

# Congress of the United States

Washington, DC 20515

November 19, 2024

James Jones  
Deputy Commissioner for Human Foods  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Deputy Commissioner Jones:

I am writing regarding the Food and Drug Administration's (FDA) role and response to growing public concerns about the safety of certain infant formulas for vulnerable infants, specifically for Very Low Birth Weight (VLBW) infants. I believe that the FDA needs to take further action – beyond its consensus statement with the Centers for Disease Control and Prevention (CDC) and the National Institute for Health (NIH) – to ensure that parents as well as their medical teams are adequately informed of 1) the potential risks that some preterm infant formula could pose for VLBW infants, and 2) the benefits of donor human milk and suspected benefits of human milk-derived human milk fortifier for VLBW infants in hospitals.

As FDA noted in their consensus statement released at the beginning of October, “available evidence supports the hypothesis that it is the absence of human milk – rather than the exposure to formula – that is associated with an increase in the risk of [Necrotizing Enterocolitis] (NEC).”<sup>1</sup> This information must be more adequately communicated to parents and medical teams so they are able to make the best decisions for the health and safety of VLBW premature infants.

As you are aware, there is ongoing litigation in federal and state courts around the country alleging that, when given to extremely low birth rate infants, traditional cow's milk-derived formulas and fortifiers are associated with higher rates of NEC.<sup>2</sup> NEC is a devastating disease of the bowel that disproportionately impacts the most vulnerable babies and can result in severe disability or death.<sup>3</sup> Already, a court in Illinois has found an infant formula manufacturer liable for the death of a premature infant due to NEC, awarding a \$60 million verdict to the mother of the child.<sup>4</sup> Similarly, a court in Missouri found a different manufacturer of cow-based infant formulas liable for close to \$500 million.<sup>5</sup> In these cases, two separate juries found that cow's milk-based infant fortifier was associated with an increased risk of NEC for extremely premature infants.<sup>6</sup>

Clinical research has repeatedly demonstrated that human – as opposed to cow's – milk lowers the risk of NEC due, likely in part, to its protective factors and ability to support the development of a healthy gut microbiome.<sup>7</sup> The recently released report from the National Advisory Child Health and Human Development (NACHHD) Council's [NEC Working Group of Council](#) concurs, and notes that “a diet containing human breastmilk appears

---

<sup>1</sup> <https://www.hhs.gov/about/news/2024/10/03/fda-cdc-nih-consensus-statement-recent-advisory-council-report-premature-infants-necrotizing-enterocolitis.html>

<sup>2</sup> <https://www.ilnd.uscourts.gov/mdl-details.aspx?Lbz1nwUsE4JWF/IQJN6GpA==>

<sup>3</sup> <https://my.clevelandclinic.org/health/diseases/10026-necrotizing-enterocolitis>

<sup>4</sup> <https://www.reuters.com/legal/reckitt-unit-hit-with-60-million-verdict-enfamil-baby-formula-case-illinois-2024-03-14/>

<sup>5</sup> [Abbott Ordered to Pay \\$495 Million in Baby-Formula Verdict - WSJ](#)

<sup>6</sup> <https://www.nichd.nih.gov/newsroom/news/020724-preterm-human-milk-study>

<sup>7</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10663262/>

to be protective against the development of NEC. In addition, the use of human milk-based fortifier in the infant’s diet, rather than bovine-based fortifier, may be useful in reducing the development of [NEC].”<sup>8</sup>

In its consensus statement with CDC and NIH, the FDA was careful to declare that “there is no conclusive evidence that preterm infant formula causes NEC,” but also clearly stated “there is strong evidence that human milk is protective against NEC.”<sup>9</sup> While this statement was importantly aimed at reassuring parents about the safety of nutrition that is regularly offered in the Neonatal Intensive Care Units (NICU), it is also critical to note that the agencies identified human milk as a powerful tool in preventing NEC. As such, the agencies’ response should be clear: promoting greater access to human milk nutrition, as the science and agencies’ own conclusions suggest, and adequately informing parents and medical providers of the most up-to-date research on premature infants and the prevention of NEC.

FDA is responsible for ensuring the quality and safety of infant formula products. Fortifiers for premature infants are regulated by the FDA as ‘Exempt Infant Formulas,’ and explicitly manufactured and marketed for this population.<sup>10</sup> Therefore, FDA must be more actively working to inform medical providers and parents about the suspected limitations of cow’s milk-based infant formula and fortifiers for premature infants in comparison with other feeding options, including donor human milk and human milk-derived human milk fortifiers. While the recent consensus statement is a first step, this statement published is not enough to address the very real concerns of parents who are unsure of how their children should be fed at this crucial time in their young lives, especially as legal challenges continue to mount and the only two manufacturers of premature infant formula are threatening to exit the market amid the increasing legal pressure of lawsuits.<sup>11</sup>

It is important that FDA be proactive on this issue, not reactive. With that in mind, I am requesting more information about the work FDA is doing within its existing authorities to increase public awareness of the current data regarding infant nutrition to drive informed and empowered decision-making by all parents and providers. Please respond to the questions below by December 13, 2024.

1. What actions are FDA taking, alone or in collaboration with the NEC Working Group of Council, to disseminate the **evidence and information** that “a diet containing human breastmilk appears to be protective against the development of NEC” and “the use of human milk-based fortifier in the infant’s diet, rather than bovine-based fortifier, may be useful in reducing the development of NEC?” Has the FDA communicated its findings to any outside stakeholders? If so, which ones?
2. What steps can FDA take, in collaboration with the CDC and NIH, to promote greater access to healthy and safe donor human milk and donor human milk-derived fortifiers, especially for VLBW infants?
3. How is FDA supporting parent education both before delivery and in the NICU about feeding practices, nutritional products, and limits of products for infants with specific conditions, including the limits that cow-derived preterm infant formulas and fortifiers can have on VLBW premature babies?
4. How is the FDA ensuring that parents and medical providers are adequately aware of the risks of NEC and how to avoid potentially increasing the chances for a preterm infant to develop NEC?

---

<sup>8</sup> [Necrotizing Enterocolitis \(NEC\) in Preterm Infants Working Group of the National Advisory Council of Child Health and Human Development \(NACHHD:\) Report to Secretary, Department of Health and Human Services \(nih.gov\)](#)

<sup>9</sup> <https://www.hhs.gov/about/news/2024/10/03/fda-cdc-nih-consensus-statement-recent-advisory-council-report-premature-infants-necrotizing-enterocolitis.html>

<sup>10</sup> <https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category>

<sup>11</sup> <https://www.axios.com/2024/09/19/baby-formula-safety-label-lawsuits>

Thank you for your attention to this important issue, and I look forward to a timely response.

Sincerely,

A handwritten signature in black ink, reading "Rosa L. DeLauro", enclosed in a light gray rectangular box.

---

Rosa L. DeLauro  
Member of Congress

CC:  
The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, D.C. 20201