



National Black Nurses Association, Inc.  
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## **National Black Nurses Association Announces Human Donor Milk Resolution**

SILVER SPRING, MD, August 1, 2017, The National Black Nurses Association announces the passage of its resolution “Creating a Culture of Safety with Human Milk Banks” at the Opening Ceremony of its 45<sup>th</sup> Annual Institute and Conference in Las Vegas, Nevada. “In collaboration with Prolacta Bioscience, a corporate roundtable member, NBNA is pleased to partner to educate nurses and the community about the need for higher donor milk safety and screening standards”, stated Dr. Eric J. Williams, NBNA President.

“NBNA firmly believes that mother’s breast milk is best for babies, providing important nutrients for a healthy baby. It is well documented that women of color have a high rate of preterm babies. There is a need to make sure that premature babies have access to high quality and safe donor milk.”

The National Black Nurses Association, Inc (NBNA) believes there are a few simple procedures the FDA could put in place to regulate human milk collection that would ensure the same protections for those receiving blood donations and transfusions for our most vulnerable population, babies.

### **These include:**

- Validation of the donation immediately upon receipt, and before mixing with any other donated milk.
- Validation that consist of a check for drugs, including nicotine, and ensure that the milk is 100% human, no cow or other adulterants have been mixed with the donor's milk supply.
- Validation of pathogen reduction processes (e.g.) pasteurization.
- Require human milk banks to report adverse effects of their products, such as disease or infection
- Require standard testing and labeling
- Require annual FDA audit of milk banks
- Codify best practices for hygienic processing and pasteurization.

The theme of the Conference is “Nursing Innovations: Building a Culture of Health”. The Opening Ceremony is open to the public on Tuesday, August 1, 6 p.m., Mandalay Bay Conference Center, Las Vegas, NV.

The NBNA mission is “to serve as the voice for black nurses and diverse populations ensuring equal access to professional development, promoting educational opportunities and improving health”.

## **NBNA Resolution Creating a Culture of Safety with Human Milk Banks**

**Whereas**, human milk is the best source of nutrition for the vast majority of babies, especially those born premature supporting the developing immune system, protecting against infections, allergies and diseases such as diabetes and certain types of cancer;

**Whereas**, the American Academy of Pediatrics (AAP) recommends human milk as the main source of nourishment for all babies for at least the first six months of life;

**Whereas**, human milk has been linked to higher Intelligence Quotient (IQ) scores;

**Whereas**, for a wide variety of reasons, not all mothers are able to breastfeed their babies. As a result, there are human milk banks for mothers producing extra milk to donate their surplus to supplement or replace the milk of birth mother that cannot produce for her own baby;

**Whereas**, over the last decade, there has been a rapid growth in the number, size and use of human milk banks, a trend we hope to see continue. However, there is a lack of standardization and guidelines to ensure patient safety and protect this vulnerable infant population;

**Whereas**, the resulting rapid growth in the number and size of human milk banks for mothers producing extra milk to donate their surplus to supplement or replace the mother's milk, the suggested guidelines for the collection, storage and donation of milk were created decades ago and remain optional, self-imposed and self-regulated;

**Whereas**, these collection guidelines generally include screening and testing the mother for diseases or infections prior to her first donation, having the milk bank's staff: (1) wash their hands, (2) transfer/pour donated milk into glass flasks, (3) pool the milk (usually a batch contains milk from three to five donors), (4) fill bottles with pooled milk, (5) pasteurize the bottles of milk, and (6) freeze the pasteurized milk.;

**Whereas**, safe collection and pasteurization are important to ensuring safe milk supply for babies, there remain significant safety concerns in having non-uniform self-imposed, self-regulated and optional guidelines for the collection of human tissue;

**Whereas**, in the US, three states (CA, MD and NY) regulate human milk as human tissue and require licensing of donor milk banks. The US Food and Drug Administration (FDA) has indicated that human milk is a food and preliminarily explored current practices in the field, but has not seriously considered specific regulations for human milk as of yet;

**Whereas**, the rapid recognition of human milk's value, human milk is widely sold without any processing, testing, or oversight. With the growth of internet commerce, anyone can go to Craigslist.com, Farebook.com, or even athletes' supplement websites to buy human milk that is completely untested and unprocessed; it is time for the federal government to

recognize that human milk carries the same risks as other biologics such as Blood and Plasma;

**Whereas**, blood and plasma regulations are designed to deal with the safety risks associated with materials from a biological source, they are a very good starting point for human milk regulations necessary to protect the public health;

**Whereas**, human milk is a critical nutritional source for babies, and regulations should not be so burdensome that they prohibit the continued increase in supply. History shows that the regulations FDA placed on human blood collection did not stop the supply of blood to those in need, it made the supply safer. It protected the recipients, as well as the donors;

**Whereas**, human milk is a vital resource, and crucial for the healthy development of babies, it is critical that the federal government ensures it is safely accessible for those most in need;

**Whereas**, history shows us what happens when human biologics are processed under subpar regulations. The HIV epidemic that resulted from infected blood transfusions in the 1970s and 1980s is a tragic example;

**Whereas**, with human milk use now growing as rapidly, the FDA must address the need for regulations on the collection and processing of human milk, and treat it as stringently as other human biologics, and;

**Whereas**, FY 2017 Appropriations Request (the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill) provides viable protection and the Committee is aware of the growing commercial human milk industry, and it's important to, in particular our most vulnerable preterm infants; now

1. **Therefore, Be It Resolved:** The National Black Nurses Association, Inc (NBNA) believes there are a few simple procedures the FDA could put in place to regulate human milk collection that would ensure the same protections for those receiving blood donations and transfusions for our most vulnerable population, babies.

**a. These include:**

- Validation of the donation immediately upon receipt, and before mixing with any other donated milk.
- Validation that consist of a check for drugs, including nicotine, and ensure that the milk is 100% human, no cow or other adulterants have been mixed with the donor's milk supply.
- Validation of pathogen reduction processes (e.g.) pasteurization.
- Require human milk banks to report adverse effects of their products, such as disease or infection
- Require standard testing and labeling
- Require annual FDA audit of milk banks
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2. **Therefore, Be It Resolved:** The NBNA supports the need for adequate regulations and laws to ensure the safety and national quality of donor human milk supply.
3. **Therefore, Be It Further Resolved,** that the NBNA respectfully request the Food and Drug Administration make known its efforts to implement regulations to protect a safe and stable supply of human donated milk.

### **References:**

American Academy of Pediatrics, Breastfeeding and the Use of Human Milk: Section on Breastfeeding Pediatrics 2012; 129:e87; DOI: 10.152/peds.2011-3552

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<http://www.marchofdimes.org/materials/premature-birth-report-card-united-states.pdf>

Nelson, M. M. (2013). The benefits of human donor milk for preterm infants.  
*International Journal of Childbirth Education*, 28, 84-89.

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Subcommittee on Agriculture, Rural Development, Food, and Drug Administration, and Related Agencies House Committee on Appropriations, U.S. House of Representatives, <http://docs.house.gov/meetings/AP/AP00/20160419/104833/HMTG-114-AP00-MState-A000055-20160419.pdf>