PMC SCIENCE AND PUBLIC POLICY COMMITTEES
MEETING AGENDA

Tuesday, September 14, 12:00 – 2:00 p.m. ET
Link to webinar: https://permedcoalition.webex.com/permedcoalition/onstage/g.php?MTID=ea05c259edb9f1dc5b4503de4275ef1a9
(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

12:10 p.m. ET  Business Meeting

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

- Discussion of PMC’s principles on regulatory oversight of laboratory-developed tests (LDTs) & the Verifying Accurate Leading-edge IVCT Development (VALID) Act

- Public Policy Updates
  - Congressional Activities
    - Congressional Personalized Medicine Caucus
      - Congress and Personalized Medicine: The Perspectives of the Co-Chairs of the Personalized Medicine Caucus

    - 21st Century Cures 2.0 Discussion Draft
      - PMC comment letter (July 16, 2021)
      - Sec. 407. Expanding Access to Genetic Testing (aka Advancing Access to Precision Medicine Act and Ending the Diagnostic Odyssey Act)

    - FY 2022 Appropriations for FDA and NIH
      - PMC outside witness testimonies (May 2021)
o **Regulation**
  - User fee program reauthorization
    - Virtual public meeting on PDUFA Re-authorization (September 28, 2021)
    - PMC’s remarks during FDA’s Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act (July 23, 2020)
    - PMC comment letter on Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027 (November 27, 2020)
  - STRIPE: A Collaborative Community in Pharmacogenomics (website)

o **Coverage and Reimbursement**
  - CMS’ Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule for FY 2022
    - PMC comment letter (June 28, 2021)

o **2022 Policy Agenda Planning**
  - 2022 Planning Discussion Questions (forthcoming)

o **Working Group Updates**
  - Pharmaceutical & Diagnostics Working Group
  - Patient Advocacy Organization Working Group

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

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- **Science Policy Updates**

    - Research Program Study No. 7: “Addressing Clinical Practice Gaps in the Implementation of Personalized Medicine in Cancer Care”
    - Research Program Study No. 4: “Improvements in Clinical Care Associated With Personalized Medicine”
    - Research Program Study No. 8: "Addressing Disparities and Improving Health Equity in Research Advancing Personalized Medicine"

  o **Working Group Updates**
    - Pharmacogenomics Working Group
    - Health Care Working Group
1:20 p.m. ET  New Business

1:30 p.m. ET  The Future of Medicare and Medicaid Innovation in Personalized Medicine

- **Lara Strawbridge, M.P.H.**
  Director, Division of Ambulatory Payment Models, Patient Care Models Group, Centers for Medicare & Medicaid Services Innovation Center (CMMI)

2:00 p.m. ET  Conclusion

- **Upcoming Public and Science Policy Committee Meetings**
  - December 2, 2021, 12:00 – 2:00 p.m. ET (virtual)