

## Human Milk Based Human Milk Fortification: At Legislative Risk

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*The National Coalition for Infant Health is a collaborative of more than 180 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCfIH's mission is to promote lifelong clinical, health, education, and supportive services needed by premature infants and their families. NCfIH prioritizes safety of this vulnerable population and access to approved therapies.*

Pennsylvania's HB 1001 PN 1126, the Keystone Mothers' Milk Bank Act, will worsen disparity for premature infants. If the bill passes, extremely premature infants being cared for in neonatal intensive care units (NICUs) in Pennsylvania would no longer have access to nutritional fortifiers made from 100% donor breast milk. There is no net gain; babies would be placed at risk for necrotizing enterocolitis needlessly, mortality would increase, and NICU costs would rise exponentially.

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The language of the bill is clear. Access would be restricted. There is no question as to the extent of those patients who would be affected. Extremely premature infants have different and more critical nutritional needs that are not easy to meet. The American Academy of Pediatrics (AAP) has provided direction on the use of an added fortifier to mother's own milk or pasteurized donor human milk to provide the requisite protein, calories, and minerals to support growth and development in preemies born weighing less than 1,500g. (1)

Bovine fortifiers are available, but they are potentially life-threatening. There are increased complications in premature babies fed a bovine fortifier. Neonatologists often delay giving cow milk fortifier, resulting in growth and developmental delays. A meta-analysis of two randomized clinical studies demonstrated that for every 10% increase in the volume of fluid containing cow milk given to premature infants weighing less than 1,250 grams, the risk of necrotizing enterocolitis (NEC) increases by 11.8%; surgical NEC, by 20.6%; and sepsis, by 17.9%. (2)

An exclusively human milk fortifier does exist. The availability of this fortifier has changed clinical practice and substantially reduced the risk. Development of this product required extensive research and development. The manufacturer of this product is the only manufacturer of a fortifier made exclusively from donor breastmilk. Providing extremely premature infants an exclusively human milk diet during the early postnatal period is associated with a lower risk of death, NEC, NEC requiring surgery, and sepsis in these most at-risk infants. (2, 3, 4) It decreases hospital costs, since a single case of NEC or sepsis can cost upwards of \$250,000 to treat. (5, 6, 7)

A fortifier made from human milk has been associated with lower risks. Importantly, extremely premature infants will have a decreased risk of immediate, life-threatening complications and can be given fortifier sooner, thus providing better nutritional support during a period where they are most at risk.

The Keystone Mothers' Milk Bank Act threatens access to these life-saving donor breast milk-based fortifiers in Pennsylvania NICUs by prohibiting remuneration of mothers who donate their surplus milk to produce this fortifier, mothers who provide this life-saving milk from their own bodies. Pumping milk is time intensive and expensive. The process requires electricity to operate the pump and freezer, constant attention to sterility and hygiene, and effort to ship the expressed milk. Remuneration is not unreasonable for the excess breast milk these women provide.

The Keystone Mothers' Milk Bank Act, as drafted, prohibits, “remuneration of value provided to a milk donor by an entity.” Effectively, this could mean that the one company that produces a human milk-based human milk fortifier would not be able to provide this product in Pennsylvania. Many fragile premature infants in Pennsylvania's NICUs depend on this product. Implementation of this act would be an unmitigated disaster for Pennsylvania NICUs most fragile premature infants, many who are already at increased risk from disparity.

Moreover, NICUs depend on donor breastmilk to feed preemies when mothers' milk is unavailable, but the Keystone Mothers' Milk Bank Act could allow adulterated, contaminated, and improperly handled breastmilk to reach NICU babies. The standards for screening, processing, and storing breastmilk in the current iteration of the bill are not stringent enough to meet the need and fail to reference the comprehensive safety standards published by the US Food and Drug Administration (FDA) for all other foods.

Further, there is no requirement to screen breastmilk for opiates,

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nicotine, or certain other drugs of abuse. As the AAP endorses, regulations regarding the handling of breastmilk by milk banks should be in the hands of the FDA and the Centers for Disease Control and Prevention (CDC), which have the resources and integrity to implement and enforce these essential regulations. Regulations must be neither propriety nor left to individual, unregulated entities. Regardless of the source, the protection of the public is at stake.

Legislators must listen to the concerns of experts in neonatology regarding this bill. These most fragile preterm infants must be protected. The intent may be good, but the ramifications are clear. "A good intention, with a bad approach, often leads to a poor result." (8) Please give our most at risk, most fragile premature babies what they need in the safest way possible. The bill, in its present form, will make this goal more challenging to achieve.

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**National Coalition for Infant Health Values (SANE)**

**Safety.** Premature infants are born vulnerable. Products, treatments and related public policies should prioritize these fragile infants' safety.

**Access.** Budget-driven health care policies should not preclude premature infants' access to preventative or necessary therapies.

**Nutrition.** Proper nutrition and full access to health care keep premature infants healthy after discharge from the NICU.

**Equality.** Prematurity and related vulnerabilities disproportionately impact minority and economically disadvantaged families. Restrictions on care and treatment should not worsen inherent disparities.

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