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.

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	
	• 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)
	• 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)
	• 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	

FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner

Pediatric Advisory Committee (PAC)
September 19, 2023

FINAL 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

FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner

Pediatric Advisory Committee (PAC)
September 19, 2023

FINAL 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