



February 14, 2018

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

Re: “Advancing Access to Precision Medicine Act”

Dear Representative Swalwell:

On behalf of the Personalized Medicine Coalition (PMC), which represents 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 coalition’s support for the “Advancing Access to Precision Medicine Act.”

PMC defines personalized medicine as an emerging 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. The goal is to provide the right treatment in the right dose to the right patient at the right time.

We appreciate that the bill directs the National Academy of Medicine (NAM) to study the use of genetic and genomic testing to improve health care, and support in particular the provision addressing the need to develop evidence for the clinical utility and appropriate use of genetic and genomic tests. There is a critical need to describe how evidence for clinical utility should be measured in order to improve health care outcomes and reduce inefficiencies.

Our coalition also appreciates 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 our previous comments requesting the study to define from its outset criteria to measure improved health outcomes, we are pleased to see the addition of a consultation section on page 4 requiring the 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. Therefore, we strongly encourage that clinical laboratories be considered under the categories of “health professional organizations” or “other health professionals.” In addition, to ensure that the study accounts for “all populations” in examining how genetic and genomic testing may reduce health disparities, as mentioned in

BOARD OF DIRECTORS

**President**

*Edward Abrahams, Ph.D.*

**Chair**

*Stephen L. Eck, M.D., Ph.D.*  
Aravive Biologics

**Vice Chair**

*Jay G. Wohlgenuth, M.D.*  
Quest Diagnostics

**Treasurer**

*Peter Maag, Ph.D.*  
CareDx

*Bonnie J. Addario*  
Bonnie J. Addario Lung Cancer  
Foundation

*Steven D. Averbuch, M.D.*  
Bristol-Myers Squibb Company

*Paul R. Billings, M.D., Ph.D.*  
Biological Dynamics, Inc.

*William W. Chin, M.D.*  
PhRMA

*Donna Cryer, J.D.*  
Global Liver Institute

*William S. Dalton, Ph.D., M.D.*  
M2Gen

*Tim Garnett, FRCOG, MFFP, FFPM*  
Eli Lilly and Company

*Brad Gray*  
NanoString Technologies

*Kris Joshi, Ph.D.*  
Change Healthcare

*Anne-Marie Martin*  
Novartis

*Susan McClure*  
Genome magazine

*Howard McLeod, Pharm.D.*  
Moffitt Cancer Center

*J. Brian Munroe*  
Endo Pharmaceuticals

*Lincoln Nadauld, M.D., Ph.D.*  
Intermountain Healthcare

*Michael Pellini, M.D.*  
Foundation Medicine

*Kimberly J. Popovits*  
Genomic Health

*Hakan Sakul, Ph.D.*  
Pfizer, Inc.

*Michael S. Sherman, M.D., M.B.A.*  
Harvard Pilgrim Health Care

*Michael Vasconcelles, M.D.*  
Unum Therapeutics

*Werner Verbiest*  
Janssen Diagnostics

Section 2, we also encourage the “patients” and “patient organizations” included in the consultation to be racially and ethnically diverse.

PMC appreciates your leadership in calling attention to the promise of personalized medicine. We believe that this bill should receive bipartisan support and look forward to seeing it advance this year. If you have any questions about the content of this letter, please contact me or David Davenport, PMC’s Public Policy Manager, at 202-589-1700.

Sincerely,



Cynthia A. Bens  
Senior Vice President, Public Policy