

## PUBLIC AND SCIENCE POLICY COMMITTEES MEETING AGENDA

Wednesday, September 27, 2023, 12:00 – 2:00 p.m. ET  
Foley & Lardner LLP  
6<sup>th</sup> Floor Conference Room  
3000 K Street NW, Washington, DC 20007

Zoom link: <https://us02web.zoom.us/j/85314797637?pwd=MjdKU3RFZHZweFJ2Y0wxL3YzREZsUT09>  
Meeting ID: 853 1479 7637 / Passcode: 563350

### 12:00 p.m. ET **Welcome & Introduction**

**Edward Abrahams**  
President  
Personalized Medicine Coalition

- PMC's [17th Annual Personalized Medicine Conference](#)  
November 30 – December 1, 2023 in Dana Point, CA

### 12:05 p.m. ET **Personalized Medicine and Medicare's Drug Price Negotiation Program**

- **Christina Ritter**  
Director, Medicare Drug Rebate and Negotiations Group  
Center for Medicare  
U.S. Centers for Medicare and Medicaid Services (CMS)

### 12:35 p.m. ET **Business Meeting**

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

- **Science Policy Updates**
  - ***A Research Program for Advancing Personalized Medicine***
    - Major New Initiative: "Implementing Precision Oncology"  
(sponsorship opportunity)
      - [Implementing Precision Oncology: Partnering with Health Care Providers to Address Clinical Practice Gaps and Streamline the Delivery of Personalized Medicine](#)

- Current project: “Addressing Disparities in Research Advancing Personalized Medicine”

**David Davenport**

Manager, Public and Science Policy  
Personalized Medicine Coalition

- **PMC’s 2024 Strategic Planning Process**
  - [Planning discussion questions](#) (feedback due by October 5, 2023)

**Cynthia A. Bens**

Senior Vice President, Public Policy  
Personalized Medicine Coalition

- **Public Policy Updates**

- **Regulation**

- FDA [final guidance](#) on *Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program*
- FDA rulemaking on laboratory-developed tests (see [unified agenda](#))
  - PMC’s [principles](#) on regulatory oversight of diagnostics
- Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver proposals
  - PMC [comment letter](#) (May 5, 2023)

- **Coverage and Reimbursement**

- CMS’ *Transitional Coverage for Emerging Technologies* proposal and *Coverage with Evidence Development* proposed guidance
  - PMC [comment letter](#) (August 28, 2023)
- CMS reconsideration of national coverage for beta amyloid PET scans in dementia and neurodegenerative disease
  - PMC [comment letter](#) (August 16, 2023)
- Quality measures under CMS’ CY 2024 *Physician Fee Schedule (PFS)* proposed rule
  - PMC [comment letter](#) (September 11, 2023)
- CMS payments for CAR T-cell therapies under the FY 2024 *Inpatient Prospective Payment Systems (IPPS)* proposed rule
  - PMC [comment letter](#) (June 9, 2023)

- Novitas and First Coast Service Options' proposed local coverage determination on *Genetic Testing for Oncology*
  - PMC [comment letter](#) (September 8, 2023)

- **Congressional Activities**

- [Congressional Personalized Medicine Caucus](#)
  - Update from Jennifer Walsh, Director of Public Affairs, Foley & Lardner LLP
- *Precision Medicine Answers for Kids Today Act* ([bill text](#) from previous Congress)
- 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)
- Artificial intelligence and machine learning (AI/ML)

**1:50 p.m. ET    New Business**

**2:00 p.m. ET    Conclusion**

- **Upcoming Public and Science Policy Committee Meetings**

- December 14, 2023, 3:00 - 5:00 p.m. ET (\*new time\*)