PMC
PERSONALIZED
MEDICINE COALITION

September 16, 2019

The Honorable Eric Swalwell
U.S. House of Representatives
407 Cannon House Office Building
Washington, DC 20003

Re: Support for the "Advancing Access to Precision Medicine Act"

Dear Representative Swalwell:

On behalf of the Personalized Medicine Coalition (PMC), which represents more than 200 innovators, scientists, patients, providers, and payers to promote the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system, I am writing to share our support for the reintroduction of the "Advancing Access to Precision Medicine Act."

PMC defines personalized medicine as a field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history and other clinical information, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans.

There is a critical need for the National Academy of Medicine (NAM) study on the use of genetic and genomic testing to improve health care that is detailed in the bill, particularly its provision addressing how evidence for clinical utility should be measured in order to improve health care outcomes. We also appreciate that the NAM study will examine how the Centers for Medicare & Medicaid Services may make coverage determinations that better suit a "precision medicine approach" to treatment. Given that studies defining the levels of evidence necessary to establish clinical utility can sometimes be cost prohibitive, we believe that NAM's report will be helpful in identifying ways to facilitate patient access to personalized medicine.

Furthermore, in response to comments PMC provided on previous versions of the bill, we are pleased to see the inclusion of a consultation section requiring NAM to consult with a diverse group of stakeholders. Clinical laboratories that develop and perform genetic and genomic testing would provide valuable feedback, and their participation should be sought alongside the other stakeholders mentioned. We strongly encourage that clinical laboratories be considered under the categories of "health professional organizations" or "other health professionals." "Health professional" representation should include primary care physicians, molecular pathologists and other thought leaders. In addition, to ensure that the study accounts for all populations in examining how genetic and genomic testing may reduce health disparities, we also encourage the "patients" and "patient organizations" included in the consultation to be racially and ethnically diverse.

Finally, we believe the bill's provisions to establish a state option that would provide DNA sequencing clinical services for certain children on Medicaid who have unresolved diseases

with suspected genetic causes will enable patient access to services that otherwise would be financially out of reach. Your efforts to expand coverage will also help determine the role sequencing plays in settling a child's diagnostic odyssey, improving their clinical outcomes, and reducing program expenditures. We understand that this language was informed by patients, clinicians, industry and other stakeholders. As a coalition representing these constituencies, we commend your efforts to incorporate their views.

Thank you for your leadership on this bill, which calls attention to the promise of personalized medicine. We look forward to seeing it advance this year. If you have any questions about the content of this letter, please contact me at cbens@personalizedmedicinecoalition.org or 202-589-1769.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy