Testimony of the Infectious Diseases Society of America (IDSA) on the Fiscal Year 2017 Department of Health and Human Services Budget Prepared for the U.S. House of Representatives Subcommittee on Labor-HHS-Education Appropriations Submitted by Johan S. Bakken, MD, PhD, FIDSA, IDSA President April 15, 2016

On behalf of the Infectious Diseases Society of America (IDSA), I offer testimony in support of the U.S. Department of Health and Human Services (HHS) agencies and programs that contribute to the prevention, detection and treatment of infectious diseases (ID). IDSA represents more than 10,000 physicians and scientists dedicated to promoting health through excellence in ID research, education, prevention, and patient care. IDSA urges the Subcommittee to provide necessary Fiscal Year (FY) 2017 funding for public health and biomedical research activities that ultimately save lives, contain health care costs and promote economic growth. More specifically, **IDSA encourages the Subcommittee to provide \$7.8** billion for the Centers for Disease Control and Prevention (CDC) and \$34.5 billion for the National Institutes of Health (NIH). IDSA also asks that the Subcommittee act swiftly to provide the \$1.9 billion requested by the administration to prevent and respond to the Zika virus.

Our community of infectious diseases professionals is particularly concerned by the growing public health crisis of antimicrobial resistance (AR). We witness firsthand the impact that AR has on individuals. As a result, we have aggressively advocated for the creation and implementation of a comprehensive federal response. IDSA applauds Congress, and in particular the many champions on this Subcommittee, for appropriating approximately \$380 million in new funding during the FY 2016 cycle to begin implementation of the *National Action Plan for Combating Antibiotic-Resistant Bacteria* (Action Plan). The Action Plan details and coordinates prevention, surveillance, antibiotic stewardship, as wells as research and development (R&D) activities across federal agencies –as recommended by the President's Council of Advisors on Science and Technology (PCAST) in their September 2014 <u>Report to the President on Combating Antibiotic Resistance</u>.

We know that the federal response to antimicrobial resistance must be sustained in order to stem the tide that already results in over 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 <u>Combating Antibiotic-Resistant Bacteria</u>. The report states that "Combating AMR [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." The president's budget for FY 2017 requests the resources necessary to continue implementation of the Action Plan. IDSA urges the Subcommittee to provide the funding increase requested for the CDC Antibiotic Resistance Solutions Initiative. We ask that the final FY 2017 Labor-HHS-Education Appropriations bill also support the Action Plan activities carried out by the NIH, Biomedical Advanced Research and Development Authority (BARDA) and the Agency for Healthcare Research and Quality (AHRQ).* The Zika virus is another serious public health threat that is of considerable interest to our members. We are witnessing the first widespread transmission of the Zika virus in the Americas. While the mosquito-borne virus generally causes mild illness or no symptoms, it has been linked to birth defects in infants born to mothers who were infected during pregnancy. The federal government now has a window of opportunity to help contain the Zika virus in Zika-endemic countries, as well as to enhance state/ local prevention and response efforts, increase epidemiology and surveillance capacity, and support R&D for vaccines, diagnostics and therapeutics. We ask that Congress immediately fund the president's request to combat the Zika virus. As a temporary measure, the Administration recently repurposed \$600 million to address the Zika Virus. However, these funds will need to be replaced and are insufficient to provide the necessary response.

CENTERS FOR DISEASE CONTROL AND PREVENTION National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

The NCEZID leads CDC efforts to address antibiotic resistance as well as helps confront emerging public health threats such as the Zika virus.

We ask that NCEZID be provided the \$629.5 million requested by the Obama administration, including \$200 million for continuation of the <u>Antibiotic Resistance</u> <u>Solutions Initiative</u>, which was initiated with FY 2016 support from this Subcommittee. The requested FY 2017 funding would allow CDC to expand FY 2016 Healthcare-Associated Infections (HAI)/AR prevention efforts from 25 states to up to 50 states, six large cities, and Puerto Rico. CDC plans to award the majority of the FY 2017 increased AR funding to states. The CDC projects that over five years the initiative will lead to a 60% decline in health-care associated carbapenem-resistant Enterobacteriaceae (CRE), 50% reduction in *Clostridium difficile*, 50% decline in bloodstream methicillin-resistant *Staphylococcus aureus* (MRSA), 35% decline in health-care associated multidrug-resistant *Pseudomonas* spp., and 25% reduction in multidrug-resistant *Salmonella* infections, eclipsing the costs of the program.

IDSA also supports the proposed budget of \$21 million for the National Healthcare Safety Network (NHSN) to increase the number of participating healthcare facilities from 19,000 to as many as 20,000 by the end of FY 2017, as well as to increase the number of sites reporting antibiotic use data from 130 in 30 states to 750 in all 50 states. Information provided to the NHSN is critical for evaluating the success of interventions designed to reduce inappropriate antibiotic use and limit the development of resistance.

IDSA recommends that at least \$30 million be allocated for the Advanced Molecular Detection (AMD) initiative in FY 2017. This funding will allow CDC to more rapidly determine where emerging diseases come from, whether microbes are resistant to antibiotics, and how microbes are moving through a population. During the 2014/2015 Ebola outbreak, AMD methods were utilized to determine whether the virus was changing as it spread through different populations, which facilitated appropriate responses.

Global Health Security

IDSA supports CDC continued efforts to implement the Global Health Security Agenda, which would accelerate the efforts of the U.S. and partner nations to prevent, detect and slow the spread of infectious diseases across borders. We ask that you provide the Global Health Security initiative with at least the funding requested in the FY 2017 PBR.

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.

CDC plays a central role in responding to new outbreaks such as of Ebola virus disease in 2014/2015 and Zika virus infections in 2015/2016. The spread of Zika virus through South America, Central America, the Caribbean and now into the U.S. is the latest example of the fact that infectious diseases respect no national borders and that the CDC must be appropriately funded to maintain readiness to be ahead of new crises. The requested funding will build response and prevention in the U.S. and territories as well as international surveillance and public health capacity. The request expands the Field Epidemiology Training Program, laboratory testing, healthcare provider training, and surveillance and control in countries at highest risk for an outbreak. The requested resources will also accelerate R&D for medical countermeasures, including vaccines and diagnostics.

IDSA also urges the Subcommittee to include \$132 million for the CDC Global AIDS Program, which plays a unique role in building sustainability by funding physicians, epidemiologists, and public health advisors in countries hit hardest by the AIDS epidemic.

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

Despite a misperception as a disease of the past, tuberculosis now causes more deaths than any other single infectious disease agent, 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). In December, 2015, the Obama administration released the *National Action Plan to Combat Multi-Drug Resistant (MDR) Tuberculosis*, a comprehensive plan to address drug-resistant TB in the U.S. and abroad and accelerate MDR-TB R&D. In order to fund the plan and put the U.S. back on the path towards TB elimination, IDSA recommends a budget of \$243 million in FY2017 for the CDC Division of Tuberculosis Elimination.

IDSA recommends an increase of \$30 million for NCHHSTP to enhance the response to the viral hepatitis epidemic that has been fueled by injection drug use associated with opioid addiction. Sustained funding of at least \$157.3 million is also necessary for HIV and STD prevention and surveillance activities.

National Center for Immunization and Respiratory Diseases

Immunizations are among the most cost-effective clinical preventive services. However, national adult immunization rates remain low for most routinely recommended vaccines. Each year in the U.S., tens of thousands of adults die from illnesses that are preventable through

vaccination. Additionally, vaccine-preventable diseases and related 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 \$611 million.

IDSA recommends that the Subcommittee provide at least the \$188 million proposed in the PBR 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 \$4.716 billion as requested in the FY 2017 PBR. 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 over the last few decades 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, better diagnostics can lead to faster and more appropriate treatments for patients, help preserve the utility of our existing drugs, and aid in identifying individuals to participate in clinical trials. 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 2017.

The <u>Antibacterial Resistance Leadership Group (ARLG)</u>, 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.

Office of AIDS Research

Federal investments in HIV/AIDS research have led to much longer lives for those living in countries where treatment is available. 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 as well as discourages individuals 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 \$607 million for BARDA in FY 2017. 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.

We also request that in any final version of FY 2017 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 undervalued. Over 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, such as 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 2017 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."

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

IDSA supports the \$12 million requested in the president's budget for FY 2017 for research to develop improved methods and approaches for combating antibiotic resistance and conducting antibiotic stewardship activities in multiple healthcare settings, with a focus on long-term and ambulatory care settings.

Once again, 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 Jonathan Nurse at <u>jnurse@idsociety.org</u> or (703) 299-0202.