



March 18, 2020

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Speaker Pelosi and Minority Leader McCarthy:

On behalf of the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA), we thank you for quickly enacting two major pieces of legislation to address COVID-19. Swift, bipartisan congressional action has been essential to support the response.

The upward trajectory of the COVID-19 pandemic and its impact on our country require additional efforts to protect our public health, health care systems, the economy, and vulnerable individuals. Below IDSA and HIVMA offer recommendations of areas where additional attention is needed. We appreciate that some of the issues outlined below have been included in one or both of the COVID-19 bills already passed. However, infectious diseases physicians, scientists, public health practitioners, and other health care providers on the frontlines of this pandemic continue to highlight these as highly urgent needs. Additional funding, oversight of federal agencies to be sure funding is disbursed appropriately, and additional policy changes may be needed.

Our nation's ability to rise to meet the greatest infectious disease challenge in several generations depends on the availability of comprehensive resources and evidence-based federal policies that allow for 1) expanded testing capacity, 2) hospital/health system preparedness, response, and surge capacity, 3) public health response, 4) access to care and treatment; 5) enhanced economic support and social services, 6) research, 7) global health preparedness and response, 8) solutions for secondary bacterial infections that require antibiotics and 9) ID/HIV physician reimbursement and health care professional workforce support.

IDSA represents over 12,000 infectious diseases physicians, scientists, and other healthcare professionals devoted to patient care, prevention, public health, education, and research in the area of infectious diseases. When new diseases emerge such as COVID-19, Ebola and Zika viruses, our members are at the forefront of the medical and public health response. Further, our members care for patients with other serious infections, including pneumonia, HIV/AIDS, tuberculosis, as well as infections that are resistant to many available antimicrobials.

HIVMA is an organization within IDSA comprised of medical professionals who practice HIV medicine. We represent the interests of HIV health care providers and researchers and their patients by promoting quality in HIV care and by advocating for policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice.

Testing Capacity

Most states still do not yet have ready access to a rapid, accurate COVID-19 test. Significant expansion of testing capacity is required to identify infected patients and allow for appropriate treatment and

prevention measures to stop the spread of COVID-19. Rollout of commercial tests will be helpful, and we greatly appreciate FDA efforts to make these tests available quickly but concerns remain about turnaround and capacity to run enough tests daily. It is essential to fully leverage the testing expertise and capacity of laboratories at academic medical centers that routinely develop and utilize laboratory developed tests (LDTs). Access to testing for first responders, frontline health care professionals, and public health leaders essential to the response should be expedited to help maintain the health of our workforce and prevent spread to vulnerable patients.

IDSA and HIVMA greatly appreciate that FDA allows immediate use of tests that are under EUA review, and we urge that such tests be covered by insurers and federal health programs with zero co-pays to ensure patient access to testing and to protect patients from surprise billing for tests administered under current policy. Importantly, in tandem, coverage of the additional associated healthcare costs for care of those with moderate to severe respiratory disease (e.g., chest X-rays, oxygen therapy, emergency care bills, etc.) must also be supported by insurers and federal health programs.

Testing Supply Shortages: IDSA and HIVMA members continue to report severe shortages of testing materials, including swabs and viral transport media for specimen collection and reagents for testing.

Lift Restrictions on Research Lab Supplies: Federal regulations regarding use of research laboratory supplies by clinical laboratories should be lifted in light of the need to ensure adequate resources. Currently, many of the supplies in research labs cannot be used in clinical labs, and Congress should encourage the relaxation of regulations to leverage these resources for patient testing by clinical labs. This may include RNA extraction kits, pipette tips, other reagents and machines, ethanol, and nitrile gloves and other PPE that could be used for molecular testing. Support for clinical validation studies of tests will be essential as well.

Standardize Validation Materials: Congress should ensure that standardized validation materials (e.g. quantitated, inactivated virus) are made available to clinical laboratories and diagnostic test manufacturers to assess analytical test performance. Importantly, it may be necessary to rapidly update these materials if the virus changes over time.

Resources for Testing Supplies: Additional resources may be needed for manufacturing and procurement of testing supplies, or at least oversight to ensure that funding allocated to support laboratory capacity is appropriately distributed and utilized. A current example is the need to ramp up manufacture of Viral Transport Media (Hardy Diagnostics) and specimen collection swabs (only specific types of swabs can be used to ensure optimal specimen collection and to avoid interaction with the molecular testing).

Academic Clinical Laboratories: Funding allocated in the emergency supplemental appropriations bill should be rapidly distributed to academic clinical laboratories to assist with rapid scale up in testing capacity (e.g. to hire support for navigating regulatory processes and additional staff to perform the increased numbers of tests, to purchase additional equipment, etc.).

Data Transparency: The number of cases tested should be publicly disclosed in order to better gauge the significance of the number of positives and help determine whether states that have few or no reported cases truly have low or no prevalence or whether low reporting is due to undertesting. This will in turn inform how aggressive testing needs to be in specific states and areas. In areas with community transmission, testing should be more aggressive. This will also ultimately help inform relaxation of social distancing policies.

Hospital/Health System Preparedness, Response, and Surge Capacity Needs

While the first emergency supplement bill provided resources to support hospital and health system preparedness, response, and surge capacity, our members are extremely concerned that their healthcare facilities do not have sufficient resources, including enough healthcare providers, to address the likely escalation of COVID-19 cases. Additional supplemental funding and oversight to ensure optimal disbursement and utilization of allocated funding is needed to ensure that hospitals and health systems can screen, diagnose and treat patients who become ill, to avoid significantly overburdening hospitals and health systems as COVID-19 transmission becomes widespread in the United States. Additional funding and oversight needs should be anticipated to erect temporary facilities, which may be needed to ensure that there are enough hospital beds to meet the needs of COVID-19 patients.

Additionally, it is critical that healthcare workers who feel sick are able to utilize paid sick leave and stay home to improve their own health and to prevent spread of infection to other health care providers and patients. In these scenarios, health care facilities will need resources to hire additional staff to maintain necessary capacity.

Hospitals and health systems will require support to increase capacity to address COVID-19 while continuing to provide other emergency and routine medically necessary care. Additionally, supplemental resources are needed for expanded preparedness, including acquisition of personal protective equipment (PPE), including N95 masks and other respirators. Many institutions are already reporting rationing and reusing of PPE, which may put health care workers at risk of contracting and spreading COVID-19.

Public Health Response Needs

While the first emergency supplement bill provided resources to support federal, state, and local health departments, additional resources and oversight to ensure optimal disbursement of resources may be necessary, especially as the number of COVID-19 cases continues to rise. Federal agencies including CDC and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) must continue coordination of the COVID-19 response, develop and update guidance, conduct testing, and lead other critical activities. Our members at state and local health departments require resources to support a large number of activities, including isolation and quarantine; securing suitable facilities; monitoring patients; serving and enforcing legal orders (including providing due process); meeting the needs of the population under isolation or quarantine and ensuring timely medical evaluation and testing when necessary, including safe and secure transport from isolation or quarantine locations to and from health care facilities.

Increased funding is also needed for contacting, testing, and monitoring patients under investigation; rapid investigation of cases; and obtaining information on their close contacts to ensure rapid identification of infected individuals and appropriate care and isolation. Resources are needed to rapidly upgrade public health surveillance systems to allow for seamless, rapid, secure data sharing across public health systems, including the federal, state, local, tribal, and territorial levels; public communication to ensure timely and accurate information about how individuals can best prevent infection, especially those at high risk and emergency operations and collaboration with all community partners, including cities, businesses, schools, and other first responders to prepare for community mitigation.

We also recommend funding for the CDC 317 Immunization Program to ensure the system is prepared to launch a possible nationwide COVID-19 immunization campaign (in accordance with public health recommendations for a potential vaccine) as soon as a vaccine is developed.

Access to Care and Treatment

Hospitals: IDSA and HIVMA greatly appreciate provisions in the Families First legislation to ensure access to COVID-19 testing with no copays and to enhance federal support for state Medicaid programs to help offset increased Medicaid costs due to COVID-19. We urge Congress to build on these important steps by working with all federal and private health care insurers to provide access to treatment for COVID-19 for all patients who need it. New resources for hospitals and health systems will be important to support care for uninsured patients. Kaiser Family Foundation estimates that the cost of COVID-19 hospital admissions could be more than \$20,000 per patient.¹ While a specific therapeutic is not yet available, the most severe cases require hospital care for critical supportive therapy, including the use of ventilators. No patients should be denied care or experience delayed care due to their insurance status, and insured patients should not face economic hardship as a result of COVID-19.

Community Health Centers: Community health centers can be the only source of health care for lower-income individuals in many communities and many are facing difficult financial situations as they care for more patients who are uninsured while urging routine patients to postpone appointments. Funding is critical to maintain these programs as frontline providers in communities regardless of a patient's ability to pay.

Financial and Social Services

Paid Sick Leave: IDSA and HIVMA appreciate provisions of the Families First Coronavirus Act that aim to ensure paid emergency leave, paid sick leave and up to three months of paid family and medical leave; enhanced unemployment insurance, and strengthened nutrition security as social distancing becomes paramount to flatten the curve of COVID-19 cases. IDSA and HIVMA strongly support the social distancing guidelines released by the administration on March 16, and call for even stronger social distancing and community mitigation measures to further slow the spread of COVID-19. In light of these new guidelines, which are essential but may place greater financial burden on many individuals and businesses, IDSA and HIVMA urge Congress to strengthen the financial security measures in the Families First bill. First, paid family and medical leave should be available to all workers, regardless of the size or type of business to allow workers to practice appropriate social distancing, quarantine if needed, and care for children if schools are closed. We recognize the strain that COVID-19 places on businesses and appreciate that the Families First bill provides relief for businesses that are directly impacted. Depending on the length and severity of the pandemic and the mitigation measures that may be required, additional support may be needed, including additional funding to support paid leave for employees.

Housing: Additional resources are needed to provide housing services to individuals who are homeless to prevent the spread of the virus and to avoid long-term hospitalizations for less severe cases that could be managed in a home setting.

Broadband Internet and Technology Support: We also encourage funding to support access to broadband internet, computers, and other appropriate devices and educational resources to allow children to continue learning in the event of extended school closures and to promote improved health messaging to all families during a national health emergency such as the COVID-19 pandemic.

¹Kaiser Family Foundation. Potential costs of coronavirus treatment for people with employer coverage. March 13, 2020.

Research

We appreciate the funding in the first emergency supplemental to support research at the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health, and below we outline specific research priorities for COVID-19, acknowledge that additional resources may be required to support this research. We need research on optimal diagnostics, including a multiplex platform for multiple coronaviruses, a quantitative platform and serology (i.e., total and neutralizing antibodies to support vaccine development). We urgently need research on treatments for COVID-19, including antivirals, anti-inflammatories, and post-exposure prophylaxis—especially in vulnerable populations. Multi-center controlled trials are needed to understand which therapies most benefit patients with COVID-19. Epidemiological studies to improve our understanding of COVID-19 will be crucial to inform our ongoing response, including studies on zoonotic escape, evolution, transmission dynamics and prospective cohort studies to classify symptomatic and asymptomatic ratios and risk factors. Pathogenesis studies are needed to better understand COVID-19 in specific populations, including children, pregnant women, and adults with risk factors for severe disease. Lastly, we must continue and expand research on vaccines for COVID-19, including funding to support all phases of vaccine research and development, from pre-clinical to licensure. Studies to understand the level of protection offered by the vaccine will also be important.

Many NIH-funded research laboratories are temporarily shutting down to better leverage resources to address COVID-19 where possible, and to appropriately comply with social distancing recommendations. We greatly appreciate that NIH policy ensures grants will continue to be paid and allows applications and reports to be submitted late. Supplemental funding may be needed to reimburse grants for monies lost while they were unable to do project-specific activities due to COVID-19 to allow these important research studies to be continued after the pandemic.

Global Health Preparedness and Responses

Providing immediate funding to meet the short-term needs of the COVID-19 response is essential, but insufficient to protect us from future global outbreaks that are certain to occur. Additional and sustained funding to strengthen capacities to prevent, detect and respond to infectious disease threats in the countries where they originate is essential for ensuring American and global health security and preventing pandemics. At the same time, existing resources to control HIV, TB, malaria and other infectious diseases must be sustained and strengthened.

High consequence pathogens with zoonotic origins, including Ebola, Zika and Nipah viruses, are emerging with increasing frequency in resource-limited countries with weak preparedness and healthcare systems. The CDC estimates it takes just 36 hours for an emerging pathogen to travel from a remote village in a low- and middle-income country to any major metropolitan city in the world, highlighting the importance of helping partner countries strengthen their abilities to stop outbreaks at their source.

We ask Congress to fund global health programs at CDC, USAID, NIH and DoD at the highest levels for ongoing efforts to strengthen preparedness and response capacities in partner countries with limited resources and technical expertise. Increased funding for CDC will help resource-limited countries strengthen abilities to detect outbreaks, support surveillance systems that enable disease tracking and reporting, build better laboratory systems, develop and improve emergency operations centers, support faster and more accurate data sharing, and train disease detectives and healthcare workers, among other essential activities. USAID requires additional resources to promote and implement One Health policies and practices to mitigate the threat of zoonotic infections, including conducting vital research on emerging zoonotic infections, training health workforces proficient in One Health practices, and helping countries develop strong preparedness and response plans. Increased resources for DoD global health security activities will strengthen efforts to counter natural, accidental and intentional biological threats through engagement with civilian counterparts at home and abroad and through research and development

of medical countermeasures. DoD efforts to protect U.S. and allied forces against infectious disease threats have resulted in extensive disease surveillance and research programs beneficial to both the military and general public.

In addition to increased funding for ongoing pandemic preparedness and health systems-strengthening activities in low-income countries, we ask Congress to provide more funding for immediate COVID-response efforts. Resource-limited countries, particularly in Asia and Africa, have reported limited capacity to effectively respond to outbreaks of COVID-19 in their countries, with many countries already juggling other outbreaks. Nigeria, home to the first confirmed case of COVID-19 in sub-Saharan Africa, is also experiencing outbreaks of Lassa fever and yellow fever. Elsewhere in Africa, outbreaks of cholera, measles, dengue and other infections are further straining already weak healthcare systems, while the Ebola outbreak in the Democratic Republic of the Congo persists.

Low- and middle-income countries have reported challenges in diagnosing COVID-19, with many countries lacking testing kits. Currently only 40 labs in Africa can perform COVID-19 testing while 23 countries have reported cases. There is evidence of community spread in some African countries, including South Africa, however with limited resources and technical capacity, countries are ill-equipped to effectively respond to the pandemic. These countries also need technical assistance to develop other detection capacities in the absence of adequate testing.

Countries have reported diverting resources and personnel away from other infectious disease response efforts, including in the DRC where some Ebola response efforts are being redirected to respond to COVID-19. Underdeveloped healthcare systems mean countries do not have the clinical capacity to respond to a surge of COVID-19 patients or manage severe cases. In Kenya, which reported its first case last week, there are only 130 intensive care unit beds in the entire country, and only 200 nurses trained in providing intensive care. Countries with HIV and tuberculosis epidemics face additional challenges in responding to COVID-19. While much is not known on how COVID-19 affects people living with HIV or TB, or survivors of TB, specifically, people living with HIV are eight times more likely to be hospitalized for respiratory infections and three times more likely to die. Survivors of TB with permanent lung damage may be at increased risk of COVID-19 infection and severe illness. Countries will need additional resources to address COVID-19 in these and other special populations.

Strengthening partnerships with international agencies is essential for controlling the pandemic. The World Health Organization announced it needs \$675 million for global preparedness and response activities through April, including strengthening capacities in resource-limited countries. Thus far WHO member states have only pledged \$150 million. The U.S. has only pledged \$7.3 million towards meeting this goal. We ask Congress to increase the U.S. commitment to WHO's response. Investment in global health is an investment in protecting the health of US citizens.

ID/HIV Physician Reimbursement and Health Care and Public Health Professional Workforce Support

ID/HIV physicians are on the front lines of the COVID-19 response, as they are for any outbreak of any infectious disease. Unfortunately, the ID/HIV workforce has been shrinking due to undervaluation of evaluation and management (E/M) codes, which cover more than 90 percent of ID/HIV physician services. E/M codes have not been comprehensively updated in 30 years, and they do not reflect the complexity of care provided by ID/HIV physicians. This resulting compensation gap combined with staggering medical debt places pressure on young physicians to pursue more lucrative career paths over ID/HIV at the same time that a strong ID/HIV physician workforce is needed.

To help ensure that ID/HIV physicians are appropriately valued during the COVID-19 pandemic, we urge Congress to:

- Establish Medicare coding and payment for **outbreak activation**, similar to Medicare’s existing trauma activation coding and payment policies, and require outbreak activation reimbursements are appropriately and proportionately directed to ID/HIV physicians
- Heavily-weight improvement activities provided by ID/HIV physicians, when central to the COVID-19 response, to improve participation and reduce the reporting burden under the Merit-Based Incentive Payment System (MIPS). This will permit ID/HIV physicians to focus appropriately on the COVID-19 response without suffering a disadvantage under the current MIPS scoring system
- Establish a technical expert panel to recommend data-driven valuation of E/M codes, including inpatient E/M codes, that will ensure fair Medicare reimbursement for the ID/HIV workforce to respond to future outbreaks and pandemics

We also recognize that the public health workforce, including ID/HIV physicians and others, needs additional support. Local and state health departments have lost nearly a quarter of their workforce since 2008, leaving many without sufficient capacity to respond to the COVID-19 pandemic. We need incentives to encourage more people to enter the public health workforce. We greatly appreciate that last year Congress granted new authority to CDC to offer loan repayment for Epidemic Intelligence Service (EIS) officers. We urge Congress to expand that effort by making these loan repayment dollars tax exempt and by extending loan repayment to others who work in public health.

Antimicrobial Resistance Needs

While there is still much to learn about COVID-19, there is already some evidence of secondary infections among coronavirus patients. It is unclear exactly how significant secondary bacterial infections will be in this pandemic, but serious viral respiratory infections typically pose some risk that increases when patients need to be hospitalized or placed on a ventilator. In a recent study of 41 patients, 10 percent had secondary infections.² Of those, 31 percent were admitted to intensive care units.³ In a broader study of 99 coronavirus patients, bacterial cultures revealed infections of superbugs including *A. baumannii*, *K. pneumoniae*, *A. flavus*, *C. glabrata*, and *C. albicans*.⁴ *A. baumannii* can be extremely resistant to antibiotics and puts patients at risk of septic shock, a life-threatening condition that damages other organs.⁵ Another report on 191 patients found that 50% of patients who died had a secondary infection.⁶

We are deeply concerned that our antibiotic research and development capacity was already insufficient to meet patient needs before COVID-19. In 2019, two small antibiotic companies with new antibiotics on the market filed for bankruptcy. On March 16, 2020, another small antibiotic company—Tetraphase—was acquired by another pharmaceutical company for only \$14 million, despite having a valuable new antibiotic on the market. This extremely low valuing of antibiotics has caused large pharmaceutical companies and the venture capitalists that sustain smaller companies to exit antibiotic R&D. Funding to provide return on investment for novel antibiotics—such as through the post-approval support that Project BioShield provided to Paratek in December 2020—is essential to prevent the collapse of new antibiotic development at this critical time.

² [https://www.thelancet.com/action/showPdf?pii=S0140-6736\(20\)2930183-5](https://www.thelancet.com/action/showPdf?pii=S0140-6736(20)2930183-5)

³ [https://www.thelancet.com/action/showPdf?pii=S0140-6736\(20\)2930183-5](https://www.thelancet.com/action/showPdf?pii=S0140-6736(20)2930183-5)

⁴ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30211-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30211-7/fulltext)

⁵ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30211-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30211-7/fulltext)

⁶ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30566-3/fulltext#tbl2](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#tbl2)

In addition, it will be crucial that antibiotics are used appropriately to ensure optimal patient outcomes and to protect antibiotics' effectiveness from the development of resistance. This is particularly critical now, as antibiotic use may increase if secondary bacterial infections are found or suspected in patients with COVID-19. We urge additional funding for CDC to support antibiotic stewardship and surveillance.

Conclusion

Once again, we thank you for the attention given to combating the COVID-19 pandemic and urge you to enact an additional emergency supplemental bill to address the pandemic as soon as possible. Our nation's health, safety, and economic security all depend on your direction and funding. If we can serve as a resource for your efforts, please have your staff contact Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at ajezek@idsociety.org, or Andrea Weddle, HIVMA Executive Director at aweddle@hivma.org.

Sincerely,



Thomas M. File, Jr., M.D., FIDSA, MSc
President, IDSA



Judith Feinberg, MD, FIDSA
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