Better Regulation of Breast Milk Banking Will Protect Vulnerable Infants

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In my capacity as a practicing neonatologist at Loma Linda University School of Medicine, I urge the U.S. Food and Drug Administration (FDA) to take immediate action regarding The Donor Milk Safety Act, legislation currently before Congress calling for breast milk and products made from human breast milk that is collected, processed, and distributed via milk banks to be treated and classified as an "exempt infant formula," rather than their current designation as simple food. Our decades of clinical data and outcomes demonstrate that for fragile premature infants, human milk is far more than nutrition; it is, quite simply, medicine.

Based on current evidence, this move is essential to ensuring that vulnerable infants in hospital neonatal intensive care units (NICUs) continue to receive lifesaving breast milk products free of any substances that might cause these infants serious harm. We already have enough experience with the harm caused by the FDA dragging its feet in these matters. Abbott Laboratories faces multiple lawsuits over contamination of its Similac, Alimentum, and Elecare formula with Cronobacter, Salmonella, and other bacteria. The FDA failed to follow up on violations uncovered in September 2021 and earlier at the manufacturing plant where the tainted formula was made. Several infants became ill, and some died due to ingesting contaminated formula. Will the FDA again wait for vulnerable infants to die before taking necessary action with breast milk products?

There is no question that feeding infants in the NICU breast milk and products made from breast milk instead of cow milk results in considerable health benefits, including decreased hospital stays and feeding intolerance; reduced risk of severe, life-altering complications; healthier weight gain; and better long-term outcomes. (1-8)

Because of improved outcomes such as these, the demand for breast milk has increased dramatically in recent years. Milk banks have rapidly emerged to fill this demand. The largest milk bank network in the United States saw its collections increase by 1400% since 2000, and its distribution grew by 22% in 2021 alone. This evolution of human milk banking has undoubtedly saved countless lives and reduced the cost of care for vulnerable preemies, (9-10) but it must be accompanied by requisite regulatory oversight to ensure safety. Unfortunately, federal regulation of milk banks has not kept up with their growth. This places infants in the NICU at considerable risk, entirely avoidable with proper regulatory standards.

Breast milk is both human tissue and biologic fluid, much like blood and plasma. The possibility exists that disease-causing germs or other toxic substances can be passed on to vulnerable infants via breast milk products unless the strictest measures that ensure this will not occur are put into place. A steady stream of new organizations that collect breast milk and distribute products made from breast milk are entering the market. Still, currently, they are required by the FDA to register only as a food manufacturer. Just a handful of states require milk banks to obtain a tissue bank license. Most banks operate based on their own set of screening, production, safety, and quality guidelines that are neither publicly nor independently audited or enforced.

In other words, the safety standards of most milk banks are primarily based on the known risks associated with the manufacture, processing, and distribution of food. These do not fully address the known risks associated with collecting, processing, and distributing human tissue and biologic fluid. Milk banks are not required to routinely test their breast milk products for viruses, bacteria, drugs, and other contaminants. As a result, vulnerable infants are at risk of being exposed via donor breast milk products to disease-causing bacteria and viruses as well as traces of medications or drugs, including nicotine, marijuana, homeopathic remedies, over-the-counter remedies, or prescription drugs such as opioid painkillers or antidepressants. These hazards are real. For instance, nicotine exposure in infants can result in damage to the liver and pancreas as well as disruption of sleep cycles. (11,12) Those milk banks that test their breast milk products have found nicotine and its byproducts to be the most common contaminant.

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We do not even know if infants have been harmed by these lax regulations because there are no strict rules on reporting adverse events or how to proceed should they occur. We certainly know from anecdotal reports that harm is possible, however. In 2019, three premature infants died after their donor milk product was contaminated with bacteria traced to the equipment used to measure and mix the milk at Geisinger Medical Center in Danville, Pennsylvania. (13) It is clear that the FDA needs to make nutrition destined for vulnerable infants a higher priority.

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Contrast the current milk banking standards with the collection and distribution of other human tissue, including blood, organs, and semen, for which strict federal regulations ensure that these lifesaving and life-giving products do not inadvertently cause harm. It is astonishing that, after we saw a multitude of patients exposed to the human immunodeficiency virus (HIV) in the 1980s from blood and tissue products, we seem to be making the same mistake once again with breast milk products. Breast milk must be handled in the same way as other products derived from human tissue. While it may be convenient to think of donated human milk as any other food product, my experiences suggest that this is not a reasonable course. After caring for the first child with documented AIDS contracted vertically from her mother through breastfeeding, I clearly understand the risk. Seeing her die because of a disease that can now be prevented is sobering. Although there have been myriad improvements in HIV treatment, this infection is lifelong and still causes significant morbidity and mortality. Indeed, the American Academy of Pediatrics recommends that "federal or state guidelines are needed regarding the preparation, handling, and transfer of human milk as well as the operation of donor human milk banks." (14)

The only way to prevent harm is via comprehensive regulation by the FDA. The proposed bill will go a long way toward protecting vulnerable infants. By regulating breast milk products collected and processed via milk banks as an "exempt infant formula," this bill will empower the FDA to treat donor breast milk products fed to vulnerable infants in the NICU as the medicine that it is. This regulation means the FDA will determine and enforce safety and manufacturing process standards for human milk banks as well as conduct audits and inspections to ensure these standards are met. It will also update the standards as necessary to address novel risks such as those posed by SARS-CoV-2, the virus that causes COVID-19. There is no time for the FDA to wait for this bill to wend its way through Congress. The time to act is now before a preventable catastrophe occurs.

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Parents of infants in the NICU trust us to provide the best possible care for their vulnerable children. They assume that all nutrition, medication, and interventions administered are evidence-based and meet the highest possible safety standards. It is unethical to feed their infants using a product that, while known to offer the best possible nutrition, may contain harmful substances because we have failed to regulate its manufacture appropriately.

As a neonatologist who has dedicated his career to protecting vulnerable infants, I urge the FDA to take action today.

References:

1. *Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive breastmilk diet. J Perinatol. 2016;36(3):216-220. doi:10.1038/jp.2015.168*
2. *Bergner EM, Shypailo R, Visuthranukul C, et al. Growth, body composition, and neurodevelopmental outcomes at 2 years among preterm infants fed an exclusive breastmilk diet in the neonatal intensive care unit: a pilot study. Breastfeed Med. 2020;15(5):304-311. doi:10.1089/bfm.2019.0210*
3. *Cristofalo EA, Schanler RJ, Blanco CL, Sullivan S, Trawoeger R, Kiechl-Kohlendorfer U, et al. Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants. J Pediatr. 2013;163(6):1592-5e1. Epub 2013/08/24.*
4. *Delaney Manthe E, Perks PH, Swanson JR. Team-based implementation of an exclusive breastmilk diet. Adv Neonatal Care. 2019;19(6):460-467. doi:10.1097/ANC.0000000000000676*
5. *Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive breastmilk–based diet. [Published correction appears in Breastfeed Med. 2017;12(10):663] Breastfeed Med. 2016;11(2):70-74. doi:10.1089/bfm.2015.0134*
6. *Sullivan S, Schanler RJ, Kim JH, et al. An exclusively breastmilk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of breastmilk and bovine milk-based products. J Pediatr. 2010;156(4):562-567. e1. doi:10.1016/j.jpeds.2009.10.040*
7. *Huston RK, Markell AM, McCulley EA, Gardiner SK, Sweeney SL. Improving growth for infants </=1250 grams receiving an exclusive human milk diet. Nutr Clin Pract. 2018;33(5):671-8. Epub 2018/02/17.*
8. *Jacobi-Polishook T, Collins CT, Sullivan TR, Simmer K, Gillman MW, Gibson RA, et al. Human milk intake*

in preterm infants and neurodevelopment at 18 months corrected age. Pediatr Res. 2016;80(4):486-92. Epub 2016/06/30.

9. *Ganapathy V, Hay JW, Kim JH. Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants. Breastfeed Med. 2012;7(1):29-37. Epub 2011/07/02.*
10. *Ganapathy V, Hay JW, Kim JH, Lee ML, Rechtman DJ. Long term healthcare costs of infants who survived neonatal necrotizing enterocolitis: a retrospective longitudinal study among infants enrolled in Texas Medicaid. BMC Pediatr. 2013;13:127. Epub 2013/08/22.*
11. *Primo CC, Ruela PB, Brotto LD, Garcia TR, Lima Ede F. Effects of maternal nicotine on breastfeeding infants. Rev Paul Pediatr. 2013;31(3):392-7. Epub 2013/10/22.*
12. *Tong VT, England LJ, Rockhill KM, D'Angelo DV. Risks of preterm delivery and small for gestational age infants: effects of nondaily and low-intensity daily smoking during pregnancy. Paediatr Perinat Epidemiol. 2017;31(2):144-8. Epub 2017/02/10.*
13. *Ortiz A. Deaths of 3 infants traced to contaminated equipment, hospital says. New York Times. November 8, 2019. Accessed September 15, 2021 https://www.nytimes.com/2019/11/08/us/pennsylvania-infant-deaths-breastmilk*
14. *Committee On N, Section On B, Committee On F, Newborn. Donor human milk for the high-risk infant: preparation, safety, and usage options in the United States. Pediatrics. 2017;139(1). Epub 2016/12/21.*

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