

PUBLIC AND SCIENCE POLICY COMMITTEES MEETING AGENDA

Wednesday, June 28, 2023, 12:00 – 2:00 p.m. ET
Foley & Lardner LLP
6th Floor Conference Room
3000 K Street NW, Washington, DC 20007

Zoom link: <https://us02web.zoom.us/j/88076318288?pwd=cUV2aGhzY2JzRlRvenh4ci9INVQxUT09>
Meeting ID: 880 7631 8288 / Passcode: 225190

12:00 p.m. ET Welcome & Introduction

Edward Abrahams
President
Personalized Medicine Coalition

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* ([bill text](#)) and the *Pharmacogenomics Education and Research Act* ([bill text](#))
 - PMC updated [support letter](#) (April 20, 2023)
 - FY 2024 appropriations for FDA and NIH
 - PMC House and Senate [testimonies](#)
 - Ad Hoc Group for Medical Research [sign-on letter](#) for NIH funding (March 14, 2023)

- S. 1000/H.R. 2377: *Saving Access to Laboratory Services Act (SALSA)*
 - ACLA [sign-on letter](#) (May 22, 2023)
- *Access to Genetic Counselor Services Act* ([factsheet](#))
- Artificial intelligence and machine learning (AI/ML)

12:30 p.m. ET Advancing Personalized Medicine in Congress

- **Lucas Lam**
Health Legislative Assistant
Office of Congressman Eric Swalwell (CA-15)
U.S. House of Representatives

1:00 p.m. ET Business Meeting (cont'd)

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

- **Public Policy Updates (cont'd)**
 - **Regulation**
 - Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver proposals
 - PMC [comment letter](#) (May 5, 2023)
 - FDA [rulemaking](#) on laboratory-developed tests (LDTs)
 - FDA [final guidance](#) on *Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program*
 - **Coverage and Reimbursement**
 - Implementation of Medicare drug price negotiation under the *Inflation Reduction Act (IRA)*
 - PMC [comment letter](#) (April 18, 2023)
 - Ways and Means Health Subcommittee Hearing on *Policies That Inhibit Innovation and Patient Access*
 - PMC [statement for the record](#) (May 23, 2023)
 - CMS [proposed rule](#) on *Transitional Coverage for Emerging Technologies* (comments due August 28, 2023)

- CMS payments for CAR T-cell therapies under the Inpatient Prospective Payment Systems (IPPS) proposed rule for FY 2024
 - PMC [comment letter](#) (June 9, 2023)

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy
Personalized Medicine Coalition

- **Science Policy Updates**
 - [A Research Program for Advancing Personalized Medicine in 2023](#)
(support opportunities available)
 - Study No. 1: “Payer Perspectives and Policies on Personalized Medicine: A Landscape Analysis” (Parts I and II)
 - FDA [Draft Guidance](#) on *Pharmacogenomic Data Submissions*
 - PMC [comment letter](#) (June 20, 2023)
 - Institute for Clinical and Economic Review (ICER)’s [2023 Value Assessment Framework Proposed Changes](#) (comments due June 30, 2023)
 - **Working Group Updates**
 - Pharmacogenomics (PGx) Working Group
 - Health Data Working Group

1:50 p.m. ET New Business

2:00 p.m. ET Conclusion

- **Upcoming Public and Science Policy Committee Meetings**
 - September 27, 2023, 12:00 - 2:00 p.m. ET
 - December 14, 2023, 12:00 - 2:00 p.m. ET