ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

July 30, 2024

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

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Delivered electronically to cures.rfi@mail.house.gov

Dear Representatives DeGette and Bucshon,

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit these comments in response to your request for information to inform the next steps of the 21st Century Cures initiative. AMP is an international medical and professional association representing approximately 2,900 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, infectious disease, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

AMP appreciates the 21st Century Cures initiative and Congress's efforts to enact policy that will help bring about the next generation of healthcare innovation. As you look to continue this work and draft legislative language, AMP respectfully requests that you consider the recommendations below.

Pandemic Preparedness

AMP appreciates the steps Congress and the Administration have taken to prepare for the next pandemic; however, we believe a more comprehensive strategy is needed. Many of AMP's members are molecular laboratory professionals who were on the front lines of the COVID-19 and the MPox responses. We surveyed our membership multiple times throughout 2020 and collected hundreds of responses from molecular laboratory professionals to understand their success and hurdles when providing the crucial and timely diagnostic services that patients needed during the COVID-19 pandemic.[1] Our findings informed multiple recommendations for improving response efforts, and we firmly believe that these recommendations should be factored into response to future infectious disease outbreaks, including the increasingly

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

concerning number of avian influenza cases in the United States.[2] We review our recommendations below and in future iterations of the Cures 2.0 Act, request that you include a section to ensure that strategies are in place to enable both rapid development and availability of diagnostics and sufficient clinical and diagnostic laboratory testing capacity during a public health emergency. We note that the House Energy and Commerce Committee is considering H.R. 3795, the Diagnostic Testing Preparedness Plan Act, and AMP encourages you to include similar legislative text as part of the 21st Century Cures initiative.

AMP recommends that you consider provisions directing the Department of Health and Human Services to develop a comprehensive national testing strategy that takes 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 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 COVID-19 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 critical roles 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 response.**

We also believe that the federal government may need a more substantial leadership role in coordinating testing efforts, especially supply allocations. For instance, HHS can assist with regional coordination to ensure that when excess testing supplies and capacity become available, these resources can be rapidly reallocated to process samples as quickly as possible. Depending upon the prevalence of an infectious disease 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. Clinical laboratories must be included in early discussions about testing supplies, as they work on the front lines of any response and can report developing supply chain challenges that may hinder access to clinical testing to address pandemics and care for patients with other health concerns. **Thus, AMP believes that HHS should work to increase transparent, efficient and non-redundant communication and real-time transmission of information between laboratories and suppliers (commercial manufacturers and government) during future public health emergencies.**

---

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

During the COVID-19 pandemic, AMP members encountered barriers to accessing positive samples to validate their tests, contributing to the US's inability to meet testing capacity needs. Many local institutions, e.g., hospitals, had requirements mandating that an institutional review board (IRB) be convened to consider consent requirements and other ethical considerations before clinical samples from patients could be used for this purpose. This dramatically slowed institutions' and industry's ability to respond to local outbreaks, and this barrier needs to be addressed to prevent the same obstacles from occurring in future public health emergencies.

During the pandemic, the HHS Office of Human Research Protections issued guidance regarding requirements in 45 CFR part 46 that created numerous flexibilities regarding IRB requirements.[3] While it did not specifically address the sharing of samples to serve as positive controls, it states, "Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require IRB approval before being implemented." **Thus, we urge you to direct the Office of Human Protections to issue guidance that clarifies that during future public health emergencies, the use of HIPAA de-identified samples from a hospital's clinical population for the purpose of validating a diagnostic test for the pathogen for which the public health emergency has been declared is considered to be an action taken for public health under 45 CFR part 46 and thus, does not necessitate IRB review.**

Expanding Access to Genetic Testing

The original Cures 2.0 legislation included provisions from the Precision Medicine Answers for Kids Today 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 barriers put in place by insurers. Notably, 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 the diagnosis of a disease that includes prediction, prognosis, screening, therapy selection, disease monitoring, and recurrence. **Recognizing that many Medicaid beneficiaries are still being inappropriately denied access to genetic testing services, AMP urges Congress to continue to work to advance policies that increase access to genetic testing services, especially for pediatric populations.**

Coverage for Breakthrough Devices

AMP appreciates the steps taken to enhance Medicare coverage for breakthrough medical devices and improve patient access to cutting-edge technologies. We believe that current Medicare coverage options have led to challenges that hamper national coverage and limit patient access to molecular diagnostic tests in certain circumstances. **However, AMP is concerned that CMS' proposed TCET pathway and the recent changes to H.R. 1691, the Ensuring Patient Access to Critical Breakthrough Products Act of 2023, exclude clinical**

[3] 2 https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html

diagnostic tests from coverage. AMP requests that these tests are treated in a similar manner as other 'Breakthrough Products' in order to foster patient access.

PhD Billing

AMP was pleased that the Cures 2.0 legislation included provisions to make precision medicine consultations a covered medical service and appreciated the inclusion of our recommendation to include pathologists as providers who can conduct a pharmacogenetic consultation. As AMP has commented before, the evaluation and interpretation of all types of test results require specialized professional training and experience. 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.[4] 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 doctoral scientists be added as a qualified healthcare provider under Medicare and able to bill Medicare directly for their professional services.**

FDA Regulation of Laboratory Developed Tests (LDTs)

Finally, given the complexity of this issue, AMP believes that any legislation regarding the FDA regulation of LDTs should not be included in conversations around the 21st Century Cures initiative. **Instead, there needs to be a separate, thoughtful conversation involving stakeholders across the laboratory community about how best to modernize the regulatory pathway for clinical diagnostics tests.**

Thank you again for the opportunity to submit these recommendations as you continue to work on the 21st Century Cures initiative. If AMP may be of further assistance, please do not hesitate to contact Annie Scrimenti, Associate Director of Public Policy and Advocacy, at ascrimenti@amp.org.

Sincerely,
Maria E. Arcila, MD
President, Association for Molecular Pathology

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