



United States Breastfeeding
COMMITTEE
PROTECTING • PROMOTING • SUPPORTING

Docket No. FDA-2010-N-0553

November 29, 2010

To: Pediatric Advisory Committee, Food and Drug Administration:

The United States Breastfeeding Committee (USBC) recommends that infants be exclusively breastfed for six months, and continue to breastfeed for at least the first year of life. When breastfeeding is not feasible, then human milk feeding is the recommended second choice. Banked human milk is recommended to use in medically indicated situations where there is absence or insufficient supply of mother's own milk. The use of donor human milk has saved infant lives and positively impacted the health outcomes of countless premature and sick infants through therapy and prevention of disease, such as in metabolic disorders or allergies. Documented research has shown that human milk protects infants from a variety of infectious diseases such as respiratory infections and diarrhea, as well as chronic conditions such as obesity, diabetes, and childhood leukemia. For preterm infants, studies have consistently demonstrated that human milk significantly reduces the risk of life-threatening conditions that are more common in prematurity, including necrotizing enterocolitis, sepsis, and pneumonia, and decreases both incidence and severity of debilitating conditions such as retinopathy of prematurity (which leads to blindness) and improves neurodevelopmental outcomes over those premature babies fed artificial formulas. The use of a total human milk diet for these fragile infants also shortens hospital stay, decreases need for parenteral nutrition, and saves health care dollars.

Banking donor milk for human consumption demands some degree of federal regulatory oversight to be considered and developed separate from organ and tissue banking. The safety of human milk that is donated, processed, and received outside the guidelines of a regulated system may create risk for the consumer. Lack of regulation also causes parents and health care providers to have concerns about milk that is appropriately screened and processed, and thus hesitancy to use it, at the risk of using formula instead. However, the high costs of becoming a donor, and the time restrictions on donation, may severely limit available supply. In addition, lack of guidelines has led to unsafe practices, such as on-line sales of human milk. For the premature or ill infants who require banked human milk for health and survival, we have an obligation to provide a product that is proven safe through donor screening and appropriate processing of milk to prevent the transmission of infectious diseases such as hepatitis. The USBC supports the role of the FDA's involvement in the system of banked human milk, and encourages the development of systems that 1) reduce costs for donors and recipients alike, 2) allows for donors with older children to continue to donate for use with non-premature, non-ill older children.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'Robin W. Stanton'. The signature is fluid and cursive, with the first name 'Robin' being the most prominent.

Robin W. Stanton, MA, RD, LD

Chair

United States Breastfeeding Committee

Reference:

United States Breastfeeding Committee, Statement on the Safe Use of Donor Human Milk (2008)