



## **Bobbie Urges Congress to Address Infant Formula Industry Vulnerabilities**

May 26, 2022

The Honorable Patty Murray  
Chair, Senate Committee on Health,  
Education, Labor, and Pension  
United States Senate  
154 Russell Senate Office Building  
Washington, DC 20510

The Honorable Richard Burr  
Ranking Member, Senate Committee on  
Health, Education, Labor, and Pension  
United States Senate  
217 Russell Senate Office Building  
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr,

I write this letter in the midst of an infant formula crisis — millions of families are living in fear, not knowing if their babies will have enough food. On behalf of Bobbie, a mom-founded and led U.S.-based infant formula company, I'm sharing our perspective on how Congress can help secure essential and safe nutrition for families across this country.

While breast milk is the optimal source of nutrition during the first 1,000 days of a child's life, we know as experts in infant feeding (and as parents ourselves) that this is simply not a reality for most American families. When breast milk is not an option, infant formula is the sole source of nutrition for many infants until solids are introduced. For the 83% of infants who consume formula in their first year of life they deserve a high quality, safe, and reliable source of food in their bottles.

Despite such widespread consumption, infant formula remains stigmatized and the industry has long remained dominated by the same 2 large companies who have kept the status quo intact for decades. That status quo is what got us here and it's what needs to change. Bobbie was founded in 2018 to offer parents a first-of-its-kind, high quality infant formula they could feel confident--rather than guilty--feeding their babies. We chose to partner with the one infant formula manufacturer in the U.S. that is using their capacity to foster competition, to develop and launch our product. Today we are proud to be serving families all across the country.

The infant formula shortage has highlighted many cracks in the marketplace that must be addressed in order to prevent another crisis in the future. The American people want and deserve the best nutrition for their babies in terms of safety, quality, supply and options. We can do better by our babies.

# **Bobbie's Perspective on Vulnerabilities in the Infant Formula Marketplace & Proposed Policy Solutions**

## **UNDERLYING ISSUES BEHIND THE INFANT FORMULA SHORTAGE**

### **Increase FDA Funding to Enhance Infant Formula Notification Approvals**

Prior to sale, all new infant formulas must go through a review process to ensure all regulatory requirements are met. This ensures the safety and efficacy of infant formula products and is important for companies as they secure secondary sources (which impacts ability to meet demand). Over the last couple years the industry has seen the timeframe of these reviews extended from 90 days to 180 days. This additional time slows innovation and significantly delays the entry of new products into the market. I urge Congress to ensure the FDA has adequate resources to meet the 90 day deadlines and avoid delaying these critical new products from market entry. In addition, we urge better enforcement of quality standards through a properly resourced FDA, with an ample team staffed and actively auditing infant formula manufacturers.

### **Diversify Manufacturing (New & Existing Players)**

We are too dependent on just a few companies and manufacturing sites to support feeding our nation's babies. The current crisis has shown the domestic infant formula supply chain is not resilient, nor is it redundant, two critical factors necessary for ensuring that all families have the amount and the type they need for their infant. I started Bobbie in an effort to diversify and transform this industry and provide more options for parents aiming to feed their babies well. I urge Congress to help evaluate barriers to entry and identify where we can incentivize innovation.

### **Increase Access and Options For Those On WIC**

Through the WIC program, the U.S. government is reliant on only three companies to produce consistently safe formula to feed our nation's most vulnerable population, which is over 1.7 million babies. We urge Congress to reimagine this essential program to allow infant formula brand choice to all WIC-eligible infants and their families to ensure no WIC participant goes without an FDA-approved infant formula and the program meets its mission of safeguarding the health of infants.

## **SYSTEMIC ISSUES WITH THE INFANT FORMULA MARKET AT LARGE**

While the safe and adequate supply of infant formula must be your top priority, we respectfully suggest Congress address other issues within the industry.

### **Update Nutritional Standards for Infant Formula**

The European Commission has historically led the way in updating nutritional guidance based on the latest science, with the U.S. following. We believe the U.S. should be leading and updating guidance at a faster pace. Case in point, an essential ingredient in infant formula,

DHA, is required at a particular amount in all European infant formulas whereas in the U.S., it can be used only if the manufacturer wants to and often at much lower levels than European products. We urge Congress to update nutritional standards for infant formula, including tighter regulations over the use of certain ingredients like corn syrup and allow for labeling amounts of nutrients like DHA. Science has evolved in 40 years, formula should too.

### **Incentivize Specific Nutritional Needs for Infants**

As it stands, the economics do not support the innovation of specialized ingredients and products to address certain need states. Infants have a variety of different needs (those with milk allergies, severe digestive problems and metabolic deficiencies, etc.) that are only addressed through the use of specialized infant formulas. For these infants, these products may be their only source of nutrition to live a healthy life. We need to support incentives for other infant formula companies to create these life saving products. As we have seen during this crisis, these formulas are in extremely short supply. Incentivizing other infant formula companies to create and manufacture these products will make them more affordable and accessible. We urge Congress to incentivize speciality product development to ensure that future generations have options available to suit their nutritional needs. This is not only the right move to increase consumer choice, it can spur a new segment of our food economy.

### **Establish Heavy Metals Limits**

Heavy metals are a focus across the infant and children's food category. While no company can achieve "zero" heavy metals due to how they naturally occur in the environment, collectively all the companies that support infant nutrition should strive towards the highest standards for heavy metals. At Bobbie we test every batch of our formula for heavy metals and believe this should be standard practice. We applaud Congress's support of FDA's closer to zero initiative to set public health protective, aggressive, but technically achievable safe harbor limits for heavy metals in infant formula.

### **Insurance Support for Those Who Can't Breastfeed**

Women and parents who physically cannot breastfeed for various medical reasons are currently overlooked and not supported by major insurance companies. New mothers can receive a free breast pump or lactation support through the Affordable Care Act, but they cannot receive insurance support for formula feeding. We should equally support every parent's feeding journey, not just those who can physically breastfeed their babies. This includes women with mastectomies, those undergoing cancer treatment, low supply, and physical or anatomical issues that prevent them from breastfeeding, same sex couples who cannot breastfeed, adoptive parents, and foster parents who should be equally supported in feeding their babies with some layer of insurance coverage for infant formula.

Thank you for taking the time to learn our perspective as an infant formula company. We are proud to serve 70,000 families and strive to feed millions. Our business has witnessed tremendous growth in the last few years as we have seen heightened demand for high quality infant formula. It will take a village to change this industry. We hope you take our perspective to

heart and consider us a resource as Congress continues to navigate this feeding crisis. Please stay hungry for change; our children deserve as much.

Sincerely,

Laura Modi  
CEO and Co-Founder  
Bobbie