ASSOCIATION FOR MOLECULAR PATHOLOGY
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July 11, 2023

The Honorable Bernie Sanders
Chair
Senate Health, Education, Labor, and Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member
Senate Health, Education, Labor, and Pensions Committee
828 Hart Senate Office Building
Washington, DC 20510

Delivered electronically to PAHPA2023Comments@help.senate.gov

Subject: Senate legislation to reauthorize the Pandemic and All-Hazards Preparedness Act

Dear Chair Sanders and Ranking Member Cassidy:

On behalf of the Association for Molecular Pathology (AMP), we would like to thank you for your work to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). AMP is an international medical and professional association representing approximately 2,900 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. Our members were at the front lines of the response to the COVID-19 pandemic, providing clinical testing throughout the United States at hospitals, reference laboratories, academic medical centers, and diagnostic companies.

We want to reiterate our initial comments, which advocated, in part, to codify the laboratory response network and include clinical laboratories in it, and to provide hazard pay for clinical laboratory professionals. After further consultation with AMP's membership, we respectively request these additional recommendations be included in PAHPA reauthorization legislation to enable adequate testing capacity during future emergencies by addressing challenges laboratories encountered during the public health emergency:

Sec. 205. Pilot program for public health data availability

During the COVID-19 pandemic, laboratories experienced a significant resource burden in efforts to comply with multiple local, state, and federal data reporting requirements. Further, outdated systems, e.g., use of fax machines, hindered the real-time exchange of information that was critical to the country's response. In order to reduce these burdens, AMP believes it is necessary for the Secretary of HHS to convene an expert panel comprised of members of the public health laboratory community, clinical laboratories, reference laboratories, electronic health record companies, medical technology companies, and other relevant stakeholders to standardize agency reporting format and processes for

reportable infectious diseases during a pandemic, including but not limited to: define minimal required and realistic data elements for supporting public health contact tracing; establish standardized reporting format that electronic health records and laboratory information systems vendors could adopt; establish a standardized and centralized reporting agency or process that minimizes delays in return of results and eliminates the need for laboratories to duplicate reporting to multiple agencies; and, provide logistical and technical support for laboratories to provide reportable infectious disease data electronically.

We applaud you for including Section 205 which would, in part, create a National Public Health Data Board that would be responsible for the implementation of data and information sharing under section 310B of the Public Health Service Act. As you understand, Section 310B is meant to improve data reporting from health care providers, public health and clinical laboratories, and health information exchanges and health information networks. We believe it is imperative that the National Public Health Data Board include medical professionals including those from the clinical laboratory community to inform this critically important work to streamline data reporting and availability. As currently drafted, the draft legislation allows HHS to appoint those with "relevant public health, medical, or scientific expertise" as members. We request that you retain this language as the bill advances.

Require that HHS develop a Diagnostic Testing Preparedness Plan

We request that you include a section to ensure that strategies are in place for the rapid development and availability of diagnostics and clinical and diagnostic laboratory testing capacity during a public health emergency. In particular, AMP believes that HHS should be required to develop a testing strategy to allow for 1) redistribution of supply allocations based on clinical testing needs and 2) real-time coordination amongst laboratories to leverage moments of excess capacity. We note that the House Energy and Commerce Committee is considering H.R. 3795, the Diagnostic Testing Preparedness Plan Act, and we believe the Senate bill should include similar legislative text.

In two surveys conducted in 2020[1], AMP found that testing supply distribution was a significant limiting factor for providing diagnostic testing to the public, with over 80% of laboratories reporting that supply interruptions delayed or decreased their testing capacity. The types of supply chain interruptions that laboratories experienced were vast and included shortages of testing platforms, testing kits, reagents, swabs, viral transport medium, laboratory consumables, and personal protective equipment. Moreover, we found that not all categories of laboratories were supported with access to supplies to the same degree regardless of their ability to contribute significantly to testing demands. AMP was alarmed by the lack of a coordinated approach to distributing testing supplies as it hampered the ability to meet the testing capacity needs in the United States. When laboratories made efforts to address shortages, approximately half of the laboratory professionals that participated in our COVID-19 survey reported that the federal government was a barrier.

In particular, we urge that a strategy be flexible enough to reprioritize supply allocations based on clinical testing capacity based on geographic location, which could change over time. Depending on the rapidly evolving needs during a public health emergency, there may be a shift in testing methodology and its corresponding supply chain requirements. The demand for testing supplies designed for acute care, surveillance, high-throughput, and other clinical testing should be monitored nationally to provide real-time feedback to agencies to support data-driven supply allocations. Ideally, these monitoring

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

systems would be proactively established, rapidly activated following novel pathogen identification, and maintained throughout the course of response.

Secondly, a national testing strategy should include real-time coordination amongst laboratories to leverage moments of excess capacity. Based on data regarding testing capacity and demand, there may be an opportunity to coordinate regionally to ensure that any excess test capacity is leveraged to ensure samples are processed as quickly as possible (e.g., a dashboard consisting of laboratories, manufacturers, and government representatives would allow real-time supply chain understanding and help to prevent communication and resource bottlenecks).

We believe that a number of the problems that arose with testing during the COVID-19 public health emergency were because the clinical laboratory community was not fully utilized. We find that the diversity of laboratories in the United States is an enormous strength. Certified public health laboratories are essential to begin testing during an outbreak and conduct surveillance in non-emergency times. However, their limited testing capacity and lack of integration with the medical system make it difficult for those laboratories to have a significant clinical diagnostic role. Due to their direct physical proximity to patients, hospital laboratories and other local community clinical testing laboratories are optimally positioned on the frontlines during pandemics to meet testing capacity needs, and to provide appropriate turnaround times necessary to manage patients that need immediate care. Unfortunately, our 2020 surveys found that academic medical centers and community health laboratories were underutilized and deprioritized. This is not to discredit the advantages provided by commercial reference laboratories, which often are able to perform a great number of tests. All of the sectors of the clinical testing landscape need to be supported to ensure a complete laboratory response effort during a pandemic. Thus, AMP has requested edits to H.R. 3795 to ensure the full breadth of the laboratory testing system within the United States is factored into a diagnostic testing plan. They are as follows:

On page 3:
‘‘(2) CONTENTS.—The plan under paragraph (1) shall be designed to facilitate coordination and collaboration among—
‘‘(A) government agencies; and
‘‘(B) critical private-sector diagnostic testing stakeholders, including ~~private-sector clinical and diagnostic laboratories~~ State or local laboratories, commercial laboratories, academic laboratories, community health laboratories, diagnostic manufacturers, health care product distributors, and research laboratories.

One page 3, insert the following new section and redesignate (d) as (e):
(d) CONSULTATION.—In developing the plan under subsection (a), the Secretary shall consult with State and local public health entities, commercial laboratories, academic laboratories, community health laboratories, diagnostic manufacturers, health care product distributors, and research laboratories.

Remove Institutional Review Board (IRB) barriers to accessing control samples during an emergency

AMP members encountered barriers to accessing samples from patients with COVID-19 needed to validate their tests, which contributed to the ability to meet testing capacity needs in the US. Many local institutions, e.g., hospitals, had requirements in place mandating that an 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 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 in regard to IRB requirements.[2] While it did not specifically address the sharing of samples to serve as positive controls, it does state that "Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require institutional review board (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.

Thank you again for the opportunity to submit these recommendations as you continue to work on the reauthorization of PAHPA. 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,

Mary Williams
Executive Director
Association for Molecular Pathology

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