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Representative Mike Callton
PO Box 30014
Lansing, MI 48909-7514

Dear Representative Callton,

RE: HB 4206

I am writing to you as Chair of the House Health Policy Committee to provide information relative to HB 4206, a bill to require human breast milk banks, companies, and cooperatives with certain standards.

I am a cooperative specialist retired from Michigan State University Extension. I currently serve as Board Chair for Mothers Milk Cooperative, a Michigan cooperative that was formed with assistance from Michigan State University.

Mothers Milk Cooperative (MMC) is the first cooperative in the country that aggregates and markets human milk. The cooperative was incorporated in 2012 to achieve two major objectives:

- Provide a safe, shelf stable human milk product to Neonatal Intensive Care Units (NICU) in hospitals to aid in the survival of the 300,000 premature babies born each year, and
- Provide income to women with babies to allow them to remain at home with their babies for a longer period of time.

Cooperatives are formed and controlled by the people who use them. Any earnings after paying expenses are distributed to the member owners on the basis of their use of the cooperative. Mothers Milk Cooperative is controlled by an 11 member Board of Directors. Six of the those members are mothers who deliver human milk to the Cooperative and five are independent directors who provide counsel in human milk, breast feeding, breast feeding education, and cooperative management.

Applicants are screened based on a complete medical history form and their blood is tested at the American Red Cross National Testing Laboratories. They must complete a blood test to

assure that there are no diseases, drugs, or other medical issues that might affect the safety of the milk they will deliver. The Mother's Milk Cooperative is the only milk bank that participates in the national pathogen surveillance program which identifies donors from geographic areas where outbreaks of infections such as West Nile Virus have been identified. Those donors are then tested at a higher level than donors in other areas. Additionally, Mother's Milk Cooperative tests for more infectious diseases than any other milk bank, including those specified by the Human Milk Banking Association of North America (HMBANA) standards, adding West Nile virus and Chagas disease to the standard blood testing. Additionally, donors are retested every 6 months while HMBANA standards do not require retesting for a donor to continue providing milk. A membership fee of $100 is required but that can be "paid" by delivering 100 ounces of milk. Women can also elect to "Pay It Forward" and gift their milk to a family in need. Milk provided to the Pay it Forward program is processed free of charge by Medolac, MMC's processing and marketing associate, and provided free of charge or at a greatly subsidized price to families in need.

While the safety of the milk delivered by the members is important, so also is the health of the members and their babies. Therefore educational training of the members is provided to assure that the mothers do not sell their milk through the cooperative in preference to feeding their own babies.

Mothers Milk Cooperative has 1,000 members in 46 states, including 70 members in Michigan. In the last year its members were paid over $1 million for the milk they delivered to the cooperative. Michigan women were paid $125,000. The milk is delivered to the Mothers Milk Coop and Medolac Laboratories facility in Lake Oswego, Oregon where it is tested and processed into Co-op Donor Milk, and soon a new human milk fortifier. Both of these products are intended for use in clinical and post discharge settings. The relationship between Mothers Milk Cooperative and Medolac Laboratories is defined in an agreement that specifies the highest quality assurance and safety testing in the industry, a commitment to the World Health Organization Code of Marketing Breast Milk Substitutes, a Commitment to Responsible Conduct, and financial support by Medolac Laboratories. Medolac Laboratories is registered as a Public Benefit Corporation which has identified its social purpose as working to end the shortage and poor access to donor milk that is sometimes costing preterm babies their lives. Due to the expense of donor milk, the lack of scale and the inefficiencies of the current supply chain, donor milk is subject to severe rationing in hospital neonatal units, forcing hospital personnel to choose which babies meet the

"qualifications" to receive it even though all babies in the neonatal intensive care unit are critically ill and could benefit from its use.

HB 4206, while I'm sure was well intentioned, seems to have been crafted as an attack on for profit milk banking to the exclusive benefit of a single entity, the Human Milk Banking Association of North America (HMBANA), and will be detrimental to nursing mothers in Michigan. The proposed legislation requires compliance with the HMBANA guidelines rather than Federal or State rules. This is particularly disturbing since safety and quality standards utilized by Mother's Milk Cooperative and Medolac Labs far exceed those of HMBANA. Codifying this lower standard through Michigan legislation would be a mistake, particularly since HMBANA functions as a professional organization for non-profit milk banks, and is not a certifying body or regulatory agency.

The proposed legislation provides that for-profit human breast milk banks, companies, or cooperatives working with women in Michigan can only accept milk from a mother who is at least 180 days postpartum. Mothers Milk Cooperative standards already require that a women be 90 days postpartum before her human milk will be accepted. The 180 days in the proposed legislation will eliminate one of the key benefits of the Co-Op which is to provide an option to an early return to work.

The Surgeon General of the United States in an annual study released in 2012 stated that the single greatest deterrent to breast feeding in the US was the short maternity leave policies of this country – the shortest of many developed countries. Women who do not have alternative sources of income are forced to return to work after 90 days and many abandon breast feeding their children. Mothers Milk Cooperative provides women an alternative after 90 days so they can remain at home, caring for their children and continuing to breast feed. The 180 day requirement is a very disturbing aspect of this legislation because it appears to completely disregard the needs of nursing mothers in Michigan while purporting to improve the opportunities for breast feeding. Additionally, it seeks to limit the impact of the tremendous increase in high quality donor milk that has resulted from the Mother's Milk Cooperative program to the detriment of mothers and the preterm infants who need donor milk. Establishing different rules for non-profit and for-profit entities also has disturbing anti-trust ramifications and would have government deciding which entities should receive preferential market access and treatment.

The proposed legislation would require that at least 50% of the human breast milk produced by participating mothers in a specific locality is distributed to hospitals in Michigan or to local nonprofit human milk banks. This requirement has no justification and could actually

harm participation in milk banking by mothers in Michigan by artificially limiting milk banking activity in the state. Michigan would be the only State in the union to impose such a restriction constraining the free exchange of donor milk, and would make Michigan the only jurisdiction in the world with such an exclusive and arbitrary requirement.

Furthermore, hospitals make decisions on the purchase of products for their neo-natal intensive care units for financial reasons and often source needs from various suppliers, both local and national. Nonprofit human milk banks choose not to compensate donors for their human milk but sell the milk donated by mothers to hospitals to defray their costs and pay staff. The proposed legislation would require that mothers who are members of a cooperative such as Mothers Milk Cooperative adhere to different, and more onerous and restrictive rules.

Contrary to the allusions of the legislation, that cooperative milk banks pose added risks, the cooperative milk banking model actually provides mothers and infants with a greater focus on safety than found with community milk banks. The Mothers Milk Cooperative has a contract with Medolac, an Oregon company specializing in human milk products for neo-natal intensive care units. This arrangement assures that its human milk is screened and processed to provide the safest possible products for babies. Medolac assures that only human milk is processed and not contaminated with milk from non-human sources. It also adheres to standards more strict than the Human Milk Banking Association of North America so the milk is free of any adulteration or contamination. There are currently no other processors in the country that can provide this level of assurance.

One of the many misguided sections of the proposed legislation is the exclusion of mother to mother milk sharing groups. A recent study conducted by Sarah Keim, a researcher at Nationwide Children's Hospital in Columbus, Ohio, and published in *Pediatrics* magazine showed that 10 out of 102 breast milk samples purchased online from mother to mother milk sharing groups contained at least 10% cow's milk, either directly from cartons or from baby formula. Other studies by this researcher found 75% of the samples were contaminated with viruses or bacteria. The FDA has warned since 2010 that milk sold or shared online can be unsafe. Why are these high risk sharing groups excluded from this Act while organizations such as Mothers Milk Cooperative that have a proven track record of providing the safest, healthiest products are subject to the Act?

Finally, the legislation would be cost prohibitive to implement from an administrative point of view, requiring scarce Department of Community Health and other agency resources to be diverted to address the requirements of the legislation, despite the fact that the agency has no

experience performing duties such as audits of for-profit enterprises and the like. The Department of Community Health would also be required to assess compliance and issue fines and would also have to develop an appeals process. All of these costs would be incurred at taxpayer expense without any evidence that the legislation would actually have any public health benefit, improve access to donor milk, lead to safer donor milk, or encourage mothers to breastfeed.

For the above reasons, I believe HB 4206 represents a misguided and flawed legislative approach that seeks to codify a punitive view of cooperative milk banks while failing to address any established, evidence based public health need and should therefore not be enacted.

Thank you,

Thomas R. Kalchik

CC: Matt Carnagie