ACLA
American
Clinical Laboratory
Association

December 19, 2019

The Honorable Diana DeGette
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Fred Upton
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Via electronic mail to: cures2@mail.house.gov

Dear Representatives DeGette and Upton,

Since the passage of the *21st Century Cures Act*, we have embarked on a new era of medicine, one that holds the promise of ground-breaking medical innovation for millions of Americans. Today, we are closer than ever before to tackling debilitating genetic disorders, chronic disease, and because of the initiatives set forth in *21st Century Cures*, we are on a path towards improving health for future generations.

The American Clinical Laboratory Association (ACLA) applauds your leadership and recognition that reforms are needed to ensure patients and their families truly benefit from and have access to these ground-breaking medical advancements. Over the past thirty years, our members have been at the forefront of progress towards personalized medicine and genomic health – critical goals of *21st Century Cures Act*. Today, clinical laboratories are working hand-in-hand with researchers, providers, clinicians, and patients to identify genomic markers that will pinpoint the clinical treatments and interventions that can ultimately stop the progression of disease.

While there is broad support for these efforts, recent policy changes from the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) stand in stark contrast to the goals of *21st Century Cures* and threaten the ultimate promise of the law. Therefore, if we are committed to achieving our many "moonshots" and the promise of cures for patients, Congress must take action to ensure that there is a clear regulatory framework that fosters clinical innovation, expands patient access to ground-breaking diagnostics and tests, and encourages future medical progress in genomic health and personalized medicine. Indeed, the Committee's recent efforts around the VALID Act and broader diagnostic reform reinforce the urgency and need for meaningful policy changes, and we urge Congress to prioritize these reforms in 2020.

Common-sense solutions exist to achieve the goals of *21st Century Cures* and the vision of Cures 2.0. We appreciate the opportunity to provide recommendations on how to build on the progress

we have made and the critical policies needed to fulfill the promise of cures and personalized medicine in the future.

Addressing Flawed Reimbursement Policies That Undermine Beneficiary Access, Innovative "Standards of Care" in Public Programs, Private Market

Patient access to innovative therapies is only possible if coverage and reimbursement policies in public programs, such as Medicare and Medicaid, are aligned with the goals of early intervention and personalized care. Cures 2.0 should seek to modernize coverage and reimbursement where appropriate to ensure patients and their families can benefit from ground-breaking diagnostics.

As you are aware, flawed implementation by CMS of Medicare Clinical Laboratory Fee Schedule (CLFS) reform enacted by *The Protecting Access to Medicare Act of 2014 (PAMA)* has set in motion year-over-year cuts to Medicare lab services, representing a real and urgent threat for millions of seniors. ACLA applauds that Congress is on the cusp of enacting *The Laboratory Access for Beneficiaries (LAB) Act* (H.R. 3584/S. 3049; Sec. 105 of H.R. 1865 as passed by the House this week). The LAB Act will delay the next PAMA data reporting period, commission a study on collecting better data and, ultimately, mitigate the harm facing more than 53 million seniors who depend on vital clinical laboratory services.

The cuts will continue in 2020, however, and are compounded by coverage issues such as CMS's recent proposal to impose broad restrictions on access to life-saving cancer testing. Earlier this year, ACLA and more than 60 other leading health care organizations called on CMS to reverse initial guidance on National Coverage Determination (NCD) 90.2 that would have imposed significant barriers to Next Generation Sequencing (NGS)-based testing – now the standard of care for cancer patients.[1]

NGS-based testing has revolutionized oncology testing, reducing the cost of performance and increasing the speed of test development and delivery for ordering providers and patients. NCD 90.2 and subsequent agency guidance has cast confusion on which oncology tests may actually be available for Medicare beneficiaries with cancer. Reimbursement and coverage taken together, we risk falling behind on diagnostic innovation and expanded patient access.

Given this risk to patients, ACLA urges Congress take action to establish clear guidelines for coverage policies to ensure beneficiaries can truly benefit from new technology and cutting-edge oncology diagnostics.

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[1] *See* ACLA November 25, 2019 Comment Letter to CMS on NGS Proposed Decision Memo CAG-00450R, https://www.acla.com/acla-comments-on-ngs-proposed-decision-memo/;
See ACLA May 29, 2019 Comment Letter on NCD 90.2 Reconsideration, https://www.acla.com/acla-comments-on-ngs-ncd-reconsideration/

Barriers to Clinical Laboratory Diagnostics and Improved Patient Care

Laboratory developed tests (LDTs) represent one of the great promises of genomic health and personalized medicine. LDTs are vital to our efforts to treat and address unmet clinical needs, including rare and emerging diseases and those conditions with small patient populations.

In recent years, ACLA and leading stakeholder groups have engaged with Congress and FDA to offer insights and expertise to better inform the creation of a new statutory framework for oversight of clinical laboratory diagnostics. We thank you for your leadership in this conversation, currently embodied in the discussion draft, the Verifying Accurate, Leading-edge IVCT Development (VALID) Act, and we further recognize that comprehensive reform is a distinct legislative track from Cures 2.0. However, we are increasingly concerned about recent actions by the FDA that directly undermine patient access to a groups of tests known as pharmacogenetic (PGx) tests, running directly counter to the goals of *The 21st Century Cures Act* and Cures 2.0.

PGx tests identify genetic markers that provide actionable information to help assess a patient's likely response to treatments, based on well-documented scientific and clinical evidence. This information informs health care professionals as they determine whether prescribing a specific drug or drug class may be unsafe or ineffective, whether adjusting dosing is necessary for optimal value, or whether identified side effects are more likely to occur. These are critical tools for providers in delivering patient care. Additionally, according to FDA's own figures, the cost of drug-related morbidity and mortality exceeds $136 billion annually. By identifying those patients more likely to suffer adverse drug reactions as well as non-responders, PGx testing helps limit the enormous costs associated with "trial and error" approaches to prescribing.

Without engaging key stakeholders, FDA has demanded that laboratories remove references to specific drugs, drug classes, or FDA approved drug labeling from PGx test reports, leaving only raw genetic mutations data in the report. Such a demand is a constructive ban on PGx tests, as raw genetic mutation data, by itself, has no clinical usefulness for the overwhelming majority of health care practitioners in helping guide patient care. As a result of this unprecedented overreach, the agency is taking away valuable tools that physicians rely on for making informed prescribing decisions. Given that physicians will be forced to revert to older methodologies (such as try and fail, try and maybe succeed) in order to make prescribing decisions without actionable genomic information, it is likely that FDA's new policy will result in more patients receiving less than optimal medications or doses, with consequential safety and cost ramifications. Further, the agency's approach undermines progress in developing a comprehensive legislative solution but also amount to an inappropriate form of backdoor regulation of LDTs.

LDTs are not medical devices, and therefore, are not regulated by the FDA. LDTs are developed by highly regulated laboratories governed by CMS under the Clinical Laboratory Improvement Amendments (CLIA). Yet, without public justification, evidence or stakeholder input, FDA has effectively banned a critical subset of LDTs and created new barriers for improved patient care.[2]

[2] *See* ACLA September 18, 2019 Letter to FDA on FDA PGx Test Actions, https://www.acla.com/wp-content/uploads/2019/09/ACLA-Letter-to-FDA-re_-PGx-Test-Policy-Sept-18-2019.pdf

Ultimately, ACLA hopes that a new statutory framework for diagnostics will provide certainty for test developers, health care providers and patients. We believe this will be accomplished if reform: 1) recognizes diagnostics as distinct and not inappropriately incorporated into regulatory frameworks designed for other products or services; 2) includes "grandfathering" and transition policies that will not disrupt patient access to currently-available clinical laboratory services; and 3) maintains an appropriate balance between both innovation, and assurances for accuracy and reliability through smart regulation.

In the immediate-term, however, the FDA's self-described "non-regulatory" approach for PGx tests has chilled innovation for PGx testing, which is otherwise an essential tool to realizing the vision of personalized and precision medicine. Together with the NGS NCD, these latest actions suggest a serious and significant misalignment with the intent and goals of *21st Century Cures* and future medical progress.

Therefore, ACLA recommends that, within the Cures 2.0 Initiative, Congress examine barriers created by federal agencies, such as with PGx tests and the NGS NCD, that impede diagnostic innovation and patient access to accurate and reliable diagnostics. This fact-finding would serve to inform both the comprehensive diagnostic reform effort and identify how to further promote the value and accessibility of diagnostics.

As we move forward with the next stage of Cures 2.0, we must advance meaningful and comprehensive solutions that bring the next generation of clinical innovation to patients. For the millions of patients and their families, it's imperative that we get this right. We look forward to working with you, the Committee and the Administration to achieve the promise of Cures 2.0.

Sincerely,

Julie Khani