Protecting Vulnerable Infants by Ensuring Safe Infant Formula Use

Steven A. Abrams, MD1, and Stephen R. Daniels, MD, PhD2

Although it is unquestionable that breastfeeding by an infant’s mother is the best route to provide nutrition for infants, it is recognized that this is not always feasible or chosen for a variety of reasons. The debate regarding the role of human milk substitutes, their marketing, and the challenges of supporting breastfeeding have dominated recent discussions about infant formula use. Lost in much of this often-contentious discussion has been a consideration of how best to ensure that infants who are receiving infant formula receive a safe product and that it is provided in a manner that optimizes neonatal outcomes. Safe use of formula is an important goal recognized by the World Health Organization (WHO) for infants receiving some or all of their feeding using infant formula. Advocacy for breastfeeding should not deter this educational and policy-related discussion.

Who Purchases and Uses Infant Formula Products?

Currently, about 83% of infants in the US will receive some breastmilk, but only about 25% are exclusively breastfed until 6 months of age, the time at which it is usually recommended to begin complementary foods.1 Thus, 75% of infants in the US will receive some non-breastmilk feeding by 6 months of age as a primary or sole nutrition source. There are important variations in this rate, such that exclusive breastfeeding at 6 months is about twice as common among those in the highest, compared with the lowest, levels of maternal education and income. Furthermore, only 18% of Special Supplemental Nutrition Program for Women, Infants and Children (WIC) recipients breastfeed exclusively at 6 months compared with 33% of WIC-ineligible women.2

The WIC Program in the US

In the US, the WIC program is operated as part of the Food and Nutrition service of the US Department of Agriculture (USDA). Funded by Congress, this program provides a large proportion of the infant formula that is used by infants. Although the exact amount varies by location, overall about one-half of the infants in the US are served by the WIC program. WIC provides substantial benefits for mothers who are either breast or formula feeding (and those doing both), including educational programming to support breastfeeding. To qualify for WIC benefits, applicants must be eligible based on household income (usually ≤185% of the federal poverty level), residence, and evidence of nutritional risk. The choice of which infant formulas are provided by WIC varies by state and is based on a competitive bidding process. The exact amount of formula provided depends on whether it is a fully or partially breast fed infant, the infant’s age and the state.

WIC is a supplemental program that is not designed to provide for 100% of an infant’s needs. In Texas, for example, the maximum amount of formula provided in the first 3 months of life is 9 cans of 12.4 oz powder or about 112 ounces of powder. Each can provides about 90 ounces (2700 mL of formula), or enough for close to 3 days. Taking into account unavoidable small amounts of wastage, this is approximately 80% of a typical infant’s needs. Thus, most families receiving WIC must obtain some infant formula beyond what is provided by WIC if their infant is fully formula-fed.

Formula Marketing and Education

The history and regulations around the marketing of infant formula are complex and contentious. Infant formula is a large global industry that is continually expanding, especially in markets outside the US, most notably China. In 2016, the top 10 selling infant formula powders in the US comprised well over 3 billion dollars in sales, and this amount is continuing to rise. The majority of these sales are for products by 3 companies, although “private label” (ie, generic store brand) sales are about 8%-10% of the US market.5 The WHO International Code of Marketing of Breast-milk substitutes sets global limitations on the marketing of infant formula.5 However, the direct marketing of infant formulas to families is widespread in the US, which has not endorsed the Code. This marketing is largely competitive between brands, and there are relatively few independent resources available relating to specific concerns about infant formula choices. Online resources are limited and often unreliable although expert, carefully reviewed

AAP American Academy of Pediatrics
FDA Food and Drug Administration
USDA US Department of Agriculture
WHO World Health Organization
WIC Special Supplemental Nutrition Program for Women, Infants and Children

From the 1Department of Pediatrics, Dell Medical School at the University of Texas, Austin, TX; and 2Department of Pediatrics, University of Colorado School of Medicine, Aurora, CO.

S.A. is a member of the scientific advisory board of MilkPep, the education program of the Milk Processor Education Program. S.D. serves as an Associate Editor for The Journal of Pediatrics.

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souces such as the American Academy of Pediatrics (AAP) Web site, www.healthychildren.org, provides useful family-centered information.

**Value-Based Considerations in Infant Formula**

Specific information related to value-based decisions (cost/benefit analyses) in selecting infant formulas are difficult to obtain both for physicians and for families. Novel components including oligosaccharides found in human milk have been added to commercial products. Other formulas such as ones labeled organic or free of genetically modified organisms are also on the market, often at an increased price. It is challenging to gain an appreciation of the relative costs that families face in the store related to choices such as the use of liquid vs powder formula, store-brand vs name-brand formulas, and specialized formulas, including hydrolysates. As such, marketing of more expensive formula choices as having unique health benefits can easily lead families to spend more money than might be necessary on formula. Furthermore, marketing, social media, or other perceptions may lead families to feel guilty about using infant formula, driving parents into choosing more expensive products that purport to be “closest to mother’s milk,” an essentially meaningless market-driven, not evidence-based, statement.

**Distrust in Government or Pediatric Advice**

Guidelines for feeding infants, including the importance of avoiding cow milk in infancy and only using Food and Drug Administration (FDA)-reviewed formulas, often are attacked on social media. Of note is that the FDA reviews infant formula submissions that include new ingredients in formulas, but does not “approve” formulas. The FDA review considers data primarily related to safety but also related to potential health benefits related to formula submission. However, current guidelines for approval do not require demonstration of long-term unique health benefits specific to what may be expensive novel ingredients. There is almost no available published literature that looks critically at long-term benefits or possible disadvantages of novel ingredients, especially bioactive ones. We suggest that pediatricians advocate for longer-term studies that look at later endpoints and consider this information in advising families. The FDA has proposed structure/function claims related to infant formula, but these have not been enacted at the present time. These proposals do not limit claims related to an infant formula being closer to breast milk, as this is not considered in the current proposed rule as a structure/function claim.

The Internet is replete with advice about the dangers of standard infant formulas, the benefit of alternative feeding approaches (eg, raw goat milk), and the supposed benefits of imported, non-FDA-reviewed formulas as being healthier for infants or better tolerated by them. Because of the general tendency for physicians to ignore such misinformation, this can be a one-sided source of advice.

**What Are the Current Primary Threats to Healthy Feeding Practices Using Infant Formulas?**

**Formulas Are Expensive, and Families Need to Cut Costs**

It is not widely appreciated how expensive infant formula is to purchase. Table I shows the approximate relative costs of feeding options over a year. This table was generated by comparing approximate costs using typical online purchasing data and assuming that families receiving WIC purchase about 20% of their infant formula at full cost. Faced with these costs, families may choose one of several nonrecommended options to reduce expenses. Each of these poses substantial health threats to infants that are seen in clinical practice.

The first of these potential parental decisions would be to overdilute the formula compared with instructions. There are few data available regarding this practice, but I study indicated that it occurred in up to 15% of families, and this number is supported by limited additional data (Perrigo Nutritional, personal communication, May 6, 2019). The consequences of such overdilution are considerable and include the risks of hyponatremia, growth failure, and anemia. Families may overdilute accidentally or, because lacking the financial resources to buy adequate formula, they believe that overdilution is a good solution to pacify their hungry baby.

A second alternative that families may choose is the early introduction of whole cow milk or diluting formula with cow milk. This exposes the infants to risks of iron deficiency and is not nutritionally optimal, especially in the first 6 months of life. Families may even use inappropriate beverages such as soda, juice, or sugar water for their crying infant when they cannot obtain enough infant formula.

The final option families may consider to save money is preparing homemade formulas. This may be done for a

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**Table I. Approximate annual infant formula cost**

<table>
<thead>
<tr>
<th>Formula Type</th>
<th>Out-of-pocket costs for WIC clients (store brands)</th>
<th>Out-of-pocket costs for WIC clients (name brands)</th>
<th>Whole cow milk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic (store-brand) formula</td>
<td>$222</td>
<td>$404</td>
<td>$215</td>
</tr>
<tr>
<td>Name-brand routine formula</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Costs calculated based on averages of largest selling name-brand formulas or store-brand (generic) as purchasable in powder form from online sources. Comparison also provided for use of whole cow milk, although this is not recommended during the first year of life. Out-of-pocket costs presume purchase of 20% of formula consumed outside of WIC program.

†Add approximately 10% for organic formula which are not available from WIC program.
variety of reasons, including the belief that homemade formulas are superior. Although this was a common approach to infant feeding before about 1960, it has long been recognized that the risks to this approach are numerous, including the possibility of bacterial contamination, inadequacy of key nutrients such as iron and minerals, and the risks related to errors in mixing complex mixtures at home.

Available online “recipes” include those made from powdered cow’s milk and much more complex ones including 10 or more ingredients, often including raw (unpasteurized) cow milk, goat milk, and many other alternatives. Web sites advocating these approaches often express concerns about the dangers of routine infant formula components such as iron and docosahexaenoic acid. There are no indications for using homemade formulas, and pediatricians may need to ask carefully to determine whether families are doing this.

Families May Be Uncertain About the Availability of Infant Formula

The recent partial US federal government shutdown (December 2018-January 2019) led to many anecdotal media reports of families saving what they perceived to be potentially limited formula supplies from WIC and either diluting standard formula or using homemade formulas due to this concern. This mirrored a similar situation in 2013 in North Carolina. Although USDA took steps to ensure the availability of WIC for families during the partial shutdown, confusion and rumors about the long-term availability of WIC created considerable concern and potentially harmful responses.

The use of WIC has decreased in recent years, continuing a long-term trend such that between 2010 and 2017 use decreased by 15%. Anecdotal reports in the media indicate that some of the most recent decrease may be due to fears related to immigration status of members of WIC recipient families. There are few data regarding the degree to which these concerns have already led to failure to use WIC or specific effects on infant nutritional intake. Nonetheless, these are widely described by pediatricians and others working with families receiving WIC and represent substantial risks to infants.

Families May Not Trust Standard Formulas

Pediatricians are well aware that families do not always trust their advice regarding critical issues such as immunizations and preventive healthcare. Advice is commonly sought from unreliable sources found on the Internet or from alternative healthcare providers. This concern is also increasingly reflected in infant formula issues. Of interest is that this concern seems to come frequently from upper income families, who have the resources to take actions such as importing infant formulas.

Some US companies routinely manufacture their FDA-reviewed formulas overseas and in this case the FDA carefully monitors the production and shipment of these formulas into the US. Families are generally unaware of the actual site of production of the infant formulas purchased from stores in the US.

However, increasingly, there has been the importation of foreign formulas, especially from Europe, into the US, that have not been reviewed, nor their product monitored by the FDA. This problem seems to be increasing based on Internet articles claiming that such foreign formulas are superior and have less perceived toxicity from contaminants, including heavy metals and pesticides or genetically modified organism ingredients. Without FDA oversight, this importation is not legal, and the safety and proper storage of these formulas is not ensured. Unlike FDA-reviewed formulas, routine testing for 30 nutrients is not required, nor is there mandatory oversight of complications related to formula. There is absolutely no evidence or reason to believe that any of these illegally imported formulas have any benefit to infants. Additional harm may be introduced through lack of compliance with FDA safety measures as noted, and it is important that pediatricians not acquiesce to their use by families and explain the risks involved.

Other families may be influenced by articles advocating for the use of raw cow or even raw goat milk in home production of supposedly superior formulas. Claims are made that these raw milks improve immune or gastrointestinal function without any scientifically supported evidence provided. Use of these products subjects infants to considerable risk of infections from unpasteurized milk or nutrient inadequacy.

Although pediatricians and the public may perceive that FDA and other federal regulations and assistance programs fully protect formula-fed infants, this is not always the case. There are no reliable data related to the frequency of hospitalizations or growth impairment due to improper use of formula, but it is likely considerable. Many cases of anemia or nutrient inadequacy are unlikely to be identified even by hospital records, making it more difficult to quantify the problem. Thus, solutions must be provided based on the concerns seen by pediatricians and other healthcare providers.

Solutions: How Can We Make the Formula Supply Safer and More Secure in the US?

We propose 6 specific actions (Table II) to achieve the goals of a safer, more secure infant formula supply and infant formula feeding. It is critical to understand that these actions are not intended to, nor will they, undermine the role and advocacy for breastfeeding in the US. However, this advocacy cannot be used to limit discussions and effective strategies to support safe formula feeding. We support implementation of the global WHO Code regarding infant formula marketing in the US, or at least careful consideration of limitations on how we market infant formula including restriction of the advertising use of phrases lacking evidence to support them, such as “closer to mother’s milk.” This, however, does not mean limiting access to education about infant formula feeding.
Table II. Specific actions to enhance infant formula safety in the US

1. Provide multidimensional educational programs focused on formula feeding for both medical care providers and families
2. Increase information and regulatory guidance from government sources and industry about contamination issues
3. Protect the WIC program from the consequences of potential government shutdowns or other perceived threats
4. Mandate that the federal government improve pricing clarity so families can see actual costs of different formula choices
5. Fund research from the USDA and US Department of Health and Human Services into all aspects of formula feeding, including behavioral interventions, social marketing effects, and the health consequences of inappropriate formula use
6. Monitor social media and provide correct information by pediatricians and licensed health experts such as registered dietitians

Recommendation #1: Provide Multidimensional Educational Programs Focused on Formula Feeding for Both Medical Care Providers and Families

Pediatricians need to return to their role as recognized thought leaders in the field of infant formula use. As such, regular evidence-based educational programming is needed for pediatricians and others providing pediatric care, including family medicine physicians and nurse practitioners, to improve their understanding of formula choices. This education should also include increased education for residents and medical students. For example, AAP’s annual National Conference and Exhibition has such a lecture given almost every year, and it is inevitably very highly attended. Pediatricians often request that the AAP Committee on Nutrition provide increased guidance regarding formula-related issues. However, such presentations need to be free of commercial bias. This is often difficult, as many of the experts in this area have worked at some point with infant formula companies on issues related to research or education. These potential conflicts of interest need to be made clear but not prevent expert guidance when needed.

We suggest that the AAP set up a specific evidence-based guidelines group, working with stakeholder groups at the AAP, including the Committee on Nutrition and the Section on Pediatric Gastroenterology, Hepatology and Nutrition to provide detailed evidence-based reviews of current infant formula products and assessment of new formulas being introduced to the marketplace. Partnership with relevant professional organizations including the Academy of Nutrition and Dietetics, the American Society for Nutrition, and the American Academy of Family Physicians would be invaluable in this effort.

Until recently, there was little available information for families to specifically address many of their formula-related concerns described previously. Reliable Web sites such as www.healthychildren.org need to have expanded areas for providing this information, and this educational material needs to be made available to families by pediatricians without concern that this violates rules of infant formula marketing.

Recommendation #2: Increase Information and Regulatory Guidance from Government Sources and Industry About Contamination Issues

A recent report from Consumer Reports highlighted the presence of heavy metal contamination of juice products, including those designed for use by children. These issues regarding contamination, which notably include aluminum toxicity, also can extend to infant formulas. Generally, there is little reliable government data about the levels of organic or heavy metal contamination of infant formulas (or human milk). An effort by relevant agencies, whether it is the FDA, the Environmental Protection Agency, or others, to provide this information is needed, as well as forthright release of toxicity data by manufacturers. Interpretation of these data by groups such as the AAP’s Council on Environmental Health would be of tremendous value to pediatricians and public discussion of this information helpful to families so that appropriate concerns can be vetted without leading to excess fear and avoidance of products.

Families and caregivers have legitimate concerns about the contamination status of the food chain. Given the unique developmental status of infants, potential toxins and bacterial contamination risks after opening containers of infant formula need to be identified and context given to the understanding the amounts of toxins or bacterial contaminants identified. Parental education on appropriate hand hygiene when handling opened infant formula remains critical. Families also need to be especially aware of the additional risks related to bacterial contamination from illegally imported products or from the use of unpasteurized cow or other mammalian milks. Funding for further research in this area is critically needed.

Recommendation #3: Protect the WIC Program from the Consequences of Potential Government Shutdowns or Other Perceived Threats

It is impossible to see how any benefit can be provided by failing to ensure that the WIC program benefits are protected from possible government shutdowns. A brief time period of inadequate nutrition can be devastating for infants, and these programs need to be, by statute, protected in full from any government shutdowns. This should include not only maintaining a secure source of infant formula but also providing access to lactation support, nutritional assessments, and the many other services provided by WIC program staff.

Understanding the role of immigration concerns in the use of WIC and other government support programs is limited by few data and the complexity of individual state policies and time-related changes in the WIC program. Already about 20% of eligible infants do not receive WIC benefits. Further decreases in enrollment may be related to improved...
economic status of families, difficulty in accessing programs, or by immigration-related concerns.¹⁸

**Recommendation #4: Mandate That the Federal Government Improve Pricing Clarity So Families Can See Actual Costs of Different Formula Choices**

We pose a simple challenge. Go to any grocery or retail store selling infant formula and try to determine the relative costs of store brand vs name brand, powder vs liquid, or routine vs hydrolyzed infant formula products on a per-served ounce basis. Bring a calculator, a lot of patience, and prepare to become very frustrated by the experience. Then go do the same thing at a different vendor.

This situation has some analogies to determining calories from a restaurant meal. It was essentially impossible to do this until it became clear to restaurants that it would become a regulatory requirement. Now, in many places it is easy to make rational choices from the calorie data, although more information would be helpful and the context of the calorie information can still be difficult for consumers. We need to have a mandate for infant formula requiring every store pricing label to show the amount the product will cost per fluid ounce when prepared based on manufacturer’s recommendations. Then families can make their own choices, or better yet, return with this information to their pediatrician to discuss the options and science behind more expensive products with added novel components.

**Recommendation #5: Fund Research from the USDA and the US Department of Health and Human Services into All Aspects of Formula Feeding, Including Behavioral Interventions, Social Marketing Effects, and the Health Consequences of Inappropriate Formula Use**

Historically, infant formula research has largely been funded by infant formula companies and has been related to the short term biological effects of formula components and their relationship to human milk components or outcomes. There are relatively few studies funded independently by the USDA or US Department of Health and Human Services related to infant formula and especially the types of social and epidemiologic issues in formula usage considered in this commentary.

An agenda of questions for a funding request needs to be developed, including issues such as the frequency and effects of overdilution of formula, and the consequences and effects of social marketing campaigns related to homemade or imported formulas. Only through independent, nonindustrial-based funding mechanisms can these data be obtained in a fashion in which consumers can rely.

**Recommendation #6: Monitor Social Media and Provide Correct Information by Pediatricians and Licensed Health Experts Such as Registered Dietitians**

When someone posts an antivaccination argument on the Internet (eg, Facebook or Twitter), numerous genuine experts including pediatricians are usually quick to respond with accurate information, doing so at times at substantial personal risk. There is nothing comparable related to infant formula. Numerous Web sites and social media groups spread inappropriate advice related to unpasteurized milk, homemade formulas, and imported formulas with virtually no response from the medical or dietetic community. It is time that pediatricians and their allies such as registered dietitians take note that these sites are real threats to the health of many children, with an escalated effort at monitoring and response as false information is propagated.

**Summary: Protecting Formula-Fed Infants**

Pediatricians and the community should recognize that the use of infant formula is common, is not necessarily intuitive, or without risks for misinformation. In addition to providing formula via the WIC program, it is necessary to have open discussions not just about when to use infant formula, but how to provide it safely when it is used. This discussion, limited historically due to concerns about market-driven biases and by a lack of independent research and evaluation of the data, must move forward within the pediatric community. The recent government shutdown highlighted the immediacy of the concern that such events could quickly lead to poor nutrition for a substantial number of infants, and we encourage an open and public dialogue about safe infant formula availability and use. One approach to begin this dialogue would be to convene the relevant stakeholders, including pediatricians, government, and industry to discuss them and make recommendations to the AAP and to legislative bodies.

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Reprint requests: Steven A. Abrams, MD, Dell Pediatric Research Institute, 1400 Barbara Jordan Blvd, Austin, TX 78723. E-mail: sabrams@austin.utexas.edu

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