

**Testimony for the Record to the Senate Appropriations Committee
on Driving Innovation through Federal Investments
Submitted by the Infectious Diseases Society of America (IDSA)
April 24, 2014**

The Infectious Diseases Society of America is pleased to provide testimony on innovation made possible by the components of the U.S. Department of Health and Human Services (HHS) that work to prevent, detect and treat infectious diseases (ID). IDSA represents more than 10,000 ID physicians and scientists devoted to patient care, prevention, public health, education, and research. Our community and, ultimately, our patients rely on federal partnerships to generate new public health strategies, outbreak detection capabilities, vaccines, antimicrobial drugs and diagnostics that together save lives as well as reduce health care expenditures. The ID community has identified several areas where federal investments in research and development need to be increased to realize maximum impact on health and the economy.

During the last century, research and development in the ID field yielded vaccines and antimicrobial drugs that saved countless lives. However, many of these achievements are at risk of being overrun in the days ahead by new threats, lagging industry participation, and declining federal support. One prominent example, the public health crisis of rapidly increasing antibiotic resistance (AR), raises the possibility of a post-antibiotic era in which we are unable to successfully treat infections or safely carry out many other healthcare activities (e.g., organ or bone marrow transplantation, other surgeries, chemotherapy, care of preterm infants) currently made safe and possible by effective antibiotics.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The ID community's partnership with the CDC has never been more necessary, as we work to address antibiotic resistance. Last fall, CDC issued a report, [*Antibiotic Resistance Threats in the United States, 2013*](#), which for the first time ranked and detailed the threats posed by antibiotic resistant microbes. Very conservative estimates indicate that more than two million Americans suffer antibiotic resistant infections each year, which result in approximately 23,000 deaths. The actual numbers are likely far higher, as our surveillance and data collection capabilities cannot yet capture the full disease burden. Infections due to antibiotic resistant microbes cost the U.S. health care system tens of billions of dollars annually, and the problem is worsening. The CDC recommended actions in four core areas to address the problem, including prevention, tracking, antibiotic stewardship, and development of new antibiotics and rapid diagnostics. Innovation is a critical component of each of these areas, and if adequately funded, federal agencies are prepared to carry out much of the necessary work.

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

The NCEZID plays a leading role in CDC efforts to address antibiotic resistance. For FY 2015, CDC has proposed continuation of activities that utilize new technologies to track and analyze data on new infections. CDC has also proposed the new [*Detect and Protect Against Antibiotic Resistance Initiative*](#), which will enhance surveillance and laboratory capacity as well

as employ evidence-based interventions that reduce the emergence and spread of AR pathogens and improve appropriate antibiotic use.

Advanced Molecular Detection (AMD)

IDSA urges the Appropriations Committee to sustain funding for AMD in FY 2015, to build critical molecular sequencing and bioinformatics capacities at the state and national levels. AMD will allow CDC to more quickly determine when and where new diseases emerge and new outbreaks occur, whether microbes are resistant to antibiotics, and how microbes are moving through a population.

Detect and Protect Against Antibiotic Resistance Initiative

The CDC AR initiative would establish regional prevention collaboratives to implement best practices for antibiotic use and infection prevention, create a detection network of five regional labs to speed up identification of the most concerning threats, improve antibiotic stewardship, and develop an isolate library that will help facilitate the development of desperately needed new antibiotics and diagnostics. The initiative directly addresses the recommended actions from the CDC 2013 AR report. The CDC projects that over five years the initiative will lead to a 50% reduction in health-care associated *Clostridium difficile* (*C. diff*), 50% decline in health-care associated carbapenem-resistant Enterobacteriaceae (CRE), 30% decline in invasive methicillin-resistant *Staphylococcus aureus* (MRSA), 30% decline in health-care associated drug-resistant *Pseudomonas* spp., and 25% reduction in drug-resistant *Salmonella* infections. These bacteria claim thousands of lives annually. CRE, for one, have become resistant to all or nearly all currently available antibiotics. Further, nearly 50% of those who develop bloodstream infections from CRE die. IDSA asks that Congress fully fund the CDC AR initiative.

Emerging Infections Programs (EIP)

EIP activities go beyond health departments' routine functions by addressing the most important issues in infectious diseases; maintaining flexibility for emergency response; developing and evaluating public health interventions; and focusing on projects that lead directly to the prevention of disease. These programs have yielded tremendous returns on investment with their ability to quickly translate surveillance and research activities into informed public health policy and practice. Additional funding is needed to sustain and expand these important activities including assessing the epidemiology of emerging antibiotic-resistant pathogens and evaluating host and pathogen components in infectious diseases of public health importance.

National Healthcare Safety Network (NHSN)

The NHSN conducts high-quality tracking and monitoring of deadly healthcare-associated infections (HAIs), including those caused by antimicrobial-resistant pathogens. The platform provides health care facilities, states, regions, and the nation with data needed to identify problem areas and measure progress of prevention efforts. NHSN also funds the EpiCenter Program, which conducts infection control and prevention research including projects on HAIs and AR infections. The program is focused on developing, implementing, and evaluating the effectiveness of strategies to improve health care quality and assure patient safety. The EpiCenters have survived on a \$2 million budget over the past fifteen years with no increase. Past investments have yielded significant health care cost-savings and produced more

than 150 peer-reviewed publications that have widely impacted infection control programs around the country. Additional funding is needed to build upon the success of the program. IDSA supports funding included in the FY 2015 President's Budget Request (PBR) for the NHSN, which would largely increase the number of healthcare facilities reporting antibiotic use and antibiotic resistance data and would develop and evaluate new infection prevention strategies.

NATIONAL INSTITUTES OF HEALTH (NIH)

National Institute of Allergy and Infectious Diseases (NIAID)

NIAID plays an essential role in funding infectious diseases research, including research on new types of treatments for tuberculosis, HIV, and other bacterial, fungal and viral diseases, as well as diagnostics and vaccines. However, the FY 2015 PBR proposes nearly flat-funding for NIAID and NIH. The proposed FY 2015 budget would limit investments in new research and serve as a disincentive for young people to pursue ID research careers so critical to the discovery of new therapies, diagnostic approaches, and preventive strategies. IDSA encourages the Appropriations Committee to increase support for NIAID to the level recognized as necessary by the Administration just two cycles ago in the FY 2014 PBR. Further, we recommend that particular consideration be given to enhancing the resources provided NIAID to help spur innovation for new antibiotics and rapid diagnostics.

Clinical Research Network on Antibacterial Resistance

The NIAID recently began funding a new [clinical trials network](#) focused on antibiotic-resistant bacterial infections. With sufficient funding, the new research network/infrastructure would conduct critical studies to address antibiotic resistance as well as begin to answer questions that would help fill the nearly empty antibiotic R&D pipeline. Severe economic disincentives have caused a mass exodus of private companies from the antibiotics market, making federally funded research in this area more critical than ever. An [IDSA report](#) issued in April 2013 identified only seven new drugs in development for the treatment of infections caused by multidrug-resistant Gram-negative bacilli (GNB). We applaud NIAID's initiative in launching the new network. However, IDSA recommends increased investment in this or similar initiatives.

Diagnostics Research and Development

Dramatic advances have been realized in diagnostic technologies. However, a need persists for easy to use rapid diagnostics that provide physicians with more timely results than current tests. A recent IDSA report, [Better Tests, Better Care: Improved Diagnostics for Infectious Diseases](#), highlights the need for advancements in diagnostic tools to address bacterial, viral and fungal infections and recommends strengthened NIAID funding for this priority. Faster, more accurate diagnostics lead to better treatments and improved patient outcomes. In addition, new diagnostics are needed to identify patients with highly contagious illnesses so that containment and prevention measures can be undertaken. Diagnostics can improve physicians' ability to discern which infections need antibiotics, and thereby help reduce the unnecessary use of antibiotics that drives the development of antibiotic resistance.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR)

Biomedical Advanced Research and Development Authority (BARDA)

ASPR plays a key leadership role in coordinating federal efforts to sufficiently protect the nation from biothreats, pandemics and emerging infections. BARDA develops and procures needed medical countermeasures (MCMs), including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural or intentional in origin. BARDA is a critical source of funding for public-private collaborations for antibiotic, diagnostic and vaccine R&D. IDSA recommends increased funding for BARDA, which has been flat-funded for several years.

Independent Strategic Investment Firm

IDSA also supports the establishment of the Medical Countermeasure Strategic Investor (MCMSI), proposed by the ASPR in August 2010. The MCMSI would be a non-government, non-profit entity that would partner with small innovator companies and private investors to address urgent needs, first focusing on: (1) novel antimicrobials for multidrug-resistant organisms, (2) novel mechanisms for disrupting pathogenesis through host pathway targeting, and (3) multiuse platform technologies for diagnostics, vaccines/prophylaxis, and therapeutics.

DEPARTMENT OF DEFENSE (DOD)

Multidrug Resistant Organism Repository and Surveillance Network (MRSN)

Within DOD, the MRSN comprises a microbiology laboratory, organism repository and a seven-facility network of Army hospitals around the world that treat both soldiers and military family members. Participating hospital laboratories submit all targeted multidrug resistant organisms (MDRO), along with clinical and demographic information, to the central laboratory. The repository performs extended analyses, preserves the specimens, and relays clinically relevant information to hospitals, medical leaders and policymakers to guide empirical therapy and enhance outbreak or emerging pathogen detection. The MRSN is positively impacting patient care and producing cost savings at participating hospitals. The MRSN needs strong funding to achieve its ultimate mission of integrating multiple levels of analysis for timely management of antibiotic resistance across the entire military health care system.

Thank you for the opportunity to submit this statement on behalf of the nation's ID physicians and scientists. The support of the Senate Appropriations Committee is critical to our efforts to combat increasing threats from infectious diseases. Please forward any questions to Jonathan Nurse at (703) 299-0202 or jnurse@idsociety.org.