



July 17, 2017

The Honorable Larry Bucshon
1005 Longworth House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, D.C. 20515

Sent via email: Jeffrey.Lucas@mail.house.gov; Polly.Webster@mail.house.gov

Re: "The Diagnostic Accuracy and Innovation Act"

Dear Representatives Bucshon and DeGette:

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 PMC's comments on the discussion draft of the "Diagnostic Accuracy and Innovation Act" (DAIA).

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.

Our interest in the discussion draft of the DAIA pertains to how it can support this emerging field. We seek to ensure that the field can move forward in enhancing patient care and improving the quality, safety, accuracy, and effectiveness of treatments, with the acknowledgement that innovation and access should be balanced with patient safety.

Many of PMC's members will present their own responses to this discussion draft 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 laboratory-developed tests (LDTs) should be regulated by the Food and Drug Administration (FDA) or by the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare & Medicaid Services (CMS). PMC's comments are focused exclusively on personalized medicine issues and are designed to communicate areas of consensus with regard to LDTs, which may be applicable to in vitro clinical tests (IVCTs) as described in the discussion draft.

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Last year, PMC moderated a series of discussions on potential legislative solutions with representatives from much of the diagnostics community, including but not limited to those with an interest in personalized medicine. Six consensus principles emerged from these conversations, and we review them in the context of the draft legislation below. PMC is committed to working with you and the relevant stakeholders on finding additional areas of consensus.

1. Protect public health labs.

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

DAIA clearly indicates that FDA review requirements will not apply to tests intended to be used solely for public health surveillance. We appreciate the inclusion of this language and urge you to retain it in any future versions of the legislation.

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.

The draft legislation would give FDA the flexibility to approve IVCTs with associated processes for allowing certain modifications, including specimen type, to take place without additional premarket review, as was proposed in FDA's white paper on LDT regulation. PMC believes this is an important feature of the framework so that improvements can be made without delaying access and increasing regulatory costs.

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.

The draft legislation attempts to clearly delineate between FDA- and CLIA-associated activities. However, the requirements associated with adverse event reporting to both FDA and CLIA contained within the draft may not be clearly delineated between the two agencies and therefore appear duplicative. We encourage you to further explore how the two reporting systems can be harmonized or unified to prevent unnecessary administrative burdens and confusion about what types of information should be reported to whom.

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

Tech firm Concert Genetics (previously known as NextGxDx) estimates that there are more than 60,000 personalized medicine diagnostics offered by about 300 labs, with another eight to ten coming to market each business day. To manage such an enormous workload, a regulatory agency must design a grandfathering system that will allow most tests to remain on the market unless there is a compelling reason to remove them.

The draft legislation would grandfather all LDTs, but require that developers of non-reviewed, high-risk tests submit certain data to FDA within five years of the bill's enactment. PMC believes this approach lessens the burdens on FDA and laboratories significantly, while also seeking to protect patients by reviewing information associated with tests that could cause a patient serious or irreversible harm, prolonged disability, or death if there is a clinically significant, inaccurate result that goes undetected when the test is used as intended. In addition, the draft legislation would prevent duplication of state activities for grandfathered tests by exempting tests that have already been reviewed by the New York State Department of Health.

Likewise, it is critical that a consistent and transparent risk classification system be described before enactment of new legislation governing the oversight of IVCTs. PMC suggests that the DAIA mandate that FDA develop and publish examples to illustrate the risk classification system in its proposed rule to implement DAIA subject to public review and comment before the new risk-based regulatory oversight framework goes into effect in a final rule. We believe that appropriate detail is needed. For example, FDA should clearly describe what elements of a diagnostic test contribute to high-, moderate-, or low-risk classification. FDA should also outline a process by which it will adapt risk classification for IVCTs that are related to submissions for further intended uses of approved tests and for modifications that may be made to various types of tests during their life cycles.

5. Ensure regulatory burdens reflect testing volumes.

Regulatory burden must reflect testing volume. For example, diagnostics designed for rare and unmet needs should be given careful and different consideration to ensure that tests are developed for micro-markets.

PMC appreciates that the draft legislation designs a special pathway for tests that fill unmet needs, and provides carve-outs for custom IVCTs and tests for rare diseases. However, the definition of a test for rare diseases might not be sufficient dependent on testing volumes. PMC urges you to consider exemption language to define and cover rare diseases more clearly. We recommend working with stakeholders to find a reasonable solution to this issue.

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

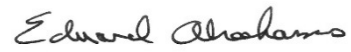
Personalized medicine challenges how health care products and services are conceived, developed, regulated, covered, paid for, and used by physicians. Evidentiary requirements for regulatory review must also evolve. The community agrees that, regarding diagnostics, valid scientific evidence should be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

The draft legislation outlines various types of evidence to demonstrate analytical and clinical validity, including peer-reviewed literature, clinical guidelines, case studies or histories, consensus standards, and reference standards. We urge you to retain this language in any future version of the legislation.

PMC appreciates the opportunity to provide comments now and in the future as you work toward the appropriate balance between regulation, innovation, and access to personalized medicine diagnostic tests. We look forward to continue working with you as the process moves forward.

If you have any questions about the content of this letter, please contact me at eabrahams@personalizedmedicinecoalition.org or 202-787-5907.

Sincerely yours,

A handwritten signature in cursive script that reads "Edward Abrahams".

Edward Abrahams
President