

Congress of the United States

Washington, DC 20515

December 5, 2025

Robert F. Kennedy, Jr.
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Kennedy:

Protecting our youngest, most vulnerable infants should be our highest priority. We request your attention to nutritional products that feed very low birthweight (VLBW) infants, particularly those born weighing 1,250 grams (2.75 lbs.) or less.

There has been a recent deluge of lawsuits against preterm infant formula manufacturers in the United States because of a failure to warn of the increased risk of a serious gastrointestinal illness, necrotizing enterocolitis (NEC), with the use of non-human milk-derived fortifiers. NEC is among the most fatal diseases in the neonatal intensive care unit (NICU), with one baby a day dying of this debilitating disease. Over 1,000 lawsuits threaten the stability of the infant formula industry and endanger our most vulnerable. We propose multiple actions that this Administration could take right now to address health concerns while ensuring the fragile preterm formula market remains stable.

One factor that has been proven to reduce the development of NEC in VLBW infants is the use of human milk. Human milk-derived formulas and fortifiers are proven to have a 77 percent reduction in the development of NEC, among other devastating complications of prematurity.¹ Human milk has proven beyond doubt to be the best source of infant nutrition, and we urge the Department of Health and Human Services (HHS) to investigate other preterm infant fortifiers and their potential impact on the gut health of premature infants.

The October 2024 Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH) consensus statement identified the absence of human milk as being associated with an increased risk of NEC. There are nearly two decades of studies consistently showing that an exclusively human milk diet (mom's own milk or pasteurized human donor milk and human milk-derived fortifier) is the best source of nutrition for VLBW babies. Of the 22 studies comparing human milk-based fortifiers to non-human milk-based fortifiers that have reported on NEC as an outcome, **all 22 studies** have shown lower rates of NEC in the babies fortified with human milk-based fortifiers. (See "*Evaluation of NEC Data from various EHMD papers*" and accompanying Exhibits attached).

¹ Sullivan S, Schanler RJ, Kim JH, Patel AL, Trawöger R, Kiechl-Kohlendorfer U, Chan GM, Blanco CL, Abrams S, Cotten CM, Laroia N, Ehrenkranz RA, Dudell G, Cristofalo EA, Meier P, Lee ML, Rechtman DJ, Lucas A. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. J Pediatr. 2010 Apr;156(4):562-7.e1. doi: 10.1016/j.jpeds.2009.10.040. Epub 2009 Dec 29. PMID: 20036378

As you further investigate this concerning connection, one thing is clear, human milk reduces the incidence of NEC. Additionally, a study released in 2024 showed that VLBW babies fed human milk-derived human milk fortifiers also experienced shorter NICU stays, with savings ranging from \$307,916 to \$2,520,000 per institution annually.² We emphasize the need for HHS to thoroughly explore how VLBW babies are impacted by the components of the fortifiers.

We recommend taking the steps below:

- 1) **Ensure that the FDA has received all adverse event reports from infant formula manufacturers related to the feeding of non-human milk derived fortifiers in this population.** Without this information, HHS cannot evaluate all data needed to determine the best nutritional sources for preemies.
- 2) **Instruct the FDA to explore ways to make pasteurized donor human milk (PDHM) safer and more accessible.** Given the overwhelming evidence supporting the use of PDHM for premature infants, the Department should solidify proper oversight of PDHM, ensuring milk banks adhere to consistent minimum safety standards. This oversight will ensure better coverage of, and access to, safe and affordable PDHM.
- 3) **Add information to the labels of non-human milk-derived infant formulas and fortifiers about their appropriate use only in preemies that weigh above 1,250 grams.** The addition of this information would give parents and providers more detailed information to make informed decisions for their infants based on their gestational age and birthweight, and ensure that non-human milk-based formula can remain available for the non-VLBW preemie population (90 percent of preemies).
- 4) **Improve access to human milk-based fortifiers.** A growing list of states have begun mandating coverage for these life-saving options³ given that doing so leads to increased survival, decreased morbidity, and savings to the health care system.⁴ CMS should issue guidance to state Medicaid agencies about the coverage pathways available to ensure access to these products, and how NICUs can appropriately bill for such products.

We appreciate your attention to this critical issue.

Sincerely,

² Swanson, J.R., Becker, A., Fox, J., Horgan, M., Moores, R., Pardalos, J., Pinheiro, J., Stewart, D., Robinson, T. (2023). Implementing an exclusive human milk diet for preterm infants: real-world experience in diverse NICUs. *BMC Pediatrics*, 23:237.

³ The following states and the District of Columbia offer some form of either commercial or Medicaid reimbursement for donor human milk and/or donor human milk-derived fortifiers: California, Connecticut, Florida, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Missouri, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oregon, Pennsylvania, Texas, Utah, Washington.

⁴ See 2022 Florida Medical Schools Quality Network (FMSQN) study prepared for Florida Legislature, finding, increasing access to donor human milk “would avoid an estimated \$4 million in health care expenditures annually, and may save more when the hospital readmissions, home health care visits, and emergency department visits are considered.” Study described here: <https://hscweb3.hsc.usf.edu/blog/2022/05/16/collaborative-effort-across-floridas-medical-schools-results-in-a-statute-expanding-medicaid-coverage-to-include-donor-breastmilk/>



Rosa L. DeLauro
Member of Congress



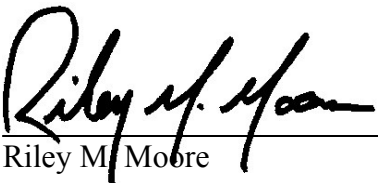
Roger Marshall, M.D.
United States Senator



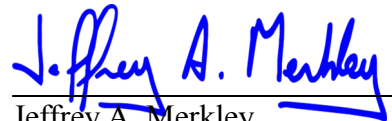
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