Members Present (Voting)
Robert Dracker, MD, MHA, MBA, CPI (Chair)
Premchand Anne, MD, MBA, MPH, FACC
David Callahan, MD
Mary Cataletto, MD, FAAP
Randall Flick, MD, MPH
Peter Havens, MD, MS
Sarah Hoehn, MD, MBe, FAAP
Bridgette Jones, MD, MSc, FAIAI, FAAP
Randi Oster, MBA
Wael Sayej, MD
Christy Turer, MD, MHS, FAAP, FTOS
Kelly Wade, MD, PhD

Temporary Voting Members (Voting Consultants)
James McGough, MD
Peggy DiCapua

Non-Voting Members
Ronald Portman, MD, FAAP

Designated Federal Official (DFO)
Marieann Brill, MBA, RAC, MT (ASCP)

Welcome and Introductory Remarks
- Robert Dracker, Chair, Pediatric Advisory Committee
- Marieann Brill, Designated Federal Officer (DFO), read the usual, customary, and required conflict of interest statement.

Office of Pediatric Therapeutics:
- Susan McCune, Director, Office of Pediatric Therapeutics – provided a personnel update, a description of the publicly available information on the status of the STRIDER trial for sildenafil, an update on the Advancing the Development of Pediatric Therapeutics (ADEPT) 5 Workshop held in September, and a description of the publicly available information on CBER and CDER non-compliance letters.
- Judith Cope, Safety Team Lead, Office of Pediatric Therapeutics – provided an update on FDA’s ongoing analysis and review of neuropsychiatric adverse events with montelukast and a description of the updated labeling for Noxafil, an antifungal product which previously went to the PAC.

U.S. Food and Drug Administration (FDA) Participants

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<tr>
<th>Office of Pediatric Therapeutics</th>
<th>CDER OSE:</th>
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<tr>
<td>Susan McCune, MD</td>
<td>Steven Bird, PharmD, PhD</td>
<td>Howard Chazin, MD, MBA</td>
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<td>Judith Cope, MD</td>
<td>Vicky Chan, PharmD</td>
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<td>LCDR Kenneth Quinto, MD, MPH</td>
<td>Carmen Cheng, Pharm D</td>
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<td>CDER DPMH</td>
<td>Kate Gelperin, MD, MPH</td>
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<td>John Alexander, MD</td>
<td>Ivone Kim, MD</td>
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<td>Ethan Hausman, MD</td>
<td>Cindy Kortepeter, PharmD</td>
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<td>Mona Khurana, MD</td>
<td>Robert Levin, MD</td>
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<td>Amy Taylor, MD, MHS</td>
<td>Shekhar H. Mehta, PharmD, MS</td>
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<td>Courtney Suggs, PharmD, MPH</td>
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<td>Peter Waldron, MD</td>
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CDER OND
- Anthony Fotenos, MD, PhD
- Robert Lim, MD
- Marc Stone, MD
- David Miller

CDER OTS:
- Olanrewaju Okusanya, PharmD, MS
Open Public Hearing
An opening statement was read by Dr. Dracker, Chair.

One presentation was given by Dr. Srinivasan, National Center for Health Research regarding safety and efficacy of Lexapro in the pediatric population under twelve years of age. She also suggested a Black Box warning be added to the Intuniv label regarding the risk of aggression, suicidality, and homicidality and she stated that other treatments may be better.

Center for Drug Evaluation and Research (CDER):

Standard Review of Adverse Event Presentations

- Lexapro – Courtney Suggs, PharmD, MPH
  
  In addition to the Safety and Utilization Review, the PAC also discussed FDA’s recommendation for posting pediatric reviews without new risks or potential safety signals on the web in the future, and asked, “What are the Committee’s thoughts about web posting future reviews without new risks or potential safety signals, such as this current review?”

  Two additional presentations regarding generic drugs were included in the review presentation.
  - Drug Ineffective Postmarketing Reports in Drug Safety Surveillance – Cindy Kortepeter, PharmD
  - Generic Drug Development and Safety Evaluation – Howard Chazin, MD, MBA

  The PAC discussed Pediatric Safety Review which concluded that there were no new safety concerns. The PAC concurred with the FDA plan to continue ongoing post-marketing safety monitoring. (vote Yes - 11; No - 1; Abstained - 0)

- Intuniv (guanfacine ER) – Amy Taylor, MD, MHS
  
  The PAC discussed and concurred with the FDA plan to continue ongoing post-marketing safety monitoring to include: monitoring for suicidal ideation and behavior; pancreatic; and medication error involving name confusion. (vote Yes - 11; No - 1; Abstained - 0)

- Exjade (defer asirox) (no vote) – Peter Waldron, MD; Olanrewaju Okusanya, PharmD, MS; Mona Khurana, MD; Steven Bird, PharmD, PhD; Kate Gelperin, MD, MPH
  
  FDA presented the tracked safety issue and further analyses that were conducted over the past three years that led to recent labeling changes and health communications. This was in follow up to the request made at the September 2015 PAC meeting following a family’s report of a child with thalassemia who died of fever and dehydration after receiving Exjade.

Updates (no vote)

- Update on the Safety of Long Acting Beta Agonists (LABAs) – Robert Lim, MD
- Update on the FDA Approach to Safety Issue of Gadolinium Retention After Administration of Gadolinium-based Contrast Agents – Anthony Fotenos, MD, PhD
Adjournment

Robert Dracker, MD, MHA, MBA, CPI, Chair

These summary minutes for the September 20, 2018 meeting of the PAC were approved on October 12, 2018.

I certify that I attended the September 20, 2018 meeting of the Pediatric Advisory Committee and that these minutes accurately reflect what transpired.

/s/  /s/
Marieann Brill, MBA, RAC, MT (ASCP)  Robert Dracker, MD, MHA, MBA, CPI
Designated Federal Officer, PAC  Chair, PAC