COLLEGE of AMERICAN PATHOLOGISTS

April 7, 2017

Representative Larry Bucshon, MD
1005 Longworth HOB
Washington, DC 20515

Representative Diana DeGette
2111 Rayburn HOB
Washington, DC 20515

Dear Representative Bucshon and Representative DeGette:

The College of American Pathologists (CAP) wants to thank you for the opportunity to comment on "The Diagnostic Accuracy and Innovation Act" (DAIA) discussion draft that provides regulatory oversight of in vitro clinical test (IVCT) , which includes laboratory developed tests (LDTs). We recognize the Energy and Commerce Committee released two discussion drafts previously that were similar to the DAIA, and appreciate your effort to address the issue of LDT oversight. Our organization does not believe the DAIA discussion draft is necessary in regulating LDTs and would only create a new and complex regulatory environment that would overburden clinical laboratories and medical professionals in their course of carrying out quality laboratory testing for patients. Therefore, the CAP opposes the DAIA discussion draft to regulate LDTs. **Instead, the CAP supports and recommends a regulatory approach for the oversight of LDTs that is flexible and uses existing regulatory structures. This framework should allow for coordination between the Center for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) in order to ensure a pathway for quality clinical laboratory testing and innovation that is unimpeded and not overly burdensome to laboratories in the process.**

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Our members, who practice clinical and/or anatomic pathology in community hospitals, independent laboratories, academic medical centers, and federal and state health facilities, are at the forefront of utilizing new methods including molecular and genomic testing that predict and diagnose disease, and guide specific patient treatment. Utilizing teams of practicing laboratory professionals as inspectors, the CAP accreditation program helps laboratories maintain consistently high levels of service throughout all levels of laboratory operations based on a rigorous and continually updated standards and requirements.

The CAP's Framework for the Oversight of LDTs

In keeping with the CAP's commitment to quality testing, the CAP released principles in 2009 as a framework for the regulatory oversight of LDTs. These principles were based off the need to ensure quality testing and continued innovation that did not over burden laboratories with regulation. The CAP has maintained that enacting enhancements to Clinical Laboratory Improvements Amendments (CLIA) with a targeted role for the FDA is

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the most effective and least burdensome approach to achieving this endeavor. Our regulatory framework includes a tiered-risk classification for LDTs based on the potential risk to patients and overall complexity of the test, and a targeted and defined role for the FDA to regulate those high-risk LDTs that cannot be adequately regulated through enhancements to CLIA and lack transparency and impose the greatest risk to patients. The CAP also believes CLIA enhancements should require analytical and clinical validity for all risk classifications to ensure quality testing in our clinical laboratories.

We believe the CAP's principles provide a flexible and manageable framework to the regulatory oversight of LDTs that is effective in maintaining quality patient testing and innovation. We support the implementation of these principles through the coordination of CMS and FDA that would use existing regulatory structures instead of creating a new process through legislation that could be costly and burdensome to laboratories especially those with limited resources.

The DAIA Legislative Approach to LDT Oversight

We believe there is an opportunity through the current regulatory process to implement a practical and balanced approach to the oversight of LDTs that is not overly complex or burdensome for laboratories. However, we believe the DAIA discussion draft runs counter to this approach, and through the legislative process would create a new and complex framework of extensive regulations that places a burden and financial strain on laboratories. Most all clinical laboratories develop and utilize LDTs for patient testing, and therefore, would be subject to the more than 200 pages of regulatory requirements outlined in the DAIA. We do not believe this is in the best interest of patients to ensure the availability of quality clinical laboratory testing.

The DAIA would reclassify all LDTs as IVCTs that is defined as a "finished product or laboratory test protocol" under the Federal Food, Drug, and Cosmetic Act (FDCA), and therefore, subject LDTs to FDA regulatory oversight. The draft would put LDTs under a complex regulatory paradigm, by creating a new center within the FDA that has regulatory authority over IVCTs. The CAP objects to this regulatory paradigm since laboratories could no longer develop low- or moderate-risk LDTs outside of the purview of the FDA's regulatory authority. We believe for most LDTs, in particular moderate- and low-risk, laboratories can provide innovative and quality laboratory testing under the current CLIA program where pathologists perform laboratory operations and develop LDTs. Furthermore, by any measure, there are tens of thousands of LDTs that are currently developed by laboratories. At a time of proposed cuts to FDA personnel and resources, we are concerned with how the FDA will handle an influx of tests that could enter the FDA pipeline for approval, and consequently how that would impact the ability of laboratories to continue the development of innovative tests for patients.

In addition, the draft subjects all LDTs to FDA regulatory authority, which creates another layer of complex regulation for laboratories to navigate while still functioning and operating under CLIA's regulatory oversight. Therefore, imposing the development of all LDTs to the FDA, especially for those tests that are well-established with validated claims, would unnecessarily stifle innovation and limit tests laboratories offer to patients that are used to

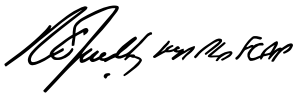
diagnose a disease or condition or to help manage a patient's therapy. Moreover, the regulatory paradigm envisioned under the DAIA would create a financial burden on laboratories that would need to expend personnel resources in compliance with FDA regulatory oversight as well as existing CLIA oversight.

The DAIA Legislative Approach to Modernization of CLIA

The DAIA also imposes new regulatory requirements on laboratories that we believe are extraneous to the purview of LDT oversight under the auspices of modernizing CLIA. The draft would create a demarcation between the development of laboratory tests and "laboratory operation" that would remain under CLIA. We believe any proposal that enhances CLIA should pertain to the oversight of LDTs, and not as an opportunity to unnecessarily add provisions extraneous to LDTs that only creates another layer of regulation and potentially imposes unintended consequences for some laboratories depending on their business model. These provisions include expanding requirements for waived testing, requiring implementation of quality systems standards throughout the testing process, and modifying improper referral requirements, and giving specific authority to the Secretary of HHS to expand specialties and subspecialties within CLIA. The CAP supports modest enhancements to CLIA that pertain to the oversight of LDTs through the regulatory process. The CAP framework for CLIA enhancement includes tiered-risk classification and requiring analytical and clinical validity for all LDTs to ensure quality testing. We also support enhancements to CLIA that require adverse event reporting by laboratories and more transparency by making test information publicly available.

In conclusion, we recognize the complexity surrounding this issue and the effort of stakeholders and Congress to resolve it. The CAP strongly believes in a framework for the oversight of LDTs with guiding principles that ensure quality testing and continued innovation without overburdening laboratories with regulation. We appreciate your effort to introduce the DAIA but we believe it falls short of the mark of having a flexible and balanced regulatory approach for the oversight of LDTs. The DAIA creates a complex and over burdensome regulatory paradigm for laboratories that would impede the innovation of LDTs. We recommend seeking a solution that utilizes existing regulatory structures for the oversight of LDTs.

Sincerely,



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