The Honorable Lamar Alexander
Chairman, Committee on Health, Education, Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

June 26, 2020

Dear Chairman Alexander:

The Infectious Diseases Society of America (IDSA) and HIV Medicine Association (HIVMA) thank you for your leadership in issuing a white paper titled "Preparing for the Next Pandemic" and providing us the opportunity to comment. As infectious diseases physicians, clinical microbiologists, researchers, public health practitioners and other health care providers on the frontlines of the COVID-19 response, we have firsthand understanding of our nation's preparedness needs and look forward to working with you to strengthen our preparedness for future infectious diseases threats. Below we offer responses to your recommendations and questions, and we look forward to continued dialogue with you and members of the HELP committee. IDSA and HIVMA members are happy to share their expertise in pandemic preparedness and we can put you, your staff or your colleagues in touch with individuals around the country who have expertise in specific areas that may be helpful as you develop a legislative plan to prepare for the next pandemic.

1. Tests, Treatments, and Vaccines – Accelerate Research and Development

ISSUE 1.1: IDSA and HIVMA agree that any potential vaccine for COVID-19 needs to be accessible and equitably distributed. Access to routine vaccinations is also essential to maintaining hospital and health care worker capacity by preventing additional outbreaks of vaccine-preventable diseases, including seasonal influenza. It is particularly important for all healthcare personnel, except those with medical contraindications, to be fully immunized in order to maintain our workforce and protect patients. Last year, President Trump issued an executive order, titled "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health", which appropriately prioritizes domestic efforts to modernize and improve the production and effectiveness of influenza vaccines and promotes increased immunization rates.

RECOMMENDATION 1.1:
IDSA and HIVMA support innovative manufacturing models to improve and maintain sustainable domestic vaccine manufacturing capacity and capabilities. We also encourage the implementation of a five-year national plan as established by the National Influenza Vaccine Task Force as well as a short-term plan for seasonal influenza vaccination to improve these vaccines over the longer term. This plan

should include sustained funding increases for programs at the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and the Biomedical Advanced Research Development Authority (BARDA).

RECOMMENDATION 1.2:
IDSA and HIVMA strongly endorse continued support for NIH research and its academic partnerships as an essential component of the COVID-19 research and clinical trial infrastructure. Additionally, we recommend increased funding for multi-center and multi-agency studies and additional public-private research partnerships. The multiple interdisciplinary questions raised by COVID-19 will require a multi-disciplinary response rooted in team science and novel partnerships. We urge Congress and the administration to prioritize support for these critical collaborations that are key to the clinical translation of novel tests and therapies.

We also highlight the importance of congressional support for the Fogarty International Center. The Center supports basic, clinical and applied research and training for U.S. and international investigators working in the developing world and serves as a bridge between NIH and the international research community. The Center has conducted vital work in the NIH response to COVID-19, including quickly analyzing data from China at the start of the outbreak, publishing several papers on the outbreak's spread in China, training health care workers on conducting testing and lab personnel on biosecurity measures in resource-limited settings, among other activities. The Center is also providing training and support to colleagues in Africa on expanding COVID-19 testing and genomic sequencing as the outbreak spreads across the continent. The Center's work to develop scientific expertise in developing countries strengthens local capacity to detect and contain outbreaks at their point of origin, ultimately benefiting American public health and health security.

RECOMMENDATION 1.3:
Collaboration between Congress and the administration is critical in preparing for the next pandemic. Significant and sustained investment across medical countermeasure programs is essential, including for research, manufacturing, procurement, and distribution. Federal leadership, in partnership with manufacturers, is critical to ensure a sufficient stockpile, the capacity to ramp up production quickly, and the equitable distribution of tests, treatments and vaccines. As part of this strategy, a sustained increase in funding is urgently needed to support BARDA and the Strategic National Stockpile (SNS) in addition to the nation's vaccine production and distribution system.

RECOMMENDATION 1.4:
IDSA and HIVMA support increased consideration of diagnostic needs within the SNS. We appreciate the $16 billion recently allocated to the U.S. Department of Health and Human Services (HHS) for the SNS, which will be required to include diagnostic testing kits and supplies. These efforts will help ensure adequate availability of critical diagnostic tests during a public health emergency. We recommend that Congress direct HHS to consult with clinical and laboratory experts to rank, prioritize, and quantify critical tests and supplies, especially reagents and instruments that can be deployed quickly for new diagnostic assays as the need arises. It is also essential that academic and clinical laboratories maintain their capacity to quickly develop, validate, and utilize testing without burdensome or inflexible oversight while ensuring accuracy. A streamlined regulatory framework that leverages existing regulatory mechanisms and improves clinical laboratory access to testing materials and supplies will augment finite CDC development capacity and enable rapid response to future outbreaks.

In addition to ensuring early development of diagnostic and laboratory-developed tests in a public health emergency, Congress should direct HHS to prioritize testing at the point of need with rapid turnaround times relative to capacity and prevalence, test type (e.g., when to use nucleic acid amplification testing versus antigen test for diagnosis), and swab type (e.g., anterior nares vs. nasopharyngeal) to inform decisions about stockpiling, manufacturing, and distributing testing kits and supplies. IDSA and HIVMA support strengthening the domestic and global supply chain pipelines and stockpile capacity to accommodate myriad geographic and patient population needs.

SECTION 1 QUESTIONS

1. What incentives can the federal government offer to the private sector to encourage development of more medical countermeasures with no commercial market?

Antibiotics are a key example of a critical medical countermeasure for which the commercial market is sufficiently limited such that federal incentives are necessary. As we are seeing with COVID-19, serious respiratory infections can be complicated by secondary bacterial or fungal infections that are very difficult to treat due to antimicrobial resistance. particularly when patients require mechanical ventilation. Multiple studies have also indicated that secondary bacterial infections contribute to morbidity and mortality in patients with COVID-19.[i] [ii] [iii]BARDA and NIH support antibiotic research and development; however, while current activities have had important successes in bringing new antibiotics to market, they alone are insufficient, as evidenced by the weak antibiotic pipeline, bankruptcies of companies that have brought new antibiotics to market, and lack of engagement by larger pharmaceutical companies. New incentives must offer a predictable opportunity for antibiotic innovators to earn a fair and reasonable return on investments. IDSA and HIVMA support a subscription model, which would meet this goal and, importantly, de-link the return on investment from individual sales and use, helping to ensure appropriate use of new antibiotics.

Incentives like a subscription model can incentivize diagnostic and other therapeutic countermeasures. Federally funded push and pull incentives can drive test development and proper uptake and utilization. Recent health innovation projects intended to incentivize the development of medical countermeasures for COVID-19 include:

- The **COVID-19 Therapeutics Accelerator** is a collaborative effort to research, develop and bring effective treatments for COVID-19 to market quickly and accessibly. Partners include the World Health Organization, the Bill and Melinda Gates Foundation, private sector organizations, and global regulators. Speed and flexibility at all stages from discovery and development to manufacturing reduces risk across the process and ensures treatments can reach everyone who needs them, particularly the most vulnerable.

- The **Rapid Response Initiative** aims to fast-track the development of tools and system that could have an immediate impact on the management of COVID-19. The Initiative was announced by the European Institute of Innovation and Technology (EIT) Health, a consortium of over 140 partners from across 15 EU countries. In May, the consortium provided €7 million to fund 14 health innovation projects with an estimated 2020 completion date. Projects cover biotechnology, diagnostics, digital health and medical technology, and will be run by 36

partners, with the direct involvement of healthcare services to ensure that tools can be built in line with clinical needs and implemented as quickly as possible.

Maintaining the accelerated progress and flexible partnerships required for the successful development of COVID-19 testing and therapeutics will be essential for continued vigilance against future public health threats. Additionally, funding for the development of COVID-19 vaccines and therapeutics should be combined with efforts to ensure that these products are made available, affordable and accessible to all individuals who need them in a transparent and equitable fashion, with particular focus on vulnerable populations who have been disproportionately impacted by COVID-19.

2. Should the federal government create government-owned-contractor-operated facilities to solve supply chain and manufacturing challenges?

IDSA and HIVMA recommend leveraging existing manufacturing facilities and systems already in daily use (e.g., data sources, implementation processes) to address supply chain challenges, that can be amplified or re-tailored to make them more valuable for crisis response needs. The U.S. government may then retain the option to create contractor-operated facilities to fill existing gaps once the current landscape is assessed and fully leveraged.

3. What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?

In the event of a pandemic, particularly of a pathogen that causes a respiratory illness indistinguishable from other respiratory illnesses, tests need to be manufactured on a scale that a government agency is unable to produce without the private sector. In the case of COVID-19, academic medical centers and manufacturers were ready to develop tests/kits, but FDA was unable to support a phased introduction of testing as the pandemic progressed. IDSA strongly recommends that any future congressional recommendations include the development of a phased regulatory pathway that can accelerate the approval and marketing of tests on a very large scale for future outbreaks.

Further, a long-term, national strategic plan for rapidly procuring or manufacturing and distributing diagnostics, medical supplies, personal protective equipment, treatments and vaccines (when available) is urgently needed to improve the COVID-19 response and to prepare for future outbreaks and pandemics. The administration should more broadly and aggressively use all of the appropriate mechanisms of the Defense Production Act (DPA) for a wider array of needed products. In future pandemics, the DPA should be utilized more rapidly. Future preparedness planning should include proactive engagement with private sector manufacturers to create manufacturing surge capacity. In addition, the federal government should leverage its purchasing power and logistical capabilities to procure diagnostics, treatments, medical supplies and vaccines on behalf of states. Full transparency regarding the distribution criteria and allotments to states should be applied throughout the process so that health care systems and health care providers can prepare accordingly at the local level.

For future planning, it is important to learn from the early distributions of remdesivir donated by Gilead Sciences after the FDA made it available under emergency use authorization. Initially, scarce supplies of the donated drug appeared to be sent randomly to hospitals without any transparency or description of

the criteria used to determine the allocations. The Office of the Assistance Secretary for Preparedness and Response (ASPR) then reformed the process to distribute the shipments to state and territorial health departments based on COVID-19 case data reports submitted by hospitals within the state. The states were much better positioned to direct the treatment to where it was most needed within their own state. ASPR also held regular stakeholder calls with hospitals and healthcare provider organizations and created a public-facing webpage with details on the process and shipments to the states. However, ASPR did not collect any data on how the drug was distributed or used, which we would recommend for future distributions in addition to facilitating transfers of supplies between states depending on fluctuations in need and demand.

In addition, continued U.S. support for and leadership in global cooperative activities to develop new tools is imperative for ensuring that the U.S. is better positioned to respond to pandemic threats. The U.S. government's failure to participate in global collaborative initiatives like the Access to COVID-19 Tools (ACT) and Accelerator to develop a COVID-19 vaccine and the Solidarity Trials to develop therapeutics – both initiatives convened by the World Health Organization – impedes our ability to access much-needed new tools. Such a failure also hurts U.S. researchers who would have otherwise benefited from strengthened international collaboration on scientific research.

The U.S. must not only participate in but lead on global cooperative efforts to develop diagnostics, vaccines and treatments for emerging infectious diseases. The Coalition for Epidemic Preparedness Innovations (CEPI) is an innovative global partnership between public, private, philanthropic and civil society organizations that is working to accelerate the development of vaccines against emerging infectious diseases and is one of the leading global partners in developing a vaccine for COVID-19. The U.S. must contribute financially and scientifically to CEPI and other global initiatives to ensure access to the tools resulting from such efforts.

4. How can the federal, state and private sector work together to more effectively distribute and administer treatments and vaccines?

The federal government should work with governors; state and local health departments; immunization, emergency preparedness, housing, aging and justice program leadership; provider organizations; and health systems to review current pandemic influenza vaccine distribution plans and identify and address any existing barriers to provider and patient access.

Distribution of any pandemic vaccine must be prioritized based on Advisory Committee on Immunization Practices (ACIP) guidelines. Distribution plans must be transparent and equitable as well as ensure appropriate access for vulnerable populations, including those disproportionately impacted by COVID-19 or future pandemics. Such plans must be simple to understand and allow flexibility for providers and local public health departments to assure that vaccine distribution is prioritized to those at highest risk but also allow for providers to use the vaccine as demand is present and assure that vaccine is quickly utilized. Because the demand for a pandemic vaccine will likely initially outpace the supply, it will be helpful to have ethical reviews prior to availability of a vaccine to take into account ethical priorities for communities and inform distribution. The CDC, in partnership with state and local health departments, must play a central role in planning for vaccine distribution. Additional providers need to be identified and enrolled as vaccinators and staffing plans must be developed for vaccination clinics in

preparation for mass COVID-19 vaccination. Surveillance to monitor the safety and effectiveness of pandemic vaccines should also be established.

In addition, federal support will be important to ensure that routine vaccinations are maintained at high rates across the lifespan of a pandemic. During COVID-19, immunization rates have dropped significantly. Leadership and new resources are needed to scale up innovative approaches, such as mobile vaccine units and drive-up and drive-through vaccine clinics, to ensure safe access to vaccination and minimize the emergence of vaccine preventable diseases during a pandemic.

7. How can Congress and HHS make sure CDC and FDA are working more closely with the private sector on diagnostic tests to detect emerging diseases?

As an initial step, we urge Congress to fund direct HHS to create a public database of partnerships that is regularly updated. Such a database would allow policymakers, researchers, industry and other stakeholders to identify opportunities and gaps. Approaches are recommended to increase communication and collaboration between the private sector, the CDC and the Food and Drug Administration (FDA), such as joint workshops for development of guidance on best practices for public-private partnerships on rapid development and deployment of new diagnostic tests for emerging diseases.

8. How can the United States better leverage public-private partnerships, industry, and academic institutions?

As previously noted, the U.S. must strengthen support for public-private partnerships and academic institutions to collaborate with the global community on emerging health threats in order to better leverage expertise from such organizations on pandemic preparedness. This includes providing support for public-private partnerships at the international level, like CEPI, to ensure the U.S. can benefit from the innovations resulting from global partnerships.

As noted above, a sustained increase in funding for BARDA is urgently needed to provide incentives for targeted commercial development of diagnostics, therapeutics, and vaccines.

In addition to maintaining support for and membership in the World Health Organization, the U.S. must support the academic institutions involved in WHO-led global health collaborative initiatives. The 80 WHO Collaborative Centers in the U.S. – most of them based at academic centers – allow for stronger collaboration with partner institutions in resource-limited countries, many of which serve as hotspots for emerging infectious diseases. Continuing support for these and other global collaborative activities is essential for improving the U.S. scientific base in emerging infectious diseases and for leveraging that expertise in times of need.

9. What lessons can be learned from the current fast tracking of tests, treatments, and vaccines to make them available even more rapidly?

The recent experience with COVID-19 antibody test development has highlighted the importance of ensuring accurate and reliable tests. Another lesson is understanding the complexity of diagnostic capability. In order to have adequate laboratory capacity, everything involved in obtaining a sample and conducting the test is needed. IDSA and HIVMA urge Congress and the administration to focus

additional efforts on supply chain management, scalability, and equitable distribution to ensure the flexible development of safe and rapid tests.

Every community in the country saw multiple laboratories offer COVID-19 testing. Providers and public health agencies had difficulty assessing whether these laboratories and the testing that they offered were valid. FDA should develop a process, including a communication plan, for fast-tracking validation of such clinical laboratory testing which allows for rapid development of capacity while also providing clearer assurance of clinical validity for medical providers, public health and the community.

2. Disease Surveillance – Expand Ability to Detect, Identify, Model and Track Emerging Infectious Diseases

ISSUE 2.1: IDSA and HIVMA agree that any response to infectious disease threats needs to capture the impact on our most vulnerable communities and populations through timely and accurate surveillance activities to allow effective targeting of prevention and response activities.

In addition to diagnostic capabilities, it's important to have information management systems that are integrated between case identification, surveillance, and laboratories and be able to share that information within state, local, and federal public health systems. As large-scale testing expands, the need to integrate a great deal of information quickly becomes challenging. How to create and implement an effective system is challenging given the current lack of integration within the U.S. public health system infrastructure. Ideally, information should be collected and reported in a uniform fashion across all states to facilitate a clear understanding of how an infectious disease is spreading throughout the population and accurately identify areas of high, moderate and low transmission.

U.S. federal public health must continue to work with global partners, especially the WHO, on emerging infectious disease detection and surveillance at the global level to ensure better surveillance and communication here at home. The administration's announcement of terminating relations with the WHO places U.S. participation in global disease surveillance networks in jeopardy, leaving us more vulnerable to emerging infections with pandemic potential.

RECOMMENDATION 2.1:

Timely communication between health professionals, states, the CDC and the public depends on accuracy of case data and ease of sharing data between different entities. IDSA and HIVMA support sustained federal funding increases for CDC surveillance activities, including the National Healthcare Safety Network (NHSN), which is playing a central role in the COVID-19 response by complementing existing state-level reporting requirements. We also strongly support uniform and comprehensive reporting on race and ethnicity and age to identify and reduce the disproportionate on underserved populations, including African Americans, Latinx populations and Native Americans.

ISSUE 2.2: IDSA and HIVMA agree that initial COVID-19 definitions for persons under investigation in the U.S. were too narrow in scope. Robust, federally led community-based surveillance may have revealed earlier evidence of community transmission of the virus. The U.S. approach was influenced by a limited laboratory capacity and resulted in 100 tests per day on average before the widespread availability of test kits, compared with tens of thousands of tests being performed in other countries.

Another challenging area is data interoperability. CDC has been working with states on developing infrastructure to handle and incorporate various types of clinical data that are ubiquitous in hospitals and other healthcare settings. The expansion of testing has exposed the substantial amount of work needed to achieve this recommendation. On the laboratory end, CARES specifies certain data and formatting elements that must be included, but many laboratories have never previously needed to collect these data (e.g., demographic information). To update all existing interfaces is an expensive and complex undertaking (e.g., LabCorp has over 70,000 electronic interfaces). All of these contribute to difficulties in getting quick data syncing, availability, and integration. IDSA and HIVMA strongly urge Congress to allocate additional federal funding and strategic planning led by multi-disciplinary expert panels to comprehensively address these challenges.

Successful rapid response relies on having reference laboratories with frameworks for a number of these diagnostic tests, especially those laboratories that have already evaluated the most likely emerging threats (e.g., global arboviruses). We therefore recommend robust federal investment in a national laboratory framework for predicting local agent/pathogen emergence. Investing in these efforts to strategically determine emerging threats will help better protect our citizens against future outbreaks.

Finally, having regulatory flexibility for assays early in a pandemic is critical. Integrating public health data is difficult when testing is split between the public and private sectors, but maintaining existing surveillance is the most important thing the U.S. can do in terms of preparing for the next outbreak.

RECOMMENDATION 2.2:
Barriers to earlier case identification include a lack of testing capacity and a lack of community-based surveillance. Expansion of syndromic and case-based surveillance would provide needed situational awareness and support a faster response.

Community surveillance must also not be discouraged by unreasonable expectations for facility response to identified cases, such as exclusion from work of health care staff with low risk exposure. Creation of guidance which allows for practical response to any identified community spread will be crucial to effective partnering with community providers.

ISSUE 2.4: The bulk of existing and future biological threats stem from zoonotic diseases; thus, an emphasis on developing and improving systems with the ability to collect both animal and human data is essential. Much of what is being put in place now will translate to a variety of epidemics in the future, including those caused by lesser known and unknown pathogens. It is critically important to address the animal health and environmental aspects of these emerging infectious diseases, for which data is currently not adequately collected, and apply a One Health approach to the next pandemic.

SECTION 2 QUESTIONS

1. What other barriers, in addition to limited testing capacity, and insufficient and outdated technology, make it difficult to detect and conduct public health surveillance of emerging infectious diseases?

Our public health infrastructure has been underfunded for decades. In addition to technology, a trained public health workforce (including epidemiologists and laboratorians) is shrinking and aging. This is essential for surveillance and specifically for contact tracing—a critical tool to reduce sustained community transmission. We strongly encourage the creation of new loan repayment opportunities to encourage more people to enter public health careers as well as increased funding for state and local health departments to support the hiring and training of needed personnel. Current CARES funding has provided invaluable resources to assist with local and state public health responses; however, the one-time, time limited nature of this funding limits opportunities for health departments to plan ahead and inhibits hiring of quality personnel.

4. Has our focus on medical countermeasure development been too much on the known threats, such as anthrax and smallpox, to the detriment of emerging threats like coronaviruses*?*

A zero-sum approach to public health is not the most effective way to address the gamut of potential pathogens, known or unknown. We should be focusing on building capacity in these areas in addition to, rather than instead of, known Category A biological agents.

3. <u>Stockpiles, Distribution and Surges – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution</u>

RECOMMENDATION 3.1
IDSA and HIVMA strongly agree that the federal government must fully leverage public private partnerships to create a stronger stockpile of medical supplies, and we support efforts to boost manufacturing capacity for personal protective equipment (PPE), including N95 masks. Multiple studies have confirmed that PPE, and specifically N95 respirators for clinicians providing care associated with the highest risks of COVID-19 transmission, is highly successful in preventing transmission. Unfortunately, despite ongoing efforts, inadequate supplies of PPE persist, and place health care professionals at serious risk of preventable infection, which they can then transmit to other patients, colleagues and family members.

GetUsPPE, a web-based platform through which health care facilities can communicate their PPE needs, reported that as of May 2, more than 6,000 health care facilities submitted requests for PPE, including hospitals, outpatient clinics, and skilled nursing facilities. N95 respirators were requested by 74% of facilities, making them the overall most commonly requested type of PPE. This is a conservative estimate of PPE need, as only facilities aware of the platform could report. Frontline health care providers continue to report that they are extending and reusing PPE, even in areas where cases of COVID-19 are declining because they cannot rely on a dependable supply over the long term. A strong U.S. supply chain for PPE is particularly critical, as some states and facilities—including Washington state—have purchased defective PPE from foreign suppliers. A more comprehensive approach to the manufacturing and stockpiling of PPE will be critical to strengthen our preparedness for future pandemics.

RECOMMENDATION 3.2
We agree that the SNS should provide guidance to states, territories and tribes on best practices to coordinate and distribute medical supplies. A federal strategy to guide distribution of medical supplies is

essential to reduce confusion and ensure comprehensive access to supplies across states. It is critical that distribution plans and procedures be transparent and equitable and include a focus on reaching health care providers that reach underserved populations who are likely to be disproportionately impacted by a pandemic. It is important that health care providers and facilities have clear and consistent routes of communication with states regarding the distribution of medical supplies. Appropriate uniformity across states will be important to ensure that needs are assessed and addressed in a fair and equitable manner.

RECOMMENDATION 3.4
We agree that the federal government, states and the private sector must work more effectively together to distribute tests, treatments and vaccines. Needs must be assessed in a consistent manner, utilizing a uniform approach to collecting and reporting data, to ensure equitable distribution.

SECTION 3 QUESTIONS

1. How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?

The tremendous response to the COVID-19 pandemic has underscored that states and hospitals need increased federal support for preparedness activities, including maintaining a reserve of supplies. In addition, federal guidance should be developed in consultation with health care providers, health care facilities and public health departments on the amount and types of supplies that are appropriate to compile. State health department budgets were already stretched prior to COVID-19, straining to respond to outbreaks of measles and other vaccine preventable diseases, the opioid epidemic and associated infectious diseases, outbreaks of hepatitis A and syphilis, the outbreak of e-cigarette use-associated lung injuries, and other public health demands. Hospitals are suffering serious financial consequences of the COVID-19 pandemic. Long-term care facilities have experienced devastating outbreaks highlighting the lack of infection prevention expertise, PPE and preparedness in those settings.

4. Public Health Capabilities — Improve State and Local Capacity to Respond

RECOMMENDATION 4.1:
The flexibilities and equitable reimbursement for telehealth services have been important to allowing medical practices to continue to provide care to their patients and to the ability of clinics to sustain their services and staffing. Maintaining these flexibilities and providing hospitals and outpatient clinics with resources to enhance their telehealth infrastructure will be important to avoid future disruptions of the magnitude seen due to the novel coronavirus.

To help ensure the safety of health care provided on site, Congress should provide funding for safety-net hospitals, outpatient clinics and long-term care facilities to reconfigure their practices and implement the appropriate safeguards throughout their facilities to prevent transmission of COVID-19 and other respiratory viruses.

RECOMMENDATION 4.2:

The flexibilities with regard to telehealth have been critical to sustaining access to healthcare during the pandemic and have led to innovations in care delivery that have allowed in some cases infectious diseases and HIV providers to re-engage patients who had fallen out of the healthcare system. While a telehealth service is not a substitute for all office/clinic visits, for some patients the use of telehealth services may reduce barriers to accessing healthcare services. We strongly urge that the following policies be maintained within the Medicare payment system and to require or incentivize state Medicaid programs and private insures to adopt these policies:

- Provide payment for telehealth visits on par with payment for a comparable office/clinic visit and including for visits conducted via telephone.
- Allow beneficiaries to receive telehealth services from any location, including their home, inpatient setting and nursing facilities.
- Remove the geographic restrictions so that beneficiaries are not required to be in a rural area.
- Waive the HIPAA requirement to allow the use of audiovisual platforms, including Apple FaceTime, Facebook Messenger Video Chat, Google Hangouts, Skype, Zoom.
- Allow for cost sharing to be waived for beneficiaries without penalty.
- Allow physicians and other practitioners to provider telehealth services from alternative locations such as their homes without changing their Medicare enrollment location.

In addition to maintaining the flexibility outlined above, an investment in resources for patients to have access to the technology and equipment that they need to engage in telehealth is essential. Currently, many of the patients who could benefit the most from telehealth services face the biggest challenges to accessing it due to limited access to Internet and phone services or not having a mobile phone, a smartphone or a computer. In addition to a significant investment in supporting broadband Internet services in communities across the U.S., we urge a significant investment in the Lifeline program to support uninterrupted access to phone and Internet service for low-income individuals.

RECOMMENDATION 4.3:
We strongly agree with the need for states to maintain their capacity to conduct contact tracing for emerging infectious diseases as well as other communicable diseases such as measles, mumps, sexually transmitted infections (STI) and HIV. Local and state jurisdictions have established large contact tracing programs. To be effective, these programs need oversight from experienced public health personnel. An ongoing baseline structure is vital to allow for a scaled-up response to a pandemic event. Significantly increasing and sustaining funding for the CDC programs to support uniform surveillance systems and community-based, culturally appropriate contact tracing is critical. Given the disparities evidenced by COVID-19, HIV and other infectious diseases in communities of color, a diverse group of contact tracers must be maintained, including individuals who are part of heavily impacted and underserved communities. In addition, we recommend the following:

- Federal public health authorities should provide guidance for utilization of multiple models of contact tracing, including traditional methods and deployment of phone-based and innovative technology-based methods to reduce reliance on limited personnel. Guidance should clearly explain the steps and elements of effective and feasible contact tracing and include recommendations for instances in which optimal tracing of all cases and all contacts is not possible.

- Contact tracing electronic reporting systems were developed and implemented by states and local jurisdictions around the country after the COVID-19 pandemic began. On-boarding these systems, which included beta testing and development processes, led to considerable confusion and delay of effective contact tracing. Such systems should be developed, validated, and in place before such events begin.
- Provide funding to support an ongoing evidence-based public education plan to encourage individuals to engage with contact tracers and share information about where they have been and with whom they have been in contact. Responses to the 2014-15 West Africa Ebola outbreak demonstrated the importance of community engagement in the success of contact tracing, and partnerships with community-based organizations in communities throughout the U.S. should be leveraged to increase the effectiveness of contact tracing.
- Provide funding for the CDC to develop a national contact tracing plan to ensure coordination of contact tracers across state lines to appropriately follow and contain the spread of communicable diseases.

RECOMMENDATION 4.4:
The CDC's Public Health Emergency Preparedness (PHEP) program and the ASPR Hospital Preparedness Program (HPP) have been severely underfunded leaving state and local health departments, hospitals and health systems ill-prepared during emergencies. Funding for PHEP has declined by one-third since 2002. The HPP, which funds states and territories to help prepare hospitals and healthcare systems for disasters, has declined by half since 2003.

Timely access to funding for PHEP and HPP to build, maintain and ramp up operations is critical. We support the funding requests recommended by Trust for America's Health[iv] that include an increase in annual funding for state, local, tribal, and territorial infrastructure of $4.5 billion to build robust local public health systems; $2 billion for the Infectious Diseases Rapid Response Reserve fund to support faster responses to infectious disease outbreaks; $824 million in annual funding for the Public Health Emergency Preparedness (PHEP) and $464 million in annual funding for the Hospital Preparedness Program.

SECTION 4 QUESTIONS

1. What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?

The U.S. public health system and workforce has been underfunded and neglected for many years.[v] A significant and sustained investment in public health infrastructure and workforce, is urgently needed to ensure every community has a public health agency that in addition to performing comprehensive public health functions, such as surveillance, STI and HIV screenings, immunizations, and public education, is well-positioned and prepared to respond to national emergencies. We urge immediate and sustained attention to and investment in public health infrastructure, lab capacity and workforce at all levels. In addition, given that nearly 80% of U.S. counties do not have a single infectious diseases physician,[vi] concerted efforts that include a loan repayment program must be undertaken to ensure wider availability of infectious diseases specialists across the U.S. As responses to outbreaks, pandemics and other public health emergencies result in considerable additional uncompensated programmatic work for infectious

diseases physicians, new reimbursement mechanisms should be developed to support pandemic preparedness and response activities.

To support hospitals in planning for emergency and quickly developing surge capacity in their hospital-bed and ICU, we urge increased and sustained funding for the HPP and Public Health Emergency Fund.[vii] In addition, to address hospital and workforce capacity, we urge Congress to create enhanced payment and authority for a Medicare coding pathway for outbreak activation activities of health care providers, similar to Medicare's existing trauma activation coding and payment policies to support frontline medical workers and hospitals in sustaining efforts during a national health crisis.[viii]

To further ensure a sufficient public health workforce, we recommend the following:

- Offer loan repayment or forgiveness opportunities for infectious diseases physicians. (*Student Loan Forgiveness for Frontline Health Workers Act*, H.R. 6720; *Health Heroes 2020 Act*, S. 3634/H.R. 6650, and *Strengthening the Public Health Workforce Act, S. 3737*).
- Provide rapid financial relief for infectious diseases physicians and other health care providers on the frontlines of pandemic response, especially those experiencing salary cuts or other financial impacts of the COVID-19 pandemic (*Pandemic Responder Service Award Act*, S. 3763/H.R. 6953).
- Better leverage the J-1 Visa program, including by creating additional J-1 visa waiver FLEX slots for each state for specialties deemed essential to pandemic response, and permitting these FLEX slots to be used in all geographic areas. The current extension of J-1 visas should continue. (*Conrad State 30 Physician Access Act*, S.948/H.R.2895 and *Healthcare Workforce Resilience Act*, S. 3599/H.R. 6788).

2. What changes can be made to Public Health Emergency Preparedness and Hospital Preparedness Program to help states prepare and respond more quickly?

As previously noted, CDC's PHEP program and ASPR's HPP have been severely underfunded. See above for specific recommendations.

3. How can the federal government ensure all states are adequately prepared without infringing on states' rights and recognizing states have primary responsibility for response?

The response to COVID-19 has demonstrated the importance of strong and consistent national leadership and guidance informed by the best available data and science in addition to the need for federal resources to support emergency responses given the limited flexibility available to states within their budgets. With strong, consistent federal guidance in developing policies and federal financial support for procuring the necessary medical equipment and supplies, states can determine how to best allocate resources and supplies within their states and modify national guidance as appropriate based on local data.

4. How should the federal government ensure agencies like CDC maintain an appropriate mission focus on infectious diseases in the periods between emergencies to strengthen readiness to respond

when a new threat arises?

A significant and sustained investment in the CDC is needed to support the CDC in fulfilling its mission to protect Americans from disease including chronic and infectious diseases and position the agency to be prepared to respond to the next infectious diseases outbreak or pandemic. From 2010 to 2019, the CDC budget decreased by 10 percent, after adjusting for inflation.[ix] We urge for the investment to start in fiscal year 2021 and recommend funding the CDC at the level of $8.3 billion. Within CDC we call for the following funding levels for infectious disease programs[x]:

- Antibiotic Resistance Solutions Initiative - at least $200 million.
- Advanced Molecular Detection - $37.5 million.
- National healthcare Safety Network - $25 million to enable the CDC to expand tracking of healthcare-associated infections (HAIs).
- Center for Global Health - $624 million, including $225 million for CDC's Division of Global Health Protection.
- Section 317 Immunization Grant Program – at least $710 million.
- Infectious Diseases Rapid Response Fund – provide at least $2 billion to be held in reserve.[xi]
- Vector-Borne Diseases - $66 million.
- Infectious Diseases and Opioids -- $58 billion.
- National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases.
- Tuberculosis Prevention - $1.921 billion.[xii]

5. Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency

RECOMMENDATION 5.2:
IDSA and HIVMA agree that plans and systems for pandemics and other public health emergencies must be routinely practiced, assessed, and improved to ensure coordinated responses from federal, state, local, tribal, and territorial governments, and health care professionals.

The expansion of emergency surge capacity in pandemics should be a central component of federal agency planning and coordination activities to enable a comprehensive response that mitigates disease outbreaks and provides high quality health care in high need areas.

IDSA urges the Committee to support the *Health Heroes Act*, S. 3634/H.R. 6650, legislation that would create a reserve corps to deal with health emergencies and disasters. The legislation would allow health professionals to continue to work in the setting of their choice but be called up in health emergencies/disasters to serve at the direction of the HHS Secretary alongside the Public Health Commissioned Corps or health departments. We believe a reserve corps as outlined in the legislation would allow the health care system to be more nimble in effectively scaling-up to meet the needs of patients and communities during public health emergencies and other disasters, and would foster the federal, state, and local pandemic planning and coordination needed to successfully respond.

In considering interagency collaboration, IDSA and HIVMA recognize that many agencies have critical roles to play and we appreciated the unprecedented efforts underway to respond to COVID-19. We also underscore the critical importance of CDC leadership in pandemic preparedness and response. Recent

reports that the administration is considering reducing the role of the CDC or embedding more political appointees in the public health agency are disturbing. We urge the HELP Committee to reinforce the importance of evidence-based responses, led by public health, medical and scientific experts.

Once again, thank you for your leadership on the critical issue of pandemic preparedness. If you have any questions or if we can support your work in any way, please feel free to contact Amanda Jezek, Senior Vice President of Public Policy & Government Relations at IDSA at ajezek@idsociety.org or Andrea Weddle, Executive Director of HIVMA at aweddle@hivma.org

Sincerely,

Thomas M. File, Jr., MD, MSc
President, IDSA

Judith Feinberg, MD
Chair, HIVMA

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for Federal HIV and Related Programs May 2020. Online at: https://www.hivma.org/globalassets/hivma-fy2021-senate-approps-lhhs-testimony-final.pdf.