Milk Bank Public Hearing Minutes

Today is October 7, 2019, I am Cristy Sellers at the Arkansas Department of Health. I call to order this public hearing on the proposed amendments to the rules pertaining to milk bank standards. It is approximately 1:00 pm and we are in the EBT Lab on the third floor of the Freeway Medical Building of the Arkansas Department of Health. Copies of the proposed rules are available on the table and on the department website. If you have not signed in please do so indicating if you would like to make comments.

The purpose of today's hearing is to take comments from the public on these rules that establish standards on the processing, storing and transportation of human breast milk pursuant to Act 216 of 2019. If you wish to make a comment, please introduce yourself and your affiliation prior to making your comment. Your comment will be duly recorded and considered by the agency. We will not be able to respond to comments today however, written responses will be provided to all parties who wish to receive them.

Hello, I am Dr. Victoria Nicklaus and I would like to make a comment please. I am the Vice President of Innovation Medical Communication of Applied? Science. I am also a Professor of Pediatrics at the UCLA Geffon School of Medicine. So I'm here today to provide comment on the proposed rules pertaining to human milk bank standards as authorized by Act 216 of 2019.

This act directs the department of health to establish by rules or standards for transporting, processing or distributing commercial human breast milk on a for profit and non profit basis in Arkansas as you just said. I sit her today wearing two hats. First as a practicing neonatologist with over 20 years of experience in the field and second as Vice President of Innovation Medical Communication for Prolacta Bioscience. Prolacta is the nation's leading hospital provider of human milk based nutritional products for fragile infants in the Neonatal Intensive Care Unit or NICU as I will refer to it.

Prolacta is a 100% human milk based nutritional products clinically proven to improve health and decrease complications and mortality and reduce hospital costs when used in replacement of cow's milk nutrition in the NICU for babies weighing less than 1250 grams. Our main produce is a breast milk derived human milk fortifier, which is mixed with mom's own milk or donor milk when mom's milk is not available to provide the most fragile babies a 100% human milk nutritionally enriched diet. Our products are currently used at St. Bernards Medical Center and Willow Creek Women's Hospital.

I'm very grateful to see the department's leadership initialing draft guidelines for the regulation of human milk banks. In the last few years Prolacta has been working with policy makers at both state and federal level in both thoughtful, comprehensive legislation of this emerging industry. I have seen first hand throughout my entire career how important the use of safe human milk is for premature infants allowing them the best fighting chance for a full and healthy life. I cannot emphasize enough how critical state action is in ensuring preterm infants are not put at risk.

While donor human milk helps nourish our most vulnerable citizens, human milk must be regulated in order to ensure that premature infants not only have access to this vital nutrition therapy but also that it is a safe product.

While I am pleased that the Arkansas Department of Health is issuing regulations for human milk banks, I am concerned that the draft guidelines are not sufficient to ensure a safe supply of human donor milk. Many of the recommended guidelines mitigate some of the biggest risk posed by donor human milk such as the requirement for pasteurization, a mainstay for bio-burden reduction. But the guidelines do not address serious risks that exist in the door milk supply chain, including traceability of donated milk, screening for contamination by nicotine or marijuana or direct screening for infectious disease agents that can be transmitted through milk.

I believe in addition to the safe handling of milk addressed in the regulations that there are three areas that the department of health must take into consideration to ensure the state's most vulnerable citizens receive safe donor milk and donor milk products. These are classification labeling, testing, and traceability and I will elaborate on those.

So first classification labeling, everyone agrees that donor milk is classified, at a minimum as a food. That is how most donor milk is classified by the US FDA. However, the guidelines for donor milk as a food, set forth by the FDA 21 CFR 100-169 require safety in labeling minimums, which are not included in the draft guidelines by the department of health. For example, the draft guidelines do not require milk banks to have a food safety management plan or to adhere to good manufacturing practices. At a minimum, the department of health's guidelines should meet the FDA's standards for human milk as a food. In fact, the FDA's Grade A pasteurized milk ordinance, which establishes standards for processing cow's milk to be consumed by individuals at a much lower risk of premature infants has a stricter set of guidelines than the state's draft guidelines. I believe that strengthening and enforcing these requirements is incumbent upon the state especially as human milk is used to feed a very vulnerable population.

Our discussion goes further than food when considering donor milk. All donor milk when distributed by donor milk banks is pasteurized, a process of heating to a specific temperature for a set time. While pasteurization is a necessary and required step to reduce the bio-burden of human milk it also alters, albeit safely, the nutrient composition of human milk. This change in nutrient composition that occurs during donor milk pasteurization according to the FDA is the definition of an exempt infant formula. Therefore as all donor milk is pasteurized and pasteurization changes the nutrient composition of donor milk relevant to mother's own milk which is as we know is food when directly fed to mom's individual baby. Donor milk should be held to a higher standard. The FDA's exempt infant formula standards would, in my opinion, be a good starting point for strengthening the department of health's regulations. Further it is under appreciated that nutritional composition of human milk varies between individual women and over the time during lactation. These differences in variability include components critical to nutrition of premature newborns, such as milk's caloric content, the fat and protein

concentration. However, there are no requirements for labeling the nutritional composition of donor milk in the department of health's guidelines, despite the fact that the FDA requires labeling of all food products to include donor milk. This is why I believe that the rules established by the Arkansas Department of Health must include a requirement for basic food labeling for all donor milk and donor milk derived products. This in turn would enable the neonate team caring for and extreme low birth weight and premature infant to administer the proper amount of nutrition, not just the volume of the donor milk, thereby meeting the nutritional needs to allow for optimal growth and development.

My comments above regarding the importance of pasteurization as the primary method for bio-reduction, which is reducing the concentration of bacteria naturally present in milk, leave me to comment on the department of health's draft rules guideline for distributing raw milk to infants. The adverse outcomes and loss of life that have resulted from the distribution and use of unpasteurized donor milk, this is data largely derived from informal milk sharing or selling is, in my opinion, ample warning for the department not to condone the use of unpasteurized breast milk for feeding to highly vulnerable and preterm infants.

Second testing, human milk is a secreted biological fluid and hence, has the potential to transmit virus, disease or pathogens. Additionally, preterm infants are known to be immune compromised and hence, more likely to develop overwhelming infections resulting in death. As I touched upon in my opening, I am concerned that the department of health guidelines in the present form do not address serious risk of transmission of infectious diseases. One prominent example is vaccila serous? Vaccila serous is a bacteria ubiquitous in our environment, largely in soil and environmental water but it is difficult to detect without a selective and differential method. While vaccila serous is effectively reduced by pasteurization, the spores it produces are resistant to pasteurization. Under certain conditions vaccila serous can produce an enterotoxin that attacks the gastrointestinal tract causing severe complications, hence the germination of vaccila serous spores can lead to fatal illness in preterm infants. A literal lifesaving requirement that the department of health should include is that all donor milk and donor milk derived products must undergo testing specific to the detection of vaccila serous and potential enterotoxins to avoid bacteria flourishing in the gut of highly vulnerable infants.

In addition to pathogens like vaccila serous, human milk is unique in that chemical substances like nicotine, marijuana, drugs abused can also pass from the blood stream into breast milk. Case in point, the opioid epidemic and the legalization of marijuana pose significant health risks to the donor milk supply. Not only are these substances alone a risk, a threat to infants, just last week, the Centers for Disease Control announced that the opioid crisis has quintupled the rate of pregnant women who have been diagnosed with Hepatitis C. We believe that all donor milk and donor milk derived products must be screened for nicotine, amphetamines, benzodiazepines, cocaine, marijuana, THC, opioids and their principal metabolites. Donor screening and blood testing in the Arkansas Department of Health draft guidelines in not

sufficient. The only way to ensure donor milk is free of chemical containments and pathogens that transmit disease is to directly test donor human milk and donor milk derived products.

And finally traceability, in their most recent donor milk guidelines the American Academy of Pediatrics stated that human milk is a biological product. Therefore, whether from the infants own mother or donor mother there will always be concerns about contamination. Prolacta agrees with this assessment and therefore it would be prudent for the department's guidelines to address the risks of biologics included in my recommendations above but also to ensure the traceability for all commercial human milk banks that collect, process, store and distribute in the state. As our Vice President of Regulatory at Prolacta likes to say, if you can find out what cantaloupe made you sick, you should certainly be able to trace the origin of the food we feed to a preterm infant.

Right now many milk banks only assume that the milk donated to them came from the qualified donor screened for appropriate risk factors. Unlike blood, plasma, and tissue milk is expressed at home by the donor. Milk mix up and errors in the collection process can and do happen. Better traceability standards are absolutely needed. I would therefore, strongly encourage the department of health to consider a traceability requirement for all donor milk and donor milk derived products like they would for any other biologic tissue being licensed by the department.

I would lastly like to thank you, the state, and the department for the leadership on this critical issue and I welcome the opportunity for further discussions and the presentation of data to support the suggestions I've made.

Joe Thompson stated all comments both written and oral here will be responded to. We will issue a written response to everybody at the same time. I will be happy to answer any questions on the legal process. Once we respond to public comments everything goes to the Governor's office for approval. From the Governor's office everything goes to Dr. Smith for approval. Then it will go to the Joint Public Health Committee and the General Assembly. Once they review it goes to Arkansas Legislative Sub Committee then it goes to the full Arkansas Legislative Council then it is deposited with the Arkansas Secretary of State.

Public comments will be entered into the record and considered by the agency. The time is now 2:00 pm and this Public Hearing is now adjourned.