



Prolacta Bioscience® Applauds New York Gov. Cuomo, Assemblywoman Solages, Senator Hannon & State Lawmakers for Providing Access to an Exclusive Human Milk Diet for Extremely Premature Infants

DUARTE, Calif., May 15, 2017 – Prolacta Bioscience, the pioneer in human milk-based nutritional products for premature infants, applauds Governor Andrew Cuomo, Assemblywoman Michaelle C. Solages, D-22, Senator Kemp Hannon, R-6, and the entire New York State Legislature for expanding Medicaid reimbursement to cover pasteurized donor human milk, including human milk-based fortifiers, for premature infants weighing less than 1,500g (3 lbs 4 oz). The measure was included as part of S. 2007, which was signed by Governor Cuomo last month.

In the U.S., more than one in 10 babies are born prematurely, and the March of Dimes reports an uptick of preterm births, especially among African Americans and other women in racial and ethnic minority groups¹. While some cow milk-based nutrition may be okay for full-term infants, clinical studies² show that for every 10 percent of cow milk in a preemie's diet, the risk of severe complications increases, particularly necrotizing enterocolitis (NEC), the most common and leading cause of death among preterm babies. NEC affects up to one in six extremely premature infants who receive cow milk-based nutrition in their diet.³

"The use of pasteurized human donor milk and human milk-based fortifiers has steadily become the standard of care for extremely high risk, low birth weight infants when a mother's own milk is not available," stated Assemblywoman Michaelle C. Solages, D-22. "State funding to cover the costs of human milk-based nutrition ensures that New York's tiniest patients will have the strongest chance to be as healthy as possible, regardless of their economic status."

Prior to this policy, New York legislators have supported bills to provide financial support for the use of donated, pasteurized human breast milk for premature babies. The new legislation extends this support and expands it to include human milk-based fortifiers, aligning with [recommendations](#) from the [National Coalition for Infant Health](#) for an exclusive human milk diet (EHMD)⁴ for premature babies born weighing less than 1,250g (2 lbs 12 oz).

Because premature infants require more protein, calcium and other minerals than what breast milk alone can supply, the American Academy of Pediatrics (AAP) recommends fortifying mother's milk or pasteurized donor milk with protein, minerals and vitamins to ensure optimal nutrient intake for preemies weighing less than 1,500g (3 lbs 4 oz)⁵. However, nearly all commercial fortifiers are made from cow milk.

An EHMD during the early postnatal period, a diet devoid of cow milk protein, is associated with lower risks of death, NEC, NEC requiring surgery, and sepsis in extremely premature infants⁶. A study published in the [Journal of Perinatology](#)⁷ found that the use of an EHMD was associated with lower total hospitalization costs for infants born weighing 490-1,700g (1 lb to 3 lbs 11 oz), compared to those fed cow milk-based fortifier and mother's milk; a mixed combination of maternal milk, cow milk-based fortifier and formula; and formula-fed infants.

- Cost savings ranged from \$27,388 to \$106,968, per infant on an EHMD⁷.
- NEC rates decreased to 1 percent, and infants reached fuller feeds faster in the EHMD group⁷.
- Up to 22 fewer days of hospitalization were observed for infants on an EHMD compared with those on a cow milk-based diet⁷.

"Prolacta applauds Governor Cuomo and the New York Legislature for taking this step to help improve access to human milk-based nutrition for families with premature infants," said Scott Elster, CEO of Prolacta. "Providing access to and coverage of an exclusive human milk diet, which includes human milk-based fortifiers, is a testament to the commitment of policymakers to raise the health policy standards for these very fragile babies in New York."

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 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.

www.prolacta.com

Media Contact:

Liesl Grebenstein

Phone: (617) 775-0923 (cell)

(617) 236-5830 x.101 (office)

liesl@adsventures.net

¹ March of Dimes. Prematurity Report Card Webpage and 2016 Premature Birth Report Card. Accessed April 5, 2017.

² Abrams SA, et al. "Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products." *Breastfeeding Medicine*. June 2014. 9(6): 281-0285. doi:10.1089/bfm.2014.0024. This cohort study included 260 extremely preterm infants born weighing less than 1,250g who received a diet that ranged from 100% cow milk to 100% human milk.

³ Combined NEC rates from the control arms of Sullivan S, et al. and Cristofalo EA studies: Sullivan S, et al. "An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products." *The Journal of Pediatrics*. April 2010. 156(4):562-567. doi: 10.1016/j.jpeds.2009.10.040. The randomized study of 207 infants weighing 500-1,250g compared the benefits of an exclusive human milk diet with a diet of both human milk-based and cow milk-based products. Cristofalo EA, et al. "Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants." *The Journal of Pediatrics*. December 2013. 163(6):1592-1595. doi: 10.1016/j.jpeds.2013.07.011. The multicenter randomized controlled study examined 53 extremely premature infants weighing 500-1,250g who were fed either a bovine milk-based preterm formula or an exclusive human milk diet, comparing the duration of parenteral nutrition, growth and morbidity.

⁴ An EHMD is when 100% of the protein, fat and carbohydrates in an infant's intake are derived solely from human milk.

⁵ American Academy of Pediatrics. "Breastfeeding and the Use of Human Milk." February 2012. *Pediatrics*. 129(3): 827-841. doi:10.1542/peds.2011-3552.

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- ⁶ Abrams SA, et al. "Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products." *Breastfeeding Medicine*. June 2014. 9(6): 281-0285. doi:10.1089/bfm.2014.0024. This cohort study included 260 extremely preterm infants born weighing less than 1,250g who received a diet that ranged from 100% cow milk to 100% human milk.
- ⁷ Assad M, et al. "Decreased Cost and Improved Feeding Tolerance in VLBW Infants Fed an Exclusive Human Milk Diet." *Journal of Perinatology*. March 2016. 36:216-220. doi: 10.1038/jp.2015.168. The study retrospectively looked at 293 preterm infants between gestational ages of 23 to 34 weeks and birth weights between 490-1,700g in the Level III NICU. The study compared the clinical and financial impacts between infants that were fed an exclusive human milk diet; cow milk-based fortifier and maternal milk; mixed combination of maternal milk, cow milk-based fortifier and cow milk-based formula; and formula between March 2009 and March 2014.