

PMC SCIENCE AND PUBLIC POLICY COMMITTEES MEETING AGENDA

Tuesday, June 25, 2019, 12:00 – 2:00 p.m. ET
Concourse Large Room (C-115)
Center for Strategic & International Studies (CSIS) building
1616 Rhode Island Ave. NW
Washington, D.C. 20036

12:00 p.m. ET Welcome & Introduction

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

12:10 p.m. ET Business Meeting

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Senior Vice President, Public Policy
Personalized Medicine Coalition

- **Public Policy Updates**

- Draft Legislation Changing Section 101 of U.S. Patent Law
 - [Press release by Office of Sen. Thom Tillis \(R-NC\)](#)
- Coverage of Next-Generation Sequencing Tests for Advanced Cancer
 - [PMC comment letter on CMS' re-opened national coverage determination](#) (submitted May 2019)
- Coverage for and Reimbursement of CAR T-cell Therapies
 - [PMC comment letter on CMS' proposed decision memo](#) (submitted March 2019)
 - [PMC comment letter on CMS' fiscal year 2020 Medicare hospital inpatient prospective payment system \(IPPS\) proposed rule](#) (submitted June 2019)
- Congressional Personalized Medicine Caucus
- *Access to Genetic Counselor Services Act of 2019* (H.R. 3235)
 - [Press release by Office of Rep. Dave Loebsack \(D-IA\)](#)
- FDA's Center for Devices and Radiological Health's [Priority List of Patient Preference Sensitive Areas](#)

- **Public Policy Updates (cont'd)**

- Fiscal Year 2020 Appropriations for FDA and the U.S. National Institutes of Health
 - [PMC outside witness testimonies](#) (submitted April/May 2019)
- Pharma & Diagnostics Working Group and Patient Advocacy Organization Working Group Updates
- PMC's Engagement Award from the Patient-Centered Outcomes Research Institute (PCORI)

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy
Personalized Medicine Coalition

- **Science Policy Updates**

- ICER's 2020 value assessment framework
 - [PMC comment letter](#) (submitted June 2019)
- PMC's [Defining the Clinical Utility of Genomic Profiling in Cancer Care](#)
- PMC's [Consumer Guide to Direct-to-Consumer Genetic Testing](#)
- The Clinical and Economic Value of NGS in Cancer
- PMC's *Analysis of the Landscape for Clinical Implementation of Personalized Medicine in the U.S.*
- Updating PMC's [Personalized Medicine Report](#)

New Business

1:30 p.m. ET The Future of Personalized Medicine and Real-World Evidence at FDA

Introduction:

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy
Personalized Medicine Coalition

Guest Speaker:

Leonard Sacks, M.D.

Associate Director, Clinical Methodology
Office of Medical Policy, Center for Drug Evaluation and Research
U.S. Food and Drug Administration