

PMC SCIENCE AND PUBLIC POLICY COMMITTEES MEETING AGENDA

Tuesday, April 19, 2022, 12:00 – 2:00 p.m. ET

Link to webinar:

<https://permedcoalition.webex.com/permedcoalition/onstage/g.php?MTID=e0b6fba0f5833cab968fcebe2c4026c58>

(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

12:05 p.m. ET Medicare Policy and Innovation in Personalized Medicine

- **Bruce Quinn, M.D., Ph.D.**

Principal

Bruce Quinn Associates LLC

- [“Valunomics: Medicare Policy: How It Can Boost or Block Innovation”](#) in *Inside Precision Medicine*

12:20 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](#)

- *Right Drug Dose Now Act* (Reps. Swalwell and Emmer [press release](#))

- PMC [support letter](#) (December 20, 2021)

- *Precision Medicine Answers for Kids Today Act* (H.R. 5989) (Reps. Swalwell, Peters and Emmer [press release](#))
 - PMC [support letter](#) (December 20, 2021)
- *Cures 2.0 Act* (H.R. 6000) (Reps. DeGette and Upton [press release](#))
 - PMC comment letter (February 28, 2022)
- *The Advanced Research Projects Agency-Health (ARPA-H) Act* (H.R. 5585)
- FY 2022 and 2023 appropriations for FDA and NIH
 - PMC [outside witness testimonies](#) (May 2021)
- **Regulation**
 - FDA Draft Guidances on CAR T-cell Therapy and Gene Editing
 - [Considerations for the Development of Chimeric Antigen Receptor \(CAR\) T Cell Products: Draft Guidance for Industry](#)
 - [Human Gene Therapy Products Incorporating Human Genome Editing: Draft Guidance for Industry](#)
 - User fee program reauthorization
 - PMC's [remarks](#) during FDA's *Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act* (September 28, 2021)
 - PMC [comment letter](#) on *Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027* (November 27, 2020)
 - Accelerated approval pathway proposals
- **Coverage and Reimbursement**
 - CMS [Transmittal 10832](#) removing “not otherwise specified” codes from use under [National Coverage Determine \(NCD\) 90.2 on Next-Generation Sequencing](#) in cancer
 - CMMI's *Oncology Care First Model*
 - CMS' *Transitional Coverage for Emerging Technologies* pathway
- **Tracking PMC members' policy issue expertise**
- **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**

- **PMC's [Research Program for Advancing Personalized Medicine in 2022](#)**

- Study No. 2: "Pharmacogenomics in Clinical Guidelines and at FDA"
 - ["Comparison of FDA Table of Pharmacogenetic Associations and Clinical Pharmacogenetics Implementation Consortium guidelines"](#) in *American Journal of Health-System Pharmacy*
- Study No. 4: "Evaluating the Clinical and Economic Value of Sequencing-Based Diagnostic Tests for Patients With Rare and Undiagnosed Diseases"
 - ["Cost-Effectiveness of Exome and Genome Sequencing for Children With Rare and Undiagnosed Conditions"](#) in *Genetics in Medicine*
- Study No. 5: "Improvements in Clinical Care Associated With Personalized Medicine"
- Study No. 9: "Addressing Disparities in Research Advancing Personalized Medicine"
- Study No. 6: "Defining the Clinical Utility of Genomic Testing in Cancer Care"
 - ["Clinical Utility of Genomic Testing in Cancer Care"](#) in *JCO Precision Oncology*

1:50 p.m. ET New Business

2:00 p.m. ET Conclusion

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

- June 9, 2022, 12:00 – 2:00 p.m. ET