U.S. FOOD & DRUG ADMINISTRATION

Public Meeting
Pediatric Medical Device Development

Monday, August 13, 2018

Meeting Introduction and Process – Why Are We Here?

9:00 am Leading the Charge –Introduction to the Meeting
Vasum Peiris – Chief Medical Officer, Pediatrics and Special Populations, Office of the Center Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA)

Evolution of Pediatric Medicine and Pediatric Medical Devices

9:15 am Audience Poll Question

Big Needs for Growing Children

9:20 am Why We Need Medical Devices for Children
Mark Del Monte - Interim CEO/Executive VP, American Academy of Pediatrics
Bob Kroslowitz – Chairman, Pediatric Medical Device Working Group, AdvaMed

9:45 am Current Landscape of Pediatric Medicine – Pushing the Envelope
Kurt Newman – President and CEO, Children's National Health System

9:55 am FDA Numbers and Facts on Pediatric Medical Devices
Mary Clare McCorry – AIMBE Scholar, American Institute for Medical and Biological Engineering

10:10 am The National Pediatric Collaborative Community
The FDA Collaborative Community Strategic Priority
Michelle Tarver – Director of Patient Science & Engagement Program, Office of the Center Director, Center for Devices and Radiological Health, FDA
The Role and Potential of Pediatric Hospitals and Health Systems
Dennis Lund– Interim President and CEO, Lucile Packard Children's Hospital Stanford

10:30 am Question and Answer

10:40 am Commissioner's Remarks
Dr. Scott Gottlieb – Commissioner of the U.S. Food and Drug Administration

10:50 am **Break: 10 minutes**

21st Century Technology for the 21 and Under

11:00 am Audience Poll Question

11:05 am Why Size No Longer Matters: The Advent and Potential of Miniature and Nanotechnology
Kevin Maher – Professor of Pediatrics, Emory University School of Medicine
Director, Cardiac Intensive Care, Children's Healthcare of Atlanta
Medical Director, Pediatric Technology Center
Georgia Institute of Technology

11:15 am Digital Natives: Children are Principal Innovators
Bakul Patel – Associate Director of Digital Health, Office of the Center Director, Center for Devices and Radiological Health, FDA

11:25 am Pediatrics, To the Future and Beyond!
Anthony Chang – Chief Intelligence and Innovation Officer and Medical Director of the Sharon Disney Lund Medical Intelligence and Innovation Institute, Children's Hospital of Orange County

11:35 am Question and Answer

11:45 am **Lunch Break: 1 hour**

Optimizing Evidence Generation

12:45 pm Audience Poll Question

12:50 pm **Opening:** Outline Session Topics and Goals
Doug Silverstein – Medical Officer, Office of Device Evaluation, Center for Devices and Radiological Health, FDA

12:55 pm Solutions to Barriers for Pediatric Evidence Generation
Steve Anderson – Pediatric Working Group, AdvaMed and CEO, Preceptis Medical

1:05 pm Use of Real World Evidence (RWE): The Vision and Demonstration of National Evaluation System for Health Technology (NEST)
Rachel Rath – Deputy Director of NEST Coordinating Center

1:15 pm Benefit-Risk & Evidence Consideration
Randy Brockman – Clinical Deputy Director, Office of Device Evaluation, Center for Devices and Radiological Health, FDA

1:25 pm The PEDs (Pediatric Extrapolation for Devices) Team – A Novel Approach to Extrapolation
Jacqueline Francis – Medical Officer, Office of Device Evaluation, Center for Devices and Radiological Health, FDA

1:35 pm Question and Answer

1:45 pm **Break: 15 minutes**

FDA-Industry Perspectives on Trial Designs

2:00 pm Audience Poll Question

2:05 pm Innovative Trial Designs
Going Beyond Randomized Clinical Trials
Martin Ho – Director of Quantitative Innovation Program, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, FDA
Industry Case Example for Novel Trial Design: MiniMed 670
Pamela Haworth – Clinical Research Director, Program Management, Diabetes, Medtronic

2:25 pm Modeling and Simulation
Study Designs Using Modeling and Simulation
Leonardo Angelone – Research Biomedical Engineer, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA
Industry Case Example: Jarvik Heart
Tim Baldwin – Deputy Chief, Advanced Technologies and Surgery Branch, National Heart, Lung, and Blood Institute

2:45 pm Question and Answer

2:55 pm ***Break: 15 minutes***

Research Networks and Infrastructure

3:10 pm Audience Poll Question

3:15pm The Potential of Mature Pediatric Specific Registries
Barbara Christensen -Senior Director of National Cardiovascular Data Registry and Accreditation Services, American College of Cardiology

3:25 pm Disease Specific Learning Networks to Generate Clinical Data
Peter Margolis – Learning Networks Program and PEDSnet, Co-Director of James M. Anderson Center for Health Systems Excellence, Cincinnati Children's Hospital Medical Center

3:35 pm Pediatric Clinical Trial and Product Development Infrastructure

Daniel Benjamin - Kiser-Arena Distinguished Professor of Pediatrics, Duke Clinical Research Institute

Edward Connor - Chairman and Chief Scientific Adviser, Institute for Advanced Clinical Trials for Children

3:55 pm Question and Answer

4:10 pm **Public Comment Period**

4:30 pm **Directed Expert Panel Discussion – Optimizing Evidence Generation**

Mark Del Monte
Bob Kroslowitz
Dennis Lund
Kevin Maher
Steve Anderson
Rachel Rath
Pamela Haworth
Barbara Christensen
Peter Margolis
Edward Connor
Elise Berliner

5:25 pm **Closing Remarks Day 1**

See next page for day 2 agenda.

Tuesday, August 14, 2018

Welcome and Recap

8:30 am Welcome and Recap
Vasum Peiris – Chief Medical Officer, Pediatrics and Special Populations, Office of the Center Director, Center for Devices and Radiological Health, FDA

Creating Regulatory Value and Simplicity

8:40 am Audience Poll Question

8:45 am **Opening:** Outline Session Topics and Goals
Eric Chen – Director, Humanitarian Use Device and Pediatric Device Consortium Programs, Office of Orphan Products Development, FDA

8:50 am Overview of Pediatric Medical Device Legislation History
James Baumberger – Senior Director in Federal Advocacy, American Academy of Pediatrics

9:10 am How the Medicines Market Developed for Children: What Can We Learn from Pediatric Drug Development Legislation?
Lynne Yao – Director, Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, FDA

9:20 am Pediatric Device Development Regulatory Landscape on the International Stage
Eliane Schutte - Chief Development Officer, Xeltis

9:30 am Question and Answer

9:40 am ***Break: 15 minutes***

9:55 am Audience Poll Question

10:00 am Importance of International Regulation Harmonization, US FDA/Japan Pharmaceutical and Medical Devices Agency Partnership
Declan Dineen - Senior Regulatory Affairs Director, Structural Heart, Medtronic

10:10 am Getting a Pediatric Device to Market – Regulatory Challenges and Solutions from the Corporate Experience
Small Company Perspective – *Bob Kroslowitz* – CEO, Berlin Heart
Large Company Perspective - *Lee Grant* - Distinguished Regulatory Affairs Advisor, Spine, Medtronic

10:30 am Pediatric Device Consortium and its Role in the Pediatric Medical Device Ecosystem
Chester Koh – Co-Founder and Co-PI of the Southern California Consortium for Technology and Innovation in Pediatrics(CTIP)

10:40 am Question and Answer

10:55 am **Public Comment**

11:30 am **Lunch Break: 1 hour**

Developing a Supportive Marketplace

12:30 pm Audience Poll Question

12:35 pm **Opening:** Outline Session Topics and Goals
Cara Tenenbaum – Senior Policy Advisor, Office of the Center Director, Center for Devices and Radiological Health, FDA

12:40 pm The Same but Different – Commonalities and Distinctions Between the Pediatric Drug and Device Markets – Just the Facts
Gabriel Movsesyan – Staff Fellow Economist, Office of Planning, FDA

12:50 pm Best Pharmaceuticals for Children Act/Pediatric Research Equity Act for Devices? - The Right Incentives for the Right Market
Sam Maldonado - Vice President of Child Health Innovation and Leadership Department, Johnson & Johnson

1:00 pm Financial Strategies/Models for Small and Large Companies: Addressing Economic Challenges
Andrew Lo – Charles E. and Susan T. Harris Professor and Director of the Laboratory for Financial Engineering, Sloan School of Management, Massachusetts Institute of Technology

1:10 pm How Does Reimbursement Impact Pediatric Device Development
Bob McDonough – Senior Director, Clinical Policy Research & Development, Aetna

1:20 am Question and Answer

1:35 pm ***Break: 15 minutes***

1:50 pm Medical Device Innovation Models
The many roads to successful early stage health technology development: Incubators, accelerators, and other ways to develop early stage ideas
James Kennedy Wall – Assistant Director at Biodesign Innovation Fellowship Program and Assistant Professor of Pediatric Surgery, Stanford University
Small Company Business Model
Mark Throdahl – President & CEO, OrthoPediatrics

The Non-profit/Academic Medical Center Model
Pedro del Nido – William E. Ladd Professor of Child Surgery, Harvard Medical School and Chairman, Department of Cardiovascular Surgery, Boston Children's Hospital

Federal-State-Private Partnerships
Tiffany Wilson – CEO, Global Center for Medical Innovation/T3 Labs

Philanthropic Model
Lijie Grace Zhang – Associate Professor, George Washington University, March of Dimes funding recipient

Venture Capital Perspective
John Parker -Founder and Managing Director, Springhood Ventures

2:50 pm Dear CEOs, What Will Incentivize You to Enter, Sustain and Innovate in the Pediatric Market? – The C-Suite Survey (CEOs for Children)
Mark Schlesinger – Department Chair and Professor of Public Health (Health Policy), Yale School of Public Health

3:00 pm Question and Answer

3:10 pm ***Break: 10 minutes***

The Next 10 Years: Steps Toward a Modern Medical Device Ecosystem for Adults and Children

3:20 pm **Directed Expert Panel Discussion**

James Baumberger
Eliane Schutte
Bob Kroslowitz
Chester Koh
Andy Lo
Bob McDonough
James Kennedy Wall
Mark Throdahl
Pedro del Nido
Tiffany Wilson
Lijie Grace Zhang
John Parker
Mark Schlesinger
Pieter Kappetein
Mike Billig

4:50 pm Closing Remarks
Vasum Peiris – Chief Medical Officer, Pediatrics and Special Populations, Office of the Center Director, Center for Devices and Radiological Health, FDA