



COLLEGE of AMERICAN PATHOLOGISTS

January 27, 2021

President Joseph R. Biden
Vice President Kamala Harris
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Dear President Biden and Vice President Harris:

On behalf of the members of the College of American Pathologists (CAP), thank you for your National Strategy for the COVID-19 Response and Pandemic Preparedness. The plan outlines how to beat COVID-19 through swift and aggressive actions to protect all Americans. As pathologists are the physician specialists who diagnose disease, CAP members and the laboratories they direct have worked tirelessly since the coronavirus outbreak to bring new COVID-19 tests online in communities throughout the United States. By the end of 2020, laboratories performed more than 2 million COVID-19 tests a day. We will continue to increase patient access to accurate and valid tests throughout 2021. Our expertise in the laboratory drives treatment decisions that optimize health outcomes for patients. Pathologists will make the diagnosis, for example, of other diseases such as cancer (breast, prostate, cervical, leukemia, kidney), hepatitis, and cirrhosis. And, as the pandemic has shown, now more than ever, the US health care system relies on the expertise of pathologists to achieve healthier outcomes for all Americans.

The CAP appreciates the detail in the Biden administration's strategy to end the pandemic and rebuild the country back to a time when all children and teachers can attend school, restaurants can reopen to welcome diners, and families can safely gather for holidays. Overall, the CAP agrees with the strategy and its direction. In addition, we respectfully request you consider our comments and recommendations as you implement the strategy, and we would welcome the opportunity to discuss our ideas with you further. As pathologists are the experts on medical diagnoses, pathologists share your desire to provide greater access to COVID-19 testing and we must also be part of the public policy decision making process. Specifically, our expertise can help address needed COVID-19 coverage and testing improvements, supply chain issues, required regulatory action, and the economics of laboratory medicine that ensure continued access to necessary services. For questions about the testing process, the College of American Pathologists can help provide the answers. Together, we will effectively combat this pandemic.

COVID-19 Testing and Supply Shortages

While testing capacity in the United States has increased dramatically, there is room for further improvement. Surveys of laboratory directors have consistently reported excess overall testing and instrument capacity as they are being constrained by several limitations. Laboratory directors cite problems acquiring testing supplies, particularly test kits, plastic pipette tips, and specimen acquisition swabs and transport media as the greatest barriers to increased testing. To address these supply chain issues, the federal government should take additional actions.

The CAP applauds the Biden administration's plan to improve the supply chain for COVID-19 tests. The CAP supports federal efforts to improve the transparency, coordination, and management of



testing supplies to laboratories. Specifically, appropriate processes and infrastructure can assist laboratories, in particular those in hot spots or hard-hit areas, with depleted stores of reagents and other testing supplies needed for specimen collection and transport. And, the CAP strongly supports a federal guarantee of priority access to health care workers for national supplies of personal protective equipment (PPE).

Better transparency and communication about the prioritization and distribution of current COVID-19 supplies will help clinical laboratories manage their testing strategies at the local level. Further, officials at the Department of Health and Human Services (HHS), in coordination with the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC), should consult with medical product manufacturers, suppliers, and other relevant stakeholders to identify specific supply needs. The federal government should also support improvements to sustained manufacturing surge capacity and capabilities to produce needed medical countermeasures, such as vaccines and therapeutics, to respond to public health threats like COVID-19 in the future.

The CAP supports utilizing the Defense Production Act (DPA) to address supply shortages. At the same time, we acknowledge some key testing supplies, such as reagents, are manufactured overseas and thus the DPA would not be applicable. However, the CAP would still urge the government to leverage its authorities to further assist manufacturers in meeting the current and future demands for COVID-19 testing.

With regards to a Strategic National Stockpile (SNS), 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 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 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.

Public Health Guidance from Federal Agencies

Since the onset of COVID-19, the CAP worked with the HHS, CDC, FDA, and Centers for Medicare & Medicaid Services (CMS) on all matters concerning testing. The CAP welcomes the opportunity to continue its role in providing additional expertise and on-the-ground experiences our members have to inform draft policy and guidance from agencies. The CAP is pleased that the Biden administration will instruct agencies to provide clear, evidence-based guidance and resources about containment and mitigation of the disease for schools, health care facilities, and the general public.



Concerning testing, a plan that deserves further study is one that would ensure that the FDA works with the National Institutes of Health to prioritize review and authorization for use of COVID-19 countermeasures and strengthen regulatory science at the FDA to make certain it has the needed resources to evaluate the safety and efficacy of new tools. The CAP has advocated for laboratory-developed tests (LDTs) to be available for use by clinical laboratories without the hinderance of unnecessary regulatory burden. There has been bipartisan agreement that the FDA has regulatory oversight of LDTs. The CAP advocates for the government to minimize burden on laboratories through coordination between the FDA and the CMS to eliminate duplicative requirements. Recently, the FDA has deferred to Congress to legislate on implementing an LDT oversight framework that leverages the strengths of the FDA to ensure quality testing for patients and allow for innovation in laboratories. In addition, LDTs should be eligible for Public Readiness and Emergency Preparedness Act (PREP Act) if they are developed and validated in a high-complexity, CLIA-certified laboratory.

The CAP and American Medical Association (AMA) can serve as a resource to reinforce guidance and best practices from the CDC and other agencies. For example, following the approval of the COVID-19 vaccine in December the CAP issued a statement encouraging its members to take advantage of access to the vaccine and complete the course for inoculation. The AMA has routinely discussed the benefits of public masking as a measure to contain the spread of the disease. And, the CAP has issued guidance to the public on serology testing. Each communication focuses on the facts, evidence, and scientific rationale for public health guidance to assist state and local governments and an informed citizenry to make the right decisions.

The CAP also notes that the COVID-19 vaccine is an important tool in the fight against the disease. The CAP supports the administration's plan to further invest in vaccine distribution and guarantee all Americans have access to the vaccine without patient cost sharing.

Addressing Health Care Disparities

The CAP applauds plans in the strategy to address health care disparities. At our organization, we condemn racism and injustice in any form and stand resolute to fight against both. The CAP is focusing on diversity, equity, and inclusion issues in the workplace and workforce. Health care disparities in the US persist as a major issue highlighted by the fallout from the pandemic and the continued fight for racial equity. The CAP Foundation is also proud to provide care to some of our most at-risk communities during a time of dire need. The CAP Foundation's See, Test & Treat program brings free breast and cervical cancer screening to thousands of women across the country regardless of financial, language, cultural, or transportation barriers. The See, Test & Treat program was started in 2001 by the late Dr. Gene Herbek and was adopted by the Foundation in 2011. So far, we have funded 86 programs, screening over 6,000 women for breast and cervical cancer.

In this light, the CAP appreciates the establishment of a COVID-19 Racial and Ethnic Disparities Task Force to provide recommendations and oversight on disparities in the public health and economic response. The CAP further supports the evolution of this entity into a permanent Infectious Disease Racial Disparities Task Force. The CAP supports the next administration's plans targeting older adults, vulnerable individuals, and people with disabilities. The CAP further



encourages the Biden administration to explore initiatives that ensure vulnerable populations have equal access to testing, as well as treatments and therapeutics.

Finally, the CAP has supported legislative efforts to hold patients financially harmless from surprise medical bills. Legislation adopted by the 116th Congress will achieve this aim while providing physicians and insurers with a process to resolve billing disputes without patients being caught in the middle. As the administration continues this work through the rulemaking process to implement the new law, the CAP stands ready to provide comments and expertise on ways to improve this process. The CAP also notes that the administration will work to ensure everyone in America receives the protection and care they deserve, and consumers are not price gouged as new drugs and therapies come to market. The CAP supports existing policies, including ethics policies adopted by the AMA, that guard against unsavory practices of those taking advantage of Americans in need.

Reimbursement for COVID-19 Tests

With several variables surrounding the pandemic outside of a laboratory's control, the Biden administration can provide consistency in one area: reimbursement. The CAP has requested that the CMS increase reimbursement rates for COVID-19 tests to better reflect the costs associated with providing these tests.

In Medicare, the rates range from \$35 to \$100, but these rates failed to account for the costs and resources necessary to bring testing online during the national public health crisis for laboratories of all sizes and localities. In particular, these rates tend to preferentially favor the large, high volume testing providers while economically disadvantaging so many primary testing providers in the acute care hospital and academic laboratory settings who are responsible for rapidly identifying and caring for COVID-19 patients in the midst of this pandemic. In fact, a majority of these frontline providers have been forced to diversify and develop more than one (and often multiple) testing methods and are now managing various different combinations of analytical platforms to help address the unprecedented shortages and unmet demands for expanded and more accessible SARS-CoV-2 testing in their local communities. We are greatly concerned that all provider laboratories cannot sustain these underpayments indefinitely, along with the other overall increased costs associated with doing business during the national public health emergency.

Further, in October 2020, the CMS stated it would cut payment for certain high-throughput COVID-19 tests by 25% while introducing an add-on code that would allow laboratories to make up the difference if they meet turnaround time requirements. In practice, the new reimbursement policy threatens to penalize laboratories for issues related to supply shortages and other factors outside its control. The CAP, as it has urged the Trump Administration, will call on the Biden Administration to abandon this flawed policy.

The CAP has also requested immediate national coverage for multiplex polymerase chain reaction (PCR) respiratory viral panel (RVP) tests and recommends that the CMS provide uniform national coverage for the clinical diagnostic laboratory tests that may be performed without a practitioner order, by removing a local coverage barrier during the COVID-19 public health emergency. Providers need the ability to rapidly identify the pathogen causing the patient's symptoms to ensure they are in fact COVID-19 negative, and then appropriately isolate or cohort a patient accordingly.



Many respiratory pathogens present similarly in patients and it is difficult to differentiate between influenza, coronavirus, rhinoviruses, and many other pathogens without accurate testing. Ensuring rapid results with uniform coverage policies is essential to triaging patients and minimizing disease transmission.

Clinical Laboratory Regulatory Issues

Previously, the CAP requested that the CMS allow the CAP to temporarily postpone inspections of CAP-accredited laboratories out of necessity. With COVID-19 spreading rapidly, inspections not only took time away from conducting tests but would also represent an exposure risk to inspectors and laboratory personnel. The CMS provided a three-week moratorium on inspections and allowed the CAP to develop a virtual inspection program. However, CMS is requiring accreditors as a part of the virtual inspection programs an on-site component. Given the rise in COVID-19 cases, clinical laboratories have lacked the resources to adequately prepare for virtual inspections. The CAP has requested that the CMS provide accreditors with more flexibility for inspections until case levels are below recommended thresholds.

Throughout the pandemic, the CAP has also supported granting a temporary waiver of Clinical Laboratory Improvement Amendments (CLIA) requirements in regard to working remotely, allowing pathologists to sign-out cases offsite, and to allow local laboratories to determine what is best for their particular situation. Additionally, the CAP has supported granting a temporary waiver of CLIA requirements to allow clinical laboratories to establish drive-thru or temporary locations for testing. While we appreciate the response, certain regulatory requirements should be automatically waived or reduced once a public health emergency is declared to avoid unnecessary delays. For example, the FDA emergency use authorization is enacted upon a public health emergency declaration. A similar process should be enacted for CLIA to allow laboratories the necessary discretion to determine what is best for their staffs to manage the pandemic.

COVID-19 reporting is a critical initiative to help our country reopen and the CAP has contributed our expertise in optimizing the response to this public health emergencies through efficient, standardized reporting structures. At the same time, there is a balance to reporting the data needed to make informed decisions without overburdening those tasked with collecting the data. While we support efforts to have the CDC 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 especially when they must rely on others outside the laboratory 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. Also, complicating COVID-19 reporting are the HHS, CDC, and state and local public health officials issuing multiple, intricate guidance documents that at times have contained conflicting information. The CAP would urge health officials in the new administration to work with the CAP to develop a workable set of requirements for laboratories to report data related to the pandemic. Data elements for COVID-19 reporting by laboratories should only be required when the elements are within the purview of the clinical laboratory. Further, while penalties compel voluntary compliance to regulatory requirements, we would urge the next administration to exercise discretion and rescind penalties when unrealistic expectations are set.

Financial Assistance



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Throughout 2020, Congress has recognized the extreme financial strain placed on providers because of the COVID-19 public health emergency, and has appropriated funds offering financial relief to physicians and other health care providers. While much of the initial stress has subsided, the shift in health care priorities, increase in non-reimbursable expenses, and pause in non-essential surgeries and other procedures continues to result in significant financial losses that threaten the viability of many small and mid-size business physician practices. Further, many small and mid-size practices were less equipped to weather this financial crisis, for example, with limited ready access to capital. Financial relief for physician, physician practices, and laboratories remains crucial so pathologists and other providers can continue to focus on the essential task of testing and ensuring proper treatment of patients. The CAP continues to support the allocation of additional financial support through the Provider Relief Fund and other direct funding mechanisms to keep pathology practices open and available to patients.

To further support frontline physicians, the CAP has also requested that Congress provide at least \$20,000 of federal student loan forgiveness or \$20,000 of tuition relief to medical students and residents. These benefits would also apply to third- and fourth-year medical students who are willing, and deemed competent, to begin providing early patient care for patients with COVID-19. The CAP also supports the establishment of a fund up to \$5 billion to support pathology and laboratory frontline providers. This assistance should provide pathologists and laboratories performing COVID-19 testing services with funds to support laboratory personnel, uncompensated testing, capital and supplies, research and development, and other costs associated with testing. The CAP also urges Congress and the Biden administration to enact targeted liability protections where health care services are provided or withheld in situations that may be beyond the control of physicians/facilities (eg, following government guidelines, directives, lack of resources) due to COVID-19.

State and Local Issues

With 450,000 Americans deceased because of the COVID-19 pandemic, medical examiner offices have faced unprecedented challenges to complete death investigations and examinations. Forensic pathology services have had a key role in understanding the effects of COVID-19 and informed treatments as the country progressed throughout 2020. As deaths increased, medical examiners and coroners further assisted communities in this public health crisis with their expertise in handling the dead by, for example, meeting needs for increased body transport and storage. The CAP encourages the Biden administration to support efforts to extend federal funds addressing the fiscal impacts of the pandemic, which include support for medical examiner services that are often overlooked.

Global Health Initiatives

The CAP's mission includes advocating excellence in the practice of pathology and laboratory medicine worldwide. With more than 20,000 laboratories in over 100 countries, we continue to expand partnerships worldwide to help laboratories achieve high quality and performance through our comprehensive programs and services. In this regard, the CAP firmly believes the United States is a leader in the global health care community and we urge the Biden administration to take the necessary steps to build or restore relationships with global entities so we can not only improve patient care worldwide but further protect the health security of Americans. As this pandemic has



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shown, positive relationships and partnerships at the global level are key to safeguarding Americans at home.

The CAP recognizes President Biden's executive order to restore the United States' relationship with the World Health Organization. Physicians support this action as, on January 12, 2021, the AMA applauded the Biden administration's commitment to rejoin the World Health Organization in order to shape health care policy for the betterment of mankind. Global health initiatives the CAP supports are:

- Relaunching the US Agency for International Development's pathogen-tracking program.
- Creating a Global Health Emergency Board to harmonize crisis response for vulnerable communities.
- Establishing an Assistant Secretary at the State Department to oversee the office of Global Health Security and Diplomacy.
- Strengthening the CDC's Field Epidemiology Training Program and Field Epidemiology and Laboratory Program.
- And, restoring the White House National Security Council Directorate for Global Health Security and Biodefense.

Thank you again for the opportunity to engage with you on the strategy to end the COVID-19 pandemic. The CAP and pathologists around the country stand ready to work with you on achieving this objective. Please contact the CAP Assistant Director Scientific Regulatory Policy Helena Duncan (hduncan@cap.org; 202-354-7131) with any questions.

Sincerely,

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Sent via email

cc: White House COVID-19 Response Team; COVID-19 Coordinator Jeff Zients; Policy Advisor for Testing Vidur Sharma; Testing Coordinator Carole Johnson