Testimony of the Infectious Diseases Society of America (IDSA) on the Fiscal Year 2018 Department of Health and Human Services (HHS) Budget Prepared for the U.S. Senate Subcommittee on Labor-HHS-Education Appropriations Submitted by William G. Powderly, MD, FIDSA, IDSA President June 2, 2017

On behalf of the Infectious Diseases Society of America (IDSA), which represents more than 10,000 physicians and scientists involved in infectious disease prevention, care, research and education, I urge the Subcommittee to reject Trump administration's proposed budget for FY2018 as short-sighted and weakening public's health with great potential for worsening the nation's budget. HHS agencies and programs currently contribute to the prevention, the detection and the treatment of infectious diseases (ID) that are more critical than ever before. IDSA urges the Subcommittee to provide robust Fiscal Year (FY) 2018 funding for public health and biomedical research activities that ultimately save lives, contain health care costs and promote economic growth. **IDSA encourages the Subcommittee to provide \$7.8 billion for the Centers for Disease Control and Prevention (CDC) and at least \$36.2 billion for the National Institutes of Health (NIH).**

IDSA members see the impact on a daily basis that antimicrobial resistance (AR) has on patients. This public health threat continues to worsen. Only with dedicated and substantial resources dedicated to AR can headway be made. We have strongly advocated for the implementation of a comprehensive federal response to AR. We ask Congress to sustain investments initiated in FY 2016 to confront this threat. Those activities include prevention, surveillance and antibiotic stewardship efforts as well as research and development (R&D) activities across federal agencies.

The federal response to antimicrobial resistance must be sustained to staunch the tide that now results in more than two million infections and 23,000 deaths each year. In March 2016, the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) released a draft of its *Initial Assessments of the National Action Plan for Combating Antibiotic-Resistant Bacteria* stating: "Combating [antimicrobial resistance] requires an adequate resource base to slow down, control, and hopefully reverse the problem. Simply stated, the USG [U.S. Government] must commit sufficient resources to solving the problem with funding continued over a long period of time." **IDSA urges the Subcommittee to increase support for the CDC Antibiotic Resistance Solutions Initiative. We ask that the final FY 2018 Labor-HHS-Education Appropriations bill also support AR activities carried out by the NIH, Biomedical Advanced Research and Development Authority (BARDA) and the Agency for Healthcare Research and Quality (AHRQ).**

CENTERS FOR DISEASE CONTROL AND PREVENTION

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

The NCEZID leads CDC efforts against antibiotic resistance as well as confronting emerging public health threats such as the Zika virus. The FY2018 administration budget proposal would drastically cut funding for the Center by \$70 million dollars, given this critical work. We ask that NCEZID be funded at \$629.5 million.

We recommend \$200 million for the <u>Antibiotic Resistance Solutions Initiative</u>. The FY2018 administration budget proposal would reduce funding for the Initiative, shifting this funding to the Prevention and Public Health Fund (PPHF) that the Administration and Congress are seeking to repeal. This threatens recent progress toward prevention and detection of infections resistant to currently available treatments. The requested FY 2018 funding would allow CDC to expand Healthcare-Associated Infections (HAI)/AR prevention efforts from 25 states to the full 50 states including six large cities and Puerto Rico. The CDC projects that over five years the initiative will lead to a 60% decline in health-care associated carbapenem-resistant Enterobacteriaceae (CRE), a 50% reduction in *Clostridium difficile*, a 50% decline in

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bloodstream methicillin-resistant *Staphylococcus aureus* (MRSA), 35% decline in health-care associated multidrug-resistant *Pseudomonas* spp., and a 25% reduction in multidrug-resistant *Salmonella* infections. This substantial payoff means a clear net positive for the federal budget recouping the direct costs of the program.

IDSA also supports funding at least \$21 million for the National Healthcare Safety Network (NHSN). This surveillance information provided to the NHSN is critical to gauge whether interventions designed to reduce inappropriate antibiotic use and limit the development of resistance in fact succeed. These funds mean a net increase the number of participating healthcare facilities from 19,000 to as many as 20,000 within the year. Funding for NHSN will also grow the number of sites reporting antibiotic data from 130 in 30 states to 750 in all 50 states.

IDSA recommends at least \$30 million be allocated for the Advanced Molecular Detection (AMD) initiative in FY 2018. This funding will allow the CDC to rapidly determine three key pieces: where emerging diseases occur, whether these microbes are antibiotic resistant and how microbes spread through human and animal populations. During the 2014/2015 Ebola outbreak, such innovative AMD techniques allowed health authorities to understand if the virus was changing as it spread through different populations. These characteristic signals greatly facilitated responses that lead to ending the epidemic by intervening more precisely in specific locations.

CDC Global Health Programs

Proposed cuts to the CDC global health programs (\$78 million, FY 2018) jeopardize efforts to end HIV as a worldwide public health threat, diminish the fight to limit drug-resistant tuberculosis, and endanger domestic health security by reducing abilities to detect, prevent and respond to infectious disease threats. IDSA urges the Subcommittee to increase, rather than diminish this investment in global health activities in FY2018. By including at least \$128 million for the Global AIDS Program, critical work toward the goal of the US investment in PEPFAR can continue leading to eliminating HIV as a global public health threat.

IDSA supports continued implementation of the CDC Global Health Security Agenda that advances efforts by the U.S. and partner nations to prevent, detect and slow the spread of infectious diseases across borders. CDC plays a central role in responding to new outbreaks such as the current Ebola virus outbreak in the Democratic Republic of Congo and the international Zika virus outbreaks across 2015/2016. The spread of Zika through South America, Central America and Caribbean to the mainland U.S. is only the most recent illustration that infectious diseases are not constrained by national borders. The CDC must be appropriately funded to maintain readiness to address future crises. Such funding should be increased to enhance international surveillance, laboratory diagnostic capacity and health care provider training. More funding for research and development to build medical countermeasures including vaccines and diagnostics is of critical importance--not reduced as proposed by the Administration's budget.

IDSA also encourages the Subcommittee to increase research, monitoring, and evaluation efforts for malaria and neglected tropical diseases. Zika and Chikungunya infections, as well as Chagas disease and dengue fever have been reported in the United States. At least 40% of the world's population is at risk for serious illness and death from mosquito-borne viral diseases.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Despite a common misperception as a conquered disease, tuberculosis now causes more deaths than any other single infectious disease agent worldwide with 9.6 million new illnesses and 1.5 million deaths in 2014. Approximately 480,000 of those cases were caused by multidrug-resistant (MDR) tuberculosis, including 9.7% that were extensively drug-resistant (XDR) the most feared and fatal form.

IDSA recommends an increase of \$63 million for NCHHSTP to enhance responses to the viral hepatitis epidemic fueled by the injection drug use epidemic associated with opioid addiction. We also urge \$157 million for sexually transmitted disease (STD) efforts, \$243 million for TB prevention and surveillance

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activities, and \$822.7 million for HIV prevention efforts. Funding to address STDs is essential, as many communities are experiencing a surge in syphilis rates, exacerbated by a shortage of bicillin—the antibiotic used to treat syphilis.

National Center for Immunization and Respiratory Diseases

Immunizations are among the most cost-effective clinical preventive services, but national adult immunization rates remain low for most recommended vaccines. Each year in the U.S., tens of thousands of adults die from illnesses that are preventable through vaccination. Diseases that include measles are a reemerging problem, as childhood vaccination rates dip too low in some communities to provide effective herd immunity—as witnessed by the Minnesota measles outbreak. Additionally, vaccine-preventable diseases and their complications result in billions of dollars annually in direct and indirect healthcare costs. IDSA asks that the CDC Immunization Grant Program (Section 317) be funded at least at the FY 2016 level of \$610 million.

IDSA recommends that the Subcommittee provide at least \$188 million for CDC efforts to control influenza. CDC plays a critical role in seasonal and pandemic influenza preparedness and response, including conducting surveillance activities that inform response efforts and providing public communications regarding influenza prevention and treatment.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases (NIAID)

Within NIH, NIAID should be funded at least at \$4.961 billion as approved by the Senate Appropriations Committee for FY 2017. Further, we believe that NIAID should be provided an increase that is proportionate to any increase provided to the NIH as a whole. The NIAID plays a leading role in research for new rapid ID diagnostics, vaccines and therapeutics. The January 2015 IDSA report, *Better Tests, Better Care: The Promise of Next Generation Diagnostics* explains that advances in biomedical research have created the potential for increasingly simple, fast and reliable diagnostic tests for infectious diseases. By allowing physicians to quickly distinguish between bacterial and viral infections, such better diagnostics can lead to faster and targeted treatments for patients that help preserve the usefulness of our existing anti-infective drugs. Last year, NIAID awarded more than \$11 million in first-year funding for research to develop diagnostics to rapidly detect antibiotic-resistant bacteria. NIAID also recently announced awards of approximately \$5 million for non-traditional alternatives to antibiotics. These efforts as well as research on new antimicrobials and vaccines are set to ramp up with the \$100 million increase made last year. We ask that the Subcommittee continue this work in FY 2018.

The Antibacterial Resistance Leadership Group (ARLG), led by researchers at Duke University and the University of California San Francisco, is an example of extramural research to address AR made possible by NIAID. The ARLG manages a clinical research agenda to increase knowledge of antibacterial resistance. The ARLG has supported early clinical research on new antibacterials as well as on diagnostics that rapidly identify resistant bacteria. Continued operation of the ARLG depends on support from the NIAID.

Fogarty International Center

IDSA is grateful for the Subcommittee's longstanding support for the Center. IDSA opposes the administration's proposed elimination of the Fogarty Center. We urge funding a minimum of \$72 million for the Center in FY2018, at least level with FY2017 funding. The program's elimination would come at a cost to our nation's global standing, global health security and our ability to detect and respond to pandemics. U.S. patients and researchers benefit from Fogarty funded breakthroughs on diseases including HIV, tuberculosis, malaria, cancer, diabetes, and heart disease. More than 80 percent of Fogarty's extramural grant budget goes to U.S. academic institutions.

Office of AIDS Research

Federal investments in HIV/AIDS research have extended and save lives of people around the world. Continued investment in HIV/AIDS research through NIH is critically important. We urge the

Subcommittee to provide at least \$3.45 billion for the Office of AIDS Research (OAR). The level-funding of HIV/AIDS research since 2015 threatens work towards a vaccine and discourages new investigators from entering the field.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR) Biomedical Advanced Research and Development Authority

BARDA is a critical initiator of public-private collaborations for antibiotic, diagnostic and vaccine R&D. PCAST has identified BARDA as best positioned to elicit private investments necessary to address antibiotic resistance. IDSA recommends that the Subcommittee provide \$520 million for BARDA in FY 2018. Such funding is necessary to allow BARDA to pursue additional work on antibiotic development while maintaining its strong focus on other medical countermeasures to address biothreats.

The BARDA-NIH Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, is one of the world's largest public-private partnerships focused on preclinical discovery and development of new antimicrobial products. CARB-X is working to set up a diverse portfolio with more than 20 high-quality antibacterial products.

We also request that in any final version of FY 2018 appropriations language, you strongly urge BARDA to include TB in their new and emerging infectious disease efforts and invest in the development of new TB diagnostics, drugs and vaccines as part of the CARB initiative and the Emerging Infectious Diseases program at BARDA.

CENTER FOR MEDICARE AND MEDICAID SERVICES

Despite the significant and vital contributions ID physicians make to patient care, research and public health, their work continues to be under compensated. More than 90% of the care provided by ID physicians is considered evaluation and management (E&M). Current E&M codes fail to reflect the increasing complexity of E&M work. ID physicians often care for patients with chronic illnesses, including HIV, hepatitis C, and recurrent infections. Such care involves preventing complications and exploring complicated diagnostic and therapeutic pathways. ID physicians also conduct significant post-visit work including care coordination, patient counseling and other necessary follow up.

New research is needed to better identify and quantify the inputs that accurately capture the elements of complex medical decision-making. Such studies should take into account the evolving health care delivery models with growing reliance on team-based care, and should consider patient risk-adjustment as a component to determining complexity. Research activities should include the direct involvement of physicians who primarily provide cognitive care. We urge the Subcommittee to include report language in the FY 2018 funding bill asking that "CMS undertake research necessary to develop new E&M codes and accompanying documentation requirements that more precisely describe the cognitive work in these physician-patient encounters, and that the results of such research be made publicly available no later than two years after the passage of this Act." We are grateful that the Subcommittee included similar language in the FY2017 omnibus bill and we are making this request in FY2018 to ensure appropriate oversight of CMS regarding this issue.

Thank you for the opportunity to submit this statement on behalf of the nation's ID physicians and scientists. We rely on strong federal partnerships to keep Americans healthy and urge you to support these efforts. Please forward any questions to Lisa Cox at <u>lcox@idsociety.org</u> or (703) 299-0202.