

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

September 19, 2023

FINAL MEETING AGENDA

The committee will discuss considerations for development plans for establishing safety and effectiveness of artificial womb technology (AWT) devices intended to treat extremely premature infants (EPIs), including regulatory and ethical considerations for first in human (FIH) studies.

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| 9:00 a.m. | Call to Order and Introduction of Committee | Robert Dracker, MD, MHA, MBA, CPI
Chairperson, PAC |
| . | Conflict of Interest Statement | Marieann Brill, MBA, RAC, MT(ASCP)
Designated Federal Officer, PAC
Office of Health Technology 6
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH) |
| | FDA Opening Remarks | Dionna Green, MD, FCP
Director
Office of Pediatric Therapeutics (OPT)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC) |
| 9:25 a.m. | FDA Background Presentations | |
| | <ul style="list-style-type: none">• Regulatory Considerations for Artificial Womb Technology Development Programs | Kalkidan Molla, MS
Lead Reviewer
Office of Cardiovascular Devices
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH) |
| | <ul style="list-style-type: none">• FDA's Regulatory Safeguards for Children Involved in Clinical Trials: Considerations for Artificial Womb Technologies | Elizabeth L. Durmowicz, MD
Medical Officer
Office of Pediatric Therapeutics (OPT)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC) |
| | <ul style="list-style-type: none">• Clinical Considerations for Evaluating Benefit versus Risk for Artificial Womb Technology Development Programs | An Massaro, MD
Supervisory Medical Officer
Office of Pediatric Therapeutics (OPT)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC) |

Clarifying Questions

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DRAFT MEETING AGENDA (cont.)

10:10 a.m. Strengths and Limitations of AWT Animal Models

FDA Perspective

- Animal Study Considerations for Artificial Womb Technology Devices

Annabelle Crusan, DVM, MS

Veterinary Medical Officer

Office of Cardiovascular Devices

Office of Product Evaluation and Quality (OPEQ)

Center for Devices and Radiological Health (CDRH)

Published Animal Models: Industry Perspective

- AWT in a Preterm Lamb Model

Alan W. Flake, MD, FACS, FAAP

Ruth M. and Tristram C. Colket, Jr. Chair in Pediatric Surgery; Director, Center for Fetal Research

Children's Hospital of Philadelphia

Published Animal Models: Expert Guest Speaker Perspectives

- Artificial Placenta in a Preterm Lamb Model

George B. Mychaliska, MD

Robert Bartlett, MD Collegiate Professor of Pediatric Surgery

C.S. Mott Children's Hospital

University of Michigan Health

- AWT in a Piglet Model

Mike Seed, MBBS, MRCPCH, FRCR

Head, Division of Cardiology

The Hospital for Sick Children (Toronto)

Clarifying Questions

11:20 a.m. *Break*

11:30 a.m. **OPEN PUBLIC HEARING**

12:30 p.m. **LUNCH**

1:30 p.m. Relevant Clinical Experience Data

- Contemporary Outcomes for Extremely Preterm Infants (EPI)

Susan R. Hintz, MD, MS, Epi

Robert Hess Family Professor of Neonatal and Developmental Medicine

Stanford University

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DRAFT MEETING AGENDA (cont.)

- Hemostasis in preterm infants undergoing extracorporeal membrane oxygenation

Gail M. Annich, MD, MS, FRCP
Professor of Pediatrics; Director of Resuscitation Oversight
The Hospital for Sick Children (Toronto)

- Cardiovascular considerations for AWT in the EPI

Peta-Maree Alexander, MBBS
Associate Professor of Pediatrics
Medical Director of Cardiac ECMO
Boston Children's Hospital

- Gastrointestinal considerations for AWT in the EPI

Josef Neu, MD
Professor of Pediatrics
University of Florida

Clarifying Questions

2:45 p.m. Ethical Considerations for a First-in-Human Trial of AWT

Mark Mercurio, MD, MA
Professor of Pediatrics and Director of the Program for Biomedical Ethics
Yale School of Medicine

Clarifying Questions

3:10 p.m. *Break*

3:30p.m. *Questions to the Committee and Discussion*

5:25 p.m. **ADJOURNMENT**

Robert Dracker, MD, MHA, MBA, CPI
Chairperson, PAC