FOOD AND DRUG ADMINISTRATION (FDA)
Pediatric Advisory Committee (PAC)
Bethesda Marriott
Bethesda, Maryland
December 6, 2010
Flash Minutes

The following is an internal report which has not been reviewed. A verbatim transcript will be posted on the FDA website at:

http://wcms.fda.gov/FDAgov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm201871.htm

The Pediatric Advisory Committee (PAC) met on December 6, 2010 at the Bethesda Marriott, Bethesda, Maryland. Prior to the meeting, the members were provided the background material from the FDA. The meeting was called to order by Geoffrey Rosenthal, M.D., (Chair); the conflict of interest statement was read into the record by Walter Ellenberg, Ph.D., (Designated Federal Official). There were approximately 100 persons in attendance. There were five speakers for the Open Public Hearing session.

This was a non-voting meeting.

Attendance:
Pediatric Advisory Committee Members Present:
Geoffrey Rosenthal, M.D., Ph.D. (Chair), Carl D'Angio, M.D., Alexander Rakowsky, M.D., Ph.D., Kathleen Motil, M.D., Ph.D., Jeffrey Krischer, M.D., Brahm Goldstein, M.D. (Industry Representative), Henry Farrar, M.D. (Pediatric Health Organization Representative)

Temporary Member:
Avital Cnaan, Ph.D, M.S., Amy Celento (Patient Representative), Norma Rogers, Ph.D. (Consumer Representative), Diane Anderson, M.D., Ph.D., Susan Baker, M.D., Jatinder Bhatia, M.D., Frank Greer, MD., Michael Msall, M.D., Benjamin Caballero, M.D, Ph.D., Pearay Ogra, M.D.

Special Government Employee Consultants Present:

Speakers (Presenting Only):
Ruth Lawrence, M.D., Jeanne Linden, M.D., M.P.H., Susan Landers, M.D., Sharon Unger, M.D., F.R.C.P., Jan Otey, B.S., M.T.(A.S.C.P.), Pauline Sakamoto, R.N., P.H.N., M.S., Scott Eaker.

FDA Participants:
Joshua Sharfstein, M.D., Dianne Murphy, M.D, Ann Myers, R.Ph., Benson Silverman, M.D., Melissa Greenwald, M.D., William Rodriguez, M.D, Ph.D.

CDC Participants:
Laurence Grummer-Strawn, MD, Kenneth Dominguez, MD

Designated Federal Official:
Walter Ellenberg, Ph.D.

Issue:

FDA's Pediatric Advisory Committee (PAC) met on December 6, 2010 to discuss current practices in human milk donation, banking, and distribution to identify the risks and benefits associated with use of donated human milk and risk mitigation. **FDA does not regulate the practice of human milk banking**. As such, FDA's knowledge and understanding of the current practices and protocols is limited. This meeting (and the open docket) provided a mechanism for gathering information on the topic of human milk banking. The meeting did **not** discuss the benefits of breastfeeding, **nor** did it assess or speculate on any future regulatory actions. FDA provided the PAC panel with a series of questions for discussion. No votes were called during the meeting.

Since the mid-1980s, a network of human donor milk banks has developed in the United States. Given the absence of regulatory oversight except in 2 states, most of these banks voluntarily follow a set of guidelines established by the Human Milk Banking Association of America (HMBANA). These banks pool, process, and distribute donated human milk from lactating women for use in other infants when their mothers' own milk is unavailable. In addition, a commercial establishment, Prolacta Bioscience, Inc., has begun processing and distributing human milk-based products.

FDA does not question the benefits of direct mother/child breastfeeding for almost all babies. However, human milk from other sources, including milk that is banked, poses greater potential for risk, and some of the benefits may be lessened by processing. Concerns have been raised regarding human milk obtained from sources other than an infant's own mother, with particular focus on risks associated with transmission of viral infections, chemical contamination and bacterial contamination. The purpose of this meeting was to explore potential risks of exposure to human breast milk from sources other than maternal, to understand state-level regulatory approaches to risk mitigation, and to describe current practices of human milk banking and human milk processing.

The Agenda was as follows:

Call to Order at 8:00 a.m. Introduction of Committee	Geoffrey Rosenthal, M.D., Ph.D. Chair, PAC Professor of Pediatrics, University of Maryland School of Medicine
Conflict of Interest Statement	Walter Ellenberg, Ph.D. Designated Federal Official, PAC

FDA Opening Remarks	Joshua Sharfstein, M.D. Principal Deputy Commissioner, FDA
Overview of Agenda and Discussion Questions for the Committee	Dianne Murphy, M.D., Director Office of Pediatric Therapeutics Office of the Commissioner, FDA
Use of Donor Human Milk	Benson Silverman M.D., Director Infant Formula and Medical Foods Staff Center for Food Safety and Applied Nutrition, FDA

Invited Speakers

Public Health Perspective on Donor Human Milk Banking	Laurence Grummer-Strawn, Ph.D. Chief, Nutrition Branch Division of Nutrition, Physical Activity, and Obesity , CDC

Current Clinical Perspectives

A Physician's View of Human Milk Banking	Ruth Lawrence, M.D. Department of Pediatrics University of Rochester School of Medicine and Dentistry
The Use of Donor Human Milk for Preterm Infants	Susan Landers, M.D., F.A.A.P., F.A.B.M. Director of NICU Lactation Services Seton Family of Hospitals Pediatrix Medical Group Austin, Texas
Human Donor Milk: The Canadian Experience	Sharon Unger, M.D., F.R.C.P. University of Toronto Mount Sinai Hospital

BREAK

Current Milk Banking Practices

The Human Milk Banking Association of North American (HMBANA)	Pauline Sakamoto, R.N., P.H.N., M.S. President, HMBANA Executive Director, Mother's Milk Bank San Jose, California
Using Donor Human Milk in Extremely Premature Infants	Scott Eaker Vice President, Quality and Regulatory Affairs Prolacta Bioscience, Incorporated

Current State Regulations

New York State Regulation of Human Milk Banks	Jeanne Linden, M.D., M.P.H. Director, Blood and Tissue Resources Program Wadsworth Center New York State Department of Health

LUNCH

Open Public Hearing

Milk Banking in California	Jan Otey, B.S., M.T.(A.S.C.P.) Examiner II California Department of Public Health Laboratory Field Services Tissue Bank Program

BREAK

Infectious Disease Risks

Potential Risk which Could be associated with the Consumption of some Human Milk	William Rodriguez, M.D, Ph.D. Science Director Office of Pediatric Therapeutics Office of the Commissioner, FDA
Human Milk Banking: Considerations related to Human Immunodeficiency Virus	CAPT Kenneth L. Dominguez, M.D., M.P.H US Public Health Service Medical Epidemiologist, CDC
Donor Screening Considerations for Donors of Human Tissues	CDR Melissa Greenwald, M.D. US Public Health Service

Chief, Human Tissue and Reproduction Branch
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research FDA

Question and Answer Session

Committee Discussion Questions
Committee Recommendations — Geoffrey Rosenthal, M.D., Ph.D.
Chair of Pediatric Advisory Committee
Professor of Pediatrics, University of Maryland School of Medicine

Summary and Wrap-up — Dianne Murphy, M.D., Director
Office of Pediatric Therapeutics
OC, FDA

Adjournment

Questions to the Committee

1. Discuss the potential risks of banked human milk and how these risks vary with the following activities:
- **Collection**
- **Donor Screening**
- **Processing**
- **Distribution**

Overall, the committee agreed that the infectious disease risk associated with the process of collection and donor screening is minimal when taken from HMBANA member banks or Prolacta Bioscience Inc. There did appear to be a wide variation in the content of the milk and the process of pooling milk may provide a more consistent nutrient content. Nutrient content analysis should not be limited to macronutrients but include information regarding critical elements such as iron content. The discussion focused on whether or not it is possible to change the risk associated with the collection process *without adversely impacting the burden of collection. Although the collection process is imperfect, the committee voiced concern that the creation of regulations for a more controlled collection process than the one already described would potentially decrease milk donation. Further, the committee also noted that improved donor education may also reduce risks linked to the collection process.*

The committee noted that many of the risks associated with the milk collection process may be mitigated in the post-collection process. The committee, however, acknowledged the difficulties

and limitations to the screening process (including the identification of specific substances and whether or not additional screening requirements would be cost prohibitive).

The committee did not express concerns regarding the distribution of milk via HMBANA or Prolacta Bioscience Inc., however, they were highly concerned with the growing practice of internet and person-to-person milk exchange. The practice of internet milk exchange was highly discouraged.

(Please see official transcripts for details)

2. Discuss the strengths and weaknesses of current controls – both voluntary and regulatory – of banked human milk.

The committee noted that the current state regulations are not consistent with each other and are only present in three states (California, New York, and Maryland). Although they would like more regulatory consistency, they noted the difficulty associated with the task. The greatest concern was the absence of a mechanism which could monitor and stop illegitimate milk banking operations. Therefore, the committee noted that some Federal oversight or guidelines might be beneficial.

The committee stressed that the trafficking of human milk over the internet is the greatest concern.

(Please see official transcripts for details)

3. What additional scientific research might be needed to further advance our knowledge concerning banked human milk?

A. Regarding Risks?

B. Regarding Benefits?

The committee stated that there is not enough data available to completely address concerns regarding the risks and benefits of banked human milk. The committee suggested some of the studies could be obtained through collaborative efforts between FDA and NIH. However, the committee also challenged HMBANA and Prolacta Bioscience Inc. to develop a donor registry and generate an outcome profile which would identify the benefits of banked milk, mother's milk, infant formula, and cow's milk as well as determine the ideal composition associated with growth.

(Please see official transcripts for details)

Meeting adjourned at approximately 6:00 pm