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October 14, 2020

The Honorable Russell Vought, Director Office of Management and Budget The White House 1600 Pennsylvania Avenue, NW Washington, D.C. 20510

Dear Director Vought:

On behalf of the Infectious Diseases Society of America (IDSA), we urge the Administration to provide increased funding in the Administration's FY2022 Budget Proposal for investments in domestic and global programs necessary to protect public health, prevent and respond to outbreaks and other emergencies, and funding that spurs biomedical research. As the current COVID-19 pandemic plainly illustrates, federal resources to address infectious diseases threats are essential to our nation's health, security and economy.

IDSA represents over 12,000 infectious diseases physicians, scientists, public health practitioners, and other healthcare professionals devoted to patient care, prevention, public health, education, and research in the area of infectious diseases. Besides serving in the frontlines caring for patients with COVID-19, our members care for patients with serious infections, including pneumonia, HIV/AIDS, influenza, viral hepatitis, tuberculosis, as well as infections that are resistant to available antimicrobials. Our members also help combat other emerging infectious diseases such as Ebola and Zika viruses. Many of our members lead biopreparedness programs at their hospitals and health systems and coordinate directly with federal, state and local authorities in preparing for and responding to a wide variety of public health emergencies.

Department of Health and Human Services

Centers for Disease Control and Prevention

Antibiotic Resistance Solutions Initiative

Antibiotic resistance is one of the greatest public health threats of our time, and IDSA urges the Administration's support for an increased investment in FY2022 commensurate with the threat AMR presents. IDSA members see the impact daily that antimicrobial resistance (AMR) has on patients. Drug-resistant infections sicken at least 2.8 million each year and kill at least 35,000 people annually in the

United States. Antibiotic resistance accounts for direct health-care costs of at least \$20 billion. If we do not act now, by 2050 antibiotic-resistant infections will be the leading cause of death globally. Early data indicate that large numbers of patients with COVID-19 are being prescribed antibiotics, which is likely to fuel further resistance. Early studies indicate that a significant proportion of patients who die from COVID-19 also have secondary bacterial and fungal infections that contribute to their mortality, and more studies are needed to better understand and limit the impact of secondary bacterial infections and resistance on patients during outbreaks or pandemics of viral respiratory infections.

The federal response to AMR must be increased to prevent and detect multi-drug resistant infections. The requested funding would allow the expansion of efforts at every state health department, multiple local health departments, Puerto Rico and other territories to prevent, detect, contain and respond to multi-drug resistant infections. Funding would also support implementation of antimicrobial stewardship programs (newly required by CMS at hospitals) to reduce inappropriate antibiotic use—both in hospitals and in community care--and improve patient outcomes. Since FY2016, CDC has provided \$300 million to 59 state and local health departments to increase capacity for faster response to outbreaks and emerging infections. Additionally, this funding improved antibiotic use, increased state and regional laboratory capacity to rapidly detect resistant infections, and enhanced tracking of healthcare-associated infections. These substantial payoffs mean a clear net positive for the federal budget to recoup the direct costs of the program, but increased funding in FY2022 is needed to effectively address current and newly emerging threats and prepare for future unexpected challenges such as we are now experiencing with COVID-19 disease.

Advanced Molecular Detection (AMD)

AMD strengthens CDC's epidemiologic and laboratory expertise to effectively detect and respond to the ever-expanding universe of emerging diseases and deadly pathogens, but proposed FY2022 funding for the program must be increased to 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 funding would 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 integrating next-generation sequencing in the COVID-19 response. Availability of hundreds of sequenced COVID-19 viruses is providing a clearer picture of how the outbreak is evolving and how cases are connected, allowing more effective targeting of response efforts. Our experience with COVID-19 has demonstrated the critical role AMD will play in future outbreaks and pandemics, underscoring the importance of strong funding.

National Healthcare Safety Network

Increased FY2022 funding for the National Healthcare Safety Network (NHSN) will enable CDC to expand tracking of healthcare-associated infections (HAIs), antibiotic use, and antibiotic resistance. The NHSN is the most widely used HAI tracking system in the country and provides facilities, states, regions, and the nation with data needed to identify problem areas and best practices, and to measure and drive the progress of prevention and stewardship efforts.

Additionally, as of April 1, 2018, 776 out of the over 5,500 U.S. hospitals have voluntarily reported antibiotic use data, and 317 hospitals have reported antibiotic resistance data to the CDC NHSN Antibiotic Use and Resistance (AUR) module. While this represents progress, it falls strikingly short of the stated goal in the National Action Plan for Combating Antibiotic Resistant Bacteria for 95% of hospitals to report these data by 2020. Comprehensive data on antibiotic use and resistance are essential to inform and evaluate antibiotic stewardship activities and other efforts to address AMR.

Center for Global Health

IDSA urges the Administration to propose increased funding in its FY2022 budget proposal for CDC's Division of Global Health Protection to aid in the global response to COVID-19, particularly in low-income countries with weak healthcare infrastructure. The rapid spread of COVID-19 has clearly shown that control of the pandemic cannot be achieved in the U.S. until it is controlled globally. The U.S. must contribute to global response efforts in order to achieve pandemic control here at home. An infection anywhere in the world is only a plane ride away from the US. More resources are needed to prevent, detect and respond to infectious disease threats in the places they originate before they reach American soil. As the response to the devastating global COVID-19 pandemic continues, global health security efforts are critical for ensuring America's health security, including strengthening laboratory capacities, disease surveillance and field epidemiology activities in resource-limited countries to detect and prevent pathogens with pandemic potential and effectively respond to health threats. Sustained funding for the Division of HIV and TB, a key implementer of 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. The CDC Center for Global Health addresses more than 400 diseases and health threats in 60 countries.

Infectious Diseases Rapid Response Fund

The ability of emerging infectious diseases to spread quickly, as illustrated by COVID-19, makes clear the need for increased funding for the Infectious Diseases Response Fund in the Administration's budget proposal for FY2022. The Fund enables CDC and other federal agencies to rapidly address public health emergencies and infectious disease outbreaks at their source, before they reach American shores. The fund allows an initial response to be mounted while Administration and Congress assess longer term needs and allocate additional funding for a more comprehensive response. A deeper investment is needed to ensure agencies, led by the CDC, can move forward with initial response activities to contain the spread of infection; treat infected individuals and launch research for vaccines, diagnostics and therapeutics.

Immunization Program

We must strengthen our nation's vaccine infrastructure to prepare to drive access and uptake of a COVID-19 vaccine once one is licensed and the CDC's Immunization Grant Program is an essential tool in these efforts. While IDSA reiterates the need for substantial and immediate funding for these activities, we urge the

Administration to propose increased funding for the Section 317 Immunization Grant Program that would build on efforts in FY2021 to allow healthcare providers to obtain necessary vaccines. The program helps decrease the number of children and adults who die each year from vaccine-preventable illnesses and helps prevent outbreaks of diseases due to inadequate vaccination rates.

Resources will also be critical to boost vaccine confidence, for COVID-19 vaccine and other routine vaccines. Efforts should include outreach and evidence-based public health messages targeted to individual communities and carried out in partnership with community-based organizations that have built trust with the populations they serve. Vaccine hesitancy is fueling a resurgence of vaccine-preventable diseases such as measles, making this a critically important time to invest in a comprehensive response. Many communities have been deemed "at risk" for outbreaks of measles and other vaccine-preventable illnesses due to insufficient vaccination rates. During January 1–October 1, 2019, a total of 1,249 measles cases and 22 measles outbreaks were reported in the United States. This is the greatest number of cases reported in a single year since 1992.

Infectious Diseases and Opioids

The opioid epidemic continues to spread and IDSA urges increased funding in the Administration's FY2022 Budget Proposal to address opioid addiction and related infectious diseases. We are very concerned about how the opioid crisis is driving higher rates of infectious diseases including hepatitis C, endocarditis, HIV, pneumonia, and skin, soft tissues, bone and joint infections. Support systems for individuals with substance use disorders are suffering disruptions due to the COVID-19 pandemic, which may be worsening the opioid epidemic and associated infectious diseases.

Vector-Borne Diseases

We appreciated increased funding in the Administration's FY2021 proposal for vector-borne diseases and advise sustained support in FY2022. Vector-borne diseases efforts to help reduce the impact of infections such as the Zika virus and tick-borne illnesses including Lyme disease. CDC found that the number of disease cases in the US due to mosquito, tick or flea bites tripled from 2004 to 2016, demonstrating the need for increased funding to support evidence-based surveillance and prevention efforts. In September, 2020, CDC released a National Public Health Framework for Vector-Borne Disease Prevention and Control in Humans, and increased funding will be needed to achieve the goals established by this framework to improve the prevention, detection and response to vector-borne diseases to reduce their impact on human health.

Assistant Secretary for Preparedness and Response (ASPR)

Biomedical Advanced Research and Development Authority

Increased funding is needed in FY2022 for the BARDA broad spectrum antimicrobials program; and <u>CARB-X</u> is needed to leverage public/private partnerships to develop products that directly support the government-wide *National Action Plan for Combating Antibiotic-Resistant Bacteria*. These programs have been successful in developing new FDA-approved antibiotics. Despite this progress, the pipeline of new antibiotics in development is insufficient to meet patient needs, and increased funding is needed to help prevent a post-antibiotic era in which we lose many modern medical advances that depend upon the availability of antibiotics, such as cancer chemotherapy, organ transplants and other surgeries. There is early evidence of secondary bacterial and fungal

infections among COVID-19 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.

Project BioShield

The Project BioShield Special Reserve Fund which is positioned to support the response to public health threats, including AMR requires increased funding in the Administration's FY2022 Budget Proposal. BARDA and NIAID efforts have been successful in helping companies bring new antibiotics to market, but those companies now struggle to stay in business and two filed for bankruptcy in 2019. In December 2019, SRF funds supported a contract for a company following approval of its antibiotic—a phase in which small biotechs that develop new antibiotics are particularly vulnerable. Additional funding is needed to expand this approach to better support the antibiotics market.

National Institutes of Health

National Institute of Allergy and Infectious Diseases

The FY2022 budget proposal for NIAID should be increased, including increased funding for antimicrobial resistance research. The NIAID plays a leading role in research for new rapid ID diagnostics, vaccines, and therapeutics. NIAID has developed a strategic research plan for COVID-19 and will need increased funding to advance our fundamental understanding of the virus and how it impacts diverse patient populations and to develop improved diagnostics, treatments and vaccines. With the requested funding to combat AMR, NIAID will advance their leadership of critical research into how to counter the ever-evolving threat posed by resistant microbes. NIAID is also planning to expand efforts to support the next generation of researchers, but this will be challenging without additional resources. Funding at the requested level would enable NIAID to increase funding and success rates for early and mid-career awards, and pilot a new innovator award to promote bold new ideas from early stage investigators. This kind of thinking is precisely what is needed to address growing ID threats.

John C. Fogarty Center

Additionally, we urge increased funding for the Fogarty Center to improve global health security and improve our ability to detect and respond to pandemics. The Fogarty Center has mobilized to respond to the COVID-19 pandemic, including providing technical assistance in low-and middle-income countries and conducting vital research on COVID-19 and its impacts. In addition to vital pandemic preparedness and response activities, Fogarty-funded breakthroughs have directly contributed to advances in longstanding epidemics including HIV, tuberculosis, and malaria.

State and Foreign Operations Appropriations (SFOPs)

Department of State

President's Emergency Plan for AIDS Relief

We urge increased funding in the Administration's FY2022 Budget Proposal for the President's Emergency Plan for AIDS Relief. This investment would allow PEPFAR to protect investments made to control the global HIV epidemic in light of the COVID-19 pandemic. The pandemic has

profoundly impacted HIV prevention, treatment and care efforts globally, with disruptions in HIV services resulting in an estimated additional 500,000 HIV-related deaths in sub-Saharan Africa alone. Years of sustained investments in PEPFAR have strengthened laboratory networks, surveillance capacity, trained health care workers and strengthened supply chains, allowing for the PEPFAR platform to be used to efficiently and effectively respond to COVID-19. However, capacity to deliver HIV services has become strained as the need to fight both epidemics continues to grow. PEPFAR requires increased funding to safeguard decades of progress against HIV in the face of COVID-19 and to scale up HIV treatment and help partner countries adhere to new HIV treatment guidelines. Increased funding is urgently needed to expand other critical HIV services such as testing and counselling, prevention of mother-to-child-transmission activities, and other efforts to prevent HIV transmission and save lives in resource-limited settings. PEPFAR currently supports 16.5 million adults and children on lifesaving antiretroviral therapy to treat and prevent the spread of HIV/AIDS. However, without increased funding, PEPFAR will not be able to expand access to treatment and other essential HIV prevention and care services to additional persons living with or at risk for HIV infection. Namely, despite global efforts, nearly 16 million people living with HIV still require immediate treatment, and in 2019, there were 1.7 million new HIV infections worldwide. Failure to fast-track investments and efforts today will result in a dramatic spike in new HIV infections – an estimated 100 million by 2030, up from 38 million in 2018 – and the AIDS response will no longer be able to keep pace with the epidemic.

Global Fund to Fight AIDS, TB and Malaria

IDSA urges increased funding in the FY2022 budget proposal for the Global Fund to Fight AIDS, TB and Malaria. The Global Fund mobilized rapidly in responding to COVID-19 globally and continues to provide assistance to low- and middle-income countries in their responses as well as mitigate the pandemic's impact on HIV, TB and malaria pandemics. The world's largest international health funding organization, the Global Fund is credited with supporting responses that have saved more than 27 million lives worldwide since its 2002 launch. In countries where the Global Fund invests, the number of deaths caused by AIDS, TB and malaria each year has been reduced by one-third. As the largest donor to the Global Fund, the U.S. contribution is pivotal, comprising a third of total funding and setting a target for other donors to reach. Maintaining the U.S. contribution to the Global Fund will catalyze greater contributions from other donors, strengthening global abilities to end the HIV, TB and malaria epidemics.

U.S. Agency for International Development

Global Health Security

We urge the Administration to include increased FY2022 funding in its budget proposal for the agency's global health security program, and additional resources are needed for USAID's emergency response fund. Over the last several years, emerging and re-emerging infectious diseases have caused substantial harmful impacts to communities, health systems, and governments. Emerging infectious disease threats like Ebola, Zika, Nipah and now COVID-19 make plain the ongoing need for solid investments in surveillance, laboratory infrastructure and well-trained human resources to ensure that the world will be better prepared for the next outbreak or pandemic. The ongoing COVID-19 pandemic further underscores the need for continued investments for preventing, detecting and responding to emerging infectious diseases, particularly

in resource-limited countries with limited technical expertise. Since 2014 most funding for global health security activities at USAID, CDC and DoD has been provided through emergency supplemental funding for the West African Ebola outbreak of 2014-2016; however, that pool of money expired at the end fiscal year 2019. A higher funding level for USAID will sustain and build upon the progress made to protect the U.S. and global community from the threat of emerging infections.

Tuberculosis

Tuberculosis is the world's biggest infectious disease killer, and as the only airborne drug-resistant disease, is responsible for 35 percent of all deaths from antimicrobial resistance. IDSA urges the Administration to include increased funding in its FY2022 budget proposal for USAID's TB program to expand prevention, detection and treatment efforts, particularly to combat drug-resistant tuberculosis, and help strengthen capacities in the most affected countries. Increased funding is needed to mitigate the impacts of the COVID-19 pandemic on global efforts to control TB. If global resources to combat tuberculosis are not increased, TB will continue to drive the global AMR crisis, which is projected to kill 10 million people by 2050. USAID's global tuberculosis program provides vital TB prevention, detection and treatment services for the most vulnerable people in high-burden countries. By combating the TB epidemic globally, USAID protects American health while contributing to global health security. USAID's TB program is vital for both improving health globally and protecting the health of Americans.

Conclusion

Once again, we thank you for the attention given to infectious diseases and urge you to provide increased funding for domestic and global infectious diseases in the Administration's 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, vaccine-preventable diseases, HIV and other STIs, and TB. Now more than ever, physicians, scientists, health care professionals, patients, as well as our nation's health and safety, all depend on your leadership and funding.

If there is more information we can provide or questions we may answer please contact If we can serve as a resource for your efforts, please have your staff contact Lisa Cox, IDSA Director of Government Relations, at lcox@idsociety.org or (703) 299-0202.

Sincerely,

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Thomas J. File, Jr., MD, FIDSA President, IDSA