ASSOCIATION FOR MOLECULAR PATHOLOGY
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February 4, 2022

The Honorable Patty Murray
Chair, Committee on Health,
Education, Labor and Pensions
U.S. Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member, Committee on Health,
Education, Labor, and Pensions
U.S. Senate
648 Hart Senate Office Building
Washington, DC 20510

Submitted electronically to HELPPandemicbill@help.senate.gov

Dear Chair Murray and Ranking Member Burr:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide comments on the draft Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics (PREVENT Pandemics) Act. We greatly appreciate your tremendous efforts to apply lessons learned from the COVID-19 pandemic in the hope of better preparing the United States for responding to future infectious disease outbreaks and we are grateful for the opportunity to work collaboratively with you and other members of the Health, Education, Labor, and Pensions Committee.

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.

Molecular laboratory professionals have been at the frontlines of this pandemic working with other essential healthcare professionals to care for patients with COVID-19 and stem the spread of SARS-CoV-2. They have developed, validated, and performed hundreds of millions of molecular tests for SARS-CoV-2 since the start of the pandemic, and they will similarly serve a critical and valuable role in any future infectious disease outbreaks. Given the considerable expertise and experience of AMP members, our organization has continuously solicited and obtained qualitative and quantitative data from its members with the objectives of creating professional resources and informing policymaking. You will find that our comments below on the PREVENT Pandemics Act are informed by this work which includes two surveys of laboratory professionals in 2020 on many important aspects of SARS-CoV-2 molecular diagnostic testing, including sample types, patient populations, methodologies, validation, performance, supply chain, public health reporting, laboratory workforce, and reimbursement. You can find the full findings from these surveys here: https://www.amp.org/advocacy/sars-cov-2-survey/

Section 101. Comprehensive Review of the COVID–19 Response

We are pleased that the PREVENT Pandemics Act would establish a Task Force to examine and assess the United States' preparedness for and response to the COVID-19 pandemic. We recommend that if not already included, policies from the Food and Drug Administration (FDA) will be included as part of this assessment. Our analysis found many FDA actions and policies negatively affected the ability of laboratories and test developers to offer timely SARS-CoV-2 tests to meet clinical testing needs throughout the pandemic. Under non-emergency circumstances, laboratories accredited by the Clinical Laboratory Improvement Amendments (CLIA) program under the Centers for Medicare and Medicaid Services (CMS) are authorized to develop, validate, and offer laboratory-developed testing procedures (LDPs) as medical services for clinical care without notifying FDA or seeking review and approval/authorization by the Agency. However, early in the pandemic, FDA made the decision to require laboratories to obtain an emergency use authorization (EUA) regardless of whether a test was a boxed-and-shipped as an in vitro diagnostic test kit or a LDP. This drastic change in review requirements for laboratories using LDPs created a barrier for professionals to institute testing services in the early days of the pandemic, greatly hampering the country's collective ability to stem the spread of SARS-CoV-2 in spring 2020.

Unfortunately, even after the FDA modified its guidance to simplify the EUA process later in 2020 in an attempt to mitigate testing delays, approximately 35% of the laboratory professionals surveyed (both AMP members and non-members) noted that it took more than a month for their laboratory to receive an EUA. Several individuals reported that their laboratory submitted their application and even after four months, had yet to receive authorization. One individual reported that FDA did not respond to their application for six weeks, and then when the agency finally did answer, staff asked questions that could have easily been answered up front. In fact, 32% of the respondents in one of our 2020 surveys said that they encountered hurdles in completing the EUA process. Laboratory professionals that participated in the survey noted FDA's lack of experience with certain kinds of technology and, combined with inefficiencies in the submission and review process, led to unnecessary delays implementing tests for clinical care. AMP's survey revealed that the FDA's inability to efficiently and expertly review EUA submissions for COVID-19 tests delayed the ability of laboratories to offer testing during times when the country was far below meeting test capacity needs. This not only delayed patient care but potentially compromised the ability to utilize contact tracing and other measures in the effort to stem the spread of COVID-19. Moreover, this additional regulatory review by FDA was unnecessary, as laboratories already adhere to the validation requirements in place under CLIA, third-party organizations, and certain states' regulations. These unfortunate regulatory barriers to access must be addressed for the US to respond promptly to infectious disease outbreaks in the future.

For these reasons, we request the following:

1. **The term "medical product" should be amended in Section 101 to be "medical product and services" to reflect that LDPs are professional services and not medical devices.**

2. **We believe this legislation should ensure that regulatory requirements for clinical laboratories are not duplicative or burdensome, especially during a pandemic. We request that legislation clarify that CMS, via the CLIA program, is the primary agency with jurisdiction of oversight of LDPs. We believe this is essential to ensuring that the United States can rapidly develop and deploy the testing needed during future public health emergencies.**

We also urge that the review in Section 101 be converted into best practices for developing a national testing strategy. The lack of a strategy was a serious misstep early in the pandemic and we found that the federal government did not take full advantage of the capabilities or diversity of laboratory types and settings during this 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 addressing infectious disease outbreaks. Certified public health laboratories are essential to begin testing during an outbreak and conduct surveillance in non-emergent 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 throughout the pandemic with regard to accessing limited testing supplies. **Based on these experiences, AMP strongly recommends that a national testing strategy be developed to 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 during the entire process.**

Supply Chain Allocation and Coordination

Thank you for the numerous sections within this draft legislation aimed at resolving supply chain issues for future pandemics. AMP is generally supportive of efforts to revamp processes associated with the Strategic National Stockpile and we appreciate your attention to this topic. We offer some other specific recommendations below.

During 2020, AMP found that over 80% of laboratories reported that supply interruptions delayed or decreased testing capacity. The types of supply chain interruptions that laboratories have experienced are vast and include shortages of testing platforms, testing kits, reagents, swabs, viral transport medium, laboratory consumables, and personal protective equipment. In addition to what you have already included, we believe that the federal government should take a stronger leadership role in coordinating testing efforts and supply allocations. For instance, the Department of Health and Human Services (HHS) can assist with regional coordination to ensure that circumstances in which there is excess testing supplies and capacity are leveraged to process samples as quickly as possible. Throughout the pandemic there was a need to shift testing methodology and related supply needs over time as the prevalence of SARS-CoV-2 varied across communities. During outbreaks, the supply of 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 be included in early and ongoing discussions about allocating testing supplies, as laboratories are working on the frontlines and can report emerging 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. Therefore, we request the following:

- **We recommend that in Section 103 on "Public health and medical preparedness and response coordination," the Office of the Assistant Secretary for Preparedness and Response be given authority to collect and disseminate information on resource availability and reagent and supply quantities in near real-time during public health emergencies.**
- Additionally, thank you for requiring HHS to issue guidance on how states, territories, and Tribes can access the Strategic National Stockpile and other countermeasures and factors the Secretary considers

when making decisions related to product distribution (Section 405. Improving supply chain flexibility for the Strategic National Stockpile). **Similarly, we also urge you to include a section requiring HHS to provide information on supply allocation decisions even for supplies not part of the Strategic National Stockpile.**

- We understand that Section 401 on "Warm base manufacturing capacity for medical countermeasures" would require that the Biomedical Advanced Research and Development Authority (BARDA) support the establishment and maintenance of warm-base domestic manufacturing surge capacity and capabilities so that medical countermeasures can be rapidly manufactured when needed to respond to public health emergencies. **We urge you to expand this language so that warm-base domestic manufacturing surge capacity can also be used for supplies and parts that are used as part of medical countermeasures.**

Modernization of Data Collection Approaches

We greatly appreciate that the PREVENT Pandemics Act seeks to resolve the numerous data collecting and reporting issues that occurred during the COVID-19 pandemic. While we support laboratory data reporting because such information is vital for responding to infectious disease outbreaks, AMP has several concerns about the requirements placed on laboratories during the current pandemic, which were communicated in our August 2020 survey (Page 26)[1]:

- HHS set deadlines requiring laboratories to comply with new requirements by August 1, 2020[2], however, reporting specifications were not released in time for state and public health departments to be ready to accept data on this date.
- Laboratories lacked sufficient resources to meet the requirements to report to a new state department of health not previously reported to within a 24-hour period.
- Our members' laboratories faced challenges accessing the data that HHS required to be reported such as demographic data elements that are often not available to laboratories nor captured on requisition forms, and additionally, laboratories also reported that "ask on order entry (AOE) responses" are not available or are difficult to implement in all orders.
- There are also patient data systems limitations that have made compliance with the HHS guidance challenging for laboratories. Common problems that we have heard from members include device identifiers have not been previously required; laboratory information systems (LIS) do not have a place to assign these identifiers in their databases; AOE questions requiring the Logical Observation Identifiers Names and Codes (LOINC) and the Systematic Nomenclature of Medicine (SNOMED) coding are not available in the electronic health record (EHR); HL7 electronic reporting is not available; and LOINC/SNOMED have not been previously required and the LIS do not have a place to assign these in their databases.

[1] https://www.amp.org/AMP/assets/File/advocacy/Survey_Report_August_2020_AMP_SARSCoV2_FINAL.pdf?pass=2

[2] https://www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html

- Lastly, AMP has asked that HHS standardize agency reporting format and processes for reportable infectious diseases during a pandemic, as compliance with multiple requirements and variable formats has been burdensome to clinical laboratories.

Thus, we support much of what the PREVENT Pandemics Act seeks to accomplish regarding data collection. Specifically, in Section 211 on "Modernizing biosurveillance capabilities and infectious disease data collection," we applaud that the following topics for discussion would be added at the public meeting required under current law:

- Strategies to integrate laboratory and public health data systems and capabilities to support rapid and accurate reporting of laboratory test results and associated relevant data.
- Strategies to improve the collection and reporting of relevant, aggregated, deidentified demographic data to inform responses to public health emergencies, including identification of at-risk populations and to address potential health disparities.
- Strategies to improve the electronic exchange of health information between State and local health departments and health care providers and facilities to improve public health surveillance.

Given the experiences of laboratory professionals, we also request that Section 211 be updated to amend 42 U.S. Code § 247d–4 to ensure representatives from the laboratory community are included in the list of experts required to be present at this public meeting.

Similarly, we also support the goals of Section 213 on "Supporting public health data availability and access." It is clear the draft bill considers data on testing orders and results as a critical part of the data needed to allow federal and local governments to properly respond to the pandemic. Moreover, it is clear that you recognize there are more streamlined approaches to comprehensively collect this important information. AMP appreciates that this section would lead to the development of standards to aid in the ability of infectious disease data to be reported electronically. **AMP has previously advocated for (1) defining minimal required data elements for supporting public health contact tracing and (2) establishing a standardized reporting format that electronic health records / laboratory information system vendors could adopt. We believe that this Section aligns well with our recommendations. However, we request that updates are made to this section to require that federal departments and agencies better coordinate internally such that laboratories are not subject to duplicative or conflicting requirements, including conflicts with state and local requirements. Further, we also request that the language be updated to direct HHS to provide logistical support for laboratories to aid in their ability to submit data electronically.** Of course**,** extensive conversations with laboratories and the public health community will be needed to implement this Section if the PREVENT Pandemics Act becomes law, and AMP looks forward to serving as a resource to refine these programs.

<u>Section 212. Genomic sequencing, analytics, and public health surveillance of pathogens</u>

AMP greatly appreciates that the draft legislation includes the Tracking Pathogens Act (S. 3534) as Section 212 – AMP strongly supports its inclusion in the PREVENT Pandemics Act as this larger bill advances. Significantly boosting genetic surveillance and viral sequencing in the United States is key to responding to the evolving challenges of the COVID-19 pandemic and other outbreaks in the future. In particular, we support the Tracking Pathogens Act's call for collaboration between public and private laboratories, and that it allows for the use of resources from a range of laboratories to strengthen and expand activities related to genomic sequencing of

pathogens. To further strengthen this Section, we recommend that all laboratory types be eligible for these partnerships. Thus, AMP requests the following changes (red text represents recommended additions and deletions within the text):

- **At Sec. 2824(c)(2) regarding the Centers of Excellence, that it read as "….as applicable, with ~~academic~~ public health, academic, research, hospital, or private clinical laboratories, or a consortium of ~~academic~~ partners that have relevant expertise, such as microbial genomics, molecular epidemiology, or the application of bioinformatics or statistics."**

AMP looks forward to working with other stakeholders to advance this critical piece of legislation.

Section 221. Improving recruitment and retention of the frontline public health workforce

Thank you for including Section 221, which would reauthorize the Public Health Workforce Loan Repayment Program and expand statutory language to ensure that those with certifications or degrees in public health, epidemiology, laboratory sciences, data systems, data science, data analytics, informatics, statistics, or other subject matter related to public health are eligible for the program. We have heard from our members that laboratories are experiencing significant personnel shortages and the latest SARS-CoV-2 surge has only exacerbated the issue. AMP has had a long-standing recommendation that the federal government should support the clinical laboratory workforce because they are essential to providing an effective medical and public health pandemic response. We believe that Section 221 aligns with this recommendation. Additionally, AMP wants to note that support for laboratory professional training programs is greatly needed, and we would be grateful for the opportunity to further discuss solutions on this topic.

FDA Review of Laboratory Testing

AMP is supportive of providing FDA with additional resources to ensure that the agency is able to efficiently and effectively ensure the accuracy and precision of in vitro diagnostic test kits. Our 2020 survey results indicated that most laboratories relied on the use of kits supplied by test manufacturers, and moreover having numerous testing options for laboratories to select from was clearly a strength in our response efforts. Laboratories implemented numerous testing approaches to build redundancy and flexibility into their processes, allowing them to pivot to alternative testing methodologies/platforms to accommodate supply shortages and maintain their capacity and ability to meet testing demand. When multiple testing approaches were able to be deployed, laboratories were able to innovate and adapt to unanticipated challenges, such as the emergency of new easily transmissible variants. This is in sharp contrast to February 2020 when the US had no access to testing, as the entire laboratory community was crippled by missteps early on when only the flawed CDC test kit was available. Thus, FDA should implement a streamlined and clear process to ensure that diverse and numerous manufactured test kit options are available to laboratories as soon as possible during an outbreak.

However, as stated above AMP opposes the actions FDA took during the COVID-19 public health emergency that required EUAs for LDPs. We believe the COVID-19 pandemic should serve as a case study of how a surge in unnecessary review submissions hampered FDA's ability to fulfill its duties in a timely manner to appropriately regulate in vitro diagnostic test kits. Crucially, FDA's regulatory policy in 2020 greatly limited the ability of this country to respond rapidly to a serious and evolving outbreak in the early months of the pandemic, and it stands in sharp contrast to the laboratory community's ability to meet clinical testing needs during previous outbreaks. For example, during the first month of the 2009 H1N1 influenza pandemic, 62% of the patients screened for

H1N1 influenza in Chicago were tested by community molecular diagnostics laboratories with a turnaround time of 24 hours. Further, a previously conducted survey of AMP members focused on H1N1 testing revealed that 93% of respondents had a molecular assay that could distinguish between influenza type A and influenza type B with the ability to expand their aggregate testing capacity to 12,000 specimens per day within one month, easily accommodating the testing needs of the entire country during that pandemic outbreak. We hope that policymakers will conclude that creating new barriers to accessing accurate and reliable testing is not in the best interest of Americans' health.

Thank you for your continued leadership and efforts to improve public health and health care delivery as our country faces new and difficult challenges. Should you have any questions or wish to discuss these issues further, please don't hesitate to Tara Burke at tburke@amp.org.

Sincerely,

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