

Prolacta Bioscience® Applauds the National Black Nurses Association Safe Human Donor Milk Resolution Calling for Higher Donor Milk Safety and Screening Standards

DUARTE, Calif., Aug. 17, 2017 – Prolacta Bioscience, the pioneer in human milk-based neonatal nutritional products for premature infants, applauds the <u>National Black Nurses Association (NBNA)</u> for its effort to improve the safety and quality of the nation's human donor milk supply. The NBNA recently approved a new resolution requesting the U.S. Food and Drug Administration (FDA) implement regulations to provide babies who receive donor milk with the same protections as people receiving blood donations and transfusions, and calls for all premature infants to receive an exclusive human milk diet (EHMD)¹.

The preterm birth rate among non-Hispanic black women is 48 percent higher than the rate among all other women, according to a <u>March of Dimes report</u> cited in the NBNA resolution. The NBNA drafted the resolution to raise awareness of the potential risks in the donor milk supply, and to emphasize the need for better protections for African American babies who receive donor milk.

"The NBNA supports the need for regulations and laws that increase the safety of the U.S. human donor milk supply," said Dr. Eric J. Williams, NBNA President. "Human milk is the best source of nutrition for babies, especially those born prematurely, and we are passionate about advocating for improved quality and access to human milk for all premature infants and their families."

Three states – California, Maryland and New York – regulate human milk as a tissue and require licensing of donor milk banks, according to the NBNA resolution. Although the FDA views human milk as a food, and has done preliminary exploration of current safety practices and standards, there are no FDA regulations in the human donor milk industry.

"We applaud the NBNA for advocating for higher quality and safety standards to improve the human donor milk supply," said Scott Elster, CEO of Prolacta. "By extending the same safety and screening standards that are in place for donor blood and donor plasma to donor milk, we can ensure the fragile population of premature infants has access to a safe human donor milk supply."

The NBNA resolution, "Creating a Culture of Safety with Human Donor Milk," notes that, "With the growth of internet commerce, anyone can go to Craigslist.com, Facebook.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."

The NBNA suggests the following procedures to regulate human donor milk:

- Validation of the donation immediately upon receipt and before mixing with any other donated milk
- Validation that consists of a check for drugs, including nicotine, and ensures that the milk is 100 percent human, no cow milk 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 NBNA is the nation's largest professional organization for African American nurses and represents more than 150,000 African American nurses with 94 chapters in 35 states.

About Prolacta Bioscience

Prolacta Bioscience, Inc. is a privately-held life sciences company dedicated to Advancing the Science of Human Milk®. The company pioneered the development of human milk-based neonatal nutritional products to meet the needs of critically ill, premature infants in the neonatal intensive care unit (NICU). Prolacta leads the industry in the quality and safety of nutritional products made from donor breast milk and operates the first and only pharmaceutical-grade manufacturing facility for the processing of human breast milk.

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¹An EHMD is when 100% of the protein, fat and carbohydrates in an infant's intake are derived solely from human milk.