

Regulating donor milk will protect infant health

Jennifer Carroll Foy, JD

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Following my twin sons’ traumatic and severely premature birth, I saw firsthand how our healthcare system failed me as a mother and my sons as vulnerable babies. After giving birth to Xander and Alex, my body was initially not ready to produce breast milk, which is universally accepted as the best food for all infants up to 6 months. I was fortunate that my preemies had access to donor breast milk. Not all babies are as lucky as mine.

While breast milk is best, providing it is an impossibility for many parents. Whether due to adoption, surrogacy, difficult births, a baby’s inability to latch onto their mother’s breast, or insufficient work policies allowing mothers to breastfeed and pump, it can be difficult, if not impossible, for parents to feed their children. Donor milk often helps in these situations.

But imagine my shock upon learning that the donor milk the Neo-



Pasteurized donor human milk sits in a refrigerator at the University of California Health Milk Bank on May 13 in San Diego. The U.S. baby formula shortage has sparked a surge of interest among moms who want to donate breast milk to help bridge the supply gap as well as those seeking to keep their babies fed. (AP Photo/Gregory Bull) (Gregory Bull/AP)

natal Intensive Care Unit doctors were feeding my tiny, vulnerable babies through a tube in their nose was essentially unregulated and had no safety or quality assurances from the FDA or Virginia Department of Health. Would you feel comfortable giving your fragile, hospitalized, 8-ounce newborn food from an unverified source containing potential contaminants with unknown side effects?

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As I spent months running back and forth between the NICU, the Virginia House of Delegates, and my full-time public defender job, I knew I needed to draw on my own personal experiences — shared by thousands across Virginia and the nation — to fight for our children. In the Virginia House, I introduced legislation providing paid family leave, so families could care for their sick children without worrying about losing their jobs or homes, and passed bills to end pregnancy discrimination and force employers to provide reasonable accommodations to pregnant and breastfeeding people and to reduce the Black maternal mortality rate by covering doula services under Medicaid. I also introduced a bill to create safety standards and reimbursement of donor human milk and human milk derived-fortifier — which saved my boys' lives in the NICU. Improving the safety of and access to donor breast milk is a personal crusade for me.

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Currently, donor milk is considered mere food by the FDA, meaning there is no requirement for FDA inspectors to scrutinize the milk banks manufacturing and distributing donor milk for infants. Similarly, there is no requirement for milk banks to meet universal quality standards or report adverse events that may arise in donor milk batches. Adverse events happen at even the most careful milk banks. Without reporting these incidents, we would

never have known about the bacterial outbreak at the Abbott Sturgis plant. In short, there are unacceptable, and frankly appalling, gaps in the regulation and safety of donor breast milk, a growing industry.

The U.S. Senate recently released its draft FY23 Agriculture/FDA appropriations bill directing the FDA to regulate donor breast milk banks and manufacturers. This is Congress' most direct action to date in favor of donor breast milk regulation and builds on the Donor Milk Safety Act introduced earlier this year. I am encouraged by this development and commend the Senate for its directive.

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As both a mom and a legislator, I hope the FDA will act in the best interest of our children. It is past time for the federal government to address the issues of safety and access to donor milk and donor milk products. Improving oversight of the infant formula industry without addressing donor milk would be a devastatingly short-sighted move, leaving us at risk of another Abbott-style tragedy. We have all been warned.

Disclosures: No disclosures noted.

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