

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*](#)

- [*Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine: A Research Program Focused on Evaluating Progress in Health Care, Assessing Clinical and Economic Value, and Examining Clinical Integration Strategies*](#)
 - 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)
 - [STRIFE: 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