Human Donor Milk: A Critical Need for Oversight

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"The July 2025 Ohio donor-milk recall, triggered by a faulty thermometer on a pasteurization machine, is a stark reminder of the persistent vulnerabilities in the current oversight framework for human donor milk. Although no contamination was detected, 5,735 bottles of donor milk had to be destroyed, and supply lines to nine states were disrupted."

The July 2025 Ohio donor-milk recall, triggered by a faulty thermometer on a pasteurization machine, is a stark reminder of the persistent vulnerabilities in the current oversight framework for human donor milk. Although no contamination was detected, 5,735 bottles of donor milk had to be destroyed, and supply lines to nine states were disrupted. The incident highlights the fragmented and inconsistent regulatory landscape that governs donor milk, especially as clinical reliance on this critical nutrition for preterm and medically fragile infants continues to rise. (1,2)

Safety is of utmost concern when recipients use products made from a biological human substance for clinical or nutritional purposes. We remember the enormous tragedy in the 80s when many people with hemophilia were infected with HIV through contaminated plasma-derived clotting factors. In later years, we saw transmission of hepatitis C through blood transfusions and the use of plasma products. And if this was not enough, there was the bacterial contamination caused by cracked vials of albumin in 1996, resulting in multiple fatalities. (3,4)

In 1997, the Food and Drug Administration (FDA) created the Team Biologics. (5) The primary focus was on ensuring the quality and safety of biological products through consistent and comprehensive inspection of the manufacturing facilities of manufacturers of biologics. This robust and thorough regulatory oversight does not currently exist for human milk.

Human donor milk is a biological tissue, not merely a nutritional supplement. It carries risks of transmitting infectious agents, pharmaceuticals, and environmental contaminants, similar to those associated with blood and plasma banking. (6-7) Some states regulate donor milk as tissue, but this is not universal, and the lack of harmonized standards leaves gaps in safety protocols. (6,8)

A Fragile Safety Framework:

The safety framework for donor milk is fragile. Regulatory inconsistencies exist between for-profit and nonprofit milk banks, with many facilities operating outside the FDA's purview. Furthermore, there is no standardized national protocol governing donor screening, milk processing, or batch-level testing. The result is a patchwork of practices that vary so widely from bank to bank that the quality of a bottle received in a California NICU may differ substantially from that of an identically labeled bottle in Ohio. (2,8,9)

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Risks extend considerably beyond the milk itself. Contamination can occur through improper breast pump sanitization, sub-optimal home storage temperatures, and uncontrolled transit environments. Failures inside processing facilities, including equipment malfunctions, bottle contamination, and batch mixing errors, can compromise product safety at any stage, from expression to distribution. (7,10)

What the 1980s Blood Bank Crisis Taught Us:

Those of us who witnessed the painful evolution of blood safety remember that the American Red Cross was issued a Consent Decree in 1993 and continued to violate this Decree for more than two decades. Only after 23 years and $47 million in fines was this Decree lifted. (11) This situation is a clear example that non-profit status did not insulate organizations from systematic failures. Regulatory oversight has proven to be instrumental in ensuring

product safety.

Blood banking emerged from that crisis with three durable pillars: 1) uniform donor-exclusion criteria, (12) 2) validated processing and pathogen-reduction steps, (13) and 3) real-time hemovigilance with barcode traceability that links every unit from donor to recipient. (14-15) Confidence followed regulation, not the other way around.

The Unique Stakes in Neonatology:

Preterm and medically fragile infants have no margin for error; even trace amounts of pathogens, toxins, or drug residues in donor milk can tip the balance between recovery and serious harm. This reality demands the highest level of regulatory rigor.

Yet demand has raced ahead of policy. The donor milk supply grew from about 400,000 ounces in 2000 to more than 11 million ounces in 2024, according to the Human Milk Banking Association of North America. While mounting data confirm the clinical value of donor milk, public confidence could erode overnight if preventable contamination prompts recalls, lawsuits, or shattered parental trust.

Regulatory oversight is not limited to the United States. The European Commission initiated a complete review of European regulations covering all Substances of Human Origin (SoHO). These substances now include human milk, bone marrow, sperm, fecal transplant, and more. The new regulation was adopted in July 2024 and must be entered into national legislation within a specified number of years after its adoption. The regulation aims to elevate safety and quality standards across member states by harmonizing regulations, requiring facility approval and inspection for milk banks, and introducing digital traceability systems to track donor milk from collection through clinical use. (17)

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A Path to Safety Improvements in the US:

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Uniform standards and harmonized guidelines provide a foundation for ensuring safe and equitable access to donor milk for vulnerable infants. Still, they do not address all potential systemic failures that may affect these processes. (1-2,9,18)

A Warning Bell for Clinical and Regulatory Vigilance:

Donor human milk is a lifeline for vulnerable infants, and ensuring its safety must be a collective priority. The recent Ohio recall serves as a clear warning that rigorous regulation, transparent oversight, and consistent quality controls are not optional; they are essential. By embracing the proven strategies developed in blood banking and learning from global role models, the U.S. can forge a safer, more reliable donor milk system that protects families and sustains trust in this vital resource. The time to act is now to ensure that every drop of donor milk delivers only hope and healing.

References:

1. Unger SL, O'Connor DL. Review of current best practices for human milk banking. Matern Child Nutr. 2024 Jun;20 Suppl 4(Suppl 4):e13657. doi: 10.1111/mcn.13657. Epub 2024 May 16. PMID: 38752309; PMCID: PMC11184574.
2. Israel-Ballard K, LaRose E, Mansen K. The global status of human milk banking. Matern Child Nutr. 2024 Jun;20 Suppl 4(Suppl 4):e13592. doi: 10.1111/mcn.13592. Epub 2024 Feb 6. PMID: 38318679; PMCID: PMC11184569.
3. Bacterial sepsis associated with receipt of albumin. JAMA. 1996 Nov 6;276(17):1373-4. doi: 10.1001/jama.1996.03540170017009.
4. The Lancet albumin recall. Lancet. 1996 Oct 12;348(9033):1026.
5. Food and Drug Administration (US). Inspection of biological drug products: compliance program guidance manual [Internet]. Silver Spring (MD): Food and Drug Administration; 2023 [cited 2025 Sep 6]. Available from: https://www.fda.gov/media/73834
6. Herson M, Weaver G. A comparative review of human milk banking and national tissue banking programs. Matern Child Nutr. 2024 Jun;20 Suppl 4(Suppl 4):e13584. doi: 10.1111/mcn.13584. Epub 2024 Apr 29. PMID: 38685628; PMCID: PMC11184565.
7. Thayagabalu S, Cacho N, Sullivan S, et al. A systematic review of contaminants in donor human milk. Matern Child Nutr. 2024 Apr;20(2):e13627. doi: 10.1111/mcn.13627. PMID: 38268226; PMCID: PMC10981490.
8. Shenker N, Linden J, Wang B, et al. Comparison between the for-profit human milk industry and nonprofit human milk banking: time for regulation? Matern Child Nutr. 2024 Jan;20(1):e13570. doi: 10.1111/mcn.13570. PMID: 37830377; PMCID: PMC10749996.
9. Kontopodi E, Arslanoglu S, Bernatowicz-Lojko U, et al. Donor milk banking: improving the future. A survey on the operation of the European donor human milk banks. PLoS One. 2021 Aug 19;16(8):e0256435. doi: 10.1371/journal.pone.0256435. PMID: 34411191; PMCID: PMC8376009.
10. Hartmann BT. Ensuring safety in donor human milk banking in neonatal intensive care. Clin Perinatol. 2017 Mar;44(1):131-149. doi: 10.1016/j.clp.2016.11.006. PMID: 28159201.

11. Red Cross gets blood consent decree lifted. NonProfit Times [Internet]. 2015 Dec 15 [cited 2025 Sep 7]. Available from: https://thenonprofittimes.com/npt_articles/red-cross-gets-blood-consent-decree-lifted/

12. Food and Drug Administration (US). Code of Federal Regulations, title 21, parts 630 & 640: donor eligibility and blood components [Internet]. Silver Spring (MD): Food and Drug Administration; 2023 [cited 2025 Sep 6]. Available from: https://www.ecfr.gov/

13. Food and Drug Administration (US). Code of Federal Regulations, title 21, part 606: current good manufacturing practice for blood and blood components [Internet]. Silver Spring (MD): Food and Drug Administration; 2023 [cited 2025 Sep 6]. Available from: https://www.ecfr.gov/

14. Centers for Disease Control and Prevention (US). National Healthcare Safety Network (NHSN): hemovigilance module protocol [Internet]. Atlanta (GA): Centers for Disease Control and Prevention; 2023 [cited 2025 Sep 6]. Available from: https://www.cdc.gov/nhsn/

15. Food and Drug Administration (US). Bar code label requirements for blood and blood components; final rule. Fed Regist. 2006 Jan 13;71(6):2552-2575.

16. Human Milk Banking Association of North America. Human Milk Banking Association of North America [Internet]. Minneapolis (MN): HMBANA; 2025 [cited 2025 Sep 4]. Available from: https://www.hmbana.org/

17. European Commission. Proposal for a regulation on substances of human origin [Internet]. Brussels (BE): European Commission; 2022 [cited 2025 Sep 6]. Available from: https://health.ec.europa.eu/

18. Weaver G, Chatzixiros E, Biller-Andorno N, Grummer-Strawn L; Human Milk Banking Consultative Working Group. International expert meeting on the donation and use of human milk: brief report. Matern Child Nutr. 2024 Jun;20 Suppl 4(Suppl 4):e13550. doi: 10.1111/mcn.13550. Epub 2024 Feb 6. PMID: 38318678; PMCID: PMC11184568.

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