



**Statement of the College of American Pathologists (CAP)
Before the House Energy and Commerce Subcommittee on Health
“Examining the Regulation of Diagnostic Tests and Laboratory Operations”**

November 17, 2015

Chairman Pitts, Ranking Member Green, and Members of the House Energy and Commerce Subcommittee on Health:

The College of American Pathologists (CAP) appreciates the opportunity to submit a written statement before the House Energy and Commerce Subcommittee on Health regarding the hearing on “Examining the Regulation of Diagnostic Tests and Laboratory Operations.” The CAP recognizes the commitment and challenges facing the committee in developing draft legislation for the oversight of LDTs and applauds the committee for holding a hearing on this complex issue. The CAP believes that any regulatory approach to the oversight of LDTs needs to ensure a pathway for quality laboratory testing and innovation that is unimpeded and does not overburden laboratories with regulation. We are committed in working with the committee, as well as the Center for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA), to accomplish this endeavor.

The CAP represents 18,000 pathologists who practice clinical and/or anatomic pathology in community hospitals, independent laboratories, academic medical centers, and federal and state health facilities. CAP members 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 Laboratory Accreditation Program helps laboratories maintain consistently high levels of service throughout all levels of laboratory operations. Based on rigorous accreditation standards translated into detailed and focused checklist requirements, the CAP program provides a quality practice blueprint for laboratories to follow and has done so for more than 50 years.

The CAP also provides laboratories with a wide variety of proficiency testing programs and has the responsibility to evaluate the accuracy of test performance and interpretation in more than 23,000 laboratories worldwide. The program allows laboratories to evaluate their performance regularly and improve the accuracy of the patient results they provide. Through these programs, the CAP provides individual laboratories with unknown specimens for testing. The participants analyze the specimens and return the results to the CAP for evaluation. In turn, each participating laboratory receives a report of its performance as well as a report summarizing the results of all participating laboratories.

The CAP’s Proposed Regulatory Approach to the Oversight of LDTs

As part of our continuing effort to improve laboratory quality, the CAP released a comprehensive legislative proposal in September to modernize the oversight of LDTs based off core principles established in 2009. We engaged the pathology and laboratory community, Congress, and other stakeholders to enhance our proposal to ensure patient safety and innovation in laboratory testing continues without overburdening laboratories with regulation. We believe the CAP’s legislative proposal is transparent and strikes the right balance by providing a flexible regulatory approach to LDT oversight that accounts for the unique roles of the CMS and FDA.



Since 2009, the CAP has maintained that enacting enhancements to Clinical Laboratory Improvements Amendments (CLIA) with a targeted role for the FDA is the most effective and least burdensome approach to achieving our mutual goals of ensuring patient safety and sustaining continued innovation in diagnostic testing. We support a tiered-risk classification for LDTs based on the potential risk to patients and overall complexity of the test. We also support a targeted and defined role for the FDA to regulate those high-risk LDTs that cannot be adequately regulated through enhancements to CLIA. The CAP believes enhancements to CLIA should require analytical and clinical validity for all risk classifications and a public-private partnership that includes a role for third parties to validate LDTs. As an accrediting body that provides quality assurance to laboratory testing, we strongly encourage the committee to consider the CAP's approach for LDT oversight when legislating in this area to ensure quality standards and innovations continue in our laboratories.

E&C Discussion Draft: Regulatory Oversight of LDTs

The CAP appreciates the E&C committee's commitment in releasing a second discussion draft for the oversight of LDTs given the complexity of this issue, and the various opinions and proposals from stakeholders. We are committed on continuing to work with the committee and others stakeholders to develop a proposal that strikes the right regulatory balance without overburdening laboratories or stifling innovation. We believe an opportunity does exist to implement a practical and balanced regulatory approach that is not overly complex by enhancing the CLIA program to include the requirement of analytical and clinical validity for all LDTs, and the FDA to have oversight for high-risk LDTs that are the least transparent and impose the greatest risk to patients.

The CAP is in the process of reviewing the committee's second discussion draft, and will provide more detailed comments, but we wanted to provide our initial feedback to the committee especially as it relates to the new or enhanced provisions in the draft. In June, the CAP submitted comments and expressed its concern to the committee regarding the regulatory framework in its first discussion draft for the oversight of LDTs. We believe many of these same concerns the CAP expressed regarding the oversight of FDA remain in the second discussion draft. We are still concerned with the complexity and expanded role of the FDA in the oversight of LDTs that unduly burdens clinical laboratories. Furthermore, we believe the second discussion draft has increased the regulatory burden on laboratories by adding unnecessary regulatory provisions superfluous to the LDT issue in the CLIA modernization section. We remain concerned with the broader construct and regulatory approach taken by the committee to regulate LDTs that we believe is unnecessarily complex and burdensome to laboratories.

E&C Discussion Draft: FDA Regulatory Authority

The second draft continues to reclassify all LDTs as in vitro clinical tests (IVCTs) that are subject to FDA oversight and defined as a "finished product or laboratory test protocol." Under the draft proposal all LDTs would fall under a new and complex regulatory paradigm, by creating a new center within the FDA that has regulatory authority over IVCTs. The CAP disagrees with this regulatory framework 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. However, subjecting all LDTs to the FDA only creates another layer of regulatory complexity and burden for laboratories that still need to operate and function under CLIA. We believe that imposing the development of all LDTs to the FDA, especially for those tests that are already 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.



E&C Discussion Draft: CLIA Modernization

The CAP still has concerns with the CLIA modernization section as well as some new provisions in the second discussion draft released by the committee. 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 expanding specialties and subspecialties within CLIA (eg, molecular pathology, genetics).

We want to highlight some of the provisions in the second E&C discussion draft we believe are extraneous to the oversight of LDTs and, therefore, should be dropped from the bill in order to simplify the bill and maintain our focus on modifying CLIA only to the extent necessary to address the LDT issue.

- Similar to the first discussion draft, the second discussion draft expands the certification and standards for specialties and subspecialties such as flow cytometry, molecular pathology, or microbiology. This expansion of specialties adds additional burdens to laboratories with regulation not integral to the oversight of LDTs. The CMS examined the issue in 2007 and concluded the benefit of expanding specialties did not justify the cost or the imposed burden on society. Furthermore, laboratory techniques are often found in several different specialties. The CMS explained they had reduced the number of specialties under CLIA in order to reduce the complexity, standardize the requirements, and reflect current technologies that may overlap specialties.
- Waived testing, as defined by CLIA, is a simple laboratory examination and procedure that has an insignificant risk of an erroneous result. The FDA determines the criteria for tests being simple with a low risk of error and approves manufacturer applications for test system waivers. While the CAP agrees more controls are needed in the area of waived testing, the proposed requirements would not address the oversight of LDTs since most of these kits are considered simple and would be classified as low-risk based on the E&C's proposal definition.
- The CAP believes including pre-analytical requirements within CLIA is beyond its scope. Addressing problems with the pre-analytic phase of clinical laboratory testing has been intensively studied. Most studies have found that pre-analytic issues are best resolved through better care coordination. Care coordination involves deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care.

The CAP Alternative LDT Legislative Proposal

At a time when the Congress is considering several approaches to the oversight of LDTs, the CAP strongly believes the best approach is to enhance the existing CLIA structure to include analytical and clinical validity, to ensure the validation of LDTs, and to establish a targeted role for the FDA to review tests with the least transparency and greatest risk to patients. We respectfully encourage the committee to consider the CAP's legislative approach, which we believe strikes the right regulatory balance to ensure innovation and quality testing without overburdening laboratories.

The major elements of the CAP's legislative proposal are:

- A tiered risk-based regulation that would focus FDA oversight to the tests that currently have the least transparency and highest potential risk to patients.



COLLEGE of AMERICAN PATHOLOGISTS

- Allowance for evaluation of patient risk based on a laboratory's claims for the test and the potential for harm to patients of an incorrect or misinterpreted test.
- Provision for achievable and targeted FDA oversight of high-risk LDTs as we define these categories in our proposal.
- Provision for assurance of both analytic and clinical validity of laboratory tests.
- Requirement for notification by laboratories to the Secretary of Health and Human Services (HHS) of each LDT in use since 2003.
- Allowance for continued CMS oversight of laboratory quality under CLIA for moderate- and low-risk LDTs as we define these categories in our proposal.
- Definition of a regulatory process for modified LDTs with significant modifications to report high-risk tests to the FDA and for moderate- or low-risk to the CMS.
- Classification of LDTs for rare diseases, unmet diseases, and traditional LDTs as low-risk tests.
- Requirement for adverse event reporting by laboratories to the Secretary of HHS or deemed accrediting agencies.
- Promotion of transparency by making test information publicly available.
- Encouragement of coordination between the FDA and the CMS to avoid duplicative or unduly burdensome requirements on laboratories.
- Exemptions for LDTs used to respond to public health and infectious disease emergencies. This ensures the continued use of LDTs in the event of a local, regional, or national public health or emergency threat by temporarily suspending regulatory requirements.
- Identifying low volume and public health testing as low-risk tests under our regulatory approach.
- A public and transparent process for classification of LDTs into risk categories, and for reclassification of LDTs from one risk category to another when necessary.

The CAP would like to thank the committee for its continued work on this complex issue. We look forward to continuing our work with the committee to find a resolution on how to regulate the oversight of LDTs that does not impede access to patient testing or innovation by over regulating clinical laboratories. We believe that any regulatory framework should provide a regulatory balance that is not too complex or burdensome to laboratories.