PMC SCIENCE AND PUBLIC POLICY COMMITTEES
MEETING AGENDA

Tuesday, February 23, 12:00 – 2:00 p.m. ET
Link to webinar:
https://permedcoalition.webex.com/permedcoalition/onstage/g.php?MTID=e793b3354e13727374828aa3d27d4103d
(passcode: pmc123)
Dial 202-800-9984 and enter meeting ID 825756.
Note: You will be muted upon entry. Please dial 4* to unmute your line.

12:00 p.m. ET  Welcome & Introduction
Edward Abrahams
President
Personalized Medicine Coalition

- Expanding the Frontiers of Personalized Medicine Through Education, Advocacy, and Evidence Development: A Strategic Plan for Advancing the Field in 2021

12:10 p.m. ET  Personalized Medicine at FDA: 2020 Progress Report

- Michael A. Pacanowski, M.P.H, Pharm.D.
  Acting Director, Division of Translational and Precision Medicine
  Office of Clinical Pharmacology
  Center for Drug Evaluation and Research (CDER)
  U.S. Food and Drug Administration

- Robert Schuck, Ph.D., Pharm.D.
  Clinical Pharmacologist, Genomics and Targeted Therapy
  Office of Clinical Pharmacology
  Center for Drug Evaluation and Research
  U.S. Food and Drug Administration

12:30 p.m. ET  Business Meeting
Daryl Pritchard, Ph.D.
Senior Vice President, Science Policy
Personalized Medicine Coalition

- Science Policy Updates
  - Personalized Medicine at FDA: The Scope & Significance of Progress in 2020

- Research Program Study No. 4: "Improvements in Clinical Care Associated With Personalized Medicine" (Not Fully Funded)
- Research Program Study No. 8: "Addressing Disparities and Improving Health Equity in Research Advancing Personalized Medicine" (Not Fully Funded)
- Research Program Study No. 9: "Addressing Challenges in Using Health Data to Advance Personalized Medicine"

Pharmacogenomics

- Research Program Study No. 2: "Pharmacogenomics in Clinical Guidelines and at FDA" (In Progress)
- STRIPE: A Collaborative Community in Pharmacogenomics

Working Group Updates

- Pharmacogenomics Working Group
- Health Care Working Group
- Health Data Working Group

Cynthia A. Bens
Senior Vice President, Public Policy
Personalized Medicine Coalition

- Public Policy Updates

  Congressional Activities

  - Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020 (see also Senate version)
  - Ending the Diagnostic Odyssey Act and Advancing Access to Precision Medicine Act
  - Draft legislation to support research, treatment and awareness for rare cancers.
  - Proposal for Personalizing Medications Act
  - Additional legislative priorities in the new Congress

- Regulation

  - User fee program reauthorization
    - PMC comment letter on Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027 (November 27, 2020)
    - PMC’s remarks during FDA’s Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act (July 23, 2020)
  - FDA’s 2021 guidance agendas

- Coverage and Reimbursement

  - CMS’ Most Favored Nations Model Interim Final Rule
    - PMC comment letter (January 26, 2021)
- Working Group Updates
  - Pharmaceutical & Diagnostics Working Group
  - Patient Advocacy Organization Working Group

1:50 p.m. ET  New Business

2:00 p.m. ET  Conclusion

- Upcoming Public and Science Policy Committee Meetings
  - April 22, 2021, 12:00 – 2:00 p.m. ET
  - June 24, 2021, 12:00 – 2:00 p.m. ET
  - September 14, 2021, 12:00 – 2:00 p.m. ET
  - December 2, 2021, 12:00 – 2:00 p.m. ET