

# Under the Microscope: Pediatric Product Development

- 8:00 - 8:30 Registration
- 8:30 - 8:35 Welcome**  
CDR Steve Morin, R.N., B.S.N  
Manager, Patient Network  
Office of Health and Constituent Affairs  
Food and Drug Administration
- 8:35 - 9:00 Historical Framework for Pediatric Product Development**  
Lynne Yao, M.D.  
Associate Director, Office of New Drugs  
Pediatric and Maternal Health Staff  
Food and Drug Administration
- 9:00 - 9:25 Challenges of Pediatric Product Development**  
Dianne Murphy, M.D. FAAP  
Director, Office of Pediatric Therapeutics  
Food and Drug Administration
- 9:25 - 9:50 Ethical Issues Impacting Pediatric Product Development**  
Robert "Skip" Nelson, M.D., Ph.D.  
Deputy Director, Office of Pediatric Therapeutics  
Food and Drug Administration
- 9:50 - 10:10** Question and Answer for previous presenters
- 10:10 - 10:25 Break
- 10:25 - 10:50 Health Disparities and its Impact on Pediatric Product Development**  
Jonca Bull, M.D.  
Director, Office of Minority Health  
Food and Drug Administration
- 10:50 - 11:15 Industry Perspective on Pediatric Product Development**  
Dr. Christina Bucci-Rechtweg, M.D.  
Head, Pediatric & Maternal Health Policy  
Global Drug Regulatory Affairs  
Novartis Pharmaceuticals Corporation
- 11:15 - 11:40 Community Perspective: Moving Pediatric Product Development Forward**  
Stephanie Krenrich  
*Cystic Fibrosis Foundation*
- 11:40 - 12:05 Clinical Trials Perspective**  
Peter J. Mogayzel, Jr., M.D., Ph.D., M.B.A,  
Professor of Pediatrics  
Director, Cystic Fibrosis Center  
Johns Hopkins Cystic Fibrosis Center
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- A young girl with curly hair is looking through a microscope. The image is semi-transparent and serves as a background for the text.

# Under the Microscope: Pediatric Product Development

12:05 – 12:20 Question and Answer for previous presenters

12:20 -1:30 Lunch *on your own*

**1:30 – 2:45 Panel Discussion: The challenges related to development of products used to treat pediatric patients, including pediatric patients with rare diseases.**

Moderator: **Dianne Murphy, M.D., FAAP,**

- Patient Perspective: **Nancy Goodman**, Kids V Cancer
- FDA Perspective: **Gregory Reaman, M.D.** , Food and Drug Administration
- Clinical Researcher Perspective: **Peter J. Mogayzel, Jr., M.D., Ph.D., M.B.A.**, Johns Hopkins Cystic Fibrosis Center
- Industry Perspective: **Lisa Percival**, Bristol-Myers Squibb

2:45 – 3:00 Break

**3:00 – 4:15 Panel Discussion: Explore ways that patients/caregivers, FDA, and Industry may work together to incorporate patient input in future pediatric product development and regulatory decision-making.**

Moderator: **Lynne Yao, M.D.**

- Patient Perspective: **Ruth Hoffman**, American Childhood Cancer Organization
- FDA Perspective: **Robert “Skip” Nelson, M.D., Ph.D.**, Food and Drug Administration
- Industry Perspective: **Mary A. Short**, Eli Lilly and Company
- Advocacy Organization Perspective: **Stephanie Krenrich**, Cystic Fibrosis Foundation

**4:15**

## **Closing Remarks**

Richard Klein

Director, Patient Liaison Program

Office of Health and Constituent Affairs

Food and Drug Administration

