

PMC SCIENCE AND PUBLIC POLICY COMMITTEES MEETING AGENDA

Tuesday, September 14, 12:00 – 2:00 p.m. ET

Link to webinar:

<https://permedcoalition.webex.com/permedcoalition/onstage/g.php?MTID=ea05c259edb9f1dc5b4503de4275ef1a9>

(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

12:10 p.m. ET **Business Meeting**

Cynthia A. Bens

Senior Vice President, Public Policy
Personalized Medicine Coalition

- Discussion of PMC’s principles on regulatory oversight of laboratory-developed tests (LDTs) & the [Verifying Accurate Leading-edge IVCT Development \(VALID\) Act](#)
- Public Policy Updates
 - **Congressional Activities**
 - [Congressional Personalized Medicine Caucus](#)
 - *Congress and Personalized Medicine: The Perspectives of the Co-Chairs of the Personalized Medicine Caucus*
 - *21st Century Cures 2.0 Discussion Draft*
 - PMC [comment letter](#) (July 16, 2021)
 - [Sec. 407. Expanding Access to Genetic Testing](#) (aka *Advancing Access to Precision Medicine Act* and *Ending the Diagnostic Odyssey Act*)
 - FY 2022 Appropriations for FDA and NIH
 - PMC [outside witness testimonies](#) (May 2021)

- **Regulation**
 - User fee program reauthorization
 - Virtual [public meeting](#) on PDUFA Re-authorization (September 28, 2021)
 - PMC's [remarks](#) during FDA's *Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act* (July 23, 2020)
 - PMC [comment letter](#) on *Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027* (November 27, 2020)
 - STRIPE: A Collaborative Community in Pharmacogenomics ([website](#))
- **Coverage and Reimbursement**
 - CMS' Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule for FY 2022
 - PMC [comment letter](#) (June 28, 2021)
- **2022 Policy Agenda Planning**
 - 2022 Planning Discussion Questions (forthcoming)
- **Working Group Updates**
 - Pharmaceutical & Diagnostics Working Group
 - Patient Advocacy Organization Working Group

Daryl Pritchard, Ph.D.
Senior Vice President, Science Policy
Personalized Medicine Coalition

- **Science Policy Updates**
 - [***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. 7: "Addressing Clinical Practice Gaps in the Implementation of Personalized Medicine in Cancer Care"
 - [Research Program Study No. 4: "Improvements in Clinical Care Associated With Personalized Medicine"](#)
 - Research Program Study No. 8: "Addressing Disparities and Improving Health Equity in Research Advancing Personalized Medicine"
 - **Working Group Updates**
 - Pharmacogenomics Working Group
 - Health Care Working Group

1:20 p.m. ET New Business

1:30 p.m. ET The Future of Medicare and Medicaid Innovation in Personalized Medicine

- **Lara Strawbridge, M.P.H.**
Director, Division of Ambulatory Payment Models, Patient Care Models Group,
Centers for Medicare & Medicaid Services Innovation Center (CMMI)

2:00 p.m. ET Conclusion

- **Upcoming Public and Science Policy Committee Meetings**
 - December 2, 2021, 12:00 – 2:00 p.m. ET (virtual)