

PUBLIC AND SCIENCE POLICY COMMITTEES MEETING AGENDA

Wednesday, February 14, 2024, 12:00 – 2:00 p.m. ET

Virtually via Zoom:

<https://us02web.zoom.us/j/85121761174?pwd=VWZCeEtUb2d6T1RFMzlrTy8ydGtrdz09>

Meeting ID: 851 2176 1174 / Passcode: 551253

12:00 p.m. ET Welcome & Introduction

Christopher J. Wells, M.P.A.

Senior Vice President, Public Affairs
Personalized Medicine Coalition

- PMC's [2024 Strategic Plan](#)
- PMC's [2023-2024 Impact Report](#)

12:05 p.m. ET Business Meeting

Cynthia A. Bens

Senior Vice President, Public Policy
Personalized Medicine Coalition

- **Public Policy Updates**
 - **Congressional Activities**
 - [Congressional Personalized Medicine Caucus](#)
 - *Precision Medicine Answers for Kids Today Act* ([bill text](#) from previous Congress)
 - *Right Drug Dose Now Act of 2023* ([revised bill text](#)) and the *Pharmacogenomics Education and Research Act* ([bill text](#))
 - PMC [support letter](#) (April 20, 2023)
 - FY 2024 and FY 2025 appropriations for FDA and NIH
 - Previous PMC House and Senate [testimonies](#)
 - Artificial intelligence and machine learning (AI/ML)
 - **Regulation**
 - FDA [proposed rule](#) on laboratory-developed tests

- Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver proposals
 - PMC [comment letter](#) (May 5, 2023)
- Improving FDA-CMS coordination
 - PMC [comment letter](#) on Cures 2.0 (February 28, 2022)
 - Bipartisan Policy Center [report](#) on *Strengthening Regulatory Collaboration Between FDA and CMS*
- **Coverage and Reimbursement**
 - Prior authorization under CMS' [proposed rule](#) for *CY 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, etc.*
 - PMC [comment letter](#) (January 5, 2024)
 - CMS' *Transitional Coverage for Emerging Technologies* [proposal](#)
 - PMC [comment letter](#) (August 28, 2023)
 - CMMI's [Cell and Gene Therapy \(CGT\) Access Model](#)
 - Implementation of Medicare drug price negotiation under the *Inflation Reduction Act (IRA)*
 - PMC [comment letter](#) (April 18, 2023)
 - CMS' forthcoming FY 2025 *Inpatient Prospective Payment Systems (IPPS)* proposed rule
- **PMC's [2024 Policy Agenda](#)**
- **PMC Working Groups**
 - Pharmaceutical & Diagnostics Industry Working Group
 - Patient Advocacy Organization Working Group
 - Artificial Intelligence Working Group
 - Health Data Working Group
 - Inflation Reduction Act Working Group
 - Pharmacogenomics (PGx) Working Group

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy
Personalized Medicine Coalition

- **Science Policy Updates**

- ***Personalized Medicine at FDA: The Scope and Significance of Progress in 2023 (forthcoming)***

- [Implementing Precision Oncology Initiative: A Roadmap for Addressing Clinical Practice Gaps and Streamlining the Delivery of Personalized Medicine](#) (sponsorship opportunity)
- Forthcoming reports from PMC's [Research Program for Advancing Personalized Medicine in 2023](#)
 - *Addressing Disparities in Research Advancing Personalized Medicine*
 - *Improvements in Clinical Care Associated With Personalized Medicine*
 - *Payer Policies and Perspectives on Personalized Medicine*

1:30 p.m. ET ICER Perspective: Personalized Medicine and Value Assessment Frameworks

- **Sarah K. Emond, M.P.P.**
President and Chief Executive Officer
Institute for Clinical and Economic Review (ICER)

1:55 p.m. ET New Business

2:00 p.m. ET Conclusion

- **Upcoming Public and Science Policy Committee Meetings**
 - April 24, 2024, 12:00 – 2:00 p.m. ET
 - June 25, 2024, 12:00 – 2:00 p.m. ET
 - September 25, 2024, 12:00 – 2:00 p.m. ET
 - December 11, 2024, 12:00 – 2:00 p.m. ET