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Cynthia Bernstein, Team Lead, Biden Harris Transition
Executive Office of the President, Management, Administration Agency Review Team

Martha Coven, Team Lead, Biden Harris Transition Office of Management and Budget

Dear Ms. Bernstein and Ms. Coven,

On behalf of the Infectious Diseases Society of America (IDSAs), thank you for your leadership of the Biden-Harris Executive Office of the President, Management and Administration Agency Review Team. We appreciate the commitment of the President-elect, Vice-President-elect, and the transition team to address pressing public health issues. IDSAs urges the Biden Administration to provide dramatically increased funding in its FY2022 Budget Proposal for investments in domestic and global programs necessary to end the COVID-19 pandemic, prepare for future threats, improve patient outcomes, protect public health, and spur biomedical research. As the current pandemic plainly illustrates, federal resources to address infectious diseases threats are essential to our nation's health, security and economy.

Robust funding for non-defense discretionary health programs is essential. This includes ensuring that public health agencies within the Department of Health and Human Services (HHS), and health programs at the State Department and U.S. Agency for International Development (USAID) have expanded budget authority to build back the nation's public health infrastructure to defeat COVID-19 and strengthen our preparedness for future health threats. We encourage the administration to support the creation of a [Health Defense Operations Fund](#) budget designation that would exempt funding for programs, projects, and activities that are critical to maintaining a strong core public health infrastructure from the Budget Control Act spending caps. We also encourage the restoration of the intended use of the Prevention and Public Health Fund, established by the Affordable Care Act, to provide reliable funding for the expansion of infectious diseases prevention, detection and surveillance programs. In addition, we support the recommendations offered by our HIV Medicine Association.

Centers for Disease Control and Prevention

National Center for Immunization and Respiratory Diseases

While significant new resources are needed immediately to support transparent, effective and equitable allocation, administration and uptake of COVID-19 vaccines in 2021, the FY22 budget must also include strong funding for our national vaccine infrastructure to improve our approach to all vaccine preventable diseases, including influenza, pneumonia, shingles, and hepatitis A. Even before COVID-19, adult immunization rates lagged far below CDC recommended targets, and during the pandemic, childhood immunization rates have [dropped considerably](#). We must fund an ongoing adult immunization infrastructure program that corresponds with the successful

Vaccines for Children Program, as recommended by the National Academies of Medicine. Such a program should boost and electronically track adult immunizations across health care systems. Vaccine hesitancy was already on the rise, even before the pandemic, as evidenced by historic measles outbreaks in 2019. New funding is needed to track vaccine hesitancy, target outreach, and support partnerships with community-based organizations with longstanding public trust to build vaccine confidence.

National Center for Emerging and Zoonotic Infectious Diseases

Antibiotics underpin modern medicine, allowing us to successfully provide cancer chemotherapy, transplantation, other surgeries, and care of complex patients, including patients with COVID-19 who develop secondary infections. But antimicrobial resistance threatens to undo decades of medical progress. The National Action Plan for Combating Antibiotic Resistant Bacteria (CARB), launched by the Obama-Biden Administration, set the stage for important progress, but significant work remains. We must strengthen public health infrastructure to improve surveillance and data collection that can better identify and understand emerging resistance threats. Antibiotic stewardship programs have been shown to reduce inappropriate antibiotic use, improve patient outcomes and lower health care costs. These programs have suffered significant strain during the COVID-19 pandemic. We must provide the resources and policy mechanisms necessary to fully implement stewardship programs across the continuum of care and effectively leverage diagnostic testing and laboratory expertise. **IDSA urges the Biden Administration to provide increased investments in FY2022 for the Antibiotic Resistance Solutions Initiative to meet domestic and global needs to prevent, detect, contain and respond to multidrug resistant infections. We also urge increased funding for the National Healthcare Safety Network in order to measure and drive progress of prevention and stewardship efforts. In addition, we urge resources to establish new grant program to support the implementation of antibiotic stewardship programs, as proposed in the bipartisan Pioneering Antibiotic Subscriptions to End Upsurging Resistance (PASTEUR) Act (S. 4760).**

The Biden Administration should provide increased funding in FY2022 for the Advanced Molecular Detection (AMD) program, the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) program and other surveillance efforts to accelerate the COVID-19 response and efforts to combat future public health threats. Increased funding in FY2022 would ensure AMD has updated cutting-edge technology to allow CDC to more rapidly determine where emerging diseases originate, whether microbes are resistant to antibiotics, and how microbes are moving through a population. AMD has a strong potential benefit on antimicrobial stewardship which is necessary to reduce AMR and optimize patient outcomes. Additional FY2022 funding would also help ensure state and local health departments have enhanced expertise to harness DNA sequencing of pathogens to ramp up early detection and response to surging disease outbreaks. AMD is leading SPHERES, a national genomics consortium that coordinates large-scale, rapid SARS-CoV-2 sequencing across the US. Widespread participation from clinical microbiology and public health laboratories, academic institutions, and the private sector has enabled the SPHERES consortium to generate information about the virus that will strengthen COVID-19 mitigation strategies. Molecular tracking will also help monitor for and identify any strain mutation, which can inform vaccine modification. Over the past six years, AMD has invested in federal, state, and local public health laboratories to expand the use of pathogen genomics and other advanced laboratory technologies to strengthen infectious disease surveillance and outbreak response.

Center for Global Health

IDSA urges the Biden Administration to provide additional resources to help countries respond to COVID-19, implement and evaluate vaccination and therapeutic programs in resource-limited countries, and sustain funding to strengthen global capacities to prevent, detect and respond to infectious diseases threats. The Center is one of our first lines of defense against global infectious disease threats, including HIV, TB, malaria and parasitic infections and emerging health threats, including

SARS-CoV-2, Ebola and other infections. While the Center received some funding through COVID-19 emergency supplemental packages, it has received four times that amount in requests for assistance from partner countries hit hard by the pandemic. The Center mobilized rapidly to help partner countries prepare for and respond to the COVID-19 pandemic, including strengthening capacities to get timelier and more accurate data to inform public health decision-making and strengthen the public health workforce globally. Additionally, sustained funding for the Division of HIV and TB, a key implementer of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), is needed to facilitate access to life-saving antiretroviral treatment for millions, including to pregnant women living with HIV to prevent transmission to their children. The Center works to find, cure and prevent TB, eliminate the global burden of malaria, stop poliovirus transmission, and reduce mortality from vaccine-preventable diseases like measles.

National Center for Preparedness and Response

IDSA recommends that the Biden Administration provide increased funding for the Public Health Emergency Preparedness Program to build federal, state and local capacity to prepare for and respond to infectious diseases outbreaks and other emergencies. 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 demonstrating the need for federal resources to support emergency responses because states have limited flexibility within their budgets. Timely communication and data-sharing across all levels of government and with health care professionals and the public is critical to successful public health responses. 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, is well-positioned and prepared to respond to emergencies. The current COVID-19 surge overwhelming hospitals throughout the country clearly demonstrates that the absence of a coordinated national pandemic plan is a recipe for disaster.

National Institutes of Health

IDSA applauds the National Institutes of Health (NIH), especially the National Institute for Allergy and Infectious Diseases (NIAID) and the Fogarty International Center (Fogarty Center) for its swift and effective mobilization of research, partnerships, and resources in a comprehensive effort to combat COVID-19. We urge the Administration to provide an increased investment at NIAID and the Fogarty Center to respond to pressing infectious disease challenges.

NIAID

COVID-19 has made a substantial and enduring impact on the U.S. biomedical research workforce. IDSA appreciates the agency's commitment to research training and increased flexibility during the COVID-19 pandemic in terms of extended deadlines, flexible submissions, and the expansion of Early Stage Investigator (ESI) status for qualified researchers. **IDSA urges the Biden-Harris administration to increase investment in the biomedical research workforce, including research training and diversity. We specifically recommend expanding funding to provide more K awards, T32 awards, F32 awards and support for the K to R transition; to support mentorship opportunities, particularly for early stage investigators from underrepresented groups; and to expand support for investigators who are caregivers.**

IDSA urges to Biden Administration to include Increased funding in its FY2022 budget proposal for AMR research at NIH including NIAID, that prioritizes the discovery and development of new antibacterial agents, supports further study and development of rapid diagnostic tests to guide more rapid pathogen-directed therapy and advance antimicrobial stewardship. The growing antimicrobial resistance crisis threatens modern medical advances, including cancer chemotherapy,

transplants and other surgeries and care of complex patients. Increased research to deepen our understanding of AMR and develop new tools to prevent, detect and treat infections caused by multidrug resistant pathogens must be a key component of our national approach to AMR. Progress has been made under the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB), but we must redouble our efforts in order to keep pace with growing patient needs, including the need to revive antibiotic research and development.

Fogarty Center

A vital part of the U.S. response to COVID-19 and other infectious diseases globally, the Fogarty International Center (Fogarty Center) quickly mobilized to respond to the pandemic, including providing technical assistance in low-and middle-income countries and conducting vital research on COVID-19 and its impacts, and studying the intersection of COVID-19 and leading infectious disease killers including HIV and tuberculosis. **We recommend Increasing funding in FY2022 for the Fogarty Center to address the research and training needs associated with the COVID-19 pandemic and its impacts on other infectious disease areas in low- and middle-income countries.**

Assistant Secretary for Preparedness and Response

Antimicrobial Resistance

IDSA urges the Biden Administration to increase funding in its FY2022 budget proposal for existing and novel approaches from the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA)

to support antibiotic research and development (R&D). Antimicrobial resistance threatens our preparedness for any pandemic or mass casualty event, as secondary infections complicate treatment, lengthen hospital stays and increase the number of lives lost. Under the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB), originally conceived and prioritized by the Obama-Biden administration, the BARDA Broad Spectrum Antimicrobials program and CARB-X initiative have been essential to leverage public private partnerships to develop new FDA approved antibiotics. These activities alone, however, are insufficient to deliver the robust and renewable antibiotic pipeline needed to address current and future threats.

Nearly all large pharmaceutical companies have abandoned antibiotic R&D and the small companies responsible for the vast majority of recent innovation are struggling to stay in business. In 2019, two small antibiotics companies filed for bankruptcy, despite launching important new antibiotics. The antibiotics market is uniquely broken. New antibiotics must be used judiciously to preserve their effectiveness, but limited use makes it extremely difficult for antibiotic developers to earn a return on their investments. Innovative approaches are needed to sustain the antibiotics market. The [Project Bioshield contract awarded to Paratek in December 2019](#) is an important first step to provide support to antibiotic innovators post-approval, a time when small companies in particular struggle to raise sufficient funds to support manufacturing post-approval studies and other requirements. Increased funding is needed to support additional contracts like the one awarded to Paratek as well as more novel financing mechanisms to sustain antibiotic R&D.

Strategic National Stockpile (SNS)

States and hospitals need increased federal support to maintain a reserve of supplies, including personal protective equipment (PPE). 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 stockpile, and increased funding should be made available for this planning and stockpiling. Unfortunately, state health departments' budgets were already stretched prior to COVID-19

and hospitals are suffering serious financial consequences due to the pandemic, increasing their reliance during the pandemic and during future pandemics on the SNS.

In addition to a demand for supplies necessary to care for patients with COVID-19, health care facilities and providers also need supplies to provide routine, essential health care during a pandemic. These needs should also be taken into account by the SNS. For example, necessary efforts to expand COVID-19 testing capacity have diverted resources from capacities for microbiologic testing of other diseases. Physicians and laboratories report serious shortages of testing supplies and trained medical technologists to perform tests necessary to treat other infectious diseases and guide appropriate antibiotic therapy.

Influenza Preparedness and Response

The executive order (EO) “Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health,” appropriately prioritizes domestic efforts to modernize and improve the production and effectiveness of influenza vaccines and promotes increased immunization rates. This includes research into better flu vaccines, using better adjuvants and new vaccine platforms, to reduce reliance on egg-based vaccines; improving current technologies and working toward the development of a universal flu vaccine which may eliminate the need for yearly administration. **We urge the Biden Administration to include funding in its FY2022 budget plan to support 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.** Additionally, the budget proposal should support implementation of the EO, including sustained funding increases for BARDA (in addition to the Centers for Disease Control and Prevention and the National Institutes of Health).

United States Agency for International Development

Global Health Security

IDSA urges the Biden Administration to include increased resources in its FY2022 budget proposal to sustain the US Agency for International Development (USAID) global health program. Now more than ever, USAID’s global health security program urgently needs greater support and resources to help partner countries respond to COVID-19 and prevent, detect and respond to emerging health threats before they reach American shores. Core funding has decreased in recent years as funding from emergency supplemental packages to address the Ebola outbreak have expired, putting us at greater risk of emerging infections. The COVID-19 pandemic puts into stark clarity the need to better prepare for pandemics by strengthening health systems and infectious disease surveillance and lab capacity, particularly for the detection of zoonotic disease outbreaks. In the 21st century, 70 percent of infectious disease threats originated from animals – including SARS-CoV-2, Ebola and Zika, among others. As a key implementor of the Global Health Security Agenda, USAID plays a critical role in strengthening global capacity to stop outbreaks at their source. While implementation of the Global Health Security Agenda is conducted through an interagency, whole-of-government approach, USAID leads on supporting One Health initiatives that will strengthen partner countries’ capacities to address zoonotic spillover and prevent pandemics.

USAID Global HIV Program

We recommend increased funding in the Biden Administration’s FY2022 budget plan for the USAID global HIV program to accelerate progress against the global HIV epidemic. The program has remained flat-funded for over a decade and before then was subject to cuts, leaving the program to do increasingly more with diminished resources. USAID’s leadership in providing essential health services for this and other infectious diseases has saved millions of lives, reduced poverty, helped stabilize fragile communities and strengthened human rights for vulnerable communities – all with flat or reduced funding

in recent years. Critical HIV, TB, malaria and neglected tropical disease programs need increased resources immediately to counter the COVID-19 pandemic's impacts on service disruptions and make headway on global disease elimination goals. As a key implementor of the President's Emergency Plan for AIDS Relief (PEPFAR), USAID's global HIV program provides invaluable technical support to PEPFAR partner countries on cost-effective, sustainable and integrated HIV/AIDS programming that harnesses the latest science and technological innovations to work towards global HIV control goals.

USAID Global TB Program

We recommend substantially increased funding for the USAID Global Tuberculosis (TB) Program to accelerate progress towards meeting global TB elimination goals, including the goals outlined in the United Nation High Level Meeting on Ending TB. While USAID leads the U.S. government's response to the global tuberculosis epidemic – the world's biggest infectious disease killer and a driver of the global antimicrobial resistance crisis, the World Health Organization found that 78 percent of countries reported disruptions to TB services as a result of COVID-19, including TB case notification which has dropped significantly. Although TB is the biggest infectious disease killer globally – killing more people than HIV and malaria combined – it receives the least funding of any USAID global infectious disease program. USAID's global TB program supports programs in 23 priority countries with high burdens of TB and provides key technical assistance to 55 countries, making it one of the largest contributors to global TB elimination efforts after the Global Fund to Fight AIDS, TB and Malaria. USAID works to improve care, strengthen TB services and provide diagnostics and drugs, including expanding the availability of new multidrug-resistant TB drugs and regimens – a key component of fighting the rising threat of antimicrobial resistance.

President's Malaria Initiative

IDSA urges the Biden Administration to prioritize malaria elimination efforts and substantially increase funding in its FY2022 budget proposal for the President's Malaria Initiative to address the COVID-19 pandemic's impact on malaria control efforts. While the USAID malaria program received very modest increases in funding in recent years, those increases have not kept up with needs. The COVID-19 pandemic has derailed progress towards eliminating malaria, threatening to reverse two decades of progress against the disease that kills over 400,000 people – primarily children – each year. We urge the administration to renew support for USAID malaria elimination efforts, including providing more resources for the President's Malaria Initiative (PMI). As the leader of PMI, USAID supports 27 countries in Africa and the Mekong subregion in Asia in delivering proven cost-effective and life-saving malaria interventions, including essential medicines and preventive therapy for pregnant women. USAID also provides technical and operational assistance to equip and empower partner countries to end malaria. The agency supports research and development of needed new tools, including the development of vaccines, novel insecticide-based vector control tools and new antimalarial drugs.

State Department

PEPFAR

IDSA urges the Biden Administration to support increased funding for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) to help **end the HIV epidemic, expand HIV treatment and prevention interventions in the most vulnerable communities, including setting bold new targets for expanding HIV treatment.** As America's flagship global HIV program and one of the biggest health programs globally, PEPFAR has saved millions of lives while transforming communities in the most vulnerable countries. Years of investments in health systems strengthening, including surveillance, laboratory and health workforce capacity, among other core functions, has strengthened PEPFAR partner countries' abilities to respond to emerging health threats, including Ebola and COVID-19. In addition to responding to HIV, PEPFAR has worked to address co-infections, including tuberculosis, viral hepatitis,

HPV and illnesses like cervical cancer. The program has screened over 560,000 women in sub-Saharan Africa for cervical cancer. While significant strides have been made in the fight against HIV globally, the world is not on track to meet global targets towards HIV elimination. Progress has stagnated, and the COVID-19 pandemic's impact on HIV testing, prevention and treatment access has set back progress even further. A greater investment is needed protect the investment the U.S. has made.

Global Fund to Fight AIDS, TB and Malaria (Global Fund)

We urge support for emergency funding to sustain the Global Fund's response to COVID-19, and for

robust funding targets for upcoming replenishment periods and providing full funding through annual appropriations. The Global Fund and PEPFAR work synergistically to leverage each program's resources and expertise to strengthen the global response to HIV. As the largest funder of tuberculosis and malaria elimination efforts globally, the Global Fund has been instrumental in saving lives and preventing new infections, including reducing deaths from malaria by nearly 50 percent and TB-related deaths by 25 percent. The Global Fund rapidly responded to the pandemic, quickly setting up the COVID-19 Response Mechanism to help over 100 implementing countries mitigate disruptions to HIV, TB and malaria services. These critical activities now face uncertainty, as the Response Mechanism has run out of funding.

Rescission of Executive Orders

Executive Order on Creating Schedule F in the Excepted Service

We urge a withdrawal of this Executive Order due to concerns that the ability to replace scientists and public health experts with politically motivated staff impinges the ability to respond, and reduces public confidence in responses, to the coronavirus pandemic and other public health crises.

Executive Order on Combating Race and Sex Stereotyping

This order, which allows federal agencies to terminate contracts intended to help promote study and understanding of diversity, equity and inclusion across government institutions, is censoring research and silencing discussion on the impacts of racism, sexism and stigma on safety, health and well-being. This EO had a swift and chilling effect, with some institutions canceling medical and scientific talks intended to inform an equitable response to the coronavirus.

DHS Docket No. ICEB-2019-0006, Establishing a Fixed Time Period of Admission and an Extension of Stay Procedure for Nonimmigrant Academic Students, Exchange Visitors, and Representatives of Foreign Information Media

This proposed policy change would severely affect the dwindling number of J-1 physicians available to deliver infectious diseases care for patients and further jeopardize the nation's ability to effectively respond the COVID-19 Public Health Emergency. **If this rule is finalized, we urge that J-1 physicians be excluded from the final rule.**

National Security Council

Directorate of Global Health Security and Biodefense

IDSA applauds provision in the Biden-Harris COVID-19 plan to immediately restore the Directorate of Global Health Security and Biodefense within the National Security Council. As infectious diseases professionals working in clinical care, public health and research and development at home and globally, we welcome the opportunity to work closely with your administration to restore American leadership and reinforce our defenses against the COVID-19 pandemic and emerging future threats. We also strongly support the President-elect's plan to ensure full U.S. participation in the World Health Organization.

Conclusion

Thank you for opportunity to outline key domestic and global infectious diseases priorities. We urge the Biden Administration to provide increased funding in its FY2022 budget proposal that will make it a breakthrough year in the ongoing fight against the COVID-19 pandemic, antibiotic resistance and antibiotic R&D efforts, and vaccine-preventable diseases. IDSA looks forward to discussing these priorities and providing additional information to the transition team.

Sincerely,

A handwritten signature in black ink, reading "Barbara D. Alexander". The signature is written in a cursive style with a long, sweeping underline.

Barbara D. Alexander, MD, MHS, FIDSA
President, IDSA