

PMC SCIENCE AND PUBLIC POLICY COMMITTEES MEETING AGENDA

Wednesday, April 21, 12:00 – 2:00 p.m. ET Link to webinar:

https://permedcoalition.webex.com/permedcoalition/onstage/g.php?MTID=e2bf7fe3adcc1b6bbb48ff be9f67bd8a5

(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

Advancing Personalized Medicine Through Inclusive Biomedical Research (<u>register</u>

here)

April 22, 2021

10:00 a.m. - 11:30 a.m. ET

12:05 p.m. ET Precision Public Health and Personalized Medicine at the U.S. Centers for Disease Control and Prevention

Muin J. Khoury M.D., Ph.D.

Director, Office of Genomics and Precision Public Health U.S. Centers for Disease Control and Prevention

- Background Materials
 - <u>"From Public Health Genomics to Precision Public Health: A 20-year Journey," Genetics in Medicine</u>
 - o From Public Health Genomics to Precision Public Health (slide deck)

12:30 p.m. ET Business Meeting

Cynthia A. Bens

Senior Vice President, Public Policy Personalized Medicine Coalition

• Public Policy Updates



- Consistent Testing Terminology in Cancer: An Update From the LUNGevity Foundation's Consistent Testing Terminology Working Group
 - Working Group Website
 - Consistent Common Cancer Testing Terms: An Infographic
 - Recommended Terms for Providers Discussing Biomarker and Germline Genetic Testing Patients: A Reminder Card
 - A White Paper on the Need for Consistent Terms for Testing in Precision Medicine

Congressional Activities

- Congressional Personalized Medicine Caucus (webpage)
- <u>Ending the Diagnostic Odyssey Act</u> and <u>Advancing Access to Precision</u>
 <u>Medicine Act</u>
- Proposal for Personalizing Medications Act
- Improving Seniors' Timely Access to Care Act of 2020 (revised bill text)
- FY 2022 Appropriations for FDA and NIH (previous PMC testimonies)

Regulation

- User fee program reauthorization
 - PMC <u>comment letter</u> on *Medical Device User Fee* Amendments for Fiscal Years 2023 Through 2027 (November 27, 2020)
 - PMC's <u>remarks</u> during FDA's Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act (July 23, 2020)

Coverage and Reimbursement

- CMS' Medicare Coverage of Innovative Technologies (MCIT) Pathway for Breakthrough Devices and Definition of "Reasonable and Necessary" Delayed Final Rule
 - PMC comment letter (April 16, 2021)
- MedPAC Report on Telehealth in Medicare after the coronavirus public health emergency

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
 - Personalized Medicine and Infectious Diseases: An Update From the Partnership to Fight Infectious Disease



- "A Quantitative Framework for Measuring Personalized Medicine
 Integration into US Healthcare Delivery Organizations" in the Journal of Personalized Medicine
- Understanding and Delivering the Clinical and Economic Benefits of
 Personalized Medicine: A Research Program Focused on Evaluating Progress
 in Health Care, Assessing Clinical and Economic Value, and Examining Clinical
 Integration Strategies
 - 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"
- Working Group Updates
 - Pharmacogenomics Working Group
 - Health Care Working Group
 - Health Data Working Group

1:50 p.m. ET New Business

- State bills to remove prior authorization requirements for biomarker testing in advanced cancer
 - o S.B. 535 in California
 - o S.D. 1084 in Massachusetts
 - o H.B. 1779 in Illinois

2:00 p.m. ET Conclusion

- Upcoming Public and Science Policy Committee Meetings
 - o June 24, 2021, 12:00 2:00 p.m. ET
 - o September 14, 2021, 12:00 2:00 p.m. ET
 - o December 2, 2021, 12:00 2:00 p.m. ET