

**Infectious Diseases Society of America's (IDSA)
Statement Concerning Fiscal Year 2011 Funding at the Department of Health and Human
Services, the Centers for Disease Control and Prevention, National Institutes of Health, and
Health Resources and Services Administration**

**Submitted to the Senate Appropriations Subcommittee on Labor, Health and Human
Services, Education and Related Agencies**

April 23, 2010

The Infectious Diseases Society of America (IDSA) appreciates this opportunity to speak in support of federal efforts to prevent, detect and respond to infectious diseases in the United States and abroad as part of the Fiscal Year (FY) 2011 funding cycle. IDSA represents more than 9,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis (TB), antibiotic-resistant bacterial infections such as methicillin-resistant *Staphylococcus aureus* (MRSA) and gram-negative bacterial infections, and emerging infections like the 2009 H1N1 virus (swine influenza).

2009 H1N1 novel Influenza virus

IDSA's leadership strongly commends Congress and the Administration for their actions in responding to the 2009 H1N1 outbreak. As the outbreak unfolded, we witnessed firsthand the importance of recent investments in a robust public health infrastructure as well as in research and product development. Specifically, we thank the Committee for the \$7.65 billion in supplemental funding it appropriated last June to support the development of a 2009 H1N1 virus vaccine, to replenish and rebuild the Strategic National Stockpile, and to assist state and local health departments in responding to the 2009 H1N1 outbreak. This year, the Administration has proposed to fund some ongoing pandemic influenza activities from these supplemental monies rather than having them come through the normal FY2011 appropriations process. IDSA disagrees with this approach and urges Congress to fund these activities through the FY2011 bill.

**The 10 x '20 Initiative: Supporting New Antibiotic Research and Development and
Combating Costly Drug-Resistant Bacterial Infections**

Since antibacterial drugs (antibiotics) were first discovered and used in the 1940s to save American soldiers during World War II, they have saved millions of lives and eased patients' suffering. In fact, antibiotics are often referred to as "miracle drugs," since patients only need to take them for a few days to completely resolve most infections. However, antibiotics also are unique among all medicines in two very unfortunate ways. First, over time, these drugs lose their ability to treat the diseases for which they were approved—due to antibiotic resistance, a serious patient safety, public health, and national security issue. Second, antibiotic resistance requires that approved antibiotics be used sparingly so that we can prolong their effectiveness.

Unfortunately, this combination of factors—antibiotic resistance, protective measures, and antibiotics ability to cure many, but not all, infections in a matter of few days—has resulted in a market failure with the result that most pharmaceutical companies have withdrawn from antibiotic research and development (R&D) to pursue more lucrative markets such as treatments

for chronic diseases. The sad result—the antibiotic pipeline is drying up, placing Americans and other people around the world at serious risk. In the January 2009 issue of the journal *Clinical Infectious Diseases (CID)*, IDSA confirmed the antibiotic pipeline is bare, particularly for drugs needed to address antibiotic-resistant bacteria known as the ESKAPE pathogens (*Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter* species). In September 2009, the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) released their own report affirming IDSA's assessment and found only 15 antibiotic drugs in development that may provide benefit over existing antibiotics. Based on past experiences, we know most of these drugs will never make it across the finish line to approval.

For nearly a decade, IDSA has raised concerns about the imbalance between the dwindling antibiotic pipeline and the significant need for new antibiotics to treat an increasing number of drug-resistant infections. The current situation has created very real challenges in physicians' ability to treat infectious diseases caused by ESKAPE pathogens, which have resulted in pain, suffering, and disfigurement in adults, children and infants, and hundreds of thousands of deaths.

In response to the antibiotic pipeline crisis, IDSA has launched *the 10 x '20 initiative*; the inaugural statement appears in the April 15th issue of *CID*. The goals of this initiative are simple to articulate, but will be difficult to achieve. We need a global commitment by the U.S. government, particularly the Department of Health and Human Services (HHS), and other governments to create a sustainable antibiotic R&D enterprise, which in the short-term can produce 10 new safe and effective antibiotics by 2020. To achieve the 10 x '20 goal, it will be necessary to bring together experts from the industrial, medical, scientific, policy, regulatory, and financial communities to determine the right combination of incentives that will work. **We urge the Subcommittee to adopt the 10 x '20 goal as its own and make new antibiotic research and development a key element of its funding for HHS for Fiscal Year 2011.**

Antibiotic-resistant infections significantly increase both health care and societal costs. A recent analysis of antibiotic-resistant infection data conducted at Chicago Cook County Hospital (*CID*, October 2009) showed that the direct and indirect economic costs of antibiotic resistance are enormously high in terms of dollars and length of hospital stays. Extrapolating the analysis nation-wide¹, the authors concluded that antibiotic-resistant infections cost the U.S. health care system in excess of \$20 billion annually as well as more than \$35 billion in societal costs and more than 8 million additional days spent in the hospital. Another study published in *Antimicrobial Agents and Chemotherapy* (January 2010), found that total hospital costs and length of stays attributable to antibiotic-resistant healthcare-associated infections (HAIs) caused by gram-negative pathogens (a segment of the ESKAPE pathogens) were 29.3 percent and 23.8 percent higher than those attributable to HAIs caused by antibiotic-susceptible gram-negative pathogens, respectively. Another study in *Infection Control and Hospital Epidemiology* (April 2010) found that the cost of treating patients with MRSA, an ESKAPE pathogen, was significantly higher than treating patients with methicillin-susceptible *S. aureus* (MSSA). The median cost for six months of treatment of an MRSA infection was \$34,657 compared to

¹ <http://www.prnewswire.com/news-releases/antibiotic-resistant-infections-cost-the-us-healthcare-system-in-excess-of-20-billion-annually-64727562.html>.

\$15,923 for treatment of an MSSA infection. The higher costs were the result of longer hospital stays, more laboratory and imaging tests, and more rehabilitation services.

To address infections caused by antibiotic-resistant ESKAPE pathogens and other infectious diseases, including on-going threats from H1N1 and other types of influenza, we need the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), and Biomedical Advanced Research and Development Authority (BARDA) to be robust and fully funded.

Centers for Disease Control and Prevention

A strong CDC is essential to the United States' efforts to rapidly detect and control antibiotic resistance and infectious diseases as it is the primary federal agency responsible for conducting and supporting public health protection through health promotion, prevention, preparedness, and research. For FY2011, IDSA recommends:

- increasing funding for CDC's core programs to \$8.8 billion;
- \$40 million for CDC's Antimicrobial Resistance programs;
- \$2.3 billion for CDC's Infectious Diseases programs;
- funding of the Emerging Infectious Diseases line item be increased to \$200 million;
- \$27.45 million for the National Health Safety Network (NHSN), as requested by the Administration;
- a funding level for the Section 317 Program of \$865.5 million, with the establishment of distinct funding floors for adult vaccine purchase and infrastructure;
- \$220.5 million for the CDC Division of TB Elimination; and
- \$1.6 billion for CDC's HIV prevention programs, as well as \$3.1 billion for HRSA's Ryan White CARE Act programs and an increase in Part C medical care by \$131 million.

Within the Preparedness, Detection, and Control of Infectious Diseases program's proposed budget, CDC's already severely strapped Antimicrobial Resistance budget would be cut dramatically by \$8.6 million—just over 50 percent! This vital program is necessary to help combat the rising crisis of antibiotic resistance, which CDC has deemed “one of the world's most pressing public health problems.” Yet the President's FY2011 budget would allow only 20 state/local health departments and health care systems to be funded for surveillance, prevention, and control of antimicrobial resistance, down from 48 this past year. It would also eliminate all grants to states for the successful Get Smart in the Community program to combat improper uses of antibiotics. IDSA believes CDC's antimicrobial resistance activities are so important to protecting Americans from serious and life-threatening infections that we urge you to boost funding for these activities to at least \$40 million in FY2011.

National Institutes of Health

NIH is the single-largest funding source for infectious diseases research in the United States and the life-source for many academic research centers. The NIH-funded work conducted at these centers lays the groundwork for advancements in treatments, cures, and other medical technologies. Between 2003 and 2009, NIH lost 13 percent of its purchasing power due to the rate of biomedical research inflation and stagnating annual budgets. Because of the flat budget, three out of four research proposals submitted to NIH were not funded. IDSA is pleased that the

American Recovery and Reinvestment Act provided additional funding to support NIH's research efforts in 2009 and 2010. Congress rightfully acknowledged the role of scientific research in stimulating the economy. However, it is vital that the momentum for medical research is sustained as it is essential to our national priorities of better health and economic revitalization. Therefore, IDSA supports a funding level of \$35 billion for NIH in FY2011.

Of great importance, given the scope of the antibiotic resistance/ESKAPE pathogen problem and its impact on everyday Americans, IDSA proposes a substantial funding increase in antibacterial resistance and antibacterial discovery research within NIH's National Institute of Allergy and Infectious Diseases (NIAID) to a total of \$500 million in FY2011. An IDSA analysis of 2009 NIAID funding found that, because of other serious medical problems, NIAID's total funding commitment for antibacterial resistance research was less than \$100 million. NIAID's support for antibacterial drug discovery research was less than \$70 million. Because of the rapid escalation in the problem of resistance, new initiatives must be developed. Significantly increasing funding in both areas will enable NIAID to support a better understanding of mechanisms of resistance as well as expanding joint ventures between academia and industry that will identify new drug targets and drugs with activity for those targets. In the end, we hope this will lead to the development of a library of target drug compounds that will support industry's efforts to find new antibiotics that treat infections caused by ESKAPE pathogens. Increased funding also will allow NIAID, in conjunction with other federal agencies such as BARDA, to create a seamless approach to new antibiotic drug R&D.

IDSA is extremely pleased that the recently enacted Patient Protection and Affordable Care Act created the Cures Acceleration Network (CAN) at NIH to help move discoveries from the lab into the next generation of therapies. IDSA supports funding of at least \$500 million in FY2011 for this critically needed new initiative.

IDSA also strongly supports increasing funding for NIH's Fogarty International Center in FY2011 to \$100 million, an increase of \$26.95 million.

Biomedical Advanced Research and Development Authority

Congress must fully fund BARDA within HHS so that the United States can begin to realize goals envisioned under the Pandemic and All-Hazards Act enacted in 2006 to address emerging infectious threats in addition to bioterrorism and pandemic influenza. IDSA recommends that at least \$1.7 billion of multi-year appropriations be allocated to BARDA in FY 2011 to fund therapeutics, diagnostics, vaccines, and other technologies, including new antibiotics to treat infections caused by the ESKAPE pathogens. Such funding would help ensure the availability of resources throughout the advanced stages of development and the flexibility for BARDA to partner effectively with industry.

Today's investment in infectious diseases research, prevention, and treatments will pay significant dividends in the future by dramatically reducing health care costs and improving the quality of life of millions of Americans and others.

IDSA Contact: Michael Ochs, mochs@idsociety.org, (703) 740-4790
1300 Wilson Blvd., #300, Arlington, VA 22209