disciplined about making the economic injury to families clear in their interactions with consumer protection regulators. For example, providing women with branded formula samples upon discharge from the hospital and at doctor’s visits comes with a potentially large economic harm to families. All infant formula sold in the US meets the FDA’s “nutritional and quality standards” meaning that “families can safely reduce their expenditures on infant formula” by taking advantage of “lower priced brands, sales and other promotions.”<sup>68</sup> Consumer research conducted by the FDA found that marketing formula through health care professionals may decrease caregivers’ willingness to switch formula brands to reduce cost because the initial brand may be perceived as endorsed by the health care provider, and parents do not want to change after the brand is accepted by their children.<sup>69</sup> If providing free formula samples via health care professionals at the behest of formula companies met the elements of deception described above (and/or unfairness), the harm to families to highlight to consumer protection regulators would be the difference in cost between the formula brand provided and a comparable lower cost brand consumers would have purchased on their own absent the deceptive marketing. In a consumer protection analysis, the health harm of increased infant formula use due to health care marketing is, unfortunately, likely less important than the economic harm of deceiving families into buying higher-priced formula. The goal, however, is the same—to stop branded formula sampling via health care professionals.

## Conclusion

This preliminary review of infant formula self-regulation and consumer protection actions has found robust industry use of the NAD system with limited benefit to consumers. To date, FTC and local consumer protection enforcement actions have been limited. Proposed guidance from the FDA for structure/function claims that largely have been handled by the NAD system, and recent private litigation to protect

consumers from deceptive infant formula marketing, are both encouraging steps forward towards more vigorous oversight. There are various opportunities for action and considerations for advocates for future work to limit harmful infant formula marketing including:

- Engage with NAD to refocus its breast milk comparison standard on the impact on consumers as opposed to the harm to competing formula products.
- Develop an infant formula-specific marketing code similar to the Better Business Bureau's standards for food marketing to children.
- Use NAD's consumer complaint system to challenge health care provider-directed advertising.
- Insist that NAD follow FDA's proposed standards to require competent and reliable scientific evidence for all structure/function health claims for infant formula.
- Continue to work with regulators to demand substantiation of claims for specially-formulated formula products for use with healthy infants.
- Analyze digital formula marketing for deception and privacy violations.
- When interacting with consumer protection regulators, focus on the economic harm to families from deceptive and unfair formula marketing.
- Craft approaches to address deceptive marketing that discourages initial intent to breastfeed and duration of exclusive breastfeeding that impacts WIC and non-WIC moms' infant feeding practices.

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<sup>2</sup> California WIC Association, Infant Formula Market and Implications for WIC (June 2008).

<sup>3</sup> Rollins NC, Bhandari N, Hajeer N, Horton S, Lutter CK, Martines JC, Piwoz EG, Richter LM, Victora CG; Lancet Breastfeeding Series Group. Why invest, and what it will take to improve breastfeeding practices? *Lancet*. 2016 Jan 30;387(10017):491-504.

<sup>4</sup> Abrams SA. Is it time to put a moratorium on new infant formulas that are not adequately investigated? *J Pediatr*. 2015 Mar;166(3):756-60; California WIC Association, Infant Formula Market and Implications for WIC (June 2008).

<sup>5</sup> Belamarich PF, Bochner RE, Racine AD. A Critical Review of the Marketing Claims of Infant Formula Products in the United States. *Clin Pediatr (Phila)*. 2016 May;55(5):437-42.

<sup>6</sup> U.S. Food & Drug Admin., Consumer Research on Infant Formula and Infant Feeding, <http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm080399.htm>.

<sup>7</sup> Id.

<sup>8</sup> Id.

<sup>9</sup> U.S. Food & Drug Admin., Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Guidance for Industry (Proposed) (Sept. 2016), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm514640.htm>.

<sup>10</sup> Id.

<sup>11</sup> Id.

<sup>12</sup> Andrew Strenio et al., SELF-REGULATORY TECHNIQUES FOR THREADING THE ANTI-TRUST NEEDLE, 18 *Antitrust* 57, 58 (2004).

<sup>13</sup> Andrea Freeman, "First Food" Justice: Racial Disparities in Infant Feeding As Food Oppression, 83 *Fordham L. Rev.* 3053(2015).

<sup>14</sup> Id.

<sup>15</sup> Id.

<sup>16</sup> NAD case reports can be accessed at <http://www.ascreviews.org/asrc-online-archive/> (membership required).

<sup>17</sup> John E. Villafranco and Katherine E. Rile, SO YOU WANT TO SELF-REGULATE? THE NATIONAL ADVERTISING DIVISION AS STANDARD BEARER, 27-SPG *Antitrust* 79 (2013).

<sup>18</sup> ASRC, NAD, Consumer Complaints, <http://www.ascreviews.org/consumer-complaint-nad/>.

<sup>19</sup> Andrew Strenio et al., SELF-REGULATORY TECHNIQUES FOR THREADING THE ANTI-TRUST NEEDLE, 18-*SUM Antitrust* 57, 58 (2004).

<sup>20</sup> NAD Case #4274, NARB Panel #128, Ross Products, Division of Abbott Laboratories, Similac Advance (08/16/05).

<sup>21</sup> Id.

<sup>22</sup> NAD Case #3699, NESTLE USA, INC. Carnation® Good Start® (11/01/00).

<sup>23</sup> NAD Case #4274, Ross Products, Division of Abbott Laboratories, Similac Advance (01/03/05).

<sup>24</sup> NAD Case #5859, Abbott Nutrition, Similac Advance with OptiGRO (6/18/15).

<sup>25</sup> NAD Case #4849, Abbott Nutrition, Similac Advance and Similac NeoSure (05/15/08).

<sup>26</sup> NAD Case #4849, Abbott Nutrition, Similac Advance and Similac NeoSure (05/15/08).

<sup>27</sup> NAD Case #4822, Mead Johnson Nutritionals, Enfamil LIPIL (04/02/08).

<sup>28</sup> Id.

<sup>29</sup> NAD Case #5859, Abbott Nutrition, Similac Advance with OptiGRO (6/18/15).

<sup>30</sup> NAD Case #5062, ABBOTT NUTRITION Similac Advance EarlyShield (07/31/09).

<sup>31</sup> NAD Case #5062C, ABBOTT NUTRITION Similac Advance EarlyShield, Compliance Proceeding from NAD Case Report #5062 (01/11/10).

<sup>32</sup> NAD Case #4274, Ross Products, Division of Abbott Laboratories Similac Advance (01/03/05).

<sup>33</sup> IFM, Infant Food Manufacturers' Commitment and Rules for Responsible Conduct (March 2014), [http://www.ifm.net/wp-content/uploads/2014/10/IFM\\_Rules-of-Responsible-Conduct\\_REV\\_26-March-2014.pdf](http://www.ifm.net/wp-content/uploads/2014/10/IFM_Rules-of-Responsible-Conduct_REV_26-March-2014.pdf); Nestle, Charter: Nestle Infant Formula Policy, [http://www.nestle.com/asset-library/documents/creating%20shared%20value/nutrition/nestle\\_charter\\_infant\\_formula\\_en\\_2011.pdf](http://www.nestle.com/asset-library/documents/creating%20shared%20value/nutrition/nestle_charter_infant_formula_en_2011.pdf).

<sup>34</sup> Id.

<sup>35</sup> World Health Organization, International Code of Marketing of Breast-Milk Substitutes (1981), [http://www.who.int/nutrition/publications/code\\_english.pdf](http://www.who.int/nutrition/publications/code_english.pdf).

<sup>36</sup> Walker M. Still selling out mothers and babies; marketing of breast milk substitutes in the USA. Weston, MA: NABA REAL 2007.

<sup>37</sup> Ved P. Nanda. 1 Transnational Business Transactions § 1:32 M. The Law of Transnational Business Transactions August 2016, ch. 1 Codes of Conduct for Transnational Corporations.

<sup>38</sup> Id.

<sup>39</sup> Saba Siddiqi, an individual, on behalf of herself and all others similarly situated, Plaintiffs, v. Gerber Products Company; Nestle USA, Inc., No. CV 12 1188, 2012 WL 420773 (C.D.Cal.) (Complaint) (Feb. 10, 2012).

<sup>40</sup> NAD Case #4274, Ross Products, Division of Abbott Laboratories, Similac Advance (01/03/05).

<sup>41</sup> U.S. Food & Drug Admin., Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Guidance for Industry (Proposed) (Sept. 2016), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm514640.htm>.

<sup>42</sup> Mello MM. Federal trade commission regulation of food advertising to children: possibilities for a reinvigorated role. *J Health Polit Policy Law*. 2010 Apr;35(2):227-76. doi: 10.1215/03616878-2009-051.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> In the Matter of The Application of Abbott Laboratories, 158164-2015, Supreme Court of the State of New York (Manhattan), <http://iapps.courts.state.ny.us/iscroll/SQLData.jsp?IndexNo=158164-2015&Submit2=Search>.

<sup>49</sup> *Brown v. Abbott Labs., Inc.*, No. 10 C 6674, 2011 WL 4496154 (N.D. Ill. Sept. 27, 2011).

<sup>50</sup> GAO, BREASTFEEDING: Some Strategies Used to Market Infant Formula May Discourage Breastfeeding; State Contracts Should Better Protect against Misuse of WIC Name, GAO-06-282 (Feb. 2006), <http://www.gao.gov/assets/250/249027.pdf>.

<sup>51</sup> FTC, Enforcement Policy Statement on Deceptively Formatted Advertisements (2015), [https://www.ftc.gov/system/files/documents/public\\_statements/896923/151222deceptiveenforcement.pdf](https://www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf).

<sup>52</sup> *Id.*

<sup>53</sup> Barbara Ross, NYC Department of Consumer Affairs investigating infant formula makers for possible consumer fraud: officials, *NY Daily News* (Aug. 7, 2015), <http://www.nydailynews.com/news/politics/nyc-dept-checking-infant-formula-makers-fraud-official-article-1.2318765>.

<sup>54</sup> In the Matter of The Application of Abbott Laboratories, 158164-2015, Supreme Court of the State of New York (Manhattan), <http://iapps.courts.state.ny.us/iscroll/SQLData.jsp?IndexNo=158164-2015&Submit2=Search>.

<sup>55</sup> *Id.*

<sup>56</sup> In re Gerber Probiotics Sales Practices Litigation, Civil Action No. 12-835 (JLL) (Aug. 23, 2013) (the complaint was amended and claims were properly alleged on year later).

<sup>57</sup> Jesus Sanchez, Carnation to Pay \$90,000 Fine in Wake of Claims Its Ads Misled, *Los Angeles Times* (July 7, 1989), [http://articles.latimes.com/1989-07-07/business/fi-3433\\_1\\_health-claims](http://articles.latimes.com/1989-07-07/business/fi-3433_1_health-claims).

<sup>58</sup> NAD Case #5724, Gerber Products Company, Gerber Baby and Toddler Foods (05/20/14).

<sup>59</sup> *Id.*

<sup>60</sup> FTC, Cases and Proceedings, Gerber Products Co., d/b/a Nestlé Nutrition, et al (Oct. 30 2014), <https://www.ftc.gov/enforcement/cases-proceedings/132-3009/gerber-products-co-doing-business-nestle-nutrition-et-al>.

<sup>61</sup> *Id.*



<sup>62</sup> Zakaria v. Gerber Products Co., No. 2:15-cv-00200 (C.D. Cal.) (this case is pending and survived a motion to dismiss).

<sup>63</sup> Gerber, Nutrition Inspired by Breastmilk: Why the First Formula Matters (Video), <https://www.gerber.com/video-library/nutrition-inspired-by-breastmilk>.

<sup>64</sup> NAD Case #3699, NESTLE USA, INC., Carnation Good Start (11/01/00).

<sup>65</sup> Abrams SA. Is it time to put a moratorium on new infant formulas that are not adequately investigated? *J Pediatr*. 2015 Mar;166(3):756-60.

<sup>66</sup> *Id.*

<sup>67</sup> Belamarich PF, Bochner RE, Racine AD. A Critical Review of the Marketing Claims of Infant Formula Products in the United States. *Clin Pediatr (Phila)*. 2016 May;55(5):437-42.

<sup>68</sup> Huang Y, Labiner-Wolfe J, Huang H, Choiniere CJ, Fein SB. Association of health profession and direct-to-consumer marketing with infant formula choice and switching. *Birth*. 2013 Mar;40(1):24-31.

<sup>69</sup> *Id.*