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=e0b6fba0f5833cab968fcedebe2c4026c58
(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)
  - 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      - *Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products: Draft Guidance for Industry*
      - *Human Gene Therapy Products Incorporating Human Genome Editing: Draft Guidance for Industry*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