Communication

FDA Expert Panel on Infant Formula “Operation Stork Speed” June 2025: Part 3, Marketing of Infant Formulas, Breastfeeding Support, Hypoallergenic Formulas, and Nutrition for Preterm Infants

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FDA Expert Panel on Infant Formula "Operation Stork Speed" June 2025: Part 3, Marketing of Infant Formulas, Breastfeeding Support, Hypoallergenic Formulas, and Nutrition for Preterm Infants

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Abstract

The U.S. formula industry utilizes aggressive marketing strategies which exploit parental anxieties, undermine breastfeeding, violate ethical international standards, all of which contribute to early formula introduction and disparities in breastfeeding. Additionally, misleading or complex labeling contribute to caregiver and provider confusion regarding the content of formulas. A centralized, Food and Drug Administration (FDA)-maintained database of infant formulas could support caregivers and healthcare professionals in countering misinformation and making evidence-based decisions. Human milk remains the gold standard for infant nutrition, with strong evidence supporting its role in reducing morbidity and mortality, especially in the Neonatal Intensive Care Unit (NICU). Despite this, disparities persist in breastfeeding rates, particularly among Black and Hispanic mothers. These are driven by structural barriers, including lack of paid parental leave and inadequate lactation support. Donor human milk (DHM) is the recommended alternative for high-risk infants in the NICU when mother's own milk (MOM) is unavailable. However, due to lack of federal funding and oversight, high cost and inconsistent insurance coverage, the use of DHM use is limited, especially in safety-net hospitals. Specialized hypoallergenic and metabolic formulas are essential for managing medical conditions including cow's milk-protein allergy and inborn errors of metabolism. These are regulated as exempt formulas but must meet rigorous clinical standards. In the NICU, adequate early nutrition for preterm infants is crucial to reduce morbidity and mortality and improve long-term neurodevelopmental outcomes. Human milk fortifiers (HMFs) are composed of similar ingredients as infant formula and are used to improve the nutritional content feedings given in the NICU and post-discharge. The use of live biotherapeutic products (LBPs) or probiotics as additives to preterm

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infants have been demonstrated in multiple studies to reduce the incidence of NEC, late-onset sepsis, and all-cause mortality.

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Special Topics Related to Operation Stork Speed

Much of the focus on Operation Stork Speed, including the request for information (RFI) from the FDA (Food and Drug Administration) has focused on nutrients and regulatory issues. However, other topics were discussed at the FDA expert panel meeting on June 4, 2025, and are important in understanding the overall landscape of infant formula use in the United States [1]. In this manuscript, we consider these topics as they relate to infant formula and healthy infant nutrition in the United States.

Marketing of Infant Formulas

Infant formula companies use many manipulative marketing strategies to prioritize profits and aggressive marketing conflicts with public health objectives for breastfeeding. An investigation of infant formula products sold online in the U.S. found that companies are widely violating the WHO (World Health Organization) Code (which is not accepted by the United States regulatory authorities) by using marketing that idealizes formula feeding and undermines breastfeeding [2]. Breastfeeding rates increased during the 2022 formula shortage in populations with historically higher reliance on infant formula, highlighting the need to address how formula marketing practices contribute to existing breastfeeding disparities [3].

Formula marketing may cause misconceptions about the benefits of formula use and can result in the early introduction of infant formula. Messages that imply a benefit of infant formula use over breastmilk are deceptive as are claims that suggest product equivalence to breastmilk. In addition, product names and various health and nutrition claims can contribute to confusion for caregivers and healthcare professionals. Claims may utilize emotional and psychological messaging; for example, one company advertises their formula as "the one you feel proud to feed your baby". Claims may also target parental anxiety with phrases such as “brain building,” “immune support,” “more efficient weight gain,” or “reduced crying within 24 hours”. Products typically lack references for their claims, but when they do, citations often fail to support these claims; industry-funded trials also present a high risk of bias [4].

Marketing tactics used by the formula industry are effective for influencing caregivers' perceptions, as evidenced by a 2020 survey, which revealed that over half of infant caregivers believed infant formula can be better than breastmilk for digestion and brain development [5]. The authors also reported that some caregivers providing “toddler milk” to infants were unaware it was not infant formula, demonstrating cross-branding causes confusion and may result in inappropriate products being offered to infants. The labels of these products should clearly state that they are not appropriate for infants. The AAP (American Academy of Pediatrics) Committee on Nutrition has recommended that these toddler products not be positioned on store shelves in proximity to infant formulas [6]. Enhanced regulatory oversight by the FDA for infant formula products and toddler “milk” marketing is needed to better protect infants and caregivers, perhaps by incorporating some aspects of the WHO Code of Marketing of Infant Formulas [7].

Responsibility is often placed upon caregivers to identify formulas that are best for their infant. Unfortunately, that information is often primarily shaped by formula companies and difficult for families to identify the accuracy and relevance of the information. Many parents are currently getting most of their information from social media and online influencer sources such as “mommy groups” and blogs [8]. These spaces can be used by infant formula manufacturers as well without clear

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understanding or statements of conflicts of interest by influencers. Consideration of rules to regulate this might be of value for consumers.

Education

In the current market, caregivers face an overwhelming number of infant formula options, with minimal guidance on how to navigate and make informed choices. Product labels on infant formula products typically include long, complex ingredient lists which can be difficult to understand. Additionally, many healthcare providers such as pediatricians and even neonatologists, may not receive standardized training on differences among infant formulas. A centralized, publicly accessible electronic database maintained by the FDA has been recommended to help with guidance in the event of another severe infant formula shortage [9].

The FDA already maintains similar databases such as the Drugs@FDA database, a website that provides comprehensive, evidence-based information on medications. A list of exempt formulas (specialized formulas which may not have nutrients at the levels mandated by the Infant Formula Act(IFA)) is also publicly maintained by the FDA. However, no such list for routine (non-exempt) formulas exists. This type of formula database would be a valuable general educational resource for healthcare professionals and caregivers for navigating and comparing the many formula products on the market. In addition to listing formulas, this type of site should include information about where the products are produced and the nutrient contents including bioactive ingredients. By providing impartial, science-backed information, this platform would enable families and healthcare professionals to better interpret and clarify the promotional messages from formula companies. Formulas could be organized by type (e.g., milk-based, partially hydrolyzed protein, soy protein). Search filters based on infant health needs could be incorporated and translated into multiple languages to promote equitable access.

Breast (Human) Milk

Maternal breast milk is considered the optimal gold standard for infant nutrition [10]. The components of breast milk include human milk oligosaccharides, growth factors, hormones, lipids, and other bioactive components that have been found to offer various protections, especially in premature infants [10]. Very low birth weight infants are more likely to be born to Black mothers and may lead to significant morbidity and mortality, including necrotizing enterocolitis (NEC) and bronchopulmonary dysplasia [11]. NEC is the leading gastrointestinal emergency in preterm neonates—with mortality rates as high as 30% [12]. Human milk is the only intervention proven to reduce the risk of NEC [13]. Prematurity and its complications result in substantial healthcare costs, approximately $332,000, compared to $7,247 for a term infant (2019) [11]. Prior studies have demonstrated that the delivery of mother's own milk (MOM) is associated with decreased costs of morbidities. Johnson et al. reported reduced incidence of NEC and hospital costs with infants who received MOM and donor human milk(DHM) as compared to those receiving MOM and formula [14].

Although the benefits of breast milk have been well documented, there are differences in mothers' milk provision in Black and Hispanic mothers as compared to other groups [10]. There are multiple obstacles, including structural, environmental, and individual factors, that may limit breastfeeding. Determinants may influence or dissuade mothers from breastfeeding, including cultural differences in acceptance of breastfeeding, limited lactation support, and the absence of paid maternity leave. Strategies such as providing culturally matched peer counselors, communicating with families in a racially and culturally sensitive fashion, enhancing maternity leave and support for nursing in public may help increase breastfeeding rates [10].

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Donor Human Milk

When mother's own milk is unavailable, the American Academy of Pediatrics (AAP) recommends DHM as the next-best option for very preterm infants and other high-risk neonates admitted to NICUs [15]. Public education about donor milk is limited, with some pediatricians not discussing it with their families [16]. In the United States, NICUs typically obtain DHM from nonprofit milk banks, most of whom are accredited by the Human Milk Banking Association of North America (HMBANA) [17]. These banks recruit and screen volunteer donors, test milk for infectious diseases, pasteurize it for safety, and distribute it frozen to hospitals. Despite this well-established system, significant barriers limit DHM access and equitable usage nationwide. Since DHM is not consistently classified as a medical necessity, many public and private insurance plans do not provide coverage. As a result, hospitals—particularly safety-net institutions serving low-income communities with higher rates of complications such as NEC—must often absorb the cost and may not be able to afford to do so. Additionally, milk banks receive no dedicated federal funding and rely solely on public donations. Awareness of milk donation remains low due to lack of large-scale public campaigns, as compared to blood donation, limiting donor recruitment and contributing to supply shortages. These shortages are exacerbated during public health emergencies, as seen during the 2022 U.S. infant formula crisis, when demand for DHM spiked [18].

To address these challenges, California implemented the Enhancing Access to Donor Human Milk law in January 2025 [19]. This law mandates insurance coverage for medically necessary DHM and reduces some regulatory barriers, allowing more acute care hospitals to distribute DHM. These policy changes have already led to a 10% increase in DHM use in California NICUs over the first six months of implementation and are expected to improve health outcomes, reduce care costs, and advance health equity.

Outside the NICU, public demand for donor milk continues to grow. In some regions, pasteurized DHM is available for outpatient use when supply allows, though costs are often prohibitive. National data on DHM use remains limited, but a 2021 survey found that 8% of over 2,000 respondents had used donor milk—about one-third of whom sourced it from unregulated channels [20]. In the absence of affordable, regulated access, some families turn to informal milk-sharing networks or purchase milk online. Online communities and social media often influence these practices, shaping perceptions of professional medical advice [21]. Cultural and religious values may also influence decisions to engage in milk sharing, with some Muslim families hesitant to use DHM unless they have transparency about the donor [22]. However, informal milk sharing poses significant health and safety concerns due to the absence of regulatory oversight. Unscreened milk may carry risks of bacterial contamination or exposure to infectious diseases, medications, and other harmful substances [23]. Adulteration is also a documented issue: one U.S. study found cow's milk in 10% of 102 human milk samples purchased anonymously online [24]. To protect infant health and ensure equitable access to safe DHM, a more robust and regulated national system—potentially under FDA oversight—is urgently needed.

Hypoallergenic Formulas

There are two main types of hypoallergenic formulas currently available: extensively hydrolyzed formulas (EHFs) and amino acid-based formulas (AAFs). In EHFs, intact milk proteins are enzymatically broken down (hydrolyzed) into smaller peptides which are less likely to trigger an allergic reaction and free amino acids. The casein hydrolysates used in these formulas have undergone extensively preclinical evaluation, including immunoassays, gel permeation chromatography, and guinea pig immunization studies. These assessments demonstrate that the resulting peptides are non-antigenic and have molecular weights <1,200 Da. [25,26]. EHFs are generally indicated for infants with mild to moderate CMPA. AAFs also referred to as "elemental formulas", contain proteins that have been completely broken down into free amino acids. These

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formulas are intended for infants with severe CMPA or multiple food allergies who do not tolerate EHF. AAFs are considered non-allergenic, as they contain no intact or partial hydrolyzed proteins.

Hypoallergenic formulas are classified as exempt infant formulas under FDA regulations. Exempt formulas are governed by the Infant Formula Act of 1980, as amended, and are regulated through 21 CFR Part 106 and 21 CFR Part 107. Exempt formulas are intended for infants with special medical or dietary needs, such as inborn errors of metabolism, cholestatic conditions, and allergies. As exempt formulas, hypoallergenic formulas are relieved from some compositional requirements that apply to routine infant formulas but must still ensure safety and efficacy for their intended populations. Hypoallergenic formulas must comply with FDA nutrient specifications for infant formulas as outlined in 21 CFR 107.100 and must support normal growth and development. To be labeled hypoallergenic, these formulas must be supported by clinical evidence demonstrating tolerance in at least 90% of infants with confirmed allergies, with 95% confidence. This rigorous standard is established through randomized, double-blind, placebo-controlled trials, in accordance with AAP guidelines, which are recognized by the FDA. Currently, all hypoallergic formulas available on the market have undergone such evaluations and meet these criteria [27]. Given their established clinical safety and efficacy, clinicians currently do not recommend any changes to these hypoallergenic formulas. It is important that the FDA clearly distinguishes that any modifications or improvements made to standard infant formulas (e.g. limiting lactose) should not be automatically applied to exempt formulas. Such changes should raise concerns among both clinicians and the infant formula industry.

Issues Related to NICU and Long-Term Follow Up

The NICU provides highly specialized care for infants requiring medical support after birth. Despite their varied diagnoses, a unifying and critical component of NICU management is the provision of optimized nutrition.

The impact of early nutrition on outcomes in premature infants is well established [28,29]. Premature birth, particularly before 28 weeks of gestation, interrupts critical stages of brain development [30]. Several studies have demonstrated that ensuring adequate caloric intake, particularly protein and energy balance, in extremely preterm infants can significantly enhance structural brain growth [31,32]. One study linked increased early protein intake with improved Bayley Mental Developmental Index scores in extremely preterm infants at 18 months corrected age [33]. In addition, early optimal nutrition reduces the severity of neonatal illnesses such as bronchopulmonary dysplasia (BPD), NEC, and late-onset sepsis [34]. In post-surgical term neonates, optimal nutrition has been associated with shorter time to wound healing, reduced incidence of postoperative complications, and decreased length of hospital stay [35,36].

For most neonates in the NICU, the American Academy of Pediatrics (AAP) recommends the use of exclusive human milk as the gold standard for nutrition [37]. The numerous benefits of human milk, especially the immunoprotective properties, are well known and are linked to reducing the risk of NEC, sepsis, and mortality. NEC is the most common gastrointestinal emergency in preterm infants with mortality rates up to 30% and human milk is the only proven prevention strategy [12]. Studies have also demonstrated reduced risk of post-discharge growth failure as well as improved long-term brain development and neurodevelopmental outcome in infants fed human milk in the NICU [38,39].

However, for the extremely preterm infant population, human milk alone is often insufficient to meet the higher caloric and nutritional demands [40]. For these patients, human milk is often supplemented or “fortified” with the addition of human milk fortifier (HMF). HMF is a concentrated liquid or powder derived from either bovine milk or human donor milk and is composed of a concentrated form of carbohydrates, lipids, and proteins along with added minerals and micronutrients [41,42]. More studies are needed to evaluate the benefits specific to use of a human milk vs bovine derived fortifier [43].

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Infant formula plays an important role in NICU nutrition when maternal breast milk is unavailable, insufficient or sometimes contraindicated. Infant formula is commonly used as a supplement to maternal milk in late preterm and term infants and/or as part of a discharge regimen to support catch-up growth in extremely preterm infants [44]. Infants who have unique medical needs, such as gastrointestinal anomalies, metabolic disorders, and post-surgical complications, require specialized formulas. For example, infants with CMPA or neonates with intestinal failure such as associated with short bowel syndrome often require extensively hydrolyzed protein or amino acid–based formulas. Infants with inborn errors of metabolism, such as phenylketonuria (PKU) or maple syrup urine disease (MSUD), require metabolic formulas that exclude specific amino acids.

The use of live biotherapeutic products (LBPs) or probiotics as additives to human milk or infant formula have been demonstrated in multiple studies to reduce the incidence of NEC, late-onset sepsis, and all-cause mortality [45]. Probiotic strains such as Bifidobacterium and Lactobacillus reduce preterm intestinal inflammation, promote healthy gut microbiota and are safely utilized in NICUs throughout Europe and Australia. However, in October 2023, the FDA issued a warning against the use of probiotics in preterm infants in the U.S., due to concerns that commercially available products are not subject to the same rigorous safety and quality standards as drugs or biologics and may therefore pose risks to this vulnerable population. Following the advisory, many NICUs in the United States discontinued usage of probiotics, raising concerns of the potential for increases in NEC and mortality. Studies using pharmaceutical-grade LBPs to evaluate are underway to evaluate the safety and outcomes in the very preterm population [46].

Conclusions

In addition to formula ingredients and regulatory issues, additional important topics related to infant feeding were discussed at the FDA Expert Panel Discussion to Operation Stork Speed. These are summarized in Tables 1 and 2. Marketing strategies from formula companies can be misleading, exploit parental anxieties and contribute to confusion amongst caregivers and providers. Stricter regulations should be enacted to protect families and promote informed feeding decisions. Additionally, healthcare providers and parents often lack access to reliable information about formula products. A centralized FDA-maintained database could address this gap and provide clarity on messaging from manufacturers.

Hypoallergenic infant formulas include extensively hydrolyzed formulas (EHFs) for mild to moderate cow's milk protein allergy (CMPA) and amino acid-based formulas (AAFs) for severe CMPA or multiple food allergies. These formulas are rigorously tested and regulated to ensure they are non-allergenic and support infant growth. Classified as exempt formulas under FDA regulations, they must meet strict clinical standards to be labeled hypoallergenic and should not be subject to modifications intended for standard formulas without thorough evaluation.

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Table 1. Key Issues and Recommendations Related to Infant Formula.

Topic	Key Issues Identified	Recommendations
Infant Formula Marketing	- Widespread marketing violations of the World Health Organization(WHO) Code (not legally adopted in the U.S.) - Complex product labels with minimal guidance or standardization - Misleading claims (e.g., "brain building," "immune support") - Emotional manipulation of parental guilt/anxiety	- Enhance Food and Drug Administration(FDA) regulation of marketing claims and digital advertising - Consider adopting WHO Code elements to support breastfeeding and ensure truthful labeling
Caregiver and Provider Education	- Many caregivers unaware of clinical evidence or appropriate use - Health professionals often lack formal training in formula types - Social media and influencers (often sponsored) dominate information sharing	- Create FDA-maintained, evidence-based online formula comparison tool (e.g., Drugs@FDA) - Provide formal training to healthcare providers on infant formulas

Breastmilk remains the gold standard for all infants. However, racial and socioeconomic disparities disproportionately affect breastfeeding rates, particularly among Black and Hispanic mothers. Systemic reforms are needed to address structural barriers such as lack of paid maternity leave and inadequate lactation support. Donor human milk (DHM) is the AAP-recommended alternative to mother's own milk, especially for premature infants, and has been demonstrated to reduce morbidity and mortality in this population. However, DHM remains inaccessible to many NICUs due to insurance coverage gaps, lack of funding and limited public awareness regarding donation. FDA regulatory oversight and federal funding is needed to expand safe, equitable access to DHM.

Early optimal nutrition for preterm infants in the NICU improves long-term neurodevelopmental outcomes and reduces complications such as NEC. While human milk is the safest, it often requires supplementation with bovine or human-derived fortifiers. Bovine-derived fortifiers contain many of the same ingredients as infant formulas. Specialized formulas also play an important role for infants with GI or surgical complications and those with metabolic disorders. Additionally, although research supports use of probiotics to reduce NEC, a 2023 FDA warning has led to their removal from U.S. NICUs, prompting debate over balancing safety concerns with potential health benefits.

Table 2. Key Issues and Recommendations on Human Milk and Probiotics.

Topic	Key Issues Identified	Recommendations
Breastfeeding Disparities	- Lower initiation and duration rates among Black and Hispanic mothers - Barriers include work pressures, lack of	- Expand workplace protections and national paid leave - Enhance public breastfeeding infrastructure

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Topic	Key Issues Identified	Recommendations
	support/maternity leave, and historical mistrust	(e.g., lactation rooms) - Fund culturally tailored lactation support programs
Donor Human Milk (DHM)	- Milk banks underfunded and reliant on public donations - Hospitals often absorb costs due to insurance gaps - Informal sharing increasing	- Federally fund milk banks - Mandate insurance coverage for medically necessary DHM (e.g., California's 2025 law) - Public education campaigns on milk donation - Ensure safe outpatient access
Probiotics and Live Biotherapeutics (LBPs)	- Proven efficacy in reducing necrotizing enterocolitis(NEC), sepsis, and mortality in preterm population - Routine use in EU/Australia NICUs - 2023 FDA warning halted U.S. use due to safety/quality concerns	- Prioritize development of FDA-regulated, pharmaceutical-grade LBP - Weigh risk/benefit before universal bans in NICUs

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Abbreviations

American Academy of Pediatrics: AAP
Amino Acid-Based Formulas: AAF
Bovine milk-derived fortifier: BMFM
Cow's Milk Protein Allergy: CMPA
Donor Human Milk: DHM
Extensively Hydrolyzed Formulas: EHF
Human Milk Banking Association of North America: HMBANA
Live Biotherapeutic Products: LBP
Mother's Own Milk: MOM
Necrotizing Enterocolitis: NEC
Neonatal Intensive Care Unit: NICU
Request for Information: RFI
World Health Organization: WHO

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