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The Honorable Bernard Sanders
Chairman
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

The Honorable Bill Cassidy, M.D,
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

The Honorable Robert P. Casey Jr.
Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

The Honorable Mitt Romney
Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney,

The Advanced Medical Technology Association (AdvaMed) greatly appreciates the opportunity to provide a response to your request for information on the reauthorization of the Pandemic All-Hazards Preparedness Act. AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing and life-saving health care technology purchased annually in the United States and globally. Our members are committed to the development of new technologies and services that allow patients to lead longer, healthier, and more productive lives. The devices made by AdvaMed members help patients stay healthier longer, recover more quickly after treatment, and enable clinicians to detect disease earlier and treat patients as effectively and efficiently as possible.

To prepare for any future extraordinary health care-related crisis requires a concerted and collaborative effort with government and industry working together. We share your commitment to ensuring America is prepared for future public health challenges.

On behalf of AdvaMed's member companies and the patients they serve, we offer the following responses to your questions. We look forward to working with you to advance these proposals.

Program Effectiveness

What specific changes could Congress make to improve the efficiency and effectiveness of current HHS programs and activities? Specifically:

Public Health Emergency Coordination and Policy

1. The responsibilities and authorities of the Secretary of Health and Human Services (HHS) prior to or during a public health emergency (PHE)

Augmenting HHS Authority to Prepare and Respond

To support swift action by HHS to prepare and respond to public health emergencies, AdvaMed recommends that Congress provide to HHS the authority to directly and swiftly contract with industry to ramp up manufacturing and procure products. Currently, HHS lacks such authority and must leverage the Department of Defense (DOD) contracting mechanisms. Direct HHS authority to establish public-private contracts to support increased manufacturing and maintenance of capacity would streamline our nation's collective response efforts.

Additional considerations should include enhanced authorities for HHS to assist the medical device sector with securing critical materials and components to ensure the nation's healthcare infrastructure and patient care can continue uninterrupted during public health emergencies.

The CARES Act included new FDA authorities, including mandatory medical device shortage reporting requirements on medical device manufacturers, during or in advance of a public health emergency. The provision requires that reports be sent to FDA for devices that are discontinued or subject to an interruption in its manufacturing with updates sent to FDA every two weeks. FDA maintains a public database of current device shortages which includes estimated duration and reasons for the shortage. The current authorities appear to be working, as FDA has information enabling it to make decisions and provide a public-facing database. AdvaMed does not support additional mandatory reporting requirements or an expansion of Section 506J of the Food, Drug and Cosmetic Act created in the CARES Act.

3. The National Health Security Strategy (NHSS)

Prioritize Sterilization, Including via Ethylene Oxide (EtO or EO): With the growing threat of resistance to disease-fighting methods, safely sterilized equipment and supplies are more important than ever. Ensuring the U.S. has adequate domestic sterilization capacity for medical devices is critical. This includes

all modalities for sterilization of medical devices. Of particular criticality is ethylene oxide (EO) which is naturally occurring, colorless gas used in the sterilization of a vast number of medical devices including drapes, gowns, heart valves and pacemakers, ventilators, neonatal breast milk supplies, and catheters. More than 50 percent of all medical devices — more than 20 billion devices each year — are sterilized with EO. The process is highly regulated and critical to patient safety. There is no alternative sterilization method for most of the devices and supplies made safe via EO. As the government looks at policies to support the domestic supply of these kinds of technologies for the SNS as well as overall sterile product infrastructure and preparedness, ensuring vital access to sterile technologies for U.S. patients and regulatory clarity around the use of EO and reasonable standards for usage will be essential.

Medical Countermeasures Development and Deployment

1. The Strategic National Stockpile (SNS)

AdvaMed recommends the following policies to strengthen the Strategic National Stockpile (SNS):

***Increase and Extend Funding*:**

The SNS is currently funded for five years, including $1.657 billion for Fiscal Year 2022. Both the amount and the funding periods should be carefully examined. Given the relatively infrequent nature of a major health care crisis such as a pandemic, ten-year funding might be more appropriate. Funding levels should ensure the stockpile is maintained at pre-determined levels, and that products are rotated in accordance with industry-recommended shelf lives and updated to recognize innovative new technologies. More funding will be required to rebuild supplies after the emergency has concluded. The U.S. government should award contracts to willing manufacturers to sell designated quantities at pre-fixed, negotiated prices as production of a particular medical device begins to exceed demand and inventories return to more normal levels. This approach will provide manufacturers greater confidence that as they ramp up to meet the initial demand surge, they will not be left with significant quantities of unsold products. This system would also fill the SNS when supplies are at more normal levels. The government's goal for each product and the amount of these contracts should be made public to enable manufacturers to plan accordingly. Each manufacturer would know how much it should continue to produce, as well as the government's total SNS goal for each product.

In brief, AdvaMed recommends an increase in funding to the Strategic National Stockpile to ensure the stockpile is kept fully stocked with a one-year supply to accommodate the highest pandemic level threat.

Reflect Innovation in Inventory: As the government reviews medical supplies and technologies for suitability in the SNS, it should account for

advances in science and technology. Some technologies may become obsolete while others need to be added for consideration. AdvaMed recommends a formal mechanism for the government to consult with the private sector regularly to ensure the latest advances in medical technology are reflected in the SNS.

Leverage Vendor-Managed Inventory: A mechanism to support effective stockpiling and efficient distribution of items in the SNS would be through Vendor-Managed Inventory (VMI). VMI of the stockpile can ensure that critical and up-to-date medical technologies are readily available and rapidly deployed during any public health emergency. Under the VMI system, the federal government would contract with a private partner to store stockpiled products in its domestic warehouses rather than in government-owned and -operated warehouses. Under such an arrangement, for example, for diagnostics products, the manufacturer or distributor would be responsible for overseeing the storage and inventory management of the stockpiled diagnostic testing equipment and supplies, such as laboratory instrumentation, test kits, extraction reagents, sample collection and transport devices, etc. To mitigate product expiration, supplies would be rotated, as is currently done under The Shelf Life Extension Program, managed by the Department of Defense (DOD) and the Food and Drug Administration (FDA). When the stockpile is activated by the United States Department of Health and Human Services (HHS) in response to an emergency, the diagnostics manufacturer would immediately deploy the stockpiled items. The advantages of VMI include mitigation of risk to the federal government and ensuring up-to-date medical technologies, as well as the efficient leveraging of the storage and distribution expertise and infrastructure of private industry partners.

AdvaMed recommends VMI be employed by HHS to manage the SNS, with product-specific policies that account for the unique factors of various medical technologies.

***Recognize Development of New In Vitro Diagnostic (IVD) Tools as Pathogens Emerge*:** The SNS should have an adequate supply of diagnostic testing equipment, materials, and supplies, as it is critical to have the ability to rapidly test and diagnose patients who are sick or have been exposed to a pathogen. While it is not possible to stockpile diagnostic tests for an unknown pathogen, certain tests can be stockpiled that can help rule out other infections. For example, every year the stockpile could ensure it has certain tests for influenza, COVID-19, Respiratory syncytial virus (RSV), and other respiratory illnesses. These tests could help rule out these particular viruses and help identify if a new pathogen causes similar respiratory symptoms.

AdvaMed recommends stockpiling the equipment necessary to process IVD tests – such as test instruments, analyzers and other capital equipment – to

rapidly scale up diagnostic testing infrastructure and help to ensure prompt testing of samples in communities that may not have an existing lab or testing infrastructure. In addition, medical supplies used in the collection, transport and processing of IVD tests should be considered for the SNS. These include swabs, collection tubes, lancets, transport medium/tubes, and reagents such as DNA/RNA extraction kits, which are generally not specific to a particular test or pathogen. Further, the stockpile should include agnostic raw materials and consumables that would support future infectious disease testing. Most laboratory based molecular instrumentation requires the same agnostic raw materials and consumables to perform any infectious disease test developed in a future public health emergency. As diagnostic tests to screen and diagnose for the new pathogen are rapidly developed, these tests should be added to the SNS as well.

Enhance Range of Ventilation Technologies: The SNS should include a range of devices that can provide ventilation support for patients with respiratory syndromes specific to COVID-19. Access to critical care ventilators has been essential to the COVID-19 response. As those resources became stretched, alternative ventilation options such as non-invasive ventilation (NIV), and bi-level and Continuous Positive Airway Pressure (CPAP) therapy were crucial to stabilize or sustain patients who required respiratory support. Studies have demonstrated that COVID-19 patients with less severe respiratory distress could benefit from non-invasive ventilation therapy, thus freeing up more invasive ventilation devices for critically ill patients. As governments and health administrations around the world responded to the global demand spike for ventilators, many issued guidance documents on the use of bilevel or BiPAP devices that deliver NIV in patients with confirmed or suspected COVID-19, including in the sub-acute and post-acute health care and home environments, on the non-invasive ventilation devices that are already used in millions of homes every day. Additionally, the government should ensure it is prepared to support the various maintenance requirements of the ventilators in the SNS.

Improve Data-Sharing Protections: Significant data sharing between the public and private sectors underpins several objectives key to our nation's response to public health emergencies, including creating visibility about inventory levels, distribution flows, epidemiological and disease state trends, demand forecasting and distribution. Given that much of this information could include sensitive data such as intellectual property, trade secrets and other competitive information, public-private data sharing should be grounded in clear communication and guidance about how this information would be solicited, secured, shared, and otherwise utilized.

Medical Distribution System Interoperability: The SNS could enhance its readiness for future emergencies, by reviewing its technology systems for

updates and upgrades. The private sector has consistently demonstrated its ability to support efficient distribution of medical and pharmaceutical products on behalf of the U.S. government. To expand on these efforts the U.S. commercial pharmaceutical and medical distribution could partner with the SNS on maintaining IT connectivity. We believe the SNS should work with all US-based medical and pharmaceutical distributors on developing and maintaining IT connectivity. Collaboration between the SNS and private sector distributors will ensure that the healthcare supply chain will have access to the IT specifications needed to implement IT interoperability with the SNS. Longstanding IT connectivity between the commercial distribution chain and SNS will improve readiness during a future emergency.

2. The Biomedical Advanced Research and Development Authority (BARDA)

The Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response, through BARDA, has been providing significant support to IVD manufacturers to advance and accelerate the development of emergency diagnostic tests. Innovation should be fully embraced to ensure a broad range of testing, from those that enable advanced surveillance to facilitate triaging of patients based on their potential risk to deterioration, and beyond. AdvaMed encourages the bolstering of this funding and new flexibility to maximize innovation, including allowing funding provided by BARDA to be used to recoup costs already incurred for emergency test development prior to receipt of the funds.

Furthermore, federal contracting procedures and timelines can delay the transfer of R&D funding to manufacturers during an outbreak. This delays the pace of IVD development and provides a significant disincentive to many manufacturers to develop tests at the risk of not being able to recoup initial development costs.

Additionally, more flexibility in how BARDA funds can be applied to reimburse development costs incurred during the earliest states of test development would be a significant incentive to manufacturers to accelerate the development of emergency diagnostic tests.

Gaps in Current Activities & Capabilities

What gaps do you see in the PAHPA framework, or how it has been implemented to date? (These gaps could be related to any of the programs noted above, or other aspects of the public health and medical preparedness and response ecosystem that are otherwise currently unaddressed.)

Additionally, aside from currently authorized programs and activities, what gaps exist in HHS' capabilities, and what types of activities or authorities are necessary for HHS to fulfill the intent of PAHPA and related laws?

Comprehensive Diagnostics Regulatory Reform

AdvaMed recommends passage of legislation to modernize oversight of all diagnostic tests, both *in vitro* diagnostics (IVDs) and laboratory developed tests (LDTs) by creating a single, diagnostics-specific, FDA regulatory framework aimed at promoting innovation and improving public health outcomes. Specifically, we urge Congress this year to move the legislative process forward to improve and pass the "Verifying Accurate Leading-Edge IVCT Development Act" (or "VALID" Act) to close existing gaps in regulation of diagnostic tests. The bipartisan, VALID Act would modernize the regulatory framework applicable to all diagnostic tests, providing much-needed clarity, while enhancing the availability of high-quality, innovative tests to improve patient care and public health. By closing gaps in regulation, the VALID Act would give confidence to patients and providers in the quality and performance of all tests, regardless of where the tests were developed.

Removing Inefficient Regulatory Barriers at CMS

The public health emergency (PHE) necessitated bold action by CMS to adapt to ongoing challenges for the healthcare system. CMS responded to the immediate needs of the PHE and believes that flexibilities afforded by the Agency have proven essential during the crisis. As the Administration, Congress, and CMS begin preparing for the end the PHE, AdvaMed believes many of these important flexibilities should be extended through the PHE recovery period to enable providers to efficiently and effectively provide much needed, equitable care to patients as they seek services from the healthcare system after the PHE ends.

Expand and Extend Access to Telehealth Services

CMS rapidly acted at the onset of the PHE to expand Medicare beneficiary access to health care services through waivers to restrictions in Medicare statute that until that point limited coverage of telehealth services. Key among the waiver expansions were provisions that have (1) allowed beneficiaries living in urban areas, not just rural areas, to receive telehealth services and (2) allowed beneficiaries to receive telehealth visits in their homes, and not just the end of the PHE and a second time by the Consolidated Appropriations Act, 2023 through the end of 2024. After three years' experience in seeing how these telehealth waivers have expanded access to care for the increasing number of beneficiaries 85 years of age and older and often with multiple chronic conditions, Congress should amend Medicare's statute to eliminate these two restrictions and make permanent coverage for telehealth for beneficiaries living in both rural and urban areas and also allow beneficiaries to receive telehealth in their homes.

In 2021 during the PHE, CMS established a new Category 3 of Medicare covered telehealth services. CMS established a Category 3 for telehealth after finding that

some services do not have enough data and evidence to allow the services to be added on a permanent basis to Medicare's covered Telehealth Services List but might be able to generate evidence if covered under an interim period. In addition, CMS allowed coverage for Category 3 services to be extended through the first 151-day extension of telehealth waivers.

AdvaMed has two recommendations for Category 3 telehealth services. First, CMS should extend interim Category 3 services coverage through the second telehealth waiver extension--the end of 2024, as CMS had for the first waiver extension. Second, AdvaMed recommends that the Category 3 concept of interim coverage during an evidence generation period should be made a permanent part of the program. This will allow broader coverage of telehealth services by avoiding situations where CMS decides to disapprove adding a service to the List on an annual basis when a requestor has had insufficient time to develop evidence to make the case for a service being added to the List. This pathway could be limited, for example, specifically to services that would fall into Category 2 services, where evidence on outcomes is generally required for approval. In this way, services could be added on an interim basis as requests are made and this would signal the beginning of evidence generation for ultimate approval/disapproval. A timeframe would be specified for generating necessary evidence.

While we believe these changes and flexibilities remain important, AdvaMed also believes that any permanent expansions of modified telehealth policies should be coupled with parallel proactive assessment of unintended consequences to patient care and/or accompanied by policies to mitigate issues that might arise.

Continue Flexible National Coverage Determination (NCD) and Local Coverage Determination (LCD) Requirements

In April 2020, CMS issued CMS-1744-IFC, Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID-19 PHE. This IFC included blanket waivers of NCD and LCD coverage requirements. Subsequent to the IFC, CMS issued guidance on these waivers specifying that treating practitioners and suppliers must, however, still: (1) ensure that items or services are reasonable and necessary, (2) continue documenting the medical necessity for all services with the medical record sufficient to support payment for the services billed, and (3) make documentation available upon request. In many if not most instances, these general requirements were far less restrictive than requirements included in the underlying NCDs and LCDs.

NCDs and LCDs cover a broad range of health care procedures and conditions and define coverage restrictions across various dimension of health care delivery. Coverage restrictions included in several NCDs/LCDs, for example, are requirements that patients have periodic face-to-face visits with a treating physician or that facilities and providers meet certain volume requirements in order to perform certain procedures.

AdvaMed recommends suspending NCD and LCD requirements on face-to-face visits through the end of 2024. As precedent for this glidepath of continued waivers for NCD/LCD face-to-face visit requirements, we cite the recently revised LCD 33822 for continuous glucose monitors (CGMs), finalized March 2, 2023. The previous LCD required that persons with diabetes and using CGMs have periodic in-person visits with their treating practitioner. The new finalized LCD allows these in-person visit requirements to be met through telehealth. Experience during the PHE with telehealth—in terms of ease of access and quality of care provided through the telehealth visit—justifies the substitution of in-person visits with telehealth visits across various NCDs and LCDs. AdvaMed believes extending waivers to allow in-person visits to be met through telehealth will facilitate continued timely access to quality care and allow frail beneficiaries with often multiple chronic conditions to receive the care they need.

AdvaMed also urges Congress to consider how ending other NCD and LCD flexibilities without a glidepath in place may impact timely patient access to life-saving treatments. These waivers should be extended until alternative sources of care can be defined by CMS for providing access to needed care.

In addition, the end of the PHE raises questions about how patients receiving services or technologies under the NCD/LCD blanket waivers will be treated once the PHE ends. For example, during the PHE, physicians have prescribed non-invasive ventilator equipment, oxygen, and sleep therapy under the relaxed standards. In other instances, patients have received insulin pumps for managing their diabetes without having to meet requirements of an underlying NCD. These are just two examples of patients potentially losing access to prescribed technologies altogether or having to go through a review process to determine whether their technologies can be covered under the original restrictive standards--at great burden to patients and their providers. AdvaMed recommends that the more balanced approach would be to grandfather patients and allow their technologies and related services to be covered into the future.

Simplify and Streamline Future Prior Authorization Requirements

AdvaMed recommends instructing Medicare Advantage (MA) plans to waive prior authorization (PA) requirements for procedures treating life-threatening conditions and to continue looking for ways to simplify and significantly streamline PA requirements. MA plans continue to grow at an accelerated pace. The Kaiser Family Foundation reports that enrollment in MA plans has doubled over the past decade, and the Congressional Budget Office projects 60% of Medicare beneficiaries will be enrolled in MA plans by 2032.[1] As MA plans play an increasingly vital role in ensuring Medicare beneficiaries have access to medically necessary covered services, it is imperative CMS ensure the services provided by MA plans appropriately align with traditional Medicare coverage without unnecessary delays in access to care.

The PA process can be time-consuming for providers who may already be facing staffing challenges, and often results in delays in patient care. As captured in the American Medical Association's provider survey there is a clear association between PA requirements and treatment delays/abandonment, negative clinical outcomes, and even serious adverse events, including hospitalizations and patient death.[2] CMS recently published two proposed rules to: (1) clarify and improve the regulations governing when and how MA plans develop and use coverage criteria and utilization management policies to ensure MA enrollees receive the same access to medically necessary care; and (2) introduce more detailed interoperability requirements for MA plans. While we appreciate CMS' efforts to improve PA processes and MA plan oversight, we remain concerned PA processes as a whole pose significant risks to patient care and impose significant burden on providers. In addition, we remain concerned delayed patient care during the PHE may be prolonged further by a backlog of prior authorizations, as pent-up demand for elective procedures resurfaces and programs transition toward recovery. We therefore urge Congress to instruct MA Plans to eliminate PA requirements for life-threatening conditions and continue simplifying and streamlining PA requirements.

Preserve Continued Access to COVID-19 Testing

The diagnostics industry's mobilization during the pandemic has expanded molecular testing infrastructure across the U.S. by increasing the number of instruments available to perform testing. This increase in critical equipment allowed laboratories to run more tests than they were previously able to do. Especially critical to COVID-19 testing efforts was the increase in *high-throughput* (e.g., highly automated) platforms—most often used in large hospital laboratories, reference laboratories and increasingly in public health laboratories—that can process hundreds of tests in a single shift.

AdvaMed data from thirteen of the largest diagnostics companies that participated in the AdvaMed COVID-19 Test Supply Registry show that from March 2020 to January 2022, the number of molecular instruments manufactured by Registry participants—and placed in laboratories across the U.S.—increased from ~11,700 to ~24,600 instruments, by 110%, over the first two years of the pandemic. This increased laboratory capacity has been able to analyze millions of patient samples per week, which, during the pandemic, have been gathered at sample-collection sites such as drive-through testing centers, schools, workplaces, skilled nursing facilities, and pharmacies.

Similarly, the placement of CLIA-waived point-of-care instruments that allow for testing in physician offices, clinics, retail pharmacies and other sites, generally delivering results in 30 minutes or less, has more than doubled. Point-of-care tests also include instrument-less rapid tests, many of which have been authorized for use at home, including as over-the-counter (OTC) tests.

During the Public Health Emergency (PHE), several policies and flexibilities were developed at the federal level to establish and support infrastructure to extend the reach of COVID-19 testing, importantly, including in underserved communities. Policy makers should strongly consider the extension of these policies beyond the PHE to maintain access to COVID-19 testing, and also bolster access to testing for all diseases and conditions beyond COVID-19 with a strong emphasis on the principle that all modalities of testing – laboratory-based, point-of-care (POC), and over-the-counter (OTC)– should be fully leveraged.

Consider, for example, the important opportunity before policy makers to extend and expand the CDC's Increasing Community Access to Testing (ICATT) program that supports free COVID-19 laboratory and point-of-care testing in pharmacies and other locations in U.S. communities that have been disproportionately affected by the pandemic. ICATT, based in over 11,000 pharmacies throughout the U.S., has facilitated well over 12 million tests being performed during federal fiscal year 2022. Currently focused only on COVID-19 testing, this new infrastructure could be extended and expanded to ensure underserved communities would have dramatically improved access to diagnostic testing for all diseases and conditions, as appropriate.

Further, during the PHE, pharmacies, clinics, physician offices and other sites in states that have not typically permitted point-of-care testing to be performed on site with results provided in under 30 minutes or less have extended the reach of POC testing effectively, with patients knowing in short order the result of their tests so that appropriate clinical steps could be taken per those results.

AdvaMed urges Congress to maintain access to lab-based, POC, and OTC COVID-19 tests created during the PHE. Tests will remain a key component of COVID-19 containment and mitigation after the PHE ends. To accomplish this, policy makers should work to extend a number of flexibilities created to ensure access to COVID-19 testing. These include, but are not limited to, mandating private and Medicare insurers cover COVID-19 testing at no cost sharing after the PHE ends; expanding ordering and performing privileges such as those for pharmacists; and sustaining the increased payment for high-throughput technologies that allow for increased testing capacity, faster results, and more effective means of combating the spread of the virus.

For example, flexibilities were put into place to reimburse pharmacist services for performing diagnostic tests and administering vaccines and therapeutics. This greatly expanded access at a time of critical need for diagnostic testing and therapeutics ("test to treat"), particularly in rural areas. Legislation that would provide for Medicare reimbursement for pharmacist services needed to address a public health need related to a public health emergency is needed. Additionally, Congress could work to ensure reimbursement for pharmacist services for respiratory illnesses, when authorized by state law. Passing this type of legislation

would not only improve access to care in the most affordable, lowest cost site of care for common respiratory viruses, but also help ensure preparations for a future pandemic.

Enhance Public Health Laboratory Testing Capacity and Surveillance

The COVID-19 PHE highlighted the inadequacy of the U.S. testing infrastructure. Even when new diagnostic tests were quickly developed to identify the virus, the lack of adequate testing infrastructure severely limited the ability to utilize these tests to meet the early and unprecedented demand for tests and to provide timely information to patients, providers, and government officials.

Through government action and support since the beginning of the pandemic, public health laboratory infrastructure has been improved. As mentioned in the section above, a dramatic increase in testing instrumentation was accomplished during the PHE, but more must be done.

AdvaMed urges Congress to increase testing infrastructure across the U.S. including in public health labs that process tests at large scale and local provider offices (particularly those serving rural and underserved populations) in need of on-site testing systems that can provide rapid analysis at the point of care.

Stop Further Cuts to Clinical Lab Services Through PAMA Reform

Robust laboratory infrastructure across the country is essential to the implementation of any national testing strategy to increase access to appropriate screening and diagnostic testing during non-emergent times and to prepare for future pandemics. Before the COVID-19 pandemic, the laboratory industry was struggling with the impacts of cuts under the Protecting Access to Medicare Act of 2014 (PAMA).

Current policy implementing the PAMA has led to rounds of dramatic Medicare reductions for most diagnostic tests, and the next reductions are set to begin January 1, 2024. Flawed implementation has led to projected reductions in Medicare reimbursement for laboratory services by $10 billion, far eclipsing the $2.5 billion in cuts originally presumed by the Congressional Budget Office. While this system was intended to result in Medicare Clinical Laboratory Fee Schedule (CLFS) rates reflecting private market rates, hospitals and physician office laboratories are largely excluded from reporting private payer rates and volumes, leaving a large portion of the laboratory market unrepresented in the CLFS rates paid by Medicare.

AdvaMed supported the Saving Access to Laboratory Services Act (SALSA) introduced in the last Congress and recommends legislative action be taken now to mitigate further Medicare cuts to laboratories through improved PAMA implementation and modernization of the Clinical Laboratory Fee Schedule to safeguard a robust national testing infrastructure.

Continuing FDA Regulatory Flexibilities

FDA issued several "immediately in effect" enforcement discretion guidances that provided flexible regulatory policies to meet pandemic needs. These guidances include a statement that they are intended to remain in effect only for the duration of the public health emergency. However, many of these policies as reflected in these guidances promote innovation in a safe manner and should be extended beyond the pandemic. AdvaMed appreciates that FDA engaged in thoughtful evaluation of these guidances, including decisions to continue some of the guidances post termination of the PHE. We particularly are pleased that FDA has opted to continue after the PHE, after revision, the PMA supplement guidance, (PMA modifications under Guidance for Industry and FDA Staff: Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the COVID-19 Public Health Emergency) which we believe is a reasonable approach that benefits FDA, industry, and the public health. We request that Congress direct FDA to work in close collaboration with industry as CDRH revises this important guidance, including opportunity for comment.

Actions to Improve the Conduct of Emergency Clinical Trials

Establish Warm Base Clinical Research Capacity

The Department of Health and Human Services (HHS) and other Federal entities can take steps that are beyond the ability and resources of the medical device industry – to develop a network of community-based health care centers, including potentially linked with historically black college or university medical programs, rural facilities and urban medical facilities with concentrations of diverse and underserved populations.[3]

This network could include community and other patient or disease specific advocacy groups that are committed to participation in clinical trials and facilitating diversity in clinical trials. These community, patient and disease groups could receive training on the benefits of participation in clinical trials such as their gold standard care, be alerted to trials seeking subjects, receive training on the value of diversity in clinical trials, and agree to be a resource to both federal and industry sponsored trials. Former acting FDA Commissioner, Janet Woodcock, has suggested that community-based health care centers could be supported by specialized Clinical Research Organizations (CROs) that could supply the education and expertise to community health care centers to facilitate clinical research. Once such networks are established, they can be utilized both to meet emergency research needs and by medical device and drug sponsors to conduct routine medical products clinical trials – helping to maintain the "warm base."

Modernize Human Subject Guidance

In the event of research which must be conducted quickly due to a public health emergency, HHS should review and modernize its human subject guidance. AdvaMed has previously recommended that guidance on payments to human

subjects be updated and modernized to reflect current views citing recommendations made in the Harvard Catalyst Guidance: Paying Research Participants: Ethical Guidance for IRBs and Investigators which establishes guidelines for: (1) reimbursement for out-of-pocket expenses incurred by participants, (2) compensation for participant time and burdens, and (3) recruitment incentives without regard for income status. These items are truly associated with participation in the trial rather than becoming a source of income for a participant which may inappropriately affect their decision to participate. In conjunction with this review, HHS should be asked to establish a fair market valuation for participation in any clinical trial (perhaps based on degree of risk) to avoid the conundrum that socioeconomic differences will result in different fair market valuations for different human subjects. The goal should rightly be to increase clinical trial diversity and participation by appropriately reimbursing and compensating human subjects, not that participation in trials serve as a source of income for human subjects.

Update Regulations and Guidance for Investigational Sites

HHS should update its regulation and guidance to allow for supplementary reimbursement of investigators and investigational sites for the additional time it may take to recruit diverse trial populations. Currently, reimbursement for these activities may be misconstrued as coercion or undue influence of human subjects.

Create Safe Harbor Regarding Financial Assistance and Anti-Kickback Standard

We also suggest that HHS clarify or establish a clearly defined safe harbor as to what types of financial assistance to subjects and how much will be considered violations of the federal Anti-Kickback Statute (AKS). Clinical trial sponsors are currently reluctant and unsure whether transfers of high value (e.g., transportation vouchers, childcare reimbursement, donations of iPads or Apple Watches to facilitate trial participation, hotel stays for patient engagement on clinical trial protocols, supplementary reimbursement of investigators for the additional time associated with recruitment of diverse trial participation, etc.) can be considered violations of the AKS.

Electronic Labeling for Medical Devices

As consumers, patients, and health care professionals rely more on electronic sources for information on medical devices and products, it is critical that legislation be enacted to allow for a broader scope of electronic labeling for medical devices. Congress last addressed electronic labeling in 2004.

Technological advances in recent decades have allowed device labeling to be made available online, with a growing number of devices distributed without hard copy instructions for use. In fact, electronic labeling provides for more rapid, even real-time, updates to labeling, such as clarifications to warnings or other notices. The ability to update labeling quickly would also be beneficial during emergency and

pandemic related situations. For example, and as experienced during the COVID PHE, FDA may need to use its authority to quickly permit under enforcement discretion or emergency use authorization, modifications to labeling, indications for use or functionalities of a medical device or diagnostic. Similarly, the FDA may allow the expiration date of certain technologies to be extended. The ability to utilize electronic labeling instead of paper labeling would allow for more rapid updates to patients and providers, facilitating the availability of these important labeling updates and ensuring they have accurate and up-to-date information.

Current law recognizes device labeling, including directions for use, may be provided electronically for a wide range of medical devices – including prescription devices and in vitro diagnostic devices, but its applicability is limited to certain intended users or settings.

Congress should enact legislation to broaden the scope of electronic labeling for medical devices, increasing its availability, utility, interactivity, and accessibility to device instructions. This would provide for the ability to utilize electronic labeling for medical devices in any setting and for any intended user, while still requiring manufacturers to produce paper labeling at a patient's request.

Antimicrobial Resistance

Antibiotic resistance is one of the biggest threats to global health. As the Centers for Disease Control and Prevention (CDC) recently observed, "[m]ore than 2.8 million antibiotic-resistant infections occur in the United States each year, and more than 35,000 people die as a result." These infections have a disproportionate impact on America's seniors. While just 15% of America's population is 65 or older, an estimated one-third of the deaths caused by antibiotic resistant pathogens – nearly 12,000 per year – occur in this population. The AMR crisis was further exacerbated by the COVID-19 pandemic when hospitals experienced an increase in AMR infections and deaths.

A main driver in the development of drug-resistant pathogens is the misuse and overuse of antimicrobials. The U.S. Federal Task Force on Combating Antibiotic-Resistant Bacteria state "there is a critical need to leverage existing capabilities to promote the validation, adoption, and appropriate use of new and currently available diagnostics." Antibiotic resistance leads to longer hospital stays, more costly treatment, and poor outcomes. Adding additional focus, the National Action Plan for Combatting Antibiotic-Resistant Bacteria (CARB) includes Goal 3, Objective 1.1: "Develop new or enhance existing diagnostics that use isolates and primary samples to determine the presence… of bacterial… infections and to identify appropriate treatment."

Incentivizing Uptake of Diagnostic Technologies

Additionally, patients need access to accurate, reliable diagnostic technologies with the ability to properly identify appropriate treatment, such as those that can

distinguish bacterial infections from viral infections. Yet, many insurers, including Medicare, do not provide coverage for these diagnostic technologies. Policy makers should work to support reimbursement policies that encourage the uptake and implementation of such technologies which will help to reduce inappropriate prescribing practices, and lead to improvements in patient outcomes.

Antimicrobial Susceptibility Tests (ASTs)
Current requirements around automated susceptibility testing devices used in the microbiology laboratory can be challenging because each time a drug is added to the system or changed, FDA clearance is required.

In addition, the improvements industry has negotiated with FDA are not formally documented and in many cases conflict with the official AST Special Controls (510(k) Guidance) document. As a result, AST companies are hesitant to pursue these for fear of rejection of 510(k)s or inconsistent interpretation/implementation by individual reviewers. Congress should direct FDA to revise special controls for ASTs. The FDA needs to ensure that breakpoints are updated in a timely fashion to promote stronger stewardship efforts. We recommend FDA convene stakeholders, including manufacturers and laboratories, and report back on the barriers to uptake for updating breakpoints

Industry had dialogue with FDA toward improving processes related to ASTs in 2019, but this was put on hold with the pandemic, and several challenges remain e.g., Reporting of drug/bug combinations, broadening claims when recognized post-clearance via the STIC website, clear and standardized pathway for updating breakpoints, in particular for legacy devices.

PASTEUR Act
The Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act would increase our nation's resilience by strengthening the antibacterial and antifungal pipeline to ensure clinicians and other medical professionals have the innovative products they need to treat patients, and ensuring antimicrobials are used appropriately. Manufacturers of new antimicrobials under PASTEUR would be required to incorporate the use of diagnostic tests to further ensure that the antimicrobials are used appropriately. We support the investment in antimicrobial stewardship for providers that is included in the PASTEUR Act.

Partnerships

What specific steps could Congress take to improve partnerships with states and localities, community-based organizations, and private sector and non-government stakeholders, such as hospitals and health care providers, on preparedness and response activities?

Enhancing Public-Private Partnerships

In the context of the COVID-19 pandemic response, public-private partnerships (PPP) come in many different forms and have a variety of positive implications. Strategic investments through BARDA, the Defense Production Act, and through other government mechanisms and authorities have been critical to supporting the private sector's response. In particular, PPE and test manufacturers were able to take advantage of strategic investments and long-term contracts to expand domestic manufacturing and capacity. In addition, government partnerships helped to facilitate regulatory procedures and processes to support industry response. Beyond financial support and incentives, a number of public-private sector coordination workstreams sprang into action throughout the pandemic to facilitate real-time coordination, information sharing and response. In particular, AdvaMed was able to support the pandemic response through its engagement in the FEMA Voluntary Agreement and the Healthcare Sector Coordination Council (HSCC). We would encourage the continuation of these workstreams, particularly those that are able to gather private-sector stakeholders on a regular basis in real time to address immediate challenges, bottlenecks and the unintended negative consequences of government actions and policies meant to support the response. There is a strong role for trade associations and other membership-based groups that have a "bird's eye" view across the various sectors.

AdvaMed recommends that these investments and collaborations be enhanced with a clear focus on ensuring long-term policy is in place to sustain manufacturing post-pandemic to prepare for the next public health emergency. Several specific programs are highlighted below.

Sustain Federal Investment and Enhance Regulatory Processes for Diagnostic Innovation

The investment in the diagnostics required to address the COVID-19 pandemic since January 2020 has exceeded that which the private sector could bear entirely on its own. Certainly, there has been tremendous private sector investment in test development and digital health tools, ramping efforts at existing manufacturing sites, adding new manufacturing, including for products previously outside of the scope of most diagnostics companies – such as precision plastics – to generate redundancies in supply chains, and more, yet the magnitude of diagnostics mobilization to date could not have been accomplished without public sector support and collaboration.

AdvaMed applauds the establishment during the pandemic of the National Institutes of Health's (NIH) Rapid Acceleration of Diagnostics (RADx) and enhanced funding to the Biomedical Advanced Research and Development Authority (BARDA).

AdvaMed recommends increased and long-term funding for RADx and BARDA with an augmented scope of work and flexibility of each program to allow for focus in areas of any pathogen with public health emergency and pandemic potential,

including mycotic diseases such as Candida auris and Aspergillosis, be included in the scope of work of these efforts.

RADx ITAP: Model Expansion to Accelerate Bringing At-Home Tests to Market for Additional Infectious Diseases

AdvaMed member companies view RADx as a tremendously successful initiative launched during the pandemic, aimed at speeding the innovation, development, and commercialization of COVID-19 testing technologies. The RADx program continues to invest in early innovative technologies to speed development of rapid and point-of-care COVID-19 testing.

At the end of 2021, RADx established the Independent Test Assessment Program (ITAP) that is providing critical acceleration to regulatory review by the FDA to increase the availability of high-quality OTC COVID-19 tests to the public. A range of diagnostic manufacturers report uniformly favorable experiences with this robust, efficient, and effective program.

AdvaMed strongly recommends the ASPR, FDA, BARDA, and RADx collaborate in using the ITAP program for other diseases and conditions for which self-collection and POC, including OTC testing, could provide significant benefit, beginning with common infectious diseases, including mycotic diseases. Presently, the only OTC tests approved or authorized by the FDA for infectious diseases are for HIV and COVID-19. As demonstrated keenly throughout the pandemic, all modalities of testing – lab-based and POC – are essential parts of our nation's testing infrastructure.

De-Risk Market for Emergency Test Development

De-risking the market can provide a meaningful incentive to industry to develop and manufacture products for which a viable market may not exist. For example, the government can de-risk the market for IVD manufacturers by negotiating minimum purchase agreements with companies in advance of development. Diagnostic tests procured by the government can be immediately deployed or stockpiled centrally within the Strategic National Stockpile (SNS), or through vendor managed inventory, for nationwide distribution as needed. Guaranteed procurement would provide assurances to IVD manufacturers and help offset opportunity costs as other commercially viable research and development projects are put on hold, and key human and manufacturing resources are redirected to emergency test development activities.

Historically, IVD manufacturers have developed emergency diagnostic tests during public health emergencies with uncertain prospects for selling those tests. These tests often go unsold or are donated, as there is often zero, or extremely limited, commercial market for emergency IVDs. While a small market is clearly favorable from a public health perspective, this phenomenon serves as a significant

disincentive for IVD manufacturers to invest in the development of emergency diagnostics.

AdvaMed recommends closer, proactive alignment between CDC and BARDA to identify diagnostics to address emerging patient and public health threats with a strong public-private collaboration to de-risk the market for companies so that technologies can be made widely available to clinicians.

Infrastructure to Develop, Manufacture, and Deploy New Diagnostics for CDC-identified Emerging Pathogens of Concern When No Commercial Test Exists

AdvaMed encourages the potential to add provisions to warm base manufacturing agreements to rapidly develop, manufacture, and deploy diagnostics that are not available on the commercial market in the laboratory or point-of-care modality sought by public health officials. It is often the case that CDC identifies a pathogen of concern causing a local or regional outbreak domestically or internationally, yet diagnostics for the pathogen in question are not available on the commercial market. This public health problem can be addressed through thoughtful public-private arrangements.

Historically, even in the case of a declared public health emergency, when IVD manufacturers have developed emergency diagnostic tests typically there is great uncertainty as to the prospects for selling those tests. Tests, such as those for ZIKA or H1N1, often went unsold or were donated, as there was zero, or an extremely limited, commercial market for these and other emergency IVDs. While a small market is clearly favorable from a public health perspective, this phenomenon serves as a significant disincentive for IVD manufacturers to invest in the development of emergency diagnostics.

Especially in cases when there is no declared public health emergency, commercialization of a new test to address an emerging pathogen is infeasible in the absence of coding, coverage, reimbursement, and clinical guideline foundation.

AdvaMed recommends close alignment between CDC and BARDA to identify diagnostics unavailable on the commercial market to address emerging pathogens that threaten patient and public health. The guidance and collaboration of the RADx program could be leveraged to facilitate technology rapidly advancing through the FDA. Engagement with companies that have existing warm-base manufacturing agreements that have the capacity to readily switch over manufacturing lines could rapidly facilitate the development, manufacturing, and deployment of these needed diagnostics. The warm base agreements with guaranteed procurement provisions could eliminate the barrier of a lack of commercial market, putting tests quickly in the hand of clinicians. While the ease of switching a manufacturing line from one product to another will vary, in general,

manufacturing lines dedicated to COVID-19 tests may be readily switched to a new test.

The benefit of such an initial diagnostic for an emerging pathogen program would be manufacturers and the USG would have a head start should any of these pathogens trigger a public health emergency.

Establish a Permanent Public-Private Diagnostic Testing Forum

The experience of the pandemic demonstrates the imperative for a formal, permanent public-private advisory entity for clinical diagnostic testing. Such an advisory board or forum would improve short- and long-term preparedness and response and for public health emergencies (PHEs) by ensuring regular and meaningful public-private coordination and collaboration among federal departments and agencies and between the government and industry (diagnostics manufacturers, laboratories etc.). This heightened, regular, data-driven coordination would allow for improved alignment of supply and demand in times of emergency and for the informed development of long-term policy to sustain bolstered manufacturing capacity and lab capacity, as drops in demand occur, in between spikes of increased need for testing, as well as preparedness for any future emergency. Such long-term policies should include warm-base manufacturing agreements and VMI of the SNS, as explained above.

Such a board or forum may have positively influenced government to maintain manufacturing capacity of over-the-counter antigen tests, for example, in the summer of 2021, as vaccination rates increased and demand for testing dropped precipitously. Industry encouraged warm-base manufacturing contracts at the time, flagging that manufacturing lines for such tests would be taken off-line without policy to generate demand signals. While a detailed prediction of the spikes of Delta and later Omicron could not have been made with precision, preparedness for the potential of spikes was encouraged as a reasonable precaution, along with preparation for the start of the new school year and the beginning of flu season. Long-term policy was not put in place, and manufacturing capacity retreated in response to low demand.

Another area of focus of a public-private advisory body could be to oversee an update to the charter of the existing CDC-CMS-FDA Tri-Agency Task Force for Emergency Diagnostics. Launched in 2019, the Task Force could have a refined focus to ensure improved coordination to hasten access to government-held patient samples to facilitate the rapid development of tests, and coordinated policy to ensure swift coding, coverage and rational reimbursement for diagnostics, screening, serology/antibody, and T-cell testing is in place. This entity may also ensure that public policy to provide clarity on the use cases for the tests was strong. The Task Force should focus on collaboration with BARDA and RADx.

Maintaining Diagnostics Infrastructure

Require HHS and DoD to submit a joint report to Congress on establishing a long-term diagnostics preparedness program that would enhance national security as it relates to biodefense. The COVID-19 pandemic demonstrated that the country must be prepared for the next public health emergency with adequate diagnostics and testing infrastructure to avoid devastating loss of life and negative societal impacts. The United States government needs to view biodefense like defense – i.e., having all of its tools *at the ready* – not waiting until the threat is present to attempt to build an effective response. Congress recognized the need for maintaining diagnostics capability by including "Warm Base Manufacturing Capacity for Medical Countermeasures" in the *Consolidated Appropriations Act, 2023*. However, a much more comprehensive approach to establishing and maintaining robust and reliable diagnostic capabilities, modeled after the DoD's long-term contracts (5-10 years) with manufacturers of defense equipment, supplies, and systems, is needed to ensure the U.S. is prepared for the next pandemic.

AdvaMed greatly appreciates this opportunity to provide the medical device industry priorities for reauthorization of the Pandemic All-Hazards Preparedness Act. To follow up please contact Kim Zimmerman at kzimmerman@advamed.org or Sarah Killeen at skilleen@advamed.org.

Sincerely,

Kim Zimmerman