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

December 31, 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), we thank you for the opportunity to provide these comments on H.R. 6000, the Cures 2.0 Act as introduced. 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 enter into a different phase of the COVID-19 pandemic, Americans have a greater understanding of the role that diagnostic and surveillance laboratory testing plays in maintaining the country's health. We appreciate that you are continuing to seek feedback on the legislation, and our comments below build upon suggestions that we have submitted previously[1,2,3,4]. We have also included specific redlined edits for several of our recommendations. We appreciate your efforts to support precision medicine and molecular diagnostics in this legislation. We look forward to continuing to work together on this topic and to meet with you to discuss these issues further.

Section 101. Further Understanding the Implications of Long COVID

AMP is pleased that the legislation acknowledges the healthcare concerns patients with "long COVID" are continuing to cope with months after the infection has cleared. Recent estimates show that almost 25 percent of all patients with COVID-19 will experience ongoing symptoms.[5] The pandemic continues to challenge our current understanding of coronaviruses, including how to predict those who will experience prolonged sequelae

[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://www.amp.org/AMP/assets/File/advocacy/AMP%20Response%20to%20Cures%202_0%20Discussion%20Draft%207-16-2021.pdf?pass=82

[5] https://time.com/6073522/long-covid-prevalence/

and how best to treat persistent symptoms. AMP supports the creation of a Learning Collaborative to compile knowledge from across the country and to work in concert with other participants to improve the health of these patients. We appreciate that you incorporated our recommendation to include clinical laboratories and those who develop diagnostic and therapeutic products in the list of participants in the Learning Collaborative. Medical laboratory professionals were involved in every aspect of testing during the pandemic, and their knowledge, training, and expertise will be of great value to the Learning Collaborative.

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 and we appreciate that the legislation would require that laboratory testing be included in this 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.[6] Our findings informed multiple recommendations for improving response efforts, and we strongly believe that these recommendations should be factored into future infectious disease outbreak efforts. 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 laboratory professionals during the COVID-19 pandemic.[7] We review our recommendations here to better inform the future development of a pandemic national strategy and urge you to review our full recommendations.

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. Academic and community molecular diagnostic laboratories, in addition to public health and reference laboratories, have had and continue to have a valuable role in managing infectious disease outbreaks. Certified public health laboratories are essential for initiating testing during an outbreak; however, their funding, structure and limited testing capacity make it difficult for those laboratories to have a significant clinical diagnostic role at larger scales. Due to their direct physical proximity and existing operational capabilities, hospital and other local community laboratories are optimally positioned on the frontlines during pandemics to 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 leverage and consider 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 from across the spectrum of laboratory types during the entire process.**

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

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

We also believe that the federal government may need to take a stronger leadership role in coordinating testing efforts and especially supply allocations. For instance, HHS can assist with regional coordination to ensure that in instances where excess testing supplies and capacity become available, these resources could be rapidly reallocated in order 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 chain challenges that may hinder access to 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)**.

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 revised to require that HHS solicit public input to inform their work.** Additionally, we recommend that on page 9, line 9, the text be modified to include:

> (1) Strategies for testing (including point-of care testing and testing at nonmedical sites as well as all types of clinical laboratories), data collection and transmission, and managing supply chain needs to foster expedient results and personalized medical responses for patients and communities, including for medically underserved populations.

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, including those with a potential global health security threat. The explosive growth of antibiotic resistance is already a global public health crisis and developing novel therapeutics is of great importance. 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 any public health emergencies involving therapy-resistant microbes. **We urge you to modify the language on page 23 of the legislative text 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:**

> ‘‘(ii) other health experts with expertise in researching antimicrobial resistance, health economics, clinical molecular pathology, or commercializing antimicrobial drugs; and”

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

AMP continues to support 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. The importance of health literacy for the use of preventive medical services, control of chronic conditions, and, ultimately, mortality is well established in the scientific literature.[8] According to the National Library of Medicine, 9 in 10 adults struggle with health literacy.[9] In addition to these negative health outcomes, it also costs $4.8 billion annually in administrative expenses for employers and insurers responsible for patient medical costs.[10] 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 continues to support updated reporting on the inclusion of demographic subgroups in clinical trials, the requirement for a Government Accountability Office study on barriers that prevent underrepresented populations from participating in clinical trials, a public awareness campaign on clinical trials in minority communities, and the creation of a task force on making *clinicaltrials.gov* more user-friendly. Currently, minority populations are underrepresented in clinical trials, especially in genetics-related research.[11] Without participation from underrepresented communities, the generalizability of clinical trial results and understanding of the effectiveness of treatments for various conditions, such as Parkinson's disease and cancer could be limited.[12,13] 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.

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 Act. This policy would codify the Medicare Coverage of Innovative Technology (MCIT) pathway, which was recently withdrawn through regulatory channels by CMS. **AMP supports the MCIT pathway to provide coverage for breakthrough medical**

[8] Levy H, Janke A. Health Literacy and Access to Care. *J Health Commun*. 2016;21 Suppl 1(Suppl):43-50. doi:10.1080/10810730.2015.1131776

[9] https://nnlm.gov/guides/intro-health-literacy

[10] https://www.forbes.com/sites/brucejapsen/2018/09/12/low-health-literacy-costs-u-s-employers-5-billion-a-year/?sh=257b842033fa

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

[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7851248/

[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4029870/

items and services and believes the inclusion of this provision will 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 diagnostic test kits, and devices that are not implanted, eligible for the MCIT pathway if it meets the program's other eligibility criteria.**

Section 407. Expanding Access to Genetic Testing

AMP commends the sponsors for working with the co-sponsors of the Precision Medicine Answers for Kids Today Act, Representatives Eric Swalwell (D-CA), Scott Peters (D-CA), and Tom Emmer (R-MN) to include provisions of their bill in the Cures 2.0 Act 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 limitations. 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 to serve a broader understanding of diagnosis of disease that includes prediction, prognosis, screening, therapy selection, disease monitoring and recurrence. **For these reasons, AMP supports the inclusion of the Precision Medicine Answers for Kids Today Act in Cures 2.0.**

AMP continues to be concerned with the reporting requirements for health care providers as a condition for receiving payment and recognizes 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 many 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 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 obtaining meaningful information that can help to shape future coverage for genetic and genomic testing. Revising these reporting requirements will help ensure robust laboratory participation in this program.**

AMP continues to support the provision in Section 407 of the legislative text that requires HHS to enter an arrangement with the National Academy of Medicine (NAM) 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[14], and as part of other related

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

studies like the Evidence Framework for Genetic Testing[15], which was commissioned by the Department of Defense. We are hopeful that NAM's work as outlined in Section 407 of the legislative text 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 continues to support the provision within Section 407 of the legislative text that would require CMS to conduct a report on Medicaid coverage for DNA sequencing clinical services, including how often genetic and genomic diagnostic testing services are covered and reimbursed, an analysis of which genetic and genomic diagnostic tests are being approved or denied, the turn-around time for prior authorization requests, and more. **AMP believes this provision will provide meaningful data on use of Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits.**

Section 408. Medicare Coverage for Precision Medicine Consultations

AMP is pleased this section of the Cures 2.0 Act 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, AMP published a position statement in 2019 on Best Practices for Clinical Pharmacogenomic Testing.[16] To further support the use of pharmacogenomic testing, AMP believes that these test reports should be comprehendible by all types of healthcare providers, including test interpretation, significance of results, and limitations of such testing. Despite the clarity and transparency in test reports, at times providers and patients will have questions regarding drug and dosing decisions based on genetic information, and as such it is critically important that they have access to specialized providers to aid in interpretation. **Hence, AMP supports policy that provides coverage for these types of consultative services.**

We commend the sponsors for their inclusion of precision medicine consultations and we appreciate that you incorporated our previous recommendation to include pathologists as providers who can conduct a pharmacogenetic consultation. As AMP has commented before, the evaluation and interpretation of 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). A recent survey by AMP found that MDs and PhDs both reported similar levels of participation in analysis, interpretation, and reporting of molecular tests for most tests surveyed[17]. Qualified PhD scientists, however, are not directly reimbursed by Medicare for interpretive services provided to Medicare patients. **To ensure that patients have access to precision medical consultations, AMP recommends that "appropriately-trained and board-certified**

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

[16] https://www.amp.org/AMP/assets/File/position-statements/2019/Best_Practices_for_PGx_9_4_2019.pdf?pass=46

[17] https://www.amp.org/AMP/assets/File/advocacy/AMP_MDx_Interpretation_Quant_Survey_Report.pdf?pass=7

doctoral scientists" be included, along with pathologists, in the list of providers who can conduct a pharmacogenetic consultation.

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 to 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,

Daniel E. Sabath, MD, PhD
President, Association for Molecular Pathology