

## 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](#)
  - *Cancer Patient Equity Act* (H.R. 5377) (Rep. Butterfield [press release](#))

- 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