



April 3, 2024

The Honorable Bill Cassidy, M.D.  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate  
Washington, D.C. 20510

**Re: Request for Information (RFI) on ways to improve regulation of clinical tests in the United States**

Dear Ranking Member Cassidy:

The Personalized Medicine Coalition (PMC) is a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum. Established 20 years ago, PMC brings together 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. PMC appreciates your continued efforts to explore issues affecting diagnostics regulation and patient access to clinical tests. Your recent request for information (RFI) presents an opportunity for Congress to identify legislative actions it can take to strike an appropriate balance between regulation, innovation, and access to diagnostic tests that underpin personalized medicine.

Personalized medicine is a rapidly evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Many patients have benefited from innovative personalized medicine tests that have drastically changed how disease is treated. As highlighted in the RFI, diagnostic technologies are the cornerstone of precision medicine and personalized therapies.<sup>i</sup> In fact, PMC has found that more than a third of treatments approved each year by the U.S. Food and Drug Administration (FDA) are personalized medicines that rely on diagnostics to guide their use.<sup>ii</sup>

Diagnostic tests have historically fallen into two main categories: laboratory-developed tests (LDTs) and in vitro diagnostic kits (IVDs). An LDT is developed and performed within a single laboratory entity. IVDs are products containing all materials needed to run the test in any laboratory and are regulated by FDA as medical devices. Only a portion of personalized medicine diagnostics falls under this category; the majority are LDTs.<sup>iii</sup> LDTs are often instrumental as clinical trial assays in the development of

BOARD OF DIRECTORS

**President**  
*Edward Abrahams, Ph.D.*

**Chair**  
*Lincoln D. Naudal, M.D., Ph.D.*  
Culmination Bio

**Vice Chair**  
*Lauren Silvis, J.D.*  
Tempus

**Treasurer**  
*Peter Maag, Ph.D.*  
Kyverna Therapeutics

**Secretary**  
*Michael S. Sherman, M.D., M.B.A., M.S.*  
RA Capital Management

*Gabrielle Allegri, M.B.A.*  
Johnson & Johnson

*Antonio L. Andreu, M.D., Ph.D.*  
European Infrastructure for Translational  
Research (EATRIS)

*Randy Burkholder*  
PhRMA

*Dawn Cardeiro, M.S.*  
Point32Health

*Brian Caveney, M.D.*  
LabCorp

*William S. Dalton, Ph.D., M.D.*  
Aster Insights

*Stephen L. Eck, M.D., Ph.D.*  
1cBio

*Helmy Eltoukhy, Ph.D.*  
Guardant Health

*Lori Frank, Ph.D.*  
Women's Health Access Matters

*Sarah Hersey*  
Bristol Myers Squibb

*Stefan Ho, M.D., Ph.D.*  
Pfizer

*Richard Knight*  
American Association of Kidney Patients

*James Lillard, Ph.D., M.B.A.*  
Morehouse School of Medicine

*Howard McLeod, Pharm.D.*  
Clarified Precision Medicine

*J. Brian Munroe*  
Bausch Health Companies

*Elizabeth O'Day, Ph.D.*  
Olaris, Inc.

*Josh Ofman, M.D., M.S.H.S.*  
Grail

*Prasanth Reddy, M.D.*

*Apostolia Tsimberidou, M.D., Ph.D.*  
MD Anderson Cancer Center

*Michael J. Vasconcelles, M.D.*  
ImmunoGen

*Jay G. Wohlgenuth, M.D.*  
Trusted Health Advisors

personalized medicines, just as they are often instrumental in supporting instrumental for early and precise diagnosis as well as monitoring and guiding patient treatment.

Many of PMC's members focus on preserving patient access to LDTs that inform different aspects of their care and maintain personalized medicine's role as a standard of care for individuals with certain cancers, rare diseases, infectious diseases and some chronic conditions. Our interest in the RFI pertains to how it can inform legislation that provides more certainty to patients, providers, and the field while advancing areas of consensus identified by the community to support personalized medicine.

### **Statement of Neutrality**

Many of PMC's members will present their own responses to this RFI and will actively advocate for those positions. To support the work of our member organizations, we therefore note the following disclaimer: nothing in these comments is intended to impact adversely in any way the ability of individual PMC members, alone or in combination, to pursue separate comments. Additionally, PMC does not hold a position on whether LDTs should be regulated by the FDA or by the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare & Medicaid Services (CMS). PMC's response is focused exclusively on personalized medicine issues and is designed to communicate areas of consensus with regard to LDTs.

### **Considerations for Diagnostics Reform Legislation**

In 2016, PMC moderated a series of discussions on potential legislative solutions with representatives from the diagnostics community, including those with an interest in personalized medicine. Six consensus principles emerged from these conversations. These principles have been reviewed periodically by PMC members and we believe they continue to represent key considerations for building a solid foundation for any diagnostics reform legislation.

#### **1. Protect public health laboratories.**

Public health laboratories should be protected by any regulatory paradigm, which means that sentinel, infectious disease, and public health laboratories must be able to design, deploy, and use rapidly developed diagnostics to address critical public health needs.

#### **2. Allow flexibility and efficiency when managing modifications.**

As diagnostic device developers have long argued, the way test modifications are managed by a regulatory system should be flexible and efficient to allow diagnostic tests to evolve with the clinical science that underpins them. This is an important feature to consider so that improvements can be made without delaying access that might negatively impact patient care.

#### **3. Mitigate regulatory burdens for government and industry.**

To reduce burdens on government and industry, regulatory agencies should recognize when

certain safeguards are already in place. These mitigation strategies can help regulatory bodies keep pace with the rapidly evolving science of personalized medicine diagnostic testing.

**4. Design a grandfathering provision for tests already on the market along with a risk classification system for novel tests.**

The U.S. market of tests tracked in the Concert Test Database had grown to more than 160,000 genetic tests by 2020. On average, 22,000 new tests were being added to the market each year.<sup>iv</sup> To manage enormous workloads like these, a grandfathering system must be designed that will allow most tests to remain on the market unless there is a compelling reason to remove them. A consistent and transparent risk classification system would need to be described prior to enactment of legislation with appropriate detail on how it would be applied to novel tests and tests with various types of uses during their lifecycle.

**5. Ensure regulatory burdens reflect low testing volumes.**

Diagnostics designed for rare diseases and unmet needs of small patient populations should be given careful and different consideration to ensure that tests are developed for micro-markets.

**6. Accept valid scientific evidence for regulatory purposes — even if that evidence does not include data from a randomized, controlled trial.**

Personalized medicine challenges how health care products and services are conceived, developed, regulated, covered, paid for, and used by physicians. Evidentiary requirements for regulatory review must also evolve. The community agrees that, regarding diagnostics, valid scientific evidence should be acceptable for regulatory review even when that evidence does not include data from randomized, controlled trials.

## Conclusion

Thank you for your interest in stakeholder feedback on updates that can improve diagnostics regulation. As noted in the RFI, clinical diagnostics play a critical role in our health care system, influencing nearly 70 percent of all health care decisions. PMC is committed to working with you and relevant stakeholders on legislation to advance the consensus principles outlined above and to identify additional areas of consensus. If you have any questions about the content of this letter, please contact me at (202) 499-0986 or [cbens@personalizedmedicinecoalition.org](mailto:cbens@personalizedmedicinecoalition.org).

Sincerely,



Cynthia A. Bens  
Senior Vice President, Public Policy

- 
- <sup>i</sup> Senate Committee on Health, Education, Labor, and Pensions. *Request for Information (RFI) on ways to improve regulation of clinical tests in the United States*. March 13, 2024. <https://www.help.senate.gov/diagnostics-reform-rfi-3-13-24pdf?download=1>.
- <sup>ii</sup> Personalized Medicine Coalition. *Personalized Medicine at FDA: The Scope & Significance of Progress in 2023*. February 2024. <https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/02/report-3.pdf>.
- <sup>iii</sup> Personalized Medicine Coalition. *The Personalized Medicine Report: Opportunity, Challenges, and the Future (Sixth Edition)*. [https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC\\_The\\_Personalized\\_Medicine\\_Report\\_Opportunity\\_Challenges\\_and\\_the\\_Future.pdf](https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_The_Personalized_Medicine_Report_Opportunity_Challenges_and_the_Future.pdf).
- <sup>iv</sup> Hooker, G. “Building an Infrastructure to Enable Delivery of Genomic Medicine.” *American Journal of Medical Genetics*. 2021; 1 – 5. <https://doi.org/10.1002/ajmg.c.31881>.