PMC PERSONALIZED MEDICINE COALITION

PMC Policy Committee Meeting
Thursday, June 8, 2017, 12:00 p.m. ET

Business Meeting: Discussion Packet

Contents:

1. PMC comment letter (revised draft) to Representatives Bucshon and DeGette on the discussion draft of the "Diagnostic Accuracy and Innovation Act (DAIA)"

2. "Lab Group Backs Draft Bill Proposing Dx Regulatory Reform; Finds Points of Agreement With FDA Paper" in *GenomeWeb*

3. PMC letter of support to Representative Swalwell on the discussion draft of the "Advancing Access to Precision Medicine Act"

4. PMC's *Legislative Update*

PMC
PERSONALIZED MEDICINE COALITION

May XX, 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 thoughts on the recently released 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 recently released whitepaper 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 10 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.**

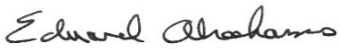
Personalized medicine challenges how health care products and services are conceived, developed, regulated, covered, paid for, and used by physicians. Evidentiary requirements for regulatory review must also evolve. The community agrees that regarding diagnostics, valid scientific evidence should be 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, reference standards, etc. We urge you retain this language in any future version of the legislation.

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

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

Sincerely yours,



Edward Abrahams
President

Lab Group Backs Draft Bill Proposing Dx Regulatory Reform; Finds Points of Agreement With FDA Paper

Jun 01, 2017 | Turna Ray

Premium

NEW YORK (GenomeWeb) – The American Clinical Laboratory Association, a group that has historically resisted the US Food and Drug Administration's attempts to regulate lab-developed tests as medical devices, recently put forth its support for a draft bill that envisions a new regulatory framework and more clearly delineates the agency's role in overseeing aspects of test development.

In March, Representatives Larry Bucshon (R-IN) and Diana DeGette (D-CO) released a discussion draft of the so-called Diagnostic Accuracy and Innovation Act, which proposes to modernize regulations by creating a new category — *in vitro* clinical tests — encompassing laboratory-developed tests (LDTs) and kits. The draft legislation clarifies the aspects of IVCT development, performance, and interpretation that the FDA, Centers for Medicare & Medicaid Services, and states would be responsible for overseeing.

Historically, kits have been regulated as medical devices by the FDA, while LDTs have been the province of CMS under the Clinical Laboratory Improvement Amendments. But for some two decades, the FDA has wanted to lift its "enforcement discretion" over LDTs, because the agency believes these tests are becoming technologically complex and labs are broadly marketing them without establishing their accuracy and safety.

The Bucshon/DeGette draft bill evolved out of industry-led efforts to advance a regulatory proposal that was a more favorable alternative to the draft guidelines issued by the FDA in 2014 to phase in oversight of LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act. The present draft bill, however, would treat LDTs not as medical devices, but as IVCTs, and would specify that the FDA would oversee their design, development, and validation; labs performing the tests would have to follow updated federal regulations under CLIA; and medical professionals' interpretation of test results would continue to be regulated by the states.

For some time now, ACLA has been working with industry stakeholders and members of the House Energy and Commerce Committee on regulatory reform approaches for LDTs, but also continued to maintain its position that the FDA lacked the statutory authority to oversee LDTs and that LDTs should not be regulated as medical devices. ACLA had even hired lawyers to make a

legal case for its position and had not ruled out taking the FDA to court if it finalized draft guidelines on LDT regulations.

However, the Bucshon/DeGette draft bill would address ACLA's concerns by changing the law, and last month, the group extended its support for the Diagnostic Accuracy and Innovation Act, calling it an "important, transparent step" toward advancing regulatory reform for lab tests. "The appropriate time has arrived to design a new, logical framework that contemplates the future of clinical laboratory diagnostics," the group said.

The statement marks an important shift for ACLA on a policy issue that is of critical interest to its membership. Building the case that LDTs aren't medical devices has been a major focus for the organization, perhaps second only to reimbursement reform. At ACLA's annual meeting earlier this year, past president Alan Mertz and successor Julie Khani both highlighted FDA's recent decision to hold off finalizing its LDT draft guidance as a victory for the organization and for the lab industry.

Now, looking to the future, "some things have changed, but a lot of things have not," said Khani, who took over the reins this year from Mertz. "One thing that ACLA has been steadfast in is that laboratory-developed tests are not medical devices and can't be regulated as such. We've been very passionate about that."

ACLA is entering a new chapter with a new leader at a time of rapid growth in the lab testing industry, driven by advances in genetics. It is estimated that there are around 60,000 genetic tests currently on the market and 10 new genetic tests enter the market daily. At the same time, a new administration entered the White House promising to lessen regulation across the board, and the Republicans, generally unsupportive of a broad expansion of the FDA's regulatory role, took control of Congress.

The political dynamic has led many industry observers to speculate that the protracted debate over whether the FDA will regulate LDTs is politically dead. Labs, dreading having to navigate the FDA premarket review process for the first time, were relieved when the agency announced after the presidential elections last year that it would not be finalizing its controversial draft guidance.

While for some, FDA's decision to pull back on regulating LDTs put a contentous debate to bed, Khani sees it as a chance for groups that were previously divided on FDA regulation to now work together on a new plan.

Earlier this year, the agency released a discussion paper outlining a framework for regulating LDTs, which it put together with extensive public comments. The plan, though not enforceable, is significantly different than its original oversight plan for LDTs, in that it would grandfather in a lot more tests, and would utilize third-party reviewers, existing standards, and proficiency testing programs under CLIA.

The FDA's discussion paper clearly showed that the agency had been listening to the lab industry's concerns about being overburdened by regulations, and this appears to have also spurred ACLA to evolve its position. "Rather than be stuck talking about LDTs are not medical devices, and FDA saying, 'Yes, they are,' and pushing for regulation in that manner, we really have an opportunity here for a diagnostic-specific solution," Khani said.

ACLA has suggested several changes to the draft bill, many of which align with the FDA. For

example, though the draft bill proposes to exempt IVCTs that are on the market before the law goes into effect from premarket review, ACLA would go further and exempt these tests from premarket review, design control, registration, notification, and listing requirements. This position, ACLA points out in its comments on the draft bill, is in line with what the FDA has proposed in its discussion paper.

"It's important to think about resources," Khani said. "FDA now has a very broad portfolio, and while there are many things about the current administration and Congress that are unclear, one thing that's likely is that there won't be an outpouring of additional resources for government agencies. So, it's important [to advance] something that's focused on a smaller subset of tests."

In recommending changes to the Bucshon/DeGette draft bill, ACLA highlighted several areas where it is on the same page as the agency, for example, the extent to which lab tests have to meet FDA's quality system regulations (QSRs).

In its discussion paper, FDA recognized that because lab tests are different than kits, they only need to be assessed under QSRs for aspects of test development that aren't reviewed under CLIA, including design controls; mechanisms ensuring tests meet certain requirements through the entire testing process; and procedures for correcting quality problems. ACLA agrees that lab tests should have to meet these three quality requirements, instead of the 16 listed in the draft bill.

Labs have also been worried that every time they tweaked something in a test's protocol, they'd have to get FDA's okay. In the white paper, however, the agency proposed that as long as the labs document their process for modifying tests and make changes according to standardized protocols, diagnostics (including grandfathered tests) would be exempt from premarket review. ACLA comments to the draft bill suggests the group is in general agreement with such a strategy.

Bruce Quinn, a nationally recognized Medicare expert who advises labs and diagnostics firms, also noted a shift in ACLA's position on LDT regulation based on its comments to the draft bill. "Absent new law from Congress, ACLA could maintain the FDA doesn't have authority to regulate LDTs, and it has published some legal research supporting that view," he said. But, "if Congress passes new laws and gives FDA new legal authorities, then ACLA is on a different ball field. In that case, they will want to comment on and contribute to the new legal framework as wisely as possible."

ACLA's comments to the draft bill signals growing consensus in the broader life sciences community that diagnostics regulations need to be updated one way or another. In comments to legislators, the Personalized Medicine Coalition didn't weigh in as to whether LDTs should be overseen by the FDA or solely by CMS, but highlighted that discussions with stakeholders had revealed several principles that they agree any new regulatory framework should include, such as flexibility in requirements for test modifications and grandfathering in already marketed tests.

"The uncertain landscape regarding the regulation of LDTs stifles investment in diagnostics, upon which the future of personalized medicine depends," said PMC President Edward Abrahams. "Comprehensive statutory reform that incorporates the principles PMC has articulated — and reflects the concerns of all stakeholders — would go a long way toward encouraging investment and innovation in personalized medicine."

Thomas Sparkman, ACLA's VP of government affairs, believes that the FDA, labs, and test manufacturers are ultimately all aligned in their goal to improve the quality of care for patients, but

it's difficult to achieve consensus without a common language for discussing complex regulatory issues. "One of the most difficult things in the conversations between the FDA and the laboratories is that we use a different vocabulary," said Sparkman.

The FDA has been used to speaking in terms of medical devices for 40 years, and the labs know regulations according to CLIA, which was last updated in 1988. "The endpoint is the same, but the vocabulary and the sequence of how we get there is different," he said. "It's been a process with the FDA because there's been some talking past each other."

In advancing the draft bill, he said, it'll be important to understand definitions for key terms like clinical validity and safety. "It's almost like international diplomacy," Sparkman said. "You need to make sure you have a good translator in the room to understand that 'oh, we really mean the same thing.'"

While life sciences stakeholders may be more willing to move ahead with a legislative overhaul of diagnostic regulations than they were willing to back the FDA's plan to regulate LDTs, it's unclear whether the Bucshon/DeGette draft bill will advance while Congress is preoccupied with bigger concerns, like healthcare reform. Congress is certainly aware LDT regulation is a contentious issue in the life sciences community, since there have been a number of hearings on the topic. Members of the House Energy & Commerce Committee, and the Senate Health, Education, Labor & Pensions Committee are interested in taking up the issue, Khani said, and pointed out that even the House Appropriations Committee asked the FDA not to finalize its draft guidance in the agriculture/FDA spending bill last year.

The draft bill is for discussion purposes, and though there are still areas of regulation that need to be ironed out, "we're optimistic that given that interest [in Congress] and from a broad range of stakeholders, we can come together," Khani said.

Filed Under Molecular Diagnostics Policy & Legislation CLIA ACLA CMS Congress FDA LDTs

PMC
PERSONALIZED MEDICINE COALITION

June XX, 2017

The Honorable Eric Swalwell
129 Cannon House Office Building
Washington, DC 20003

Sent via email: XXX

Re: "Access to Precision Medicine Advancement 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 your draft legislation, the "Access to Precision Medicine Advancement 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 your draft legislation directs the National Academy of Medicine (NAM) to study the use of genetic and genomic testing to improve health care outcomes, and support in particular the provision addressing the need to develop evidence for the clinical utility and the appropriate use of genetic and genomic tests. As PMC explains in its enclosed signature document, *The Personalized Medicine Report: Opportunity, Challenges, and the Future*, there is significant opportunity on how evidence for clinical utility should be developed and employed to improve health care outcomes and reduce inefficiencies.

Our coalition welcomes a study from NAM and a CMMI demonstration project identifying ways in which genetic and genomic testing can be better utilized in improving patient outcomes, as well as identifying what the government can do to help develop evidence for clinical utility. To be most impactful, we encourage the study to define from its outset criteria to measure improved health outcomes.

PMC appreciates your leadership in calling attention to the promise of personalized medicine, and we would like to request a meeting to discuss how we can assist your efforts.

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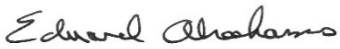
If you have any questions about the content of this letter, please contact me at eabrahams@personalizedmedicinecoalition.org or 202-787-5907.

Sincerely yours,



Edward Abrahams
President

Enclosure

PMC PERSONALIZED MEDICINE COALITION

Legislative Update
Personalized Medicine Coalition
115th Congress – 1st Session

Diagnostic Regulation

Discussion Draft: [Diagnostic Accuracy and Innovation Act (DAIA)] (view draft)
Sponsors: Reps. Larry Bucshon (R-IN-8) and Diana DeGette (D-CO-1)
Description: A bill to establish a regulatory framework for in vitro clinical tests that advances innovation for patient benefit, protects patients, provides a predictable and timely path to market, ensures reasonable risk-based regulation, avoids duplicative regulation, advances precision medicine, and applies the same regulatory principles to the same activity regardless of entity type, and for other purposes.
Summary: "In vitro clinical tests (IVCTs) would have their own regulatory structure under the Food, Drug, and Cosmetic Act—separate and apart from traditional medical devices—that was developed with their unique attributes in mind from the outset. To eliminate duplicative regulation, the [DAIA] clearly establishes FDA jurisdiction over test development and manufacturing activities and maintains oversight of laboratory operations under the Centers for Medicare and Medicaid Services (CMS) pursuant to an updated Clinical Laboratory Improvement Amendments (CLIA) framework" (from Buschon's press release).
Status: March 20, 2017 – Discussion draft released by Representatives Buschon and DeGette, requesting feedback and comments on the discussion draft from stakeholders.

Use of Genetic Information

H.R. 1313: Preserving Employee Wellness Programs Act (view bill)
Sponsor: Rep. Virginia Foxx (R-NC-5); Co-Sponsors: 0 Democrats, 5 Republicans
Description: A bill to clarify rules relating to nondiscriminatory workplace wellness programs.
Summary: This bill exempts workplace wellness programs from: (1) limitations under the Americans with Disabilities Act of 1990 on medical examinations and inquiries of employees, (2) the prohibition on collecting genetic information in connection with issuing health insurance, and (3) limitations under the Genetic Information Nondiscrimination Act of 2008 on collecting the genetic information of employees or family members of employees. This exemption applies to workplace wellness programs that comply with limits on rewards for employees participating in the program.
Workplace wellness programs may provide for more favorable treatment of individuals with adverse health factors, such as a disability.
Collection of information about a disease or disorder of a family member as part of a workplace wellness program is not an unlawful acquisition of genetic information about another family member.
Status: March 8, 2017 – Ordered to be reported (amended) by the Yeas and Nays: 22 – 17 by the House Education and the Workforce Committee. On March 2, 2017 was deferred to the Committee on Education and the Workforce, in addition to the Committees on Energy and Commerce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned. Introduced in House on March 2, 2017.

(continued on back)

Research on the Use of Genetic Testing

Discussion Draft: Advancing Access to Precision Medicine Act (view draft)
Sponsor: Rep. Swalwell (D-CA-15)
Description: A bill to provide for a study by the National Academy of Medicine on the use of genetic testing to improve health care, and for other purposes.

Reimbursement & Coverage

S.794: Local Coverage Determination Clarification Act of 2017 (view bill)
Sponsor: Sen. Johnny Isakson (R-GA); Co-Sponsors: 2 Democrats, 1 Republican
Description: A bill to amend title XVIII of the Social Security Act in order to improve the process whereby Medicare administrative contractors issue local coverage determinations under the Medicare program, and for other purposes.
Status: March 30, 2017 – Introduced in Senate and referred to the Committee on Finance.

Funding for Biomedical Research

2017 Appropriations: Labor, Health and Human Services, and Education and Related Agencies Appropriations Bill, 2017 Omnibus Agreement Summary (view summary)
Summary: Includes a $2 billion increase for NIH funding.

President's 2018 Budget Blueprint: America First: A Budget Blueprint to Make America Great Again (view budget)
On Department of Health and Human Services (excerpt): "The President's 2018 Budget requests $69.0 billion for HHS, a $15.1 billion or 17.9 percent decrease from the 2017 annualized CR level. This funding level excludes certain mandatory spending changes but includes additional funds for program integrity and implementing the 21st Century CURES Act" (page 21).
On National Institutes of Health (excerpt): "Reduces the National Institutes of Health's (NIH) spending relative to the 2017 annualized CR level by $5.8 billion to $25.9 billion. The Budget includes a major reorganization of NIH's Institutes and Centers to help focus resources on the highest priority research and training activities, including: eliminating the Fogarty International Center; consolidating the Agency for Healthcare Research and Quality within NIH; and other consolidations and structural changes across NIH organizations and activities. The Budget also reduces administrative costs and rebalance Federal contributions to research funding" (page 22).

President's 2018 Budget Proposal: A New Foundation for American Greatness (view budget); **HHS FY 2018 Budget in Brief:** Putting America's Health First (view brief)
On Biomedical Research and Development: "*Support the Highest Priority Biomedical Research and Development*. The Budget institutes policies to ensure that Federal resources maximally support the highest priority biomedical science by reducing reimbursement of indirect costs (and thus focusing a higher percentage of spending on direct research costs) and implementing changes to the National Institutes of Health's (NIH) structure to improve efficiencies in the research enterprise. In 2018, the Department of Health and Human Services (HHS) and NIH will develop policies to reduce the burden of regulation on recipients of NIH funding consistent with the Administration's initiatives on regulatory reform and the goals articulated for the new Research Policy Board established in the 21st Century Cures Act" (page 10 of budget).
The total request for the National Institutes of Health (NIH) is $26.92 billion, more than $7.1 billion (21 percent) below current levels. The budgets for all individual Institutes at NIH are cut (page 36 of HHS brief).
On 21st Century Cures Appropriations: Includes $1 billion (outside of discretionary caps) in appropriations for 21st Century Cures innovation projects in 2018 (page 41 of budget). Specifically, $496 million is designated for NIH Innovation programs (page 39 in HHS brief).