

**Testimony of the Infectious Diseases Society of America (IDSA)
On the Fiscal Year 2016 Department of Health and Human Services Budget
Prepared for the U.S. Senate, Committee on Appropriations
Subcommittee on Labor, Health and Human Services, Education and Related Agencies
Submitted by Stephen B. Calderwood, MD, FIDSA, IDSA President
April 3, 2015**

On behalf of the Infectious Diseases Society of America (IDSA), thank you for the opportunity to provide 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 ID physicians and scientists devoted to patient care, prevention, public health, education, and research. IDSA recommends increased Fiscal Year (FY) 2016 federal investments in public health and biomedical research to save lives, contain health care costs, and promote economic growth. More specifically, IDSA encourages the Subcommittee to provide a program level of \$7.8 billion for the Centers for Disease Control and Prevention (CDC) as well as at least \$32 billion for the National Institutes of Health (NIH).

IDSA is particularly supportive of initiatives contained in the [President's Budget Request \(PBR\) for FY 2016](#) to address the growing public health crisis of antibiotic resistance. These proposals enable implementation of the recently released [National Action Plan for Combating Antibiotic-Resistant Bacteria \(CARB\)](#). The Action Plan reflects recommendations put forward by the President's Council of Advisors on Science and Technology (PCAST) in their September 2014 [Report to the President on Combating Antibiotic Resistance](#). In particular, IDSA urges the Subcommittee to fund the proposed CDC [Antibiotic Resistance Solutions Initiative](#). We ask that the final FY 2016 Labor-HHS-Education appropriations bill also support the role of the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) in stimulating research and development (R&D) for rapid ID diagnostics and antibiotics.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The recent outbreak of Ebola virus disease (EVD) in West Africa and subsequent cases in the United States demonstrates that infectious diseases respect no national borders and that the CDC must be appropriately funded to maintain readiness ahead of new crises. IDSA members are partnering with the CDC and other federal agencies to respond to the EVD crisis. We ask that the Subcommittee support collaborations between government, industry, academia and other non-governmental organizations to address the full range of infectious diseases confronting the public. Our country requires on a fully engaged and stably supported CDC to address public health needs such as slowing the rise of antibiotic resistance, increasing immunization rates and stopping the spread of HIV.

Conservative estimates indicate that more than two million Americans suffer from antibiotic-resistant infections each year and that approximately 23,000 will die. Additionally, there were half a million *Clostridium difficile* (*C. difficile*) infections in the United States in 2011, and 29,000 died within 30 days of the initial diagnosis. *C. difficile* is a unique bacterial infection that, although not significantly resistant to the drugs used to treat it, is directly related

to antibiotic use and resistance. Carbapenem-resistant Enterobacteriaceae (CRE) has been labeled a “nightmare bacteria.” Nearly half of individuals who develop a bloodstream infection from CRE will die. Each year, antibiotic resistance results in an additional 8 million hospital days and costs in excess of \$20 billion to the U.S. health care system. The actual human and financial costs are likely far higher, as our surveillance and data collection capabilities cannot yet capture the full disease burden. The death and financial tolls rise with each day that we fail to act.

PCAST and the CDC have recommended actions in four core areas to address the problem, including prevention, tracking, antibiotic stewardship, and development of new antibiotics and rapid ID diagnostics. The CDC has proposed FY 2016 activities in each of these areas for which new funding is needed.

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

The NCEZID leads CDC efforts to address antibiotic resistance. As such, we ask that it be provided at least the \$699 million requested by the Administration, including at least \$264 million for the Antibiotic Resistance Solutions Initiative. This initiative would build prevention programs in all 50 states and 10 large cities, utilizing evidence-based approaches to stop the spread of drug-resistant bacteria and preserve the effectiveness of existing antibiotics. The initiative also supports a new network of regional labs to improve tracking of and response to outbreaks of serious and potentially deadly bacteria. The CDC projects that over five years, the initiative will lead to a 60% decline in health-care associated CRE, 50% reduction in *C. 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, more than covering the costs of investing in these programs now.

IDSA also supports the proposed \$14 million increase for the National Healthcare Safety Network (NHSN) to expand the number of participating healthcare facilities to 17,000 and increase the number of sites reporting antibiotic use and antibiotic resistance data. Information provided via NHSN is critical for evaluating the success of interventions designed to reduce inappropriate antibiotic use and limit the development of resistance and is therefore an integral component to broader efforts to address resistance.

IDSA thanks Congress for funding the Advanced Molecular Detection (AMD) initiative in FY 2015 and recommends that at least \$30 million be allocated for it in FY 2016. AMD strengthens CDC’s molecular sequencing tools and bioinformatics capacity to more rapidly and accurately detect infectious diseases and resistance. During the most recent Ebola virus disease outbreak, AMD methods were utilized to determine whether the virus was changing as it spread through different populations, which facilitated appropriate responses.

Global Health

IDSA supports CDC efforts to expand the Global Health Security Agenda, which would strengthen the capacity of nations to prevent, detect and slow the spread of infectious diseases across borders, simultaneously reducing threats to the United States. We ask that you provide the initiative with at least the funding requested in the FY 2016 PBR.

IDSA also encourages the Subcommittee to increase research, monitoring, and evaluation efforts for malaria and neglected tropical diseases. Chikungunya, 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 of serious illness and death from mosquito-borne viral diseases.

National Center for Immunization and Respiratory Diseases

Immunizations are among the most cost-effective clinical preventative services. However, according to the CDC [February 2015 Morbidity and Mortality Weekly Report](#), national adult immunization rates remain low for most routinely recommended vaccines. Each year in the United States, 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. During the last year, measles outbreaks and a sub-optimal influenza vaccine have reminded us of the importance of immunizations to public health.

IDSA opposes the \$50 million reduction to the CDC Immunization Grant Program (Section 317) contained in the PBR. Although the Affordable Care Act requires insurers to cover immunizations, this alone will not guarantee access or utilization. Section 317 funds are critical to help providers obtain and store vaccines; establish and maintain vaccine registries; as well as to educate providers and the public about vaccine recommendations, effectiveness and safety; and promote universal vaccination of health care workers.

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. Insufficient funding for these efforts could lead to increased incidence and severity of influenza, as well as increased hospitalization costs and mortality rates. Sustained support for these efforts is more cost-effective than periodic emergency supplemental funding.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases (NIAID)

Within NIH, we believe that the National Institute of Allergy and Infectious Diseases should be funded at least at \$4.62 billion as requested by the Administration in the FY 2016 PBR. Decreases in the purchasing power of NIAID have limited investment in new research and provided a disincentive for the pursuit of ID research careers so critical to the discovery of new vaccines, antimicrobials, diagnostics, and prevention strategies.

The NIAID is central to pursuits of new rapid ID diagnostics and antibiotics. A recent IDSA report, [Better Tests, Better Care: The Promise of Next Generation Diagnostics](#) explains that advances in biomedical research over the last few decades create 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 stated its intention to place special emphasis on rapid diagnostics. Several initiatives

have been announced, such as funding for diagnostics to quickly detect bacteria responsible for drug-resistant infections acquired in hospital settings and tests to identify reservoirs of latent HIV infection.

While increased funding is urgently needed, IDSA also recommends that the Subcommittee promote necessary and appropriate collaboration between academic researchers who receive NIH funding and industry by urging HHS to clarify its conflict of interest (COI) rules. Diagnostic test developers often require expert input or independent validation of a potential test during development from individuals at academic institutions. Institutional COI policies are often much more strict than the [HHS COI regulatory framework](#), which was intended to provide guidance to institutions on how to manage COI. These COI policies vary widely between institutions and are sometimes misinterpreted. This results in an unnecessary stifling of needed collaboration between academic researchers and industry when appropriate, which in turn forces developers to forgo expert input or use laboratories lacking the expertise for independent validation.

The NIAID supports the [Antibacterial Resistance Leadership Group \(ARLG\)](#), led by researchers at Duke University and the University of California San Francisco. With sufficient funding, the research network/infrastructure will continue studies to address antibiotic resistance. Severe economic disincentives continue to cause private companies to leave the antibiotics market, making federally funded research in this area more critical than ever.

The ARLG has supported early clinical research on diagnostics that rapidly identify resistant bacteria. The research group has created a virtual biorepository, which is a web-based portal that provides researchers with unique access to clinically well-characterized bacteria for the development of diagnostic tests and other research. Diagnostics research is often hampered by lack of clinical samples for testing. IDSA urges the Subcommittee to support NIAID exploration of opportunities to develop virtual biorepositories for viruses, fungi, and other pathogens already collected through its existing funded research.

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

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. However, the BARDA budget has been flat-funded for several years, with inflation leading to loss of purchasing power. Increased funding would allow BARDA to work with industry as a counter to current market failures. IDSA recommends that the Subcommittee provide at least the \$522 million requested for BARDA in the president's budget for FY 2016. 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.

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 jnurse@idsociety.org or (703) 299-0202.