

Action Items: Meeting of PMC's Public and Science Policy Committees February 27, 2020

During the February 27, 2020, meeting of its Public and Science Policy Committees, shortly before the COVID-19 pandemic took its foothold, PMC members discussed the latest developments in personalized medicine as well as the priorities in education, advocacy, and evidence development that would frame its activities for the first part of the year. Below, please find a summary of the action items discussed. We invite your engagement in the following activities.

1. **Supporting [PMC's Research Program Studying the Clinical and Economic Utility of Personalized Medicine in Multiple Disease States](#).** To develop evidence that personalized medicine improves clinical outcomes while making health care more efficient and therefore less costly, we shared a [sponsorship prospectus](#) calling on organizations from multiple sectors of the health care ecosystem to support a research program tackling issues across a wide spectrum of topics. The prospectus includes ten research projects in various stages of progress that will help advance personalized medicine. If you or your organization are interested in being involved in or supporting these projects, please contact Daryl Pritchard at dpritchard@personalizedmedicinecoalition.org and/or Kayla Smith at ksmith@personalizedmedicinecoalition.org.

2. **Joining PMC's various working groups.** In addition to its Public and Science Policy Committees, PMC has a number of working groups to convene our members representing particular perspectives from the community and our members sharing an interest in specific topics. If you are interested in joining any of the following working groups, please contact David Davenport at ddavenport@personalizedmedicinecoalition.org.
 - a. PMC's **Pharmaceutical & Diagnostics Working Group** provides a forum for our pharmaceutical and diagnostic industry members to inform PMC's policy strategy and advocacy activities related to research and development, regulatory oversight, reimbursement, payment reform, and health care quality. The group meets quarterly and as needed by phone.
 - b. PMC's **Patient Advocacy Organization Working Group** provides a forum for our patient advocacy organization members to inform PMC's policy strategy, align on legislative priorities, and develop shared messages that can empower individual patients to advocate for policies that bring personalized medicine closer to them. The group meets quarterly and as needed by phone.
 - c. PMC's **Health Care Working Group** provides a forum for our members involved in health care delivery to discuss common challenges and potential solutions for integrating personalized medicine into clinical practice. The group meets as needed by phone to provide strategic advice, support, and work product evaluation on issues and projects related to PMC's *Integration of Personalized Medicine into Health Care* initiatives.

- d. PMC's **Intellectual Property Working Group** will convene members who have an interest in and expertise with intellectual property (IP) issues and will be charged with developing consensus principles on how IP can continue to foster innovations relating to personalized medicine and provide high-quality patent examination that allows patents of appropriate scope and quality. The group will meet as needed by phone.
 - e. PMC's **Pharmacogenomics Working Group** (new in 2020) convenes members with interest or expertise in issues related to pharmacogenomic (PGx) testing. The group will meet as needed by phone to guide PMC's efforts in the PGx space, including our engagement with FDA, clinical guidelines developers, and other stakeholders, as well as a PMC-led landscape analysis of PGx in clinical guidelines.
 - f. PMC's **Value Assessment Framework Working Group** convenes members with interest or expertise in value assessment policies and practices. The group meets as needed by phone to discuss challenges and strategies for appropriately accounting for personalized medicine in value and health technology assessments.
 - g. PMC's **Information Management Working Group** (new in 2020) will convene members with expertise and interest in information technology, data, real-world evidence, and privacy issues. The group will meet as needed by phone to help develop PMC principles encouraging institutions to share data in ways that keep patients engaged as fully informed research partners.
3. **Asking members of Congress to join the Congressional Personalized Medicine Caucus.** Earlier this year, Sens. Tim Scott (R-SC) and Kyrsten Sinema (D-AZ) and Reps. Eric Swalwell (D-CA) and Tom Emmer (R-MN) launched the bicameral, bipartisan Personalized Medicine Caucus to cultivate support for personalized medicine in Congress and advocate for policies supporting its advancement to benefit patients and the United States' health care system. You can download materials, including a PMC press release, "dear colleague" letters to House and Senate members, and an overview of the caucus, [here](#). If you have any questions or are interested in pitching membership in the caucus to your members of Congress or to offices your organization has relationships with, please contact Cynthia Bens at cbens@personalizedmedicinecoalition.org.
 4. **Contributing to the drafting of comment letters or other statements of PMC's policy positions.** During the meeting, PMC members discussed its plans to engage a variety of policy opportunities covering reimbursement policy, regulatory policy, and government appropriations. If you are interested in participating in any of the following policy efforts, please contact Cynthia Bens at cbens@personalizedmedicinecoalition.org. PMC will continue to share drafts of comment letters for the committees' feedback and review before submitting.
 - a. **Congressional Activities**
 - **Reforming Regulatory Oversight of Diagnostic Tests:** Since PMC's policy principles (see comments [here](#)) are three years old, PMC will convene interested members to review and discuss the possibility of updating those principles. If you are interested in contributing to the preliminary discussion, please contact Cynthia Bens at cbens@personalizedmedicinecoalition.org.

- **H.R. 5741: *Strengthening Innovation in Medicare and Medicaid Act*** ([more information](#)): PMC members agreed to join a sign-on letter led by the Part B Access Coalition to support this bill, which would establish guardrails for the Center for Medicare and Medicaid Innovation (CMMI). The [letter](#) was published March 10.
 - **FY 2021 Appropriations for the National Institutes of Health and the Food and Drug Administration:** PMC members supported increased funding for the NIH and FDA in Fiscal Year 2021. In March and April, PMC submitted [outside witness testimonies](#) to appropriations subcommittees in the House and Senate highlighting the impact of increased funding for these agencies on important initiatives for personalized medicine. We encourage you to reference these programs in your own advocacy efforts.
- b. **Coverage and Reimbursement**
- **Establishing an MS-DRG for CAR T-cell therapies:** PMC members supported sending a letter to CMS encouraging the agency to create a new Medicare Severity-Diagnosis Related Group, or MS-DRG, to improve reimbursement for CAR T-cell therapies. In April, PMC sent the [letter](#) to CMS highlighting the importance of establishing an adequate, permanent Medicare reimbursement solution in fiscal year 2021 to ensure continued patient access to CAR T-cell therapy.
- c. **Regulation**
- **Activities in PGx:** PMC members supported the formation of a new Pharmacogenomics Working Group to inform the Coalition’s next steps in engaging any potential collaborative community with FDA and conducting a landscape analysis of pharmacogenomics in clinical guidelines. To join the group, please contact David Davenport at ddavenport@personalizedmedicinecoalition.org.

In case you missed it, at the beginning of this year PMC also:

- Finalized its [2020 Strategic Plan](#)
- Finalized its [2020 Policy Agenda](#)
- Published [Personalized Medicine at FDA: The Scope & Significance of Progress in 2019](#), an annual review of how FDA’s recent approvals and clearance decisions expand the frontiers of personalized medicine for the benefit of patients and health systems.

We look forward to our **next meeting of the Public and Science Policy Committees on May 7, 12:00 – 1:00 p.m. ET**, where we will discuss with PMC members our latest activities to advance personalized medicine against the backdrop of the COVID-19 pandemic. The meeting will be held virtually. To join, please [register here](#).