COLLEGE of AMERICAN PATHOLOGISTS

February 14, 2022

The Honorable Patty Murray
Chair, Health, Education, Labor, and Pensions Committee
U.S. Senate
Washington, DC 20510

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

Dear Chair Murray and Ranking Member Burr:

The College of American Pathologists (CAP) appreciates the opportunity to provide comments on the committee's PREVENT Pandemics discussion draft. The CAP is the world's largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As you are aware, pathologists are physicians who specialize in the diagnosis of disease, while the expertise they provide drives treatment decisions that optimize outcomes for patients. During the COVID-19 public health emergency, pathologists have been on the frontline of the crisis, responsible for ensuring prompt and accurate testing for patients and health care providers alike.

The battle against COVID-19 has highlighted critical areas of concern that must be addressed to better prepare for future pandemics. The discussion draft outlines proposals in several of these areas that the CAP supports, including addressing social determinants of health, supporting genomic sequencing and advanced molecular detection, enhancing public health surveillance of pathogens – particularly through the Advanced Molecular Detection program, improving recruitment and retention of the public health workforce, and modernizing the supply chain for vital medical products. As such, the CAP offers the following feedback and suggested amendments to the committee's discussion draft.

TITLE 1 STRENGTHENING FEDERAL AND STATE PREPAREDNESS

Section 101. Comprehensive Review of the COVID-19 Response

The CAP asks the committee to consider including language in section 101(c)(3)(C)(i) to ensure that a physician who has training in and is currently practicing laboratory medicine is represented on the task force. The current use of the broader term "medicine" includes any number of specialties, but the CAP believes expertise in laboratory medicine specifically is an important qualification for any examination and assessment of the COVID-19 preparation and response. For example, during the COVID-19 public health emergency, pathologists in hospitals and independent laboratories around the country have been responsible for developing and/or selecting new test methodologies, validating, and approving testing for patient use, and expanding the testing capabilities of the communities they serve to meet emergent needs. Pathologists also assure compliance with all laboratory regulatory and accreditation standards, while preventing overuse or improper application of tests. The influence of all these pathology services on clinical decision-making is pervasive and

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constitute a critical infrastructure and foundation of appropriate care. This insight would be an invaluable contribution to the task force.

TITLE II IMPROVING PUBLIIC HEALTH PREAREDNESS AND RESPONSE CAPACITY

Section 201. Addressing Social Determinants of Health and Improving Health Outcomes
The CAP lauds the committee's effort to address social determinants of health and improve health outcomes. Consistent with that effort, the CAP asks that the committee consider amending section 317(V)(b) to include medical organizations and historically Black colleges and universities (HBCUs) and other minority serving institutions (MSIs) to fully address social determinants of health in their communities. Broadening the eligible entities beyond community-based organizations while maintaining the important purposes of the funding will increase opportunities to reach the outlined goals. For example, in addition to the everyday work pathologists do, the CAP Foundation created the See, Test and Treat program, which delivers free cervical and breast cancer screenings to medically underserved women in the United States who face language, cultural, financial, and transportation barriers to health care. Every See, Test & Treat program takes place in a hospital or clinic that has agreed to create an electronic medical record for each woman and commits to ensure follow-up care for all women who participate.

The CAP supports additional resources to further bolster state, local, and tribal communities' abilities to address social determinants of health while strengthening the ties between technology and social services to directly influence health outcomes. The CAP recognizes addressing social determinants of health requires a robust, diverse, and interdisciplinary approach across all sectors and communities to improve health outcomes in underserved communities.

Section 211. Modernizing Biosurveillance Capabilities and Infections Disease Data Collection
Section 213. Supporting Public Health Data Availability and Access
The CAP asks the committee to consider amending Section 211(2)(C)(ii)(II) of the draft by inserting before "experts in privacy and data security," experts in laboratory informatics, in parathesis, after experts in informatics as written in the current statute. The CAP supports the goals of Sections 211 and 213 because rapid and accurate reporting of laboratory test results during a public health emergency is critical. The CAP has contributed our expertise in optimizing the response to the COVID-19 public health emergencies through efficient, standardized reporting structures. However, there is a balance to reporting and standardizing the data needed to make informed decisions without overburdening those tasked with collecting the data.

While the CAP supports efforts to establish publicly available real-time dashboards for tracking COVID-19 cases, hospitalizations, transmission, etc., there are limits to what laboratories can be expected to provide during a public health emergency (PHE) when they must rely on others outside the laboratory environment to provide certain data elements. For example, testing data may be housed in a laboratory information system (LIS), while patient ZIP codes may be in an electronic health record (EHR), which is inaccessible to the laboratory. Further complicating matters is the fact that the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), and state and local public health officials issue multiple, intricate guidance documents that may contain conflicting information. The CAP would urge health officials to work with

the CAP to develop a workable set of requirements and standards for laboratories to report and collect data related to the PHEs. Data elements for PHE reporting by laboratories should only be required when the elements are within the purview of the clinical laboratory. Further, while penalties compel compliance to regulatory requirements, the CAP would urge discretion and rescinding of penalties when unrealistic expectations are set.

Section 212. Genomic Sequencing, Analytics, and Public Health Surveillance of Pathogens
The CAP supports this provision. Significantly boosting U.S. genetic surveillance and viral sequencing is key to moving beyond the COVID-19 pandemic and effectively responding to future challenges, including novel and evolving infectious diseases, as well as seasonal threats like antimicrobial resistance and foodborne pathogens. Several of our members are receiving funds through their local department health to sequence COVID-19 variants, which allows them to provide important information about COVID-19's impact and its evolution. This public health information is important and necessary responding to the current crisis.

Specifically, the CAP fully supports the language in this section to enhance existing genomic sequencing and surveillance activities, support continued partnerships between public health entities and the broader academic research and clinical laboratory ecosystem, and codifying the CDC Centers of Excellence in Genomic Sequencing and Molecular Epidemiology. We also are pleased that the bill authorizes multi-year funding for the Advanced Molecular Detection (AMD) program at the CDC. This investment will ensure that we are far better prepared for future outbreaks.

Since 2014, the AMD program has employed next generation sequencing (NGS) to bring the concept of precision medicine to bear for "precision public health." AMD has given us new tools to detect disease faster, identify outbreaks sooner, and protect people and the food supply from emerging and evolving disease threats.

Section 214. Epidemic Forecasting and Outbreak Analytics
The CAP supports the authorization of the CDC Director to continue activities related to epidemic forecasting and outbreak analytics as described. Further, the CAP urges the committee to include language to modernize the U.S. disease warning system to forecast and track hotspots for public health emergencies and infectious disease outbreaks.

Section 221. Improving Recruitment and Retention of the Frontline Public Health Workforce
The CAP asks that the committee consider amending Section 221, as appropriate, to ensure that medical examiners and forensic pathologists are considered part of the public health workforce and are eligible for the public health workforce loan repayment program.

Forensic pathologists are board-certified, physicians who are experts in medicolegal death investigation. The majority are employed by state or local governments and are required by statute to investigate unexpected, suspicious, and unnatural deaths including sudden infant deaths, drug overdoses, motor vehicle and mass disaster fatalities, suicides, homicides, and suspected infectious deaths (e.g., meningitis, COVID-19).

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Medical examiner offices have faced unprecedented challenges to complete death investigations and examinations. Forensic pathology services have played a key role in understanding the effects of COVID-19 and informed treatments as the country progressed through 2020 and 2021. Further, as COVID-19 deaths increased, medical examiners assisted communities in crisis with their expertise in handling the dead by, for example, fulfilling the need for increased body transport and storage. There continues to be a marked shortage of practicing forensic pathologists. With the current opioid crisis and COVID-19 pandemic, this shortage has become critical. There are currently an estimated 500-700 practicing forensic pathologists while more than double that number is needed to cover all the jurisdictions in the U.S. This shortage has been documented and described by the National Academy of Science's "Strengthening Forensic Science in the United States: A Path Forward (2009)" and the NIJ's "Report to Congress: Needs Assessment of Forensic Laboratories and Medical Examiner/Coroner Offices (2020)." This shortage exists because of decreasing supply (i.e., not enough forensic pathologists) with an increasing demand (i.e., increasing workloads).

Further, the CAP supports expanding and increasing support to/for the public health workforce by making awards to state, local, and territorial public health departments. Workforce investments that include laboratory personnel are an important piece of our ability to address the pandemic.

TITLE III ACCELERATING RESEARCH AND COUNTERMEASURE DISCOVERY

Section 304. Accessing Specimen Samples and Diagnostic Tests
The CAP supports this provision. While testing capacity in the United States has increased dramatically, there is room for improvement. Laboratory directors have and continue to cite problems acquiring testing supplies, particularly test kits, plastic pipette tips (which are also used to test for other diseases, including sexually transmitted infections), specimen acquisition swabs, and transport media as the greatest barriers to increased testing. For example, smaller health systems continue to struggle to get supplies. This has limited their capacity for rapid testing to triage patients in emergency room departments, placement in behavioral health and psychiatric programs, and testing for women who are in active labor.

TITLE IV MODERNIZING AND STRENGTHENING THE SUPPLY CHAIN

Section 402. Supply Chain Considerations for the Strategic National Stockpile
Section 404. Improving transparency and Predictability of Processes of the Strategic National Stockpile
Section 410. Grants for State Strategic National Stockpiles
The CAP supports Sections 402, 404, 410. The CAP supports establishing state stockpiles of medical products and supplies needed during a public health emergency, such as personal protective equipment, ventilators, and other medical products. The CAP urges the HHS to publish guidance on how states and tribes can request and access resources from the Strategic National Stockpile (SNS). The HHS has a role in ensuring that state stockpiles will be appropriately administered and maintained by establishing an audit process and, if necessary, withholding funds if a state fails to submit a state stockpiling plan or meet certain benchmarks and other metrics set by the HHS. The CAP further supports improvements to the SNS by partnering with medical product manufacturers, distributors, or other entities to increase the stockpiling and manufacturing capacity

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of reserve amounts of medical products to be provided during or in advance of a public health emergency. Finally, the HHS should be charged with ensuring that the contents of the SNS are in good working order and, as necessary, conduct maintenance on the stockpile's contents. The federal government can improve the SNS financial security by allowing it to sell products to other federal departments or agencies within six months of product expiration. The HHS must also be required to develop improved and transparent processes for SNS requests and identify clear plans for future communication between the SNS and states.

TITLE V ENHANCING DEVELOPMENT AND COMBATING SHORTAGES OF MEDICAL PRODUCTS

Section 502. Modernizing Clinical Trials
The CAP supports this provision because it begins to address barriers to entry for underrepresented diverse populations in clinical trials, which improves clinical research and safety, increases access to lifesaving therapeutics, and ensures high-quality care in disease diagnosis and management. Pathologists play a key role in the design, recruitment, analysis, and quality of clinical research in clinical trials. For example, pathologists conduct the foundational work of selecting and evaluating biomarker testing to assess for targeted therapies and for purposes of determining eligibility for clinical trials. The CAP supports diversifying clinical trials during COVID-19 and beyond to meet the highest level of efficacy and safety for all patients. Finally, the CAP encourages additional focus on expanding access to testing to decrease disparities in access to clinical trials for purposes of eligibility and enrollment in addition to exploring accessible methods to ensure patients can fully participate in clinical trials.

Section 515. Strengthening Medical Device Supply Chains
The CAP supports this provision. The CAP believes manufactures of certain critical medical devices should be required to develop, maintain, and implement risk management plans to ensure supply chains are more resilient. As noted, smaller health systems continue to struggle to get supplies, which limit capacity for rapid testing for triage in emergency room departments, placement in behavioral health and psychiatric programs, and testing for women who are in active labor. These risk management plans will be crucial to plan for and mitigate future pandemics.

As Congress works to prepare and respond to future pandemics the CAP welcomes the opportunity to work with your offices on these issues. Please contact Darren Fenwick via email at dfenwic@cap.org or via phone at (202) 361-1062 if you have any questions regarding these comments.

Sincerely,

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President

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