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Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Delivered electronically to: Innovation@help.senate.gov

Re: The report on Innovation for Healthier Americans

Dear Chairman Alexander and Ranking Member Murray:

Thank you for the opportunity to submit feedback on the challenges outlined in the report "Innovation for Healthier Americans." The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from academic and community medical centers, commercial reference laboratories, the government, and the in vitro diagnostics (IVD) industry.

AMP is greatly appreciative of your efforts to evaluate and modernize the government's approach to the oversight of biomedical research and products. Laboratory developed testing services (LDTs) are an important and growing area of medical practice and have historically been central to the advancement of public health. These services are usually the first offering of new, clinically valid tests to patient care, typically at the request of and in consultation with other clinicians. They are integral to medical practice at academic medical centers and major cancer centers. They bridge gaps in our diagnostic and prognostic needs, and allow treating physicians to tailor treatments for their patients. They are tools in the hands of board-certified professionals with extensive clinical training such as specialist physicians and geneticists, who apply current medical knowledge to optimize patient care. These testing services are revolutionizing the way medicine is practiced and the molecular pathology field continues to evolve and innovate at unprecedented rates. Now, more than ever, it's crucial to continue the investment in this emerging field and promote policies that will help realize the dream of precision medicine for all patients.

While the Committee's report addresses many challenges that our nation faces to ensure that innovative medical products are appropriately and efficiently made available to patients, the regulation of laboratory developed testing services is exceedingly important to AMP, especially in light of the U.S. Food and Drug Administration's (FDA or Agency) intention to regulate LDTs. FDA's draft guidance titled, "Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Framework for Regulatory Oversight of Laboratory Developed Tests" will apply medical device regulations to clinical laboratory services and the physicians and other professionals who provide these services, thereby imposing substantially new, inappropriate requirements on clinical laboratories, hospitals, physicians, and other health care providers. Although FDA is moving forward with this dramatic shift in regulatory policy, the Agency has presented no evidence of widespread or systemic problems with laboratory testing in the United States that would justify the imposition of this costly new regulatory burden.

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AMP believes that FDA regulation of laboratory testing services would be inefficient, ineffective, and probably unworkable unless the regulatory framework is comprised of unique laboratory-specific oversight requirements that both acknowledge and accommodate the irreplaceable and professional nature of these services, and distinguishes laboratory developed test services from IVD diagnostic kits that are sold and distributed to laboratory customers. In its white paper, "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests—Preliminary Discussion Paper," released to inform its February 20, 2015 public workshop, FDA states that technologies capable of detecting genetic variation other than next generation sequencing (NGS), i.e., polymerase chain reaction (PCR) and single nucleotide polymorphism (SNP) arrays are "generally designed to capture predefined data points that are known in advance of testing, and therefore are more suited to regulation under traditional approaches. However, even these technologies may benefit from a different approach for capturing data related to clinical performance." Clearly FDA believes that non-traditional regulatory pathways are essential to foster innovation, allow the public to have access to newly-developed tests, and ensure that those tests are accurate, reliable, and clinically relevant. Analytical performance, or validity, of any test that is developed by any lab, could be demonstrated by means of methodologic quality-based standards that laboratories could meet and FDA should partner with AMP and other professional societies to design these standards.

Applying traditional regulations designed for manufacturers of distributed tests to laboratory develop testing services threatens to significantly hinder patient access to the significant benefits these tests offer. FDA's proposed framework outlined in the LDT draft guidance will drastically reduce the ability of laboratories to offer new laboratory testing services. With the reduction of various services will be a concomitant reduction of physicians, geneticists, and infectious disease specialists with the training and expertise to offer these services. The Agency's proposed regulation will markedly dampen the ground-breaking innovations developed by these professionals as part of their laboratory clinical practice—innovations that are the genesis of commercial tests kits.

At the same time that FDA's regulation will result in additional impediments to medical advancement in the United States, and will significantly increase costs, with no guarantee of improved patient outcomes. AMP is also very concerned that laboratories without the means necessary to navigate FDA's regulatory pathways will be forced to pull essential services from their menus creating monopolies on certain tests. Clinical service monopolies of this nature are contrary to public interest and adverse to public health because they remove competition in testing services thereby raising costs, reducing patient access, eliminating opportunities for confirmatory (second opinion) testing, and removing the possibility of basic quality control measures such as proficiency testing. For the reasons listed above, using medical device regulations and FDA to regulate laboratory developed testing services is inappropriate.

To the extent that the Committee and others are interested in developing new incentives to accelerate the commercialization of mass-produced testing kits, we strongly urge reform to FDA's current regulation of mass-produced in vitro diagnostic test kits. We further support modernizing the Clinical Laboratory Improvement Amendments (CLIA) program to enhance the oversight of laboratories where molecular pathology professionals' services are offered as opposed to the extension of FDA commercial kit regulation framework to these services.

AMP encourages the Committee to advance legislation that:

- Directs FDA to rescind the Agency's proposed guidance to regulate laboratory developed testing services and clarifies that the Agency is prohibited from regulating professionals or the clinical procedures and analyses they perform within the scope of their education, clinical training, professional board certifications, applicable licensure, and/or clinical organization's credentialing;
- Modernizes CLIA to, among other things, strengthen the role and responsibility of third party accreditors;

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- Reforms current FDA regulation of in vitro diagnostic (IVD) commercial diagnostic kits distributed by manufacturers in order to address the extensive and well-documented concerns of manufacturers that current FDA regulation of commercial diagnostics kits is costly, overreaching, and so slow that commercial kits may become obsolete before they reach market;
- Confers limited authority on a third party (though it need not be FDA) to apply premarket review regulations to testing services where incorrect results could cause significant morbidity or mortality to patients and the test is performed by a single laboratory, there is no proficiency test, and the methodology is not transparent (as in the case of tests that use black box complex algorithms to produce results).

We expand upon our thoughts on a set of issues relevant to the Committee's work in this area below.

Regulation should not interfere with the practice of medicine.

Unlike conventional, distributed, manufactured IVD test kits, laboratory developed tests are a medical service throughout the design, performance and interpretation of the results. As professional services, they have additional opportunities to promote patient safety due to the professional judgment used at every stage. To clearly distinguish the professional services that molecular pathology professionals provide using their education and experience, AMP refers to these services as laboratory developed procedures (LDPs). AMP defines an LDP as "a professional service that encompasses and integrates the design, development, validation, verification, and quality systems used in laboratory testing and interpretative reporting in the context of clinical care." The term LDP better represents the nature of complex laboratory testing, which is very much a medical service, and emphasizes the ongoing involvement of appropriately trained and qualified professionals in every aspect of the procedure, in addition to the provided interpretation. The term also acknowledges the inherent connectedness and interdependence amongst the components of the test, the results, and the role of the health care professionals.

Regardless of whether the laboratory performing a service for a patient resides in the same building or health system as that patient, the defining measure of quality is the direct involvement of an appropriately qualified professional in every aspect of design, performance, and interpretation of a testing service. Molecular pathology professionals are qualified to offer these services because they have completed extensive post-graduate education and clinical training, taken board-certification examinations administered by the American Board of Pathology and/or the American Board of Medical Genetics and Genomics under the umbrella of the Accreditation Council for Graduate Medical Education, or other recognized professional board. They continue to maintain their certification as required and they insure their professional practice activities with medical malpractice insurance.

As the Committee considers legislative language on diagnostics, AMP strongly encourages you to refer to and define these services as LDPs.

AMP believes that placing restrictions on a molecular pathology professional's ability to develop an LDP, freely select the appropriate use of an LDP, interpret results of an LDP, and/or have candid conversations with treating physicians hinders the practice of medicine and impedes innovation. Medical professionals are not manufacturers. It is in the best interest of patient care to have regulations that permit professionals to focus on patient care rather than on increasing burdensome and inter-agency duplicative regulation.

Laboratories, their personnel, and the processes to detect biological compounds of interest are already regulated under a multi-pronged framework consisting of CLIA, state laws, and accreditation by authorities, such as the College of American Pathologists. All of these together provide oversight of the laboratories, the personnel, and the services they provide, yet also allows them the flexibility to develop and validate laboratory

tests in requisite timeframe. AMP is a vigorous advocate for the principle that only high-quality, clinically and analytically valid diagnostic tests should be used in clinical practice. LDPs should be, and are currently, reviewed for analytical validity – the accuracy and reliability of a test. Assessing the clinical performance (clinical validity) of a test, i.e., how well the test identifies the presence, absence or risk of a specific disease, can be implied from the current CLIA regulations. Modernizing CLIA regulations to address issues related to clinical validity and reassuring the public of the accuracy and reliability of laboratory tests is the most appropriate mechanism of enhancing regulation while preserving the scope of professional practice.

Molecular pathology professionals practicing within their scope will utilize reagents (products that are subject to FDA regulation) and instruments (which may or may not be FDA regulated) when conducting testing, but the laboratory testing services are the technical expertise and clinical judgment of the professional who develops and validates the test performed under conditions that are already subject to oversight under CLIA. The molecular pathology professional makes a clinical determination as to what products to utilize, what patient specimen is appropriate, and what instruments to use in order to develop and perform the testing services. The molecular pathology professional that develops, validates, and performs the testing procedures is knowledgeable of each component part and each step and procedures involved with the test. These professional services cannot be packaged and shipped to multiple laboratories.

With LDPs, the professional development, monitoring and application to clinical care are inseparable and inextricably linked. As a result of the close interaction of the professional, who provides oversight and responsibility for design, development, validation, continual monitoring and updating, interpretation, reporting and communicating results and their implications that are attendant to LDPs, these functions are so intertwined that they cannot logically be separated. LDPs are within the scope of a board-certified molecular pathology professional practice and these professionals have a legal responsibility for them. In contrast, with commercial diagnostic kits the design, development and manufacturing are physically and distinctly separate from the laboratory operations, including sign-out of tests (meaning the reporting, record review, and other components of communication with treating physician colleagues). It is not appropriate to regulate commercial diagnostic products and LDPs the same. Molecular pathology professionals are medical service providers and not manufacturers.

Medical device regulations are inappropriate for laboratory developed testing services.

LDPs are not “plug & play” test systems, but are assembled from a collection of components that may include FDA cleared or approved IVDs, analyte specific reagents, general purpose reagents, and instruments. Currently, FDA only regulates individual components of an LDP such as reagents and AMP supports continued FDA oversight of only these components. The composition of these components can change as a result of numerous factors, many outside of the control of the laboratory.

Current medical device regulations were designed for massively produced boxed and shipped laboratory kits that are distributed interstate to customers who are independent from the company that manufactured them. IVDs are intended to be distributed and used in accordance to their FDA cleared or approved package insert and labeling. Medical device regulations have been put in place, in part, because IVDs are used by laboratory staff other than the experts that designed and developed the tests; therefore, providing labeling information that includes detailed instructions and descriptions for these distributed kits is warranted. However, laboratories should not be expected to meet the same device manufacturing requirements for LDPs that are designed and used within the same facility.

AMP generally agrees with the American Medical Association and other major stakeholders that risks posed by clinical tests are different from therapeutic medical devices. The current FDA medical device classification, therefore, is not appropriate for clinical tests. A new risk-classification for clinical testing, developed with

significant stakeholder input, that more flexibly balances the relative risks posed by clinical tests with the potential benefit of the information that they provide would be most appropriate. Given the risk associated with rapid multiplication of potential erroneous testing that accompanies commercial manufactured diagnostic kits, FDA establishes rigid rules for test performance to substitute for professional judgment that is not appropriate or desirable for molecular pathology professional services. Most of the ways FDA's current regulations mitigate risk are unworkable in clinical laboratories (e.g. cGMP, labeling, pre-market review and post-market surveillance). Alternatively, the entire process in developing, validating, and performing an LDP (the test, the personnel, controls, interpretation) governed by the medical professional primarily mitigates the risk of an LDP. Therefore, AMP believes that FDA oversight is not warranted for the vast majority of LDPs. Specifically, AMP believes that only the highest risk tests should be reviewed by a third party and AMP defines these tests as:

> LDPs that are used to predict risk or risk of progression of a disease or patient eligibility for a specific therapy to treat a disease that is associated with significant morbidity or mortality ***if*** the test is performed in a single laboratory ***and*** uses methodologies that involve proprietary algorithms or computations such that the test results cannot be tied to the methods used and/or do not allow for inter-laboratory comparisons to be performed, proficiency testing, or other confirmation analyses.

The threat of harm for LDPs that meet these criteria warrants independent verification, though it need not be by FDA.

While AMP believes that the current FDA classification system is inappropriate for procedures performed by appropriately qualified medical professionals, if an FDA-like classification system was applied, all remaining LDPs should be by default class I instead of class III. Additionally, any high risk LDPs (as defined above) that have formal or alternative third-party proficiency testing should also be class I. As stated above, LDPs are a medical professional service, and as such, have additional opportunities to ensure patient safety due to the direct involvement of an appropriately qualified professional, further supporting their designation as class I. Examples of processes currently in place to mitigate risk include:

- Training programs (medical students, residents, and fellows) that essentially means the entire process (teaching the validation, technical and interpretive aspects of the assay) is repeatedly "reviewed."
- Board-certified professionals periodically have their credentials peer-reviewed for continued employment. This includes certain lab-specific data (turn-around time, error-rate, etc.).
- There is a process of internal 'peer-review' for the functioning of tests as the results are presented in conjunction with all other findings. If a test is felt to be producing unsatisfactory or unexpected results, the molecular pathology professional can review, repeat, adjust and otherwise modify an LDP.

When taking into account the potential of a misinterpreted result to cause harm to a patient, one must keep in mind the number of "checks and balances" that accompany LDPs. Every laboratory performing clinical testing is CLIA-certified which assures laboratory performance standards and tests' accuracy and reliability. Additionally, those performing high-complexity tests must, under CLIA, undergo regular proficiency testing. Even further, almost every clinical laboratory chooses to obtain accreditation by a third-party, such as the College of American Pathologists, which holds laboratories to rigorous quality standards and regular inspections.

Once the laboratory test has been run, it is reviewed and signed by the laboratory director – a physician or other board-certified clinical professional who is legally responsible for the result. The ordering physician then receives that result and, often in consultation with the laboratory director, uses his or her expertise to subsequently manage patients. This application of professional expertise – by highly trained experts in

laboratory medicine and patient care – is essential in mitigating the risk of harm that could come to a patient through a misinterpreted result. This professional responsibility is present now, without FDA oversight of LDPs, and will continue irrespective of additional oversight.

The professional responsibility of a laboratory director is to ensure that a test run in his or her laboratory produces accurate and reliable results. This often means evaluating the methodology and components of tests and optimizing performance in the laboratory. However, it is impossible to apply these activities to many commercial kits that use "black-box" methodology, i.e., those that use complex, non-transparent, or proprietary algorithms to determine a result. While the results of many tests impact patient care and could potentially cause harm to patients if misinterpreted, those that do not lend themselves to evaluation by the laboratory professional and the patient's treating physician are most concerning to AMP and are the type of test that belongs in the high-risk category. Third party pre-market review should only be required for the highest risk tests and this review process must be clear, concise, consistent and greatly expedited. Specifically, third party reviewers should provide an initial response to an application within 30 days and the entire review completed within 90 days.

AMP recommends that all LDPs be subject to rigorous post-market review under modernized CLIA regulations that strengthen the role and responsibility of third party accreditors and expand access to proficiency testing. In addition, AMP also recommends that third party reviews enhance the transparency of test validation summary information and adverse events.

Moreover, the federal government should invest resources in developing standardized reference materials so that performance standards can be met during the development of LDPs. Standardized reference materials are essential to the design and validation of a molecular test and can help ensure necessary accuracy and reliability. Additionally, these materials may also be of use to commercial IVD test kit manufacturers. We recommend that the Committee encourage FDA to work actively in both the public and private sectors and the National Institute of Standards & Technology to facilitate the development of and increase production of these desperately needed materials.

Off-label use is an important component in the practice of medicine.

FDA has proposed designating laboratories that modify cleared or approved tests as remanufacturers, subjecting them to premarket submission requirements under 21 CFR 807.81(a)(3) and 21 CFR Part 814, as well as the Quality System Regulation at 21 CFR Part 820. FDA has stated that intended use "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." (21 CFR 801.4) AMP is concerned that molecular pathologists will be unable to have candid conversations that would benefit the patient and potentially lead to new and important uses of an LDP, even in cases in which the information conveyed by the pathologist is neither false nor misleading because it would be interpreted by FDA to be modifying the intended use of the test. Under FDA's proposed regulation of LDPs, a laboratory that changes the intended use, verbally or in a more formal manner, is required to submit a new premarket review application.

Even when tests are adapted to better meet the needs of the laboratory and their patients, AMP believes that medical professionals are not acting as "re-manufacturers" when they validate modifications, but as medical professionals using FDA cleared or approved tests off-label. Moreover, this practice is a central component to innovation that leads to better medical tools and approaches.
Off-label use of FDA cleared or approved tests is very common, and can range from employment of different nucleic acid extraction systems, to alternative specimens, sample matrices, or test purposes. The reasons for this variation include highly specific, overly restrictive labeling that is inconsistent with automation or other

aspects of laboratory work flow, the ability of laboratories to improve test kit performance, and clear, demonstrable patient needs. For many tests, once DNA of acceptable quality is obtained, its source becomes irrelevant.

Our treating physician colleagues increasingly obtain specimens by less invasive means than in the past. As a consequence, laboratories need to process and test smaller specimens from tissue types prepared and stored in different matrices than those for which a test was originally cleared or approved. Performing testing on a fine needle aspirate, for example, may spare a patient an open biopsy or allow testing in a patient from whom a specimen could not otherwise be obtained. Performing this type of testing serves patient needs, and laboratories that offer such testing employ highly skilled physicians and scientists for whom clinical and analytical validation of off-label uses of tests are well within the scope of their medical practice. Therefore, we strongly that any legislation on the oversight of LDPs permit off-label use of IVD kits as it does in other medical contexts involving cleared or approved products.

Oversight of laboratory developed testing services should allow for an efficient means to modify a test.

An essential component to the continued advancement of personalized, or precision medicine, is the nimble environment that promotes innovation and allows testing services to be quickly adapted and improved. In almost all cases, third party pre-market review is unnecessary when modifications are made to an LDP or when an LDP is validated for a different specimen type. Much of this modification activity is only necessary due to the barriers imposed by FDA, which have disincentivized companies from improving or updating their commercial kits or expanding their intended use to additional necessary specimen types. Supplemental premarket submissions should only be required for those tests for which premarket review by a third party is required, i.e. the highest risk tests (as defined above). In this case, subsequent submissions should only be required for those where modifications significantly change the clinical performance (clinical validity) or reduce analytical validity. The process for reviewing modifications should be likewise expedited as the initial review.

Manufacturers have laid out a compelling case that FDA's current approach lacks an appropriate balance between pre-market review versus post-market controls. Reforming FDA's authority over commercial kits in both areas would level the respective positions of commercial kits and professional testing services while increasing options and protecting the medical professional's clinical decision-making. In short, only clinically meaningful performance modification should trigger a supplemental submission requirement for commercial kits. The CLIA model of oversight has served as the engine of innovation in this space and rapid application of validated clinical discovery to patient care; therefore, any change of oversight of LDPs should involve enhancements to CLIA and institute clear prohibitions against FDA regulation of medical services.

Significant regulatory policy changes should be promulgated and adopted using notice and comment rulemaking.

The Chairman's report questioned the increasing use of guidance documents to implement regulatory policy and the inherent problems this creates for regulated entities. AMP shares the Committee's concern and supports the use of notice and comment rulemaking for significant policy changes, in place of non-binding guidance documents, to encourage clarity and create greater legal certainty with respect to the new requirements that FDA intends to impose. For approximately 40 years, FDA has not attempted to regulate laboratory developed testing services, referring in recent years to its position as one of "enforcement discretion." Last year, FDA announced its intention to designate clinical laboratories that provide LDPs as medical device manufacturers, and to implement regulation of these laboratories and the LDPs they use in providing services. Given the substantial new requirements that FDA proposes to impose on clinical laboratories, hospitals, physicians, and other health care providers, and the reformulations of existing medical device regulations this would entail, we

strongly urge the Committee to require that FDA pursue notice and comment rulemaking as required under the Administrative Procedure Act (APA).

The use of notice and comment rulemaking prior to implementing regulation of LDPs would ensure that FDA to respond to all stakeholder comments. Importantly, it would require FDA to undertake an economic impact analysis that would guarantee that any putative benefits of the Agency's proposed new regulatory approach will exceed its costs to patients and to society. Further, FDA's use of notice and comment rulemaking is likely to aid the Department of Health and Human Services (HHS) in minimizing redundancy, duplication, and inconsistency in the oversight of clinical laboratories. As a consequence, this process will help ensure that patients continue to have access to medically necessary laboratory testing services and will assist in preserving future advancements in testing and patient care.

There are several other ways that FDA can support the advancement of diagnostic testing.

The ability and capacity of FDA to approve or clear commercial diagnostic kits has been paltry when compared with the breadth and range of testing services offered to patients under CLIA—with high rates of accuracy and rapid application of new and validated clinical knowledge. There are FDA approved commercial diagnostic tests for only six molecular biomarkers with direct implications for targeted oncology therapies (KRAS, EGFR, CKIT, HER2, BRAF, and ALK). Moreover, the clinical indications are very narrow and the only approved specimen type is formalin-fixed, paraffin-embedded tissue, ignoring other essential specimens such as those taken during minimally invasive procedures. The Committee should carefully consider that comprehensive reform of testing services should not expand the reach of an FDA regulatory model that has created barriers to innovation, limited patient access to testing improvements, failed to provide any viable pathway for rare diseases and conditions, and utilizes a top-down, bureaucratic approach to outbreaks and potential biothreats. In addition to CLIA modernization, there is an urgent need to address and streamline FDA's regulation of manufacturers of mass-produced commercial kits consistent with AMP's recommendations provided to the Agency in June 2010.[1]

In summary, AMP identified three barriers:

1. The paucity of standard reference materials for all areas of molecular diagnostics, i.e., genetic, oncology, and infectious disease testing, inhibits the production of appropriate control materials and methods.
2. The difficulty of obtaining rare specimens for studies presents a barrier to submission of applications for the approval of new indications for currently approved tests.
3. Test manufacturers perceive that there is an inconsistent and unclear regulatory pathway for their submissions. Manufacturers have faced uncertainty and/or inconsistency in the review of device submissions, in enforcement discretion, in device classification [510(k), 510(k) de novo, PMA, ASR, etc.], in requirements for acceptable analytical and clinical validations, and in requirements changing from the time of pre-IDE meetings through mid-trial. IVD test manufacturers must then function within this uncertain regulatory environment and are limited in their efforts to anticipate regulatory requirements and appropriately amend business models.

To address these barriers, AMP recommended:

- FDA should work actively in both the public and private sectors to facilitate the development of standardized reference materials.

[1] AMP comments to FDA CDRH Council on Medical Device Innovation: Barriers to Market for Molecular Diagnostic Tests. http://www.amp.org/Position%20Statements/AMPComments_FDAMedicalDeviceWorkshop_062410_final.pdf

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- FDA should ensure that policies and requirements are consistently applied, and that the scientific evidence and rationale for decisions are communicated effectively to diagnostic test manufacturers.
- Communication from FDA to diagnostic test manufacturers should be as clear and as comprehensive as possible at the outset of the submission process. This will help manufacturers better plan their resources and time. It will also assuage undue angst that the regulatory bar will change during the process.
- FDA should improve communication between branches so that consistent requirements are developed and applied and demonstrations of clinical utility in one branch are recognized by the other branches.
- FDA should involve the expert opinion of medical professional associations regarding clinical utility.

Current inadequate coverage and reimbursement pose barriers as great as inappropriate regulation.

The Center for Medicare and Medicaid Services (CMS), the nation's largest insurer and whose actions are frequently mimicked in the private sector, has taken a heavy handed approach in denying coverage or reducing payment for many medically necessary molecular pathology tests. This has created a challenging environment for innovators to translate new genomic discoveries into clinical applications. In addition, it threatens the ability of even the nation's most prominent cancer centers to continue offering molecular testing services and, thus, patient access to these important services, which have quickly become standard of care. We urge the Committee to work with the Senate Finance Committee to resolve these interconnected barriers. Earlier this year, AMP published a white paper, *A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Innovations in Genomic Medicine*. Additionally, AMP provided comments to the House of Representatives Energy and Commerce Committee on improvements in the Medicare Local Coverage Determination (LCD) process. Please find links to these documents below.

Conclusion

The issues being considered by the Committee have significant consequences regarding whether patients and their physicians will be able to obtain the testing services they need. AMP hopes that the comments provided to the Committee help ensure that minimally burdensome regulations will be put into place so that patients continue to have access to medically necessary laboratory testing services in a way that also allows for future advancements in testing and patient care. If AMP may be of any additional assistance, please contact its Executive Director, Mary Williams, at mwilliams@amp.org. We look forward to having an active role in developing sections related to the regulation of laboratory developed testing services.

Sincerely,

Janina Longtine, MD
AMP President

Additional materials:

- A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Innovations in Genomic Medicine; http://www.amp.org/publications_resources/position_statements_letters/documents/PerfectStorm-FINAL-CD.pdf
- Comments to the House of Representatives Energy and Commerce Committee on the 21st Century Cures Act; http://www.amp.org/publications_resources/position_statements_letters/documents/AMPlettertoECo nCuresAct-FINAL.pdf