ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
6120 Executive Blvd., Suite 700, Rockville, MD 20852
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

July 16, 2021

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide these comments on the Cures 2.0 discussion draft. AMP is an international medical and professional association representing approximately 2,500 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 the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. Now, as we are recovering from the COVID-19 pandemic, Americans have a greater understanding of the role diagnostic and surveillance laboratory testing plays in maintaining the country's health. We appreciate that you have sought out comments as this legislative proposal was developed and our comments below build upon suggestions that we have submitted previously[1,2,3]. We appreciate your efforts to support precision medicine and molecular diagnostics in this draft and we look forward to continuing to work together and meet with you to discuss these issues further.

Section 101. Further Understanding the Implications of Long COVID

AMP is pleased that the bill's sponsors are acknowledging the healthcare concerns patients with "long COVID" are continuing to cope with months after the infection has cleared. Recent estimates are that almost 25% of all patients with COVID-19 will experience ongoing symptoms.[4] The pandemic continues to challenge our current understanding of coronaviruses, including how to predict those who will experience prolonged sequela and how best to treat persistent symptoms. AMP supports the creation of a Learning Collaborative to collate knowledge across the country and work in concert to improve the health of these patients. Medical laboratory professionals were some of the first to develop SARS-CoV-2 diagnostic tests and their knowledge, training, and expertise

[1] https://www.amp.org/AMP/assets/File/advocacy/AMP_Recommendations_Cures2_0-12-16-2019-FINAL.pdf?pass=32
[2] https://www.amp.org/AMP/assets/File/advocacy/AMP%20Response%20Cures%202_0%20PHE%20Sections%205-29-2020.pdf?pass=42
[3] https://www.amp.org/AMP/assets/File/advocacy/AMP%20CURES%202_0%20Concept%20Paper%20Response%20Non-PHE%20Sections_FINAL.pdf?pass=13
[4] https://time.com/6073522/long-covid-prevalence/

would be of great value to the Learning Collaborative. **As you work to advance this legislation, we recommend that in addition to including developers of diagnostic products (i.e., industry) in the Learning Collaborative, that you also include medical laboratory professionals who directly develop and administer these laboratory testing procedures, including those practicing in both community and academic settings.**

Section 102. National Strategy to Prevent and Respond to Pandemics

AMP thanks the sponsors for incorporating Section 102 to create a national strategy to prevent and respond to future pandemics. We support the need for a national strategy to address future pandemics and appreciate that you indicate that the national strategy should cover testing; however, we believe that further consideration is needed to develop a more comprehensive national strategy. Our members consist of molecular laboratory professionals who have been on the frontlines of responding to the COVID-19 pandemic by developing and providing molecular-based diagnostics for patients across the United States. We surveyed our membership multiple times over the course of 2020 and collected hundreds of responses from molecular laboratory professionals to understand their successes and hurdles when providing the crucial and timely diagnostic services that patients needed during the COVID-19 pandemic.[5] Our findings resulted in the formation of numerous recommendations for improving the response efforts and we strongly believe that these recommendations should be factored into future infectious disease outbreak efforts. As such, in June 2020, AMP provided a detailed response on how to prepare for the next future pandemic to former HELP Committee Chair Lamar Alexander that draws from the experiences of these professionals during the COVID-19 pandemic.[6] We review our recommendations here to better inform the future development of a pandemic national strategy and also urge you to review our full recommendations.

In order to have a comprehensive national testing strategy, AMP believes that the federal government needs to take full advantage of the diversity of laboratory types and settings during a public health emergency. We find that academic and community molecular diagnostic laboratories, in addition to public health and reference laboratories, have had and continue to have a valuable role in addressing infectious disease outbreaks. Certified public health laboratories are essential to begin testing during an outbreak; however, their limited testing capacity makes it difficult for those laboratories to have a significant clinical diagnostic role. Due to the direct physical proximity of hospital laboratories and other local community testing sites, they are optimally positioned on frontlines during pandemics and can provide more timely patient care for the critically ill than certified public health laboratories. Unfortunately, our survey found that academic medical centers and community health laboratories were underutilized and deprioritized throughout the pandemic with regard to accessing limited testing supplies. **Based on these experiences, AMP strongly recommends that a national testing strategy during a pandemic effectively leverages and considers the role of each type of laboratory. Additionally, we recommend that federal efforts to support and steer testing needs throughout a pandemic should involve laboratory professionals during the entire the process.**

[5] https://www.amp.org/advocacy/sars-cov-2-survey/

[6] https://www.amp.org/AMP/assets/File/advocacy/AMP%20Future%20Pandemic%20White%20Paper%20Response.pdf?pass=29

Diversity in both the US laboratory system and among test types offered is a strength during a public health emergency. However, at the beginning of the COVID-19 pandemic, FDA's policy requiring emergency use authorization (EUA) for laboratory-developed procedures (LDP) negatively affected the ability of clinical laboratories and developers to offer high quality SARS-CoV-2 molecular diagnostic tests to meet the surging clinical need for patient testing. This policy severely limited the ability of laboratories to innovate and adapt to pandemic needs during a crucial time in the country's response. After the FDA provided more flexibility in its guidance, laboratories were able to quickly offer validated tests for clinical use and provide innovative solutions to respond to the disrupted supply chain (such as developing methods that allowed patients to collect their own specimens to circumvent the need for scarce PPE and validating the use of alternative testing components, materials, and specimens to address supply shortages). Additionally, clinical laboratories rapidly developed tests to ensure that the needs of their patients were met, such as tests with the ability to identify different viral strains and ensuring that testing in a geographic area is sensitive and specific for that particular region. **In order to provide laboratories with the flexibility to use LDPs and provide diverse test types in a public health emergency, we recommend that policy ensures that LDPs are not inappropriately treated as medical devices, including during public health emergencies.**

We also believe that the federal government should take a stronger leadership role in coordinating testing efforts and supply allocations. For instance, HHS can assist with coordination regionally to ensure that moments of excess testing supplies and capacity are leveraged to process samples as quickly as possible. Depending upon the prevalence of SARS-CoV-2 in a community, there may be a shift in testing methodology and related supply needs over time. The need for testing supplies designed for acute care, surveillance, high-throughput testing, and other clinical needs should be monitored widely to provide real-time feedback to agencies to support data-driven supply allocations. It is imperative that clinical laboratories are included in early discussions about testing supplies, as they are working on the front-lines and can report developing supply challenges that are poised to hinder clinical testing both to address the pandemic and to care for patients with other health concerns. **Further, AMP believes that HHS should work to increase transparency, efficient and non-redundant communication, and real-time transmission of information between laboratories and suppliers (commercial manufacturers and government).** There is a need for laboratories to have real-time access to resource availability and reagent and supply quantities.

We thank the sponsors for including Section 102 and the opportunity to provide comments on developing a national strategy to better prevent and respond to future pandemics. **We believe input from diverse stakeholders is a key aspect to the creation of a successful future strategy, so AMP respectfully requests that Section 102 be edited to require that HHS solicit public input to inform their work.**

Section 105. Developing Antimicrobial Innovations

AMP supports the creation of a Critical Need Antimicrobial Advisory Group to advise the interagency Committee on Critical Need Antimicrobials of its work to develop a list of infections for which new antimicrobial drug development is needed and type, including those with a potential global health security threat. The explosive growth of antibiotic resistance is likely to become a global public health crisis and developing novel therapeutics

is of great importance. Of equal importance, however, is supporting clinical tests to diagnose, monitor, and report bacterial and fungal infections that are likely or confirmed to result from an antibiotic resistant strain. Clinical diagnostic laboratories, especially those providing molecular diagnostic tests that determine if pathogens contain genes or biomarkers that confer antibiotic resistance, will be crucial to the response to this public health emergency. **We urge you to modify the language on page 19 of the discussion to draft to include a practicing molecular pathology expert on the Critical Need Antimicrobial Advisory Group to ensure that any policies developed will support the necessary clinical testing and reporting.**

Section 202. Increasing Health Literacy to Promote Better Outcomes for Patients

AMP supports the requirement for the Centers for Medicare and Medicaid Services (CMS) to elicit ways the agency can work with federal health care program stakeholders to promote increased patient health literacy. Low health literacy has negatively impacted patient outcomes through difficulty understanding and communicating health concerns to healthcare providers appropriately and poorer physical and mental health.[7] In addition to these negative health outcomes, the cost of low health literacy can be extraordinarily high with some estimates ranging $106 billion to $238 billion annually.[8] Improving health literacy provides the opportunity to empower patients and promote better healthcare outcomes while reducing healthcare costs. For these reasons, AMP commends the sponsors for focusing on this important issue.

Section 203. Increasing Diversity in Clinical Trials

AMP supports updated reporting on the inclusion of demographic subgroups in clinical trials, the requirement for a GAO study on barriers that prevent underrepresented populations from participating in clinical trials, a public awareness campaign on clinical trials in minority communities, and creating a task force on making *clinicaltrials.gov* more user-friendly. Currently, minority populations are underrepresented in clinical trials, especially in genetics-related research.[9] Without participation from underrepresented minorities, healthcare providers may not be able to provide equitable care for patients from minority backgrounds and may miss opportunities to provide life-saving tests and treatments.[10] Recruitment of underrepresented populations in clinical trials is crucial in ensuring that new and innovative tests and treatments are useful and safe for patients from minority populations. Action is needed to help address these disparities and ensure that clinical trial participation is accessible and understandable for underrepresented participants.

---

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2909377/; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855442/

[8] https://publichealth.gwu.edu/departments/healthpolicy/CHPR/downloads/LowHealthLiteracyReport10_4_07.pdf

[9] https://www.fda.gov/media/145718/download; https://www.nature.com/articles/538161a; https://pubmed.ncbi.nlm.nih.gov/28770442/

[10] https://www.nejm.org/doi/full/10.1056/NEJMsb025007; https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-019-0516-4

Section 404. Coverage and Payment for Breakthrough Devices Under the Medicare Program

AMP commends the sponsors for working with Representatives Suzan DelBene (D-WA) and Gus Bilirakis (R-FL) to include the Ensuring Patient Access to Critical Breakthrough Products Act in the Cures 2.0 discussion draft. This policy would codify the current Medicare Coverage of Innovative Technology (MCIT) pathway at CMS. **AMP supports the MCIT pathway to provide coverage for breakthrough medical items and services and believes this proposal aligns well with CMS' goals to bring new and innovative technologies to beneficiaries sooner to help improve their health outcomes.**

AMP believes that current Medicare coverage options have led to challenges that hamper national coverage and limit patient access to molecular diagnostic tests in certain circumstances. We especially applaud the fact that this legislation will provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continue for up to four years. We believe that this will only serve to expedite patient access to innovative products and devices to diagnose and treat life-threatening illnesses. **Additionally, AMP greatly appreciates the foresight to make any clinical laboratory diagnostic test, including in-vitro diagnostics, and devices that are not implanted, eligible for the MCIT pathway if it meets other MCIT eligibility criteria.**

Section 407. Expanding Access to Genetic Testing

AMP commends the sponsors for working with the co-sponsors of the Advancing Access to Precision Medicine Act, Representatives Eric Swalwell (D-CA) and Scott Peters (D-CA), to include provisions of their bill in the Cures 2.0 discussion draft to increase access to genetic and genomic testing for children with rare diseases. AMP believes that no patient should be denied access to a medically necessary test because of insurance coverage. Frequently, Medicare strongly influences Medicaid, as Medicaid policies traditionally follow Medicare coverage policies. In many instances, however, this is not ideal as Medicare policies have resulted in limited or non-coverage for many molecular diagnostic tests. Further, the Medicaid patient population is broader, with different medical needs than the Medicare population. AMP is supportive of methods that improve and expand coverage of molecular diagnostic procedures for the Medicaid patient population, particularly efforts that examine the value of molecular testing's utility beyond diagnosis of disease to other purposes including but not limited to predictive, prognosis, therapy selection, disease monitoring and recurrence. **For these reasons, AMP supports the inclusion of the Advancing Access to Precision Medicine Act in Cures 2.0.**

In our response to your Cures 2.0 Concept Paper dated January 29, 2021, we recommended that provisions of H.R. 4393 as introduced in the 116th Congress should be included in Cures 2.0; however, we outlined concerns with the coverage and reporting requirements in that version of the Advancing Access to Precision Medicine Act.[11] First, AMP was concerned with the coverage requirement that all children be referred or admitted to an intensive care unit. We recommended that Cures 2.0 allow for the coverage of genomic sequencing for children who have not yet been admitted to an intensive care unit. AMP is pleased to see that our concerns were

[11] https://www.amp.org/AMP/assets/File/advocacy/AMP%20CURES%202_0%20Concept%20Paper%20Response%20Non-PHE%20Sections_FINAL.pdf?pass=98

resolved in Section 407 of the Cures 2.0 discussion draft, which allows for coverage of genomic sequencing for a child who "has been referred or admitted to an intensive care unit, or has been seen by at least one medical specialist, for a suspected genetic or undiagnosed disease; or is suspected by at least one medical specialist to have a neonatal-onset or pediatric-onset genetic disease." **We thank you for including this revised language in the Cures 2.0 discussion draft and believe this will ensure appropriate access to testing for children with undiagnosed rare diseases.**

While we were glad to see that the coverage requirements were addressed in Section 407 of the discussion draft, AMP continues to be concerned with the reporting requirements for health care providers as a condition for receiving payment and recognize that the reporting requirements have expanded to include not only "quality" of services, but "efficacy" as well. We fear that the requirements may discourage laboratories from participating in the demonstration project, diminishing effectiveness of this important effort for Medicaid patients. Further, we are concerned that laboratories do not have access to patient-specific information that would best inform any measures for quality and efficacy. This information is best obtained from the ordering healthcare provider. We have expressed our concerns to Representative Swalwell's staff and they have been amenable to revising this language in their bill. **We support the inclusion of the Advancing Access to Precision Medicine Act in Cures 2.0 legislation, with the recommendation that the reporting requirements be altered before the discussion draft is finalized to ensure robust laboratory participation in this program. Specifically, we request that the cosponsors work with stakeholders to refine the reporting requirements to ensure they are not overly burdensome to laboratories but still result in meaningful information that can help to shape future coverage for genetic and genomic testing.**

AMP continues to support the provision in Section 407 of the discussion draft that requires HHS to enter an arrangement with the National Academy of Medicine (NAM) for the academy to study usage of genetic and genomic testing, including how to reduce barriers to the utilization of such testing. AMP is very supportive of the work that has already been done by NAM's Roundtable on Genomics and Precision Health[12], and as part of other related studies like the Evidence Framework for Genetic Testing[13], which was commissioned by the Department of Defense. We are hopeful that NAM's work as outlined in Section 407 of the discussion draft will build upon these efforts and work to identify ways the government can improve access to these important services that help guide and improve patient management and care, as well as how to better ensure reimbursement of medically relevant and necessary molecular testing.

Finally, AMP recognizes that the Cures 2.0 discussion draft includes a new provision within Section 407 that would require CMS to conduct a report on Medicaid coverage for DNA sequencing clinical services, including which types of DNA clinical sequencing options are covered and under what circumstances, the impact of coverage on patient outcomes, and the impact of coverage on subsequent health care costs. **AMP applauds this effort and believes this will provide meaningful data on the effects of this demonstration project.**

[12] http://www.nationalacademies.org/hmd/Activities/Research/GenomicBasedResearch.aspx

[13] https://www.nap.edu/catalog/24632/an-evidence-framework-for-genetic-testing

Section 408. Medicare Coverage for Precision Medicine Consultations

AMP is pleased this section of the Cures 2.0 discussion draft makes precision medicine consultations a covered medical service. We have long maintained that personalized treatment and management are going to continue to evolve and become increasingly incorporated into routine clinical care in many disciplines of medicine; as such, CMS' coverage policies must evolve along with them to ensure Medicare beneficiaries have access to medically reasonable and necessary care, including molecular diagnostic testing. Recognizing the growing importance of integrating pharmacogenomic information into clinical care, in 2019, AMP published a position statement on Best Practices for Clinical Pharmacogenomic Testing.[14] To further support the use of pharmacogenomic testing, AMP believes that these test reports should be comprehendible by all types of healthcare providers, including the test's interpretation, significance of the results, and the limitations of the test. Despite the clarity and transparency in test reports, at times, providers and patients will have questions in regard to drug and dosing decisions based on genetic information, and as such, it's critically important that they have access to specialized providers to aid in their interpretation. **Hence, AMP supports policy that provides coverage for these types of consultative services.**

While we commend the sponsors for their inclusion of precision medicine consultations, the drafted proposal only addresses one aspect of optimizing precision medicine. Under current law, when physicians order a genetic test on a patient or a molecular test to detect an infectious disease, the sample is sent to a clinical pathology or genetics laboratory for testing. The evaluation and interpretation of the test results requires specialized professional training and experience, and the medical professionals performing these services have a doctoral degree, either medical (MD, e.g., pathologist) or scientific (PhD). Physicians such as pathologists as well as qualified doctoral scientists have the appropriate education, training, and certification to perform such professional work and a recent survey by AMP found that MDs and PhDs both reported similar levels of participation in analysis, interpretation, and reporting of molecular tests in most tests surveyed[15]. Qualified PhD scientists, however, are not directly reimbursed by Medicare for the interpretive services provided to Medicare patients. **AMP strongly recommends expanding the discussion draft to include a provision to allow qualified non-physician doctoral scientists to bill Medicare directly for their professional work involved in performing and interpreting a molecular diagnostic test.**

Covering the services of PhD scientists in this section of the legislation will allow these non-physician doctoral scientists to practice at the top of their licenses by billing for the interpretive services they provide when reviewing the results of molecular diagnostic testing, a critical tool in precision medicine. In our comments dated January 29, 2021[16] on the Cures 2.0 Concept Paper, AMP recommended that §1861(s) of the Social Security Act be amended to designate PhD scientists with appropriate fellowship training and board certification as Qualified Health Care Practitioners for Molecular Diagnostics Interpretive Services. **We request that the cosponsors work with interested stakeholders to draft legislative language to allow qualified non-physician doctoral scientists**

[14] https://www.amp.org/AMP/assets/File/position-statements/2019/Best_Practices_for_PGx_9_4_2019.pdf?pass=46
[15] https://www.amp.org/AMP/assets/File/advocacy/AMP_MDx_Interpretation_Quant_Survey_Report.pdf?pass=7
[16] https://www.amp.org/AMP/assets/File/advocacy/AMP%20CURES%202_0%20Concept%20Paper%20Response%20Non-PHE%20Sections_FINAL.pdf?pass=98

to bill Medicare directly and ensure that these professionals are able to contribute the optimization of precision medical care of Medicare beneficiaries.

Thank you for your continued efforts to modernize the delivery of treatments to patients. AMP would be happy to have a follow-up conversation with your offices to discuss our suggestions and answer any questions that you may have. Should you have any questions or wish to discuss these issues in the meantime, please do not hesitate to contact Sarah Thibault-Sennett, Senior Manager, Public Policy & Advocacy at sthibaultsennett@amp.org.

Sincerely,

Antonia R. Sepulveda, MD, PhD
President, Association for Molecular Pathology