PMC SCIENCE AND PUBLIC POLICY COMMITTEES
MEETING AGENDA

Wednesday, March 2, 2022, 12:00 – 2:00 p.m. ET

Link to webinar:
https://permedcoalition.webex.com/permedcoalition/onstage/g.php?MTID=eeaf74ba484879e0b5065b10d6346918d
(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  Personalized Medicine at FDA

- Daryl Pritchard, Ph.D. (moderator)
  Senior Vice President, Science Policy
  Personalized Medicine Coalition

- Michael A. Pacanowski, M.P.H., Pharm.D.
  Director, Division of Translational and Precision Medicine
  Office of Clinical Pharmacology
  Center for Drug Evaluation and Research (CDER)
  U.S. Food and Drug Administration

- Wendy Rubinstein, M.D., Ph.D.
  Director, Personalized Medicine
  Office of In Vitro Diagnostics and Radiological Health
  Center for Devices and Radiological Health (CDRH)
  U.S. Food and Drug Administration
12:35 p.m. ET  Business Meeting

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

- Science Policy Updates
  - Personalized Medicine at FDA: The Scope & Significance of Progress in 2021
  - PMC's Research Program for Advancing Personalized Medicine in 2022
    - 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
    - Study No. 5: “Improvements in Clinical Care Associated With Personalized Medicine”
    - Study No. 9: “Addressing Disparities in Research Advancing Personalized Medicine”

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

- Public Policy Updates
  - Congressional Activities
    - Congressional Personalized Medicine Caucus
    - Cures 2.0 Act (H.R. 6000) (Reps. DeGette and Upton press release)
      - PMC comment letter (February 28, 2022)
    - Precision Medicine Answers for Kids Today Act (H.R. 5989) (Reps. Swalwell, Peters and Emmer press release)
      - PMC support letter (December 20, 2021)
    - Right Drug Dose Now Act (Reps. Swalwell and Emmer press release)
      - PMC support letter (December 20, 2021)
    - Telehealth Extension and High-Cost Laboratory Test Sign-On Letter
- 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)
  - Ad Hoc Group sign-on letter (November 15, 2021)

- Regulation
  - 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)

- Coverage and Reimbursement
  - NGS LCD on Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (revisions published February 2, 2022)
  - CMS’ Transitional Coverage for Emerging Technologies pathway

- PMC’s 2022 Policy Agenda

- Tracking PMC members’ policy issue expertise

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

1:50 p.m. ET  New Business

2:00 p.m. ET  Conclusion

- Upcoming Public and Science Policy Committee Meetings
  - April 19, 2022, 12:00 – 2:00 p.m. ET
  - June 9, 2022, 12:00 – 2:00 p.m. ET