## Infant formula and toddler milk marketing: opportunities to address harmful practices and improve young children's diets

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Children's diets in their first 1000 days influence dietary preferences, eating habits, and long-term health. Yet the diets of most infants and toddlers in the United States do not conform to recommendations for optimal child nutrition. This narrative review examines whether marketing for infant formula and other commercial baby/toddler foods plays a role. The World Health Organization's International Code of Marketing Breast-milk Substitutes strongly encourages countries and manufacturers to prohibit marketing practices that discourage initiation of, and continued, breastfeeding. However, in the United States, widespread infant formula marketing negatively impacts breastfeeding. Research has also identified questionable marketing of toddler milks (formula/milk-based drinks for children aged 12–36 mo). The United States has relied exclusively on industry self-regulation, but US federal agencies and state and local governments could regulate problematic marketing of infant formula and toddler milks. Health providers and public health organizations should also provide guidance. However, further research is needed to better understand how marketing influences what and how caregivers feed their young children and inform potential interventions and regulatory solutions.

A child's diet in the first 1000 days (conception to 24 mo) has enormous influence over their development of healthy food preferences, dietary patterns, obesity risk, and long-term health.<sup>1</sup> Feeding recommendations from public health and pediatric organizations are simple and straightforward. As breastfeeding provides substantial health benefits for babies,<sup>2-4</sup> the World Health Organization (WHO)<sup>5</sup> recommends exclusive breastfeeding until 6 months and continued breastfeeding through age 2, while the American Academy of Pediatrics recommends exclusive breastfeeding through about the first 6 months and continued breastfeeding through age 1 year or more.<sup>6</sup> For infants who are not breastfeeding, plain whole milk and/or other sources of calcium and vitamin D should replace infant formula after 12 months.<sup>6</sup>

At approximately 6 months, infants should be gradually introduced to complementary foods, including a wide variety of healthy foods of differing tastes, flavors, and textures.<sup>1</sup> At age 1–2 years (12–24 mo), toddlers' diets should help them learn to enjoy the healthy foods that the family eats and transition to the family diet. All children should consume a variety of fruits and vegetables daily. Experts also recommend limiting consumption of added sugar, saturated fat, and sodium, while the American Heart Association recommends not serving any products with added sugar to children younger than 2 years.<sup>7</sup>

## Concerns about US infant and toddler diets

However, the diets of most US infants (up to 12 mo) and toddlers (12-36 mo) do not conform to expert

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recommendations. Rates of exclusive breastfeeding at 6 months doubled from 2004 to 2015,<sup>8</sup> and 83% of infants were ever breastfed in 2015, compared with 73% in 2004.<sup>9</sup> However, despite recent progress, just onequarter of US infants in 2015 were exclusively breastfed at 6 months.<sup>8</sup> Furthermore, breastfeeding rates decline substantially after 3 months – to 58% at 6 months and 36% at 1 year, and there are significant disparities in breastfeeding. Breastfeeding rates were found to be approximately twice as high for infants in high-income vs low-income households<sup>8</sup> and significantly lower for non-Hispanic black, compared with Hispanic and non-Hispanic white, infants.<sup>9</sup>

In addition, food intake does not conform with expert recommendations for many US infants and toddlers. Most infants (73%) are introduced to complementary foods before the recommended 6 months, with 17% being introduced before 4 months.<sup>10</sup> Among 2- and 3-yearolds, 27% do not consume any vegetable on a given day,<sup>11</sup> and fried potatoes are the most common vegetable consumed. Approximately one-quarter (23%) do not consume any fruit, while 45% consume 100% fruit juice on a given day.

The majority of US infants and toddlers consume adequate micronutrients, although low iron intake is a concern for older infants (6-11.9 mo).<sup>12</sup> However, sodium intake exceeds tolerable upper limits for more than one-third (39%) of younger toddlers (12-23.9 mo) and 70% of older toddlers (24-35.9 mo), and 68% of older toddlers consume more than the recommended level of saturated fat. In addition, according to the Feeding Infants and Toddlers Study (FITS),<sup>13</sup> the proportion of younger toddlers who consume 25% or more of energy from added sugars ranges from 2.0% in higher-income households to 7.9% among low-income households. These proportions increase to 8.8% and 13.7%, respectively, for older toddlers. Much of the excess sugar, sodium, and saturated fat comes from that added to commercial food and drinks. In particular, sugarsweetened beverage consumption presents significant health risks.<sup>1</sup> Approximately 30% of toddlers (18-23.9 mo) consume sugar-sweetened beverages on a given day,<sup>10</sup> increasing to 45% of 2- and 3-year-olds.<sup>11</sup> Fruitflavored drinks are the most common type of sugarsweetened beverage consumed by toddlers (34%), while 15% consume flavored milk.<sup>11</sup> In addition, one-third of 2- and 3-year-olds consume savory snacks (eg, chips, crackers) on a given day.<sup>11</sup>

#### Marketing and caregivers' feeding decisions

Researchers posit that conflicting advice from health professionals (eg, optimal breastfeeding duration, age to introduce complementary foods) may confuse parents, which could explain why caregivers do not follow expert recommendations for feeding young children.<sup>14</sup> Moreover, it is unclear how parents interpret public health and population guidelines or how they receive and apply advice from health professionals. However, marketing may also play a significant role in caregivers' feeding decisions. In 2015, US manufacturers spent \$56.5 million on advertising baby and toddler food and drinks across all media, and messages portrayed in this marketing often contradict experts' advice.<sup>15</sup> For example, infant formula marketing minimizes the importance of exclusive breastfeeding for young infants and breastfeeding through 12 months.<sup>15</sup> continued Marketing of food and drinks specifically for toddlers also presents these products as easy and nutritious options and acceptable alternatives to optimal feeding practices recommended by experts, including serving young children a variety of fruits and vegetables as snacks and transitioning to a healthy family diet.<sup>15</sup>

Furthermore, the nutritional content of commercial toddler food and drinks may also contribute to unhealthy taste preferences in young children. For example, the majority of toddler snacks are high in sugar; and threequarters of toddler dinners are high in sodium.<sup>16</sup> A relatively new category of products for toddlers, known as "toddler milks" ("growing-up milks" outside of the United States), also raises considerable concerns. These milk-based products are marketed for children aged 12-36 months, but they consist primarily of powdered milk, corn syrup solids or other caloric sweeteners, and vegetable oil.<sup>15</sup> Toddler milks contain more sodium and less protein than whole cow's milk, and the added sugars in these products are not recommended for children younger than 2 years.<sup>7</sup> However, the marketing for these sweetened milk products positions them as a solution for caregivers concerned about their toddlers' nutrition.

This narrative review presents the existing literature on the extent and impact of marketing of commercial products for infants (up to 12 months) and toddlers (12– 36 mo), focusing on US-based research. It focuses on the infant formula and toddler milk product categories, as few studies have examined marketing of other categories of baby/toddler foods. Opportunities for policy-level actions to improve infant and toddler feeding, including industry self-regulation, guidance from healthcare and public health organizations, and government legislation and regulation are discussed. Finally, it presents an agenda for future research that can be used to inform potential interventions and regulatory solutions.

## CONSUMPTION OF COMMERCIAL PRODUCTS

Widespread provision of infant formula in the United States has been well documented, but research has not

yet examined consumption of toddler milk or other commercial products marketed specifically for young children. However, reports of US sales of commercial baby and toddler food and drinks (collectively "baby/ toddler foods") demonstrate the popularity of these products. Consumer purchases of all baby/toddler foods totaled \$7 billion in 2016, while formula products, including infant formula and toddler milks, represented the majority of sales (\$4.7 billion).<sup>17</sup> Consumers spent 2.5 times as much on formula as on all baby and toddler food, snacks, and juice combined, which contributed \$1.9 billion in sales. In addition, total formula sales have increased, up by 4.3% compared with 2012. As the number of US children younger than 3 years increased by just 0.3% during this time,<sup>18</sup> companies appear to have found new strategies (eg, higher prices, new product categories, expanded consumer base) to continue to grow their sales.

Another analysis of US infant formula and toddler milk sales from 2006 to 2015, using Nielsen scanner data, found that trends in purchases of the 2 product types differed notably. During this time, annual volume sales of infant formula declined by 7%, whereas dollar sales increased by 24% owing to a 33% increase in average price per ounce (\$0.97/oz in 2006 to \$1.28/oz in 2015). In contrast, annual volume sales of toddler milks increased by 158% from 2006 to 2015. Toddler milk dollar sales also increased by 133%, while average price declined from \$0.84 per ounce to \$0.76 per ounce. In this national sample of retailers, infant formula sales totaled \$1259 million in 2016, compared with \$98 million in toddler milk sales. Sales of formulas and milk-based drinks for older infants and toddlers have also grown rapidly worldwide. From 2008 to 2013, sales of followup formula (for infants aged 6-12mo) increased by 31%, while toddler milk sales grew by 53%.<sup>19</sup>

#### **Consumption of infant formula**

When breastfeeding is not an option, infant formula is an acceptable substitute until 12 months.<sup>6</sup> However, the US Preventive Services Task Force<sup>20</sup> recommends interventions by primary care clinicians to promote exclusive breastfeeding through 6 months, and the US Centers for Disease Control and Prevention (CDC) includes exclusive and other breastfeeding objectives in its Healthy People 2020 goals.<sup>8</sup> Nonetheless, early provision of infant formula and formula supplementation with breastfeeding is common. About 1 in 6 infants consumes infant formula within the first 2 days of life.<sup>8</sup> By 3 months, 29% of breastfed infants also consume infant formula.<sup>8</sup> Overall, 65% of younger infants (0–5.9 months) and 70% of older infants (6– 11.9 months) consume infant formula.<sup>12</sup> Furthermore, 8% of toddlers (up to 23.9 months) continue to consume infant formula past the recommended 12 months.<sup>12</sup>

The US government also provides infant formula to approximately 2 million WIC participants each month. WIC provides vouchers for supplemental food packages for infants and children aged up to 5 years living in low-income households, including formula for infants younger than 12 months.<sup>21</sup> Although WIC encourages breastfeeding by providing additional food in packages for lactating mothers who do not receive formula, infant formula accounts for 42% of WIC costs, and WIC participants represent more than half of formula-fed infants in the United States.<sup>21</sup> WIC provision of infant formula may contribute to lower breastfeeding rates in low-income households.<sup>22</sup>

#### MARKETING OF COMMERCIAL BABY/TODDLER FOODS

Analysis of advertising spending data by baby/toddler food category (ie, the amount that companies spend to advertise their products across various media, including TV, radio, magazines, and internet) demonstrates how much manufacturers invest in marketing these products. Of the total \$57 million spent on advertising in 2015, approximately 30% each was spent on toddler milk and baby food, followed by toddler food (23%) and infant formula (17%). Compared with 2011, advertising spending increased the most for toddler milk (+74%), while advertising for infant formula declined by 68%. In 2014, for the first time, US manufacturers spent more on advertising toddler milks than advertising infant formulas.

Research on marketing tactics and messages used to promote infant formula and toddler milk products has identified the following 3 main problematic practices: (1) promotion of breast-milk substitutes (BMSs) (especially infant formula) that discourages initiation of, and continued, breastfeeding; (2) promotion of formula products (including specialty formulas and toddler milks) that are not necessary for most babies and toddlers, more expensive than recommended milkbased products (ie, regular infant formula and plain milk), and potentially harmful to young children's diets; and (3) product claims and other marketing messages that may mislead caregivers about optimal products and feeding practices for babies and toddlers.

#### Infant formula marketing

In 1981, the World Health Assembly (WHA) of the WHO ratified the International Code of Marketing of Breast-milk Substitutes (the Code) with a vote of 188 to 1 (United States). The Code recognizes that breast milk

is the ideal food for infants' health, growth, and development; that infants are uniquely vulnerable to malnutrition, morbidity, and mortality from inappropriate feeding; and that improper BMS marketing can contribute to these public health issues.<sup>23</sup>

The Code's aim was to "contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution."<sup>23</sup> The Code that the WHA ratified in 1981 contained 11 articles that defined the aim and scope of the Code, acceptable and unacceptable marketing practices, and implementation and monitoring at the country level. It defined BMS as any food marketed as a partial or total replacement of breast milk, whether or not it was a suitable replacement, including infant formula (for infants aged up to 6 mo), milk products, and bottle-fed complementary foods.

Since 1981, the WHA has adopted subsequent resolutions to address loopholes and new developments in BMS marketing. In 2016, the WHA unanimously adopted Resolution 69.9 to address growing concerns about toddler milk products. The definition of BMS now specifies that complementary foods, including milks or milk replacements (in liquid or powder form) specifically marketed for feeding infants and young children aged up to 3 years, are covered by the Code.<sup>24</sup>

The Code addresses numerous marketing practices that may discourage breastfeeding (Table 1). It calls for prohibition of many forms of BMS marketing altogether, including advertising and other promotion to the general public, promotion through the healthcare system, and health worker endorsement by association.<sup>25</sup> It also sets requirements for labeling and product quality and calls for regulations on information and educational materials about infant feeding.

The WHO has identified elimination of all advertising and promotion of BMSs to the general public and in healthcare facilities as a key priority for member countries.<sup>25</sup> As of 2018, 70% of countries (136 of 194) had adopted legal measures that covered at least some of these provisions, and 35 countries had adopted full provisions of the Code.<sup>25</sup> Legislation prohibiting BMS promotion to the general public and requirements for product labels constitute the most commonly adopted measures. More than 50% of countries with legal measures prohibit advertising, sales promotions, and/or samples and gifts to the general public and require labels to communicate the superiority of breastfeeding and preparation instructions. The most widely adopted provision bans pictures and text that idealize infant formula (included in 79%). In addition, 50% of countries require

# Table 1 Provisions of the WHO International Code of Marketing of Breast-Milk Substitutes<sup>2</sup>

- Article 4 regulates information and educational materials about infant feeding:
- All materials should include information on the benefits and superiority of breastfeeding, the risk of artificial feeding, the negative effect on breastfeeding of partial bottle feeding, the difficulty of reversing the decision to not breastfeed, and health hazards of improper use of infant formula.
- Industry-prepared educational materials should not be provided to the general public.

Article 5 prohibits all promotion to the general public:

- All advertising in any form;
- Providing product samples, both directly and indirectly;
- Promotions at retailers, including post-of-sale displays, coupons, premiums, and short-term price discounts (ie, sales); and
- Any contact between manufacturers or distributors and pregnant women or mothers of infants, including company helplines, direct mail, baby clubs, and online chats.

Article 6 prohibits all promotion through the healthcare system:

- Providing free or low-cost samples;
- Donations of branded equipment or materials; and
  Demonstrations of infant formula feeding by marketing representatives from manufacturers/distributors.

Article 7 prohibits health workers from endorsement by association:

- Financial or material inducements to promote products;
- Fellowships, research grants, or professional development from manufacturers/distributors; and
- Provision of product samples to pregnant women, mothers, or families.

Article 9 sets requirements for labeling and quality:

- No nutrition or health claims;
- No images or text that idealize infant formula feeding; and
- Must clearly state that breastfeeding is superior, use only with the advice of a health worker, and instructions and warnings about proper preparation.

Articles 10 and 11 cover implementation and monitoring:

- Governments are responsible for monitoring.
- Manufacturers and distributors are responsible for adherence, even in countries where governments have not fully implemented the Code.

informational and educational materials to state the benefits and superiority of breastfeeding. Less than half of the member countries that have adopted legal measures prohibit provision of free or low-cost supplies (43%) and/or branded materials and gifts (48%) to health workers and/or healthcare facilities.

The WHO has also called for monitoring and enforcement of Code provisions in countries with legal measures, including sanctions for violations. Although 71% of countries mandate monitoring mechanisms for their provisions, just 7% require independent and transparent monitoring and 12% require monitoring to be free from commercial influence.

Infant formula marketing in the United States. The United States did not ratify the original Code in 1981

and is one of the few countries not to have adopted any Code provisions.<sup>25</sup> Although WHA recommendations are nonbinding, marketing of infant formula in the United States disregards nearly all recommendations for appropriate BMS promotion specified in the Code. Research has shown that most marketing techniques that would be prohibited under the Code are common in the United States, including advertising and other promotion to the general public, messages and claims in marketing and on product packaging, and promotion through the healthcare system and health workers.

*Infant formula advertising* directed at pregnant women and new mothers often appears in various media. Magazine advertising represents the majority of infant-formula advertising spending, followed by television.<sup>15</sup> Other media (primarily internet) contributes 13% of spending. In a study by Basch et al,<sup>26</sup> approximately 5% of all ads in 2 popular parenting magazines promoted infant formula. Moreover, in a large cross-sectional study of mothers of infants (2005– 2007), approximately 70% reported prenatal exposure to infant formula advertising on TV or radio, and 85% reported exposure to print advertising (magazine, newspaper, posters. and/or billboards).<sup>27</sup>

Total advertising spending for infant formula products has declined substantially, from \$30 million in 2011 to \$10 million in 2015,<sup>15</sup> and formula manufacturers have changed their marketing strategies to focus on their specialty formulas. In 2015, specialty formulas represented 79% of all infant formula advertising (\$7.7 million). These formulas (eg, "Soothe," "Gentle," and "Advance" varieties) include additional ingredients, such as docosahexaenoic acid (DHA) and prebiotics & probiotics, purportedly designed to address specific infant needs (eg, gassiness, fussiness) and/or be "closer to breast milk."

Promotion of infant formula to the general public through digital media also appears to be increasing. Infant formula brands place ads on retail websites (eg, Amazon.com, Walmart.com), social media websites (eg, Facebook.com, YouTube.com), and family and parenting sites (eg, CafeMom.com, BabyCenter.com).<sup>15</sup> These brands are especially active on social media. A 2011 analysis found infant formula brands on Facebook, YouTube, Twitter, mobile apps, and parenting blogs as well as social media links on brand websites.<sup>28</sup> One brand garnered more than 20 million views of its video campaign on Facebook and YouTube. More than one-half of mothers of infants who provided infant formula at 1 month reported receiving prenatal information about infant formula on the internet.<sup>27,29</sup>

Content analyses of US TV and magazine ads also reveal widespread use of nutrition and health claims and messages that idealize serving infant formula. One analysis found that three-quarters of ads promoted benefits for infants' digestive health, mental performance, and/or physical development.<sup>15</sup> All ads for one brand claimed that it was recommended by pediatricians, and one-half promoted its scientific formula. In addition, one-half of infant formula ads showed mother-child bonding (ie, idealizing formula use). Another study of infant formula ads in pregnancy and early parenting magazines found that more than one-half of ads made health statements, typically about ingredients that support brain, eye/vision, and immune system development.<sup>30</sup> Only 16% cited a clinical study as proof of these claims. In addition, 89% of the ads presented breast milk and infant formula in the same sentence, which could confuse caregivers about their similarities and differences.

Analyses of digital marketing also document common techniques that violate the Code.<sup>15,28,31</sup> For example, in social media and on company websites, marketing personnel directly contact families of young children (through posts, tweets, online message boards); provide free samples and coupons (frequently invitations to join "baby clubs"); and provide manufacturercreated educational materials with feeding or nutrition advice, but not the required disclaimers about formula feeding. An analysis of promotions through mom bloggers found that infant formula brands frequently provided incentives for mom "influencers" to create posts about their experiences with the brands.<sup>32</sup> Health workers employed by the manufacturer (eg, dietitians, lactation consultants) also provide feeding advice to new mothers. Furthermore, users often discuss the difficulties of breastfeeding in commercially sponsored public forums, which may increase perceived difficulties of breastfeeding.

Packaging and labeling of US infant formula products also violate many provisions of the Code. One market research company analyzed and summarized the strategy utilized by infant formula manufacturers: "Regarded by some as an inferior alternative to breastfeeding, formula brands have turned to innovation, featuring formulations that highlight their benefits to infants' health and development, with options tailored to improve brand and nervous system function, immunity and digestion."<sup>17</sup> Common nutrition and "functional" claims on formula launches in 2017 included the following: vitamin/mineral-fortified claims; brain and nervous system claims; immune system claims; genetically modified organism-free claims (80% of launches); other functional, low/no/reduced allergen, and prebiotic claims (60%-70%); and gluten-free, digestive, premium, and organic claims (20%-50%).

Infant formula packages averaged 5.9 nutrition claims and 3.1 child development messages each in a

2017 study.<sup>15</sup> All packages included some type of message about breastfeeding (eg, "Breastfeeding is best," "Experts agree on the many benefits of breast milk," or "Breast milk is recommended"). However, none clearly stated the superiority of breastfeeding or risks of formula feeding, and some did not include the required disclaimer to contact a health provider before use.

These claims may also mislead consumers about the benefits of serving infant formula. One analysis found that more than one-half of infant formula product labels made claims about colic and gastrointestinal symptoms.<sup>33</sup> However, there is insufficient evidence that product formulations supporting such claims (removing/reducing lactose, using hydrolyzed or soy protein, or adding prebiotics or probiotics) benefit fussiness, gas, or colic. There is also insufficient scientific evidence to support other common claims, including the links between provision of DHA through infant formula and brain development or between prebiotics and the immune system.<sup>34</sup>

Experts have raised concerns about these types of structure/function claims that link ingredients with benefits to bodily functions.<sup>33,34</sup> Such claims do not refer to disease treatment, so they do not qualify as health claims, which would require significant scientific agreement and preapproval by the US Food and Drug Administration (FDA). However, they do imply that formulas are as good as, or better than, breastfeeding. They may also encourage purchases of costly infant formula and prescription requests for specialty formulas through WIC when they are not necessary. Furthermore, they associate normal infant behavior (eg, crying) with infrequent medical conditions (eg, lactose intolerance). In 2016, the FDA issued draft guidance recommending that infant formula manufacturers substantiate structure/function claims on product labels to such claims are truthful and not ensure that misleading.35

*Promotion by health workers and through healthcare systems* is also common in the United States. Examples of infant formula marketing through the healthcare community include formula ads and free samples to pregnant women in doctors' offices, free or reduced-price formula provided to hospitals, free samples in hospital discharge packs, letters to health providers and training to explain the benefits of specific products, and branded promotional items (eg, baby name cards).<sup>22</sup>

Widespread provision of formula to new mothers in hospitals and gifts at discharge is well documented. Nearly all new mothers who fed formula at 1 month had received a hospital discharge pack with formula samples (84%).<sup>27</sup> In another study, 35% of new mothers received breastfeeding supplies in a hospital discharge pack (with or without a formula sample or coupon), but approximately one-half received a formula sample or coupon and no breastfeeding supplies.<sup>29</sup> An estimated 86% of WIC mothers received hospital discharge packs in 1997.<sup>36</sup>

To specifically address infant formula marketing in hospitals, UNICEF (the United Nations Children's Fund) and the WHO established the Baby-Friendly Hospital Initiative (BFHI) in 1991.<sup>37</sup> To receive BFHI accreditation, birthing facilities must implement the WHO/UNICEF's Ten Steps to Successful Breastfeeding. In 2017, the accreditation requirements were revised to explicitly require full compliance with all Code provisions as part of the Initiative's Ten Steps. In the United States, the number of accredited baby-friendly hospitals and birthing centers rose from 60 facilities, provisioning for less than 3% of US births, in 2007 to more than 500 facilities, provisioning for more than 25% of births, in 2018.<sup>38</sup> Nonetheless, physicians with hospital privileges at baby-friendly hospitals are not required to abide by these restrictions at their private offices, where most follow-up appointments take place.

Limited information exists about other types of infant formula marketing, including retail strategies and direct-to-consumer marketing. However, a US Government Accountability Office study indicated that formula companies prominently display infant formula products on store shelves to appeal to shoppers.<sup>22</sup> Another study found that 57% of new mothers received free formula in the mail before their child was 1 month old.<sup>29</sup>

Formula manufacturers and the Code. Article 11.4 of the Code calls on manufacturers to comply with the Code: "Manufacturers and distributors of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them," including in countries that have not passed legal measures.<sup>23</sup> However, a 2018 evaluation of the 3 largest US formula companies found no policies regarding any form of BMS marketing in the United States, despite companies' statements that they support the Code.<sup>39</sup> Most company policies applied only to high-risk countries (ie, those with high infant mortality and young child malnutrition) and included caveats that they comply with country regulations (ie, that they abide by the law in those countries), even in countries with weak regulations.

Even in countries with legal Code provisions, research demonstrates noncompliance by infant formula manufacturers and distributors. Extensive evaluations by various nongovernment organizations (NGOs), academic institutions, and research survey firms document numerous violations in countries with legislation worldwide.<sup>40–43</sup> Moreover, US-based internet marketing also reaches consumers in other countries, including those where promotion to the general public is illegal. Common BMS marketing practices worldwide include unsupported health and nutrition claims, the rise of digital marketing and other technologically advanced marketing tools, and a new trend to combine marketing initiatives with public health campaigns.<sup>25</sup> A study of "lessons learned" in Code monitoring and compliance suggests that legislation is "necessary but not sufficient."<sup>44</sup> Effective enforcement and public monitoring of compliance are essential, and monitoring must be transparent, scientifically valid, and adequately funded.<sup>24,25</sup>

## **Toddler milk marketing**

WHA Resolution 69.9 expanded the definition of BMS in response to the introduction and aggressive marketing of new categories of BMS aimed at young children older than 6 months, including "follow-up formula" for babies aged 6–12 months and "growing-up milks" (or toddler milks) for young children aged 12–36 months. Toddler milks and other formulas often use similar branding, packaging, and labels as infant formulas from the same manufacturers. As a result, introducing these products has allowed manufacturers to circumvent the Code and indirectly promote infant formula brands in countries that ban advertising of infant formula for babies younger than 6 months.<sup>19,41,45</sup>

Most countries that have adopted any provisions of the Code already regulate some of these products.<sup>25</sup> As of 2018, 90% included follow-up formula (for ages 6– 12 months), 44% covered complementary foods, and 16% covered milk products for children aged up to 36 months in their Code provisions. In its 2018 compliance report, the WHO called on countries to explicitly include follow-up formula and toddler milks in all Code provisions. Resolution 69.9 also calls for bans on packaging and labeling of toddler milks and complementary foods that look similar to infant formula packages, which serves to cross-promote infant formula. In addition, messages on foods marketed for infants and young children must include a statement about the importance of continued breastfeeding for up to two years.

*Concerns about toddler milks.* As noted earlier, increased marketing of toddler milks in the United States accompanied by declines in infant formula advertising indicate an increased emphasis on promoting this product category. However, the poor nutritional quality of toddler milks raises concerns. The American Academy of Family Physicians also notes the additional cost of

toddler "formulas" and no proven advantages over whole milk for 1- to 2-year-olds.<sup>46</sup> It counsels parents concerned about picky eating and potential missing nutrients to provide their child with a multivitamin instead. The WHO deems toddler milks to be "unnecessary."<sup>24</sup>

An analysis of formula products in the United States found no available follow-up formulas specifically for older infants (6-12 mo).<sup>47</sup> However, US manufacturers offer another unique category of formulas marketed as appropriate for children aged 9–18/24 months, known as "transition formulas." Transition formulas appear to contain the same product formulation as infant formula.

*Toddler milk marketing.* Researchers have also documented problematic toddler milk marketing practices, including potentially misleading claims and consumer confusion about differences between infant formula and toddler milks as well as labeling practices that do not align with existing FDA regulations.

Toddler milk marketing and labeling claim numerous benefits for toddlers' nutrition, cognitive development, and growth.<sup>24,47</sup> US toddler milk products averaged 4.0 nutrition-related and 2.6 childdevelopment messages per package,<sup>15</sup> including numerous structure/function claims that link nutrients or ingredients to children's health and/or development.<sup>47</sup> For example, some promised "DHA and iron to help support brain development," and "prebiotics" or "probiotics" to "help support digestive health." Others claimed, "Lutein like that found in spinach for eyes" and "Vitamin E like that found in broccoli for development." TV advertising implies benefits for children's cognitive development, "since 85% of brain growth is complete by age 3 and now is the time to nourish them," and "DHA, an important building block of the brain," with images of a toddler successfully completing a puzzle.<sup>15</sup> As a result, caregivers may attribute unproven nutrition and health-related benefits from serving their child these products. This marketing could also convince parents that young children require expensive commercial products and that family meals are inadequate.

Furthermore, cross-promotion of toddler milks with infant formulas from the same manufacturer likely confuses caregivers about the appropriate ages for each. As noted, toddler milks often use an existing brand name or variation of an infant formula brand name, with the brand name in larger text on the label than the product category (ie, infant formula, toddler milk). The possibility that caregivers are providing toddler milks instead of infant formula to infants younger than 12 months is especially concerning as toddler milks do not provide the required nutrients for optimal infant development. The potential for consumer confusion has been documented.<sup>47,48</sup> Three-quarters of Australian participants in a qualitative study used the terms "formula," "infant formula," or "baby formula" to describe toddler milk products and believed that the product was suitable for infants and just as good as breast milk for children aged up to 2 years.<sup>49</sup> These mothers also rated the ads as believable and accepted the claims uncritically; the use of scientific and technical language was most persuasive for them. This cross-branding may also mislead parents into believing that toddler milks are the appropriate "next" drink for their toddler at 12 months.

In the United States, there is no standard of identity or naming requirements for transition formulas or toddler milks.<sup>47</sup> Product packaging identified transition formulas (for children aged 9- 18/24 mo) as "infant and toddler formula" or "toddler formula," while toddler milks (for children aged 12-36 mo) were identified as "toddler formula," "milk drink," or "toddler drink." Although product labels for toddler milks often refer to such products as "formula," these products are not required to meet the same standards or nutrient requirements as infant formulas. Furthermore, transition formulas follow labeling and content requirements for infant formula even though the product labels indicate that they are also appropriate for children aged up to 18 or 24 months. This practice implies that infants and young toddlers have the same nutrient requirements, which may further confuse caregivers. Moreover, it encourages parents to serve infant formula to children older than 12 months, which is not recommended.

The FDA requires infant formula packages to carry a disclaimer that caregivers should "Use as directed by a physician," but does not require this disclaimer on toddler milks or other food or drinks for infants or children older than 12 months.<sup>50</sup> In a study by Pomeranz et al,<sup>47</sup> just 2 of the 5 transition formulas and 1 of the 12 toddler milks examined included such a disclaimer. Finally, toddler milk is less expensive than infant formula and more readily available; it is typically stocked on store shelves, whereas infant formula may be stocked in a locked display case or behind the counter. These marketing practices also increase the likelihood that caregivers will purchase toddler milks to serve to infants younger than 12 months. Together, these findings support the WHO's conclusion that marketing of formula products for older infants and young children "undermines progress on optimal infant and young child feeding."24

#### IMPACT OF MARKETING

As described in the previous section, research has documented widespread marketing of infant formula and toddler milk in the United States and numerous problematic practices. However, much less research has documented the impact of this marketing. A review of the global research on the impact of BMS marketing concluded that marketing influences social norms by making formula use appear to be common, modern, and comparable to breast milk.<sup>51</sup> In addition, providing free samples in maternity facilities and promotion through health workers has a clear negative impact on breastfeeding initiation and exclusive breastfeeding. It also found a link between recall of direct-to-consumer marketing and feeding decisions. Nonetheless, the majority of these studies have focused on infant formula marketing in low- and middle-income countries. US studies have predominantly examined the relationship between exposure to some forms of infant formula marketing, especially through the healthcare sector, and breastfeeding initiation and/or duration. Studies have not measured effects of marketing for toddler milks or other baby/toddler foods on provision of unhealthy products or young children's diets.

## Associations between infant formula marketing and formula use

Global studies have not evaluated whether legal adoption of Code provisions affects formula sales, but researchers have compared breastfeeding rates between countries with differing policies. For example, India restricts marketing of BMSs up to 2 years and maintains an implementation and monitoring system, while China restricts marketing up to 6 months and has no monitoring mechanism.<sup>51</sup> Compared with China, India has much higher rates of exclusive breastfeeding (46% vs 28%, respectively) and any breastfeeding (88% vs 37%) at 1 year.

In addition, infant formula consumption is relatively high in the United States - one of the few countries that do not regulate infant formula marketing. In a global comparison using Euromonitor sales data, US infants (0-6 mo) consumed 45 kg of formula per capita in 2013, exceeded only by per capita consumption in the United Kingdom.<sup>19</sup> High rates of marketing for specialty formulas in the United States also appeared to be related to relatively high consumption of these products. Specialty formula represented 36% of infant formula sales in the United States, and per capita consumption of specialty formula was almost 3 times higher than the next highest country examined (16.4 kg per infant vs 5.7 kg in the United Kingdom). Furthermore, US consumption of toddler milk was 5.0 kg per child aged 13-36 months, exceeded by just 6 other countries (United Kingdom, France, China, Mexico, Turkey, and Indonesia).

US researchers have also examined reported exposure to formula marketing via broadcast (TV and radio), print, and websites using data from the Infant Feeding Practices Study II - a longitudinal study of mothers through babies' first year.<sup>29</sup> Mothers' recall of infant formula print advertising was associated with intentions to breastfeed for a shorter time, while reported exposure to formula information on websites was associated with breastfeeding initiation, including lower intent to breastfeed and breastfeeding initiation. However, reported exposure to TV/radio marketing was not related to breastfeeding intentions or outcomes. Another analysis of data from the Infant Feeding Practices Study II measured exposure to infant formula marketing (including media exposure during pregnancy and formula samples or coupons at the hospital) and reasons for formula switching.<sup>27</sup> Researchers found that 57% of mothers chose a specific formula at 1 month because it was used in their hospital or their doctor recommended it. Other common reasons given for choosing a formula included receiving a sample or coupon (20%) or another form of direct-to-consumer marketing (13%). In addition, 14% indicated that they were given the formula through WIC, while 19% reported using the formula they fed to an older child. Mothers were less likely to switch to another formula if their doctor recommended it than if their hospital used the formula, but more likely to switch if they received a sample in the mail or chose it because of other forms of consumer marketing.

## Impact of WIC (Special Supplemental Nutrition Program for Women, Infants, and Children) formula provisions

WIC provision of infant formula also serves as an indirect form of marketing for designated WIC formula brands. The US Department of Agriculture (USDA) establishes requirements for WIC packages, but individual states use a competitive bid process to determine the brand of infant formula included in their WIC package. Thus, WIC designation leads to direct sales of the designated WIC infant formula brand. However, research has also shown that WIC designation benefits infant formula manufacturers in other ways. It has led to price increases for infant formula overall and increased the popularity of more expensive specialty formulas (eg, DHA and arachidonic acid (ARA) formulas now included in WIC packages).<sup>52</sup> Spillover effects also increase non-WIC sales of a state's WIC contract brands owing to greater shelf space and better product placement for WIC-contract brands at retailers; hospital purchases and provision of the WIC-contract brand; physicians recommending the WIC brand to all mothers; and brand loyalty from WIC and non-WIC parents who are hesitant to change formula brands. Spillover effects also lead to increased purchases of non-WIC products offered by the state's contract formula brand (including toddler milks).<sup>52,53</sup> Additionally, WIC provision and hospital use of the WIC-contract brand may imply endorsement of the brand. A US Government Accountability Office study demonstrated that formula manufacturers recognize the value of this implied endorsement.<sup>22</sup> Formula marketing materials use the WIC acronym, such as prescription pads, posters for health providers, consumer ads, and coupons, despite contracts that forbid manufacturers from using the WIC acronym and logo in any marketing.<sup>22</sup>

#### Impact of marketing through the health sector

Most studies examining causal effects of infant formula marketing have focused on marketing through the health sector, especially offering samples in hospital discharge packs. In randomized controlled trials, providing commercial hospital discharge packs (sponsored by formula manufacturers) reduces exclusive breastfeeding vs noncommercial discharge packs or no packs.<sup>54</sup> Some studies found that receiving commercial packs also led to earlier solid food introduction. A US Government Accountability Office<sup>22</sup> report examined US studies on the impact of receiving formula samples in discharge packs on breastfeeding rates and found that 7 of 11 studies demonstrated reduced breastfeeding rates for women who received formula samples. Two studies also found that WIC participants who received discharge packs were less likely to initiate breastfeeding and more likely to provide infant formula. Of the 4 studies that showed no effect of commercial packs, 2 were funded by infant formula manufacturers.<sup>55,56</sup>

A more recent study examined new mothers who reported receiving commercial discharge packs (67% of a sample of 3895 women) and found 39% higher odds of exclusive breastfeeding for less than 10 weeks compared with women who reported that they did not receive a commercial discharge pack.<sup>57</sup> One hospital conducted an experiment where they provided industry-sponsored discharge packs during a 6-month period and hospital-sponsored diaper bags for the next 6 months.<sup>58</sup> Receiving hospital diaper bags increased any reported breastfeeding at 10 weeks (49% vs 44%) but did not affect exclusive breastfeeding at 10 weeks (10% vs 8%) or duration of exclusive breastfeeding (47 vs 44 d). However, those who reported that they did not receive formula in their bags reported significantly higher exclusive breastfeeding when they received the commercial discharge bag (9% vs 36% at 10 wk) as well as the hospital bag (8% vs 22%). These findings indicate

considerable confusion about the source of infant formula samples as well as greater impact of samples on new mothers who may be less committed to exclusive breastfeeding.

One experiment measured the impact of formulasponsored educational packs provided to pregnant women in obstetrician offices.<sup>59</sup> Researchers randomly assigned women to receive the commercial pack the office had been providing at the first prenatal visit (including a formula-company diaper bag; company materials on pregnancy, infant feeding, and infant growth and development; a can of formula; and baby club and formula coupons). The control group received a noncommercial pack with similar contents, monetary value, and esthetic appeal. In this study, 21% of mothers receiving the commercial packs used a reply card to request a case of formula before the birth. Researchers then interviewed breastfeeding mothers at their postnatal visits (through 24 wk). This study also found that women who were less committed to exclusive breastfeeding were most affected by infant formula marketing. The packs reduced breastfeeding duration by 35 days in total and 11 fewer days of exclusive breastfeeding, but only for women who were uncertain or intended to breastfeed for less than 12 weeks (44% of breastfeeding women).

#### Methodological issues in marketing effects research

One issue with evaluating marketing impact is the ubiquity of this marketing. As noted earlier, nearly all new mothers reported exposure to formula marketing in the media and the majority received formula samples in the mail and/or in hospital discharge packs.<sup>29</sup> Therefore, it is difficult to isolate a control group of caregivers who have not been exposed to formula marketing. Moreover, recall of formula promotion, as well as seeking out formula information through digital sources (eg, websites, social media), may be more common among caregivers who are considering formula and less committed to exclusive breastfeeding.

Research examining the effects of interventions to reduce commercial marketing through health providers also demonstrates the difficulty of eliminating all commercial marketing influence. In the experiment on replacing commercial discharge bags,<sup>58</sup> 35% of mothers who received the hospital (noncommercial) bag misreported receiving formula in their "diaper discharge bag," and approximately 50% of mothers in both conditions reported receiving bottles of formula from the hospital separately (not in the bag). In the studies on provision of formula-sponsored educational packs through obstetricians' offices,<sup>59</sup> 56% of women reported receiving formula promotion items from other sources

before birth, and 40% reported receiving them after birth. Therefore, creating a true control group with no exposure to infant formula marketing in intervention evaluations may be virtually impossible.

Aggressive efforts by formula company representatives to undermine intervention efforts in hospitals have also been reported, as well as staff resistance to changes. In the experiment to remove commercial hospital discharge bags,<sup>58</sup> the hospital continued to receive free formula and branded supplies (eg, bassinet cards) from formula manufacturers, and industry representatives met many times with hospital administrators and researchers to argue against the study. They also approached obstetric and pediatric practices affiliated with the hospital to provide diaper bags and samples. To thwart industry efforts, the hospital had to train their staff, limit hospital access to pharmaceutical representatives, and place formula in a locked unit with signature requirements for access. One New York City campaign focused on provider education, changes in hospital and workplace practices, and a proposed Breastfeeding Bill of Rights to increase exclusive breastfeeding and breastfeeding duration. In a study of lessons learned, the authors reported extensive public and vocal resistance from formula companies and others with a stake in the formula industry.<sup>60</sup> These experiences highlight potential issues for baby-friendly hospital initiatives and the importance of limiting provision of formula, including restricting staff access to it, in the postpartum ward.<sup>5</sup>

#### **POLICY OPPORTUNITIES**

Although further research is required in many areas, this review of the existing literature demonstrates extensive marketing of infant formula and toddler milks that likely misinforms parents about potential benefits to children and contributes to suboptimal feeding practices. Additional parent education and resources about optimal feeding are required. However, substantial industry efforts to contradict expert advice demonstrate the need for broad systemic changes through policylevel actions.

Eliminating infant formula marketing directly to consumers and through healthcare providers would be an important step toward exclusive breastfeeding. In 2011, the US Surgeon General called for actions to "ensure that the marketing of infant formula is conducted in a way that minimizes its negative impacts on exclusive breastfeeding."<sup>3</sup> Recommended implementation strategies included the following: (1) Infant formula marketers should be held accountable for complying with the Code, in particular stopping advertising directly to consumers and distribution of supplies

to the public, and public health entities should monitor and publicize violations. (2) Ensure that formula claims are truthful and not misleading, including research on how consumers perceive the claims, whether messages are believable, and how they affect behavior. (3) Discontinue promotion of infant formula through healthcare clinicians, such as distribution of free samples and logo materials and formula company posters and other displays in clinicians' offices, hospitals, and clinics, which implicitly endorses formula feeding.

Policies should also address potential harm from toddler milk marketing.<sup>24,47</sup> Such actions are increasingly necessary for several reasons: Infant formula manufacturers appear to be redirecting marketing efforts toward these products; they are using similar questionable marketing tactics as those promoting infant formula, such as unsupported structure/function claims; cross-promotion with infant formula brands confuses consumers; and serving these sweetened toddler milks contradicts health experts' advice for healthy eating in young children. Policies should also address the nutritional content of toddler milks and transition formulas.

Policy-level actions could be initiated by multiple key stakeholders, including industry (eg, formula manufacturers, media companies), healthcare professional organizations (eg, organizations of physicians, hospitals, nutritionists), public health agencies (eg, CDC, USDA, Surgeon General), US regulatory agencies (eg, FDA, US Federal Trade Commission), and state attorneys general or state and local regulatory authorities (Table 2).

#### **Industry self-regulation**

The United States has relied primarily on industry selfregulation to address problematic marketing of other products,<sup>61</sup> but there are currently no US selfregulatory frameworks to cover marketing of infant formula or other baby/toddler food and drinks. Manufacturers and media companies who accept advertising could voluntarily adopt Code provisions and/or establish their own self-regulatory body. Formula manufacturers should comply with the Code in all countries (including the United States), as set forth by the WHO.<sup>23</sup> Compliance should encompass infant formula, toddler milk, and other BMSs, and include all marketing to the general public and through the healthcare system. Manufacturers should also prohibit their representatives from actively thwarting policies set by others (eg, baby-friendly hospital initiatives).

Manufacturers should also set minimum nutrition and safety standards for all products intended for babies and young children. Proper nutrition at this key developmental stage is vital for establishing healthy food preferences and diets to prevent long-term health consequences. Therefore, all products for young children should not contain added sugar or high levels of saturated fat or sodium. The Children's Food and Beverage Advertising Initiative (CFBAI)<sup>62</sup> food industry self-regulatory program sets standards for products that can be advertised directly to children, but it does not cover products advertised to adults (ie, parents). The CFBAI should also require participating companies to pledge that all food products intended for infants and young children meet optimal nutrition and safety standards. Media companies can also set standards for products that can be advertised in their magazines, websites, and other properties. There is precedent. Two magazine publishers reported that they do not allow any infant formula ads,<sup>30</sup> and the Walt Disney Company<sup>63</sup> has nutrition standards for products that can be advertised in its media properties or promoted through its licensed character agreements.

## Guidance from healthcare professional organizations and government agencies

Healthcare professional organizations and government agencies can set nutrition and public health guidance and goals to raise public awareness of the importance of breastfeeding and concerns about nutritionally poor foods marketed for babies and infants. Such guidance would also inform healthcare providers about important topics to address with their patients and clients, and help set the agenda for public health campaigns.

The American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, and the National Association of Pediatric Nurse Practitioners have clear policy statements recommending exclusive breastfeeding through about 6 months and/or endorsing efforts to optimize breastfeeding.<sup>6,64-66</sup> However, none of them offer explicit guidance about toddler milks or mention the importance of limiting products with added sugar, sodium, or saturated fat in young children's diets. The American Academy of Pediatrics, American Academy of Family Physicians, and other physician organizations should evaluate toddler milks and other foods marketed for young children and advise parents about serving these products to children. Associations of nutritionists (eg, Academy of Nutrition and Dietetics) and other health professionals could also publish policy and guidance statements. Healthy Eating Research feeding guidelines for infants and toddlers from birth to 24 months were developed by an expert panel and provide standards that could be adopted by health professional organizations.<sup>1</sup>

Furthermore, Code provisions specifically prohibit healthcare providers from directly or indirectly

#### Table 2 Potential US policy actions to address infant formula and toddler drink marketing

Key stakeholder	Potential policy-level actions
Industry (manufacturers and distributors, media companies)	<ul> <li>Comply with the Code and cease marketing of infant formula, toddler milks, and other BMS.</li> </ul>
	<ul> <li>Set minimum nutrition and safety standards for all food products intended for infants and young children.</li> </ul>
	<ul> <li>Expand CFBAI to require nutrition standards for all products intended for babies a toddlers.</li> </ul>
	<ul> <li>Set standards for products that can be advertised to parents through media properties.</li> </ul>
Professional organizations (eg, AAP, AAFP, AND)	<ul> <li>Establish guidance about serving toddler milks and other nutritionally poor produ- to infants and young children.</li> </ul>
	<ul> <li>Require healthcare providers to follow Code provisions and not market BMS in healthcare settings.</li> </ul>
	Cease accepting funding from infant formula manufacturers.
	<ul> <li>Create or update CMEs on proper feeding practices to address marketing influence</li> </ul>
	including guidelines on toddler milks.
Government agencies that set guidance and goals and provide nutrition educa- tion (CDC, USDA)	• Establish limits for sugar, sodium, and saturated fat for children under 2 in 2020–2025 DGAs.
	<ul> <li>Include objectives for reducing BMS marketing and set dietary goals for children u der 2 in Healthy People 2030.</li> </ul>
	<ul> <li>Provide guidance about unnecessary commercial products in nutrition education programs that serve parents of young children.</li> </ul>
	Collect data and track toddler use of BMS.
Federal regulatory agencies (FDA, FTC, USDA)	<ul> <li>Create a new regulatory structure for baby/toddler products, including regulating toddler milks on par with infant formula (CDC).</li> </ul>
	<ul> <li>Address nutrient content and structure/function claims for products intended for children under 3 (FDA).</li> </ul>
	<ul> <li>Consider enforcement action against unfair and deceptive marketing and labeling practices (FTC).</li> </ul>
	<ul> <li>Require infant formula manufacturers with WIC contracts to comply with the Code (USDA).</li> </ul>
	<ul> <li>Pass legislation to require regulatory agencies to enact such regulations (Congress</li> </ul>
State and local authorities	<ul> <li>Use AGs' consumer protection authority to address misleading and deceptive labe ing and marketing practices.</li> </ul>
	<ul> <li>Include toddler milks in definitions of SSBs for tax and pricing laws.</li> </ul>
	<ul> <li>Require certain items to be sold from behind the counter, including transition for- mulas and toddler milks.</li> </ul>

Academy of Nutrition and Dietetics; BMS, breast-milk substitute; CDC, Centers for Disease Control and Prevention; CFBAI, Children's Food and Beverage Advertising Initiative; CME, continuing medical education; DGAs, Dietary Guidelines for Americans; FDA, US Food and Drink Administration; FTC, Federal Trade Commission; SSB, sugar-sweetened beverage; USDA, US Department of Agriculture

marketing BMSs (including infant formula and toddler milks) to their patients (eg, providing free samples, branded promotional materials, or branded posters or educational materials for waiting rooms), as well as accepting financial or material support from BMS manufacturers and distributors (eg, fellowships, research grants, professional development). US healthcare professional organizations should prohibit industrysponsored activities by their organizations and members in accordance with the Code.

Government agencies can also monitor, provide guidance, and/or set goals for breastfeeding and dietary recommendations for young children. For the first time, the 2020–2025 Dietary Guidelines for Americans will include guidelines for infants and toddlers younger than 2 years.<sup>67</sup> These guidelines provide an important opportunity to identify products marketed for young children that do not conform to nutrition requirements established for this age group. The CDC's Healthy People 2020 objectives include breastfeeding goals and goals to support breastfeeding in hospitals and workplaces.<sup>8</sup> Healthy People 2030 could include additional goals for reducing marketing of infant formula and dietary goals for infants and young children, such as reducing sugar and sodium intake.

The US government also supports nutrition education programs through WIC, the Supplemental Nutrition Assistance Program, the Child and Adult Care Food Program, and Head Start. These programs could provide education to specifically counteract misinformation that parents receive through marketing. The USDA and state agencies should also ensure that information provided by WIC nutrition counselors reflects the current science and expert recommendations. These counselors meet individually with low-income mothers to advise them on child feeding, providing a prime opportunity for understanding barriers and providing information to identify lower cost and more nutritious alternatives to commercial products.

#### **US government regulation**

In the United States, Congress can pass legislation or require federal agencies to act.<sup>47</sup> All government actions must be consistent with the First Amendment protections for commercial speech. However, the FDA and the USDA have the authority to create new regulatory schemes regarding commercial baby/toddler foods, and the Federal Trade Commission could bring actions against unfair and deceptive acts and practices. The USDA could also set requirements for infant formula manufacturers to participate in state WIC contracts.

The FDA has the authority over food standards and labels. The agency currently regulates infant formula, including the naming and definition of "infant formula," manufacturing and quality control, nutrient, labeling requirements, directions for use, and required disclaimers.<sup>47</sup> It could establish a statement of identity and similar requirements for toddler milks. The FDA has issued draft guidance for manufacturers regarding structure/function claims on infant formula,<sup>35</sup> but requirements for toddler milks and other baby/toddler food claims (including nutrient content, structure/function, qualified health and health claims) are currently the same as those for all food and drink products. The FDA could also establish stricter requirements for claims on all food and drinks intended for children younger than 3 years. In addition, it could encourage manufacturers to voluntarily provide data to support structure/function claims and "Generally Recognized as Safe" status for formula ingredients.<sup>34</sup> Alternatively, Congress can require the FDA to strengthen its requirements, especially for products intended for infants and toddlers.

The Federal Trade Commission has the authority to address false, unfair, or deceptive marketing, including advertising on TV and the internet, and can use this authority to bring individual cases against companies engaging in these practices. Marketing described in this review might warrant Federal Trade Commission action, including cross-promotion of toddler milks and infant formula that confuses parents and could harm infants' health.<sup>47</sup> Structure/function and nutrition claims and other marketing messages (eg, formula is "closest" to breast milk) could also be considered misleading and deceptive if shown to influence parents' purchases of unnecessary products and/or products that are not recommended by experts for their children. Investigation into the feeding advice on infant formula websites would be similarly warranted.

Finally, the government has substantial purchasing power through WIC, which the USDA could use to require infant formula manufacturers to stop engaging in certain misleading or deceptive marketing practices. For example, WIC could only purchase infant formula for which manufacturers substantiate all their claims.<sup>34</sup> The USDA could also reduce the impact of implied endorsement of WIC brands by requiring the USDA to only purchase nonbranded infant formula with a generic label. The US government could also do more to incentivize breastfeeding and reduce barriers to breastfeeding. It could increase the WIC food basket for lactating women and support actions by communities, health care, employers, and childcare facilities, such as those recommended in the US Surgeon General's Call to Action to Support Breastfeeding.

## State and local regulations

At the state and local level, attorneys general and regulatory authorities or policies can directly address the marketing, sale, and distribution of infant formula and other commercial baby/toddler foods. State and some city attorneys general have the consumer protection authority to address a range of issues identified with these products.<sup>47,68</sup> For example, the New York State Attorney General successfully brought action against the manufacturer of PediaSure SideKicks, arguing that its advertising was false, misleading, and unfair and may be dangerous to children's health.<sup>69</sup> Attorneys general could also bring actions for unfair and deceptive marketing and labeling practices, questionable healthand nutrition-related claims, cross-branding of toddler milks with infant formula, and marketing suggesting that infant formula is equivalent or even superior to breastfeeding.

States can also regulate retail practices, including requiring certain products to be located behind the counter. For example, New York law requires that ipecac be located behind the counter to protect consumers from unintended harmful use.<sup>70</sup> States can similarly require that toddler milks be located behind the pharmacy counter.<sup>71</sup> Retailers often place infant formula under lock and key to prevent theft. Regulations could mandate that infant formula and toddler milks be located in a place that requires customer assistance by pharmacy staff trained to provide guidance on their ageappropriateness.

State and local governments can include toddler milks in their definitions of a sugar-sweetened beverage for taxation purposes,<sup>72</sup> when enacting new excise taxes

on sugar-sweetened beverages. Further, states with sales taxes on consumer goods often exempt necessity food products while taxing non-necessities. In those states, laws could ensure that toddler milks are also subject to sales taxes. State and local governments could also enact minimum price laws so that toddler milks cannot be priced lower than infant formulas. Such laws would ensure that consumers do not inappropriately purchase toddler milk for an infant because it is cheaper.

## **Advocacy Actions**

Child health advocates also play an important role in raising awareness of potentially harmful marketing practices and persuading industry and policymakers to enact improvements. Researchers who have evaluated monitoring and compliance with the Code in other countries have noted the importance of advocates in the successful implementation of legislation and regulation. For example, public reports of industry practices can damage corporate reputations and pose high costs for companies, and may be more effective than economic sanctions.<sup>44</sup> Furthermore, NGOs can leverage public opinion and pressure governments and companies to affect change. To that end, NGO reports<sup>39,42,44,72</sup> highlight Code violations and loopholes that manufacturers exploit, and a public website provides recent Code violations<sup>73</sup> and a mechanism for interested parties to report violations. These efforts have been critical in supporting new WHA resolutions and strengthening Code provisions. Advocates could also publicize professional societies that accept funding from infant formula manufacturers. This strategy was successful in the United Kingdom, where, in 2019, the Royal College of Pediatrics and Child Health agreed to stop accepting event sponsorships and advertising from formula companies.74

In the United States, NGOs have raised awareness and increased support for compliance with Code provisions in some sectors. Baby-Friendly USA has been instrumental in expanding the number of birthing facilities that follow the Code.<sup>38</sup> 1000 Days advocates for improving nutrition for children younger than 2 years, including by encouraging companies to follow Code guidelines for ethical marketing and promotion of infant formulas and young child foods and beverages.<sup>75</sup> Advocates should continue to publicize concerns about unfair marketing practices and pressure formula manufacturers, hospitals, and healthcare providers to comply with the Code.

Advocates can also help raise awareness about marketing that encourages purchases of infant formula and nutritionally poor baby/toddler foods and begin to counteract misinformation about child feeding that parents receive from commercial interests. For example, they could challenge nutrition advice provided by companies' paid experts, utilize social media and parent blogs to inform caregivers, and call for consumer protection actions to address misleading information conveyed through marketing. Advocates can refer to the Healthy Eating Research evidence-based guidelines for advice about what, and how, to feed infants and toddlers to help counteract corporate messages.<sup>1</sup>

#### **FUTURE RESEARCH**

Public health and nutrition researchers also play an important role in monitoring, assessing the impact, and raising awareness of problematic marketing practices. Advocates and policymakers rely upon research to help identify potential issues and provide evidence to support policy solutions. Studies showing the link between marketing, policy, and health outcomes have been essential to enacting improvements to the Code.<sup>44</sup> As noted throughout, numerous research questions remain regarding infant formula and toddler milk marketing, which presents significant opportunities for researchers.

Table 3 summarizes key research questions identified in this review. First, owing to the relatively recent introduction and emerging concerns regarding some products (eg, toddler milks, specialty formulas), it is not clear how many parents are serving these products or how often. Studies that monitor breastfeeding and/or young children's diets (eg, the Feeding Infants and Toddlers Study, the CDC National Immunization Survey), as well as cross-sectional studies examining infant and young child feeding, should track provision of commercial products in addition to infant formula. The National Health and Nutrition Examination Survey has a wealth of data on consumption patterns of infants and young children, as well as consumer behavior questions, that could begin to answer many of these open questions.<sup>76</sup> Studies should also examine demographic characteristics of households that purchase these products and contextual factors that may lead to greater use by these caregivers. For example, are Hispanic parents more likely to serve products that are disproportionately advertised on Spanish-language TV, such as toddler milks?<sup>15</sup> Are low-income caregivers more likely to purchase higher-cost specialty formulas?

Research has primarily examined marketing of infant formula in traditional media (ie, TV, magazines). Other traditional forms of marketing have not been well studied, including marketing at retailers and in obstetrics and pediatric offices. Additional studies are required to understand companies' use of newer marketing techniques, such as social media, baby clubs, and smartphone

#### Table 3 Future research agenda

Research topic	Examples of unanswered research questions
Consumption of commercial products	<ul> <li>Incidence and frequency of consumption of toddler milks, specialty formulas, and other commercial products by infants and young children</li> <li>Sociodemographic characteristics of households where children are served these products including differences by income, education, race/ethnicity, and geography</li> <li>Contextual factors that may lead some caregivers to use formula more than others</li> </ul>
Extent, content, and exposure to marketing	<ul> <li>Extent and content of newer forms of marketing, including social media, influencers, baby clubs, and smartphone apps</li> <li>Extent of traditional marketing that has not been well-studied (eg, retail displays, shelf placement, price promotions)</li> </ul>
	<ul> <li>Accuracy of feeding advice provided by manufacturers</li> <li>Extent of marketing for formula and toddler milks in hospitals and obstetrics and pediatric offices (including direct promotion and indirect promotion through branded materials)</li> <li>Marketing of newer product categories, including toddler milks and specialty formulas</li> </ul>
Impact of marketing	<ul> <li>Relationship between advertising/other marketing, product salesand/or consumer purchasing behavior</li> <li>How marketing influences caregivers' decisions about products to serve their children, including attitudes about commercial products and normative beliefs about appropriateness and benefits</li> </ul>
	<ul> <li>How marketing affects beliefs that commercial products are required for common child feeding issues (eg, specialty formulas for gassiness, toddler milks for picky eaters).</li> <li>How provision of problematic commercial products, such as sweetened toddler milks, influences young children's development of healthy preferences and eating behaviors</li> <li>Clinician, hospital, and other healthcare worker attitudes about formula marketing through the healthcare system</li> </ul>
	<ul> <li>Cost of providing infant formula, specialty formula, and toddler milks for family budgets, healthcare, and WIC</li> </ul>
Misleading and deceptive practices	<ul> <li>Caregivers' interpretation of common product claims, beliefs in these claims, and claims' impact on purchases</li> <li>Confusion about differences between infant formula and toddler milks owing to cross-pro-</li> </ul>
	<ul> <li>Consumer beliefs that commercial products are the same or better for their child than recommended products (eg, toddler milks vs plain milk)</li> </ul>

Abbreviation: WIC, the Special Supplemental Nutrition Program for Women, Infants, and Children.

apps, and whether these marketing messages are consistent with recommended feeding practices.

Furthermore, few studies have examined any type of marketing for other baby/toddler food categories. In addition to toddler milks, researchers have identified concerns with the nutritional content of some categories of baby and toddler foods. More than 80% of infant and toddler desserts, cereal bars, fruit-based snacks and grains, and toddler fruit products contain added sugar, and the majority are high in sugar (ie, equate to >35% of calories).<sup>16</sup> In addition, three-quarters of toddler dinners are high in sodium (averaging 212 mg per 100 g), and one-third contain added sugar. Just 5% of baby and toddler snacks qualified as nutritious options for young children.<sup>15</sup>

Perhaps the most important, but least understood, research question is how marketing affects the foods that caregivers serve their infants and young children and caregivers' attitudes and beliefs about nutrition and feeding practices more generally. As discussed earlier, it is difficult to isolate the impact of individual marketing techniques on account of exposure to multiple forms of marketing for the same products. However, research can assess whether attitudes and beliefs about products conform to messages presented in marketing. For example, do caregivers believe that specialty formulas solve common infant conditions (eg, gassiness, fussiness) or that toddler milks help children's cognitive development? Marketing may also affect the attitudes and beliefs of health professionals and others who advise caregivers about what to serve their children, but research has not examined these potential effects. Marketing can also affect social norms about what is appropriate to serve to children, which affect the products that parents serve their own children.<sup>51,77</sup>

Another critical area for future research is to understand how serving young children these highly marketed commercial products affects children's development of healthy taste preferences and eating habits. For example, does serving sweetened toddler milks to a child transitioning from infant formula or breast milk reduce their preferences for plain milk? It is also important to measure the cost impact of serving these products on family budgets, as these products tend to be more expensive than alternatives. Healthcare costs resulting from suboptimal child feeding practices should also be assessed.

Finally, research can provide evidence for advocates and policymakers to enact policy solutions. In particular, research is needed to examine whether claims and other marketing messages mislead or deceive caregivers about the benefits of serving these products. The recent proliferation of structure/function claims on infant formulas and their unproven scientific basis has been questioned by the FDA.<sup>35</sup> Yet similar claims also appear on toddler milks. Furthermore, nutrition-related claims are common on other nutritionally poor baby and toddler foods,<sup>15</sup> and such claims have been shown to mislead parents about product healthfulness and benefits in other product categories (eg, sugary drinks<sup>32</sup> and children's cereals<sup>78</sup>). Research should ensure that product claims are truthful and not misleading, including how caregivers perceive these claims and their effect on purchases and feeding practices. Further research is also needed in the United States to evaluate concerns about cross-promotion of infant formula and toddler milks and potential misunderstanding about which products are age-appropriate for infants and young children.

#### CONCLUSION

Faced with increasing breastfeeding rates and stable numbers of potential consumers for their products (ie, infants and young children), manufacturers have found creative ways to grow their businesses. Marketing strategies include introducing new product categories (eg, toddler milks, specialty formulas), adding features to differentiate products from competitors' (eg, DHA, prebiotics/probiotics, organic ingredients), and creating a consumer need, which these products are positioned to solve (eg, fussy babies, picky eaters, unique toddler nutrition requirements). Unfortunately, marketing for these products often positions them as "better" than the optimal dietary options for infants and young children, including breast milk, plain dairy, fruits and vegetables, and other healthy family foods. Additional research is required, but extensive marketing of less-than-ideal baby and toddler products likely contributes to poor diets in young children and impedes optimal development of taste preferences and eating behaviors. The WHO Code provides a blueprint for US policies to reduce the harmful impact of marketing for infant formula and other BMSs. However, additional regulatory and legislative options are available at the federal, state and local, and industry levels. Manufacturers, policymakers, health professionals, advocates, and researchers

all have an important role to play in identifying and stopping the marketing of food and drinks that can harm the long-term nutrition and health of the youngest and most vulnerable children.

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