

**Infectious Diseases Society of America's (IDSA)
Statement Concerning Fiscal Year 2012 Funding at the Department of Health and Human
Services, the Centers for Disease Control and Prevention, and National Institutes of Health**

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

April 15, 2011

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) 2012 funding cycle. IDSA represents more than 9,300 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 drug-resistant gram-negative bacterial infections, and emerging infections like the 2009 H1N1 influenza virus.

Although IDSA supports strong funding levels for infectious diseases efforts within each federal agency, the growing crisis in antibiotic resistance that is occurring in the United States (US) and globally has led IDSA to focus our testimony this year on funding for this issue alone.

The Antibiotic Resistance Crisis

The past approaches our society has employed to manage antibiotic development and their uses are now failing. Bacterial infections are becoming increasingly resistant to existing antibiotics, and, ironically, as the number of patients succumbing to these infections rises, the number of new antibiotics in development is plummeting. Remarkably, in 1990, there were nearly 20 pharmaceutical companies with large antibiotic research and development (R&D) programs. Today, alarmingly, there are only two large companies with strong and active programs, and only a small number of companies have more limited programs. As a nation, we have an obligation to our children and grandchildren to create a sustainable global antibiotic R&D enterprise that will produce these precious drugs in perpetuity and to invest in new ways to protect their effectiveness once approved.

The discovery of antibiotics in the 1930s fundamentally transformed the way physicians care for patients, shifting their approach from a focus on diagnosis without means to intervene to a treatment-focused approach that saves lives. Seven decades of medical advances enabled by antibiotics are now seriously threatened. Without effective antibiotics, diverse fields of medicine will be severely hampered, including surgery, the care of premature babies, cancer chemotherapy, care of the critically ill, and transplantation medicine, all of which are feasible only in the context of effective antibiotic therapy.

The antibiotic pipeline is bare particularly for drugs needed to address antibiotic-resistant bacteria. Collectively, highly problematic antibiotic-resistant organisms are summarized by the ESKAPE mnemonic: *Enterococcus*, *Staphylococcus*, *Klebsiella*, *Acinetobacter*, *Pseudomonas*, and *ESBL* (*Enterobacter* and *E. coli*). These bacteria have developed defenses that permit them to escape the actions of available antibiotics. The ESKAPE pathogens are currently the most

important causes of the antibiotic resistance crisis in the US and other developed countries. Such pathogens also are spreading through developing countries, which already are experiencing significant public health problems from extreme drug-resistant and pan drug-resistant TB and HIV/AIDS.

We are at risk not only from health care-associated and community-acquired antibiotic-resistant infections, but from threats (bioterrorism, pandemics) that could affect our nation's security. The longer we wait to invest in and implement solutions the harder and more expensive it will be to solve these problems. The time to act is *now*. On April 7, 2011, IDSA issued a new policy paper entitled "Combating Antimicrobial Resistance: Policy Recommendations to Save Lives" (http://cid.oxfordjournals.org/content/52/suppl_5/S397.full.pdf) to address this global public health and national security threat through policy strategies in eight broad areas of focus. (See Table 2 in that paper for a comprehensive list of IDSA supported funding recommendations, which we are unable to fully describe in this testimony.) The US Government must act immediately to: 1) adopt economic incentives and support other collaborative mechanisms to address the antibiotic market failure by rekindling antibiotic R&D; 2) create new regulatory approaches to facilitate the clinical development of antimicrobials; 3) more effectively coordinate federal antimicrobial resistance efforts; 4) enhance antimicrobial resistance surveillance and data collection; 5) strengthen activities to prevent and control antimicrobial resistance; 6) strengthen investments in antimicrobial-focused research; 7) strengthen investment in development and utilization of rapid molecular diagnostics for infectious diseases; and 8) eliminate non-judicious antibiotic use in agriculture and other settings.

In particular, investments for antibiotic resistance activities within the Department of Health and Human Services (HHS) and its related agencies, including for the Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and other agencies must be robust and fully funded.

Adopt Incentives and Support Collaborative Efforts that Yield Novel Antibiotics

To create a sustainable, national and global antibiotic R&D enterprise, it is necessary to identify and invest in the right combination of financial incentives ("push" and "pull" mechanisms) that will entice companies to reenter this product R&D area and to help companies, big and small, with innovative technologies to succeed. These incentives are intended to change the "return on investment" or net present value calculation of antibiotics to make them more competitive with other medical products. The Independent Strategic Investment Firm proposed by the HHS Secretary as part of ASPR's Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) review is a good first step in this direction. *IDSA calls for at least \$200 million to support ASPR's proposed strategic investment firm to leverage antibiotic venture capital investments. In addition, we support an allocation of at least \$1.7 billion of multi-year funding for BARDA to facilitate advanced development of therapeutics, diagnostics, vaccines, and other technologies, including new antibiotics and diagnostics to treat and detect infections caused by ESKAPE and other serious and life-threatening pathogens.*

Strengthen Coordination of Federal Agencies' Antibiotic Resistance Efforts

Federal agencies with programs related to antibiotic resistance, antimicrobial stewardship, and product R&D include: CDC, NIH, the Food and Drug Administration (FDA), ASPR, BARDA,

the Centers for Medicare and Medicaid Services (CMS), Agency for Healthcare Research and Quality (AHRQ), Health Resources Services Administration (HRSA), and the US Departments of Agriculture (USDA), Defense (DoD), Veterans Affairs, Homeland Security, State (including US Agency for International Development), and Education. Although an Interagency Task Force on Antimicrobial Resistance exists (authorized under Section 319E of the Public Health Service Act) there is inadequate coordination of activities among these agencies. Further, woefully insufficient funding has been provided to support the Task Force's work.

Although many dedicated federal officials sit on the Task Force, no centralized office exists to facilitate the coordination of the Task Force's activities, prioritize the federal response, establish benchmarks by which to measure progress, or provide a platform for ongoing discussion and action across agencies as well as with non-government experts. IDSA has long-championed the creation of a lead office and director within HHS reporting to the ASPR or the Assistant Secretary for Health. The director would lead the existing Task Force, bring new energy and a broad vision, and help to facilitate better coordination of the federal response. We also strongly support the formation of an advisory board of non-government experts that would work with the director and Task Force to establish priorities and ensure progress toward achieving its goals. We are pleased that the Task Force recently released, after a nearly 3 year delay, an updated draft Action Plan that attaches action items to federal coordinators and collaborators. Congressional appropriators should sufficiently fund the Task Force and Action Plan. ***Specifically, IDSA recommends \$30 million in funding be provided to HHS in FY2012 to support the Task Force's efforts to implement the revised Action Plan, and that additional funding be provided in future years once a lead office/director has been established.***

Strengthen Resistance Surveillance, Data Collection, and Control and Prevention Efforts

CDC currently employs several important surveillance systems and other strategies to address antibiotic resistance. Only by understanding the scope and severity of the problem can the US develop and target interventions that will save lives. To respond to current resistance trends and plan for emerging trends, it is necessary that we do a better job in surveying the frequency of resistance to antibiotics among medically important pathogens across geographical areas. To accomplish this, IDSA supports the creation of an integrated network of sentinel sites with diverse geographic representation. Data is necessary for a variety of infections and pathogens. The US also needs to strengthen data collection on the type and quantity of antibiotics used throughout the spectrum of patient care as well as in agricultural settings to define the overuse and misuse of antibiotics. In addition, specimen collection is needed for the evaluation of emerging resistance mechanisms in pathogens of clinical importance. IDSA also supports the adoption of effective antimicrobial stewardship programs in all health care and agricultural settings where antibiotics are prescribed/provided so that these precious drugs are used wisely and their effectiveness is protected. To this end, CDC needs to more aggressively promote the uptake of stewardship programs as well as better infection control practices and immunization policies. CDC's Get Smart programs already play an important role in educating providers and patients about appropriate antibiotic use and their outreach needs to be further extended.

The expansion of CDC's antimicrobial resistance surveillance, data collection, and prevention and control activities is crucial to protect Americans from serious and life-threatening antibiotic

resistant infections. *To support the activities highlighted above, CDC's antibiotic resistance program funding should be significantly and immediately increased to at least \$50 million. IDSA also supports an overall CDC funding level of \$7.7 billion.*

Significantly Expand Investments in Antimicrobial-Focused Research

There is a compelling need for more, better funded, and better coordinated federal antimicrobial resistance-related research. *For this reason, we are calling for an additional \$500 million to expand NIH's National Institute of Allergy and Infectious Diseases' (NIAID) support for antibiotic resistance and antibiotic discovery research.* NIAID's current budget level limits the institute's ability to sufficiently fund critically needed antibiotic resistance-related research, although NIAID has tried to expand its portfolio in recent years. Of importance, in recognition of the growing crisis, NIAID recently announced the establishment of a new clinical trials network focused on antibiotic-resistant bacterial infections. The institute noted, however, that limited funds will be available to support the network, which will be modeled on NIAID's successful HIV/AIDS clinical trials infrastructure. We applaud NIAID's announcement; but this critical work cannot be accomplished without significant additional funding. With such funding, the new network could conduct research on natural histories of disease, surrogate endpoints, pivotal drug trials, post-licensure comparative studies, validation of predictive biomarkers and molecular diagnostics, antimicrobial stewardship studies, and perhaps assessment of the clinical equivalency of generic drugs. All of these research efforts are essential to address both the antibiotic resistance and antibiotic R&D pipeline problems, and few of these studies will be undertaken by industry.

IDSA also has long sought the creation of an Antimicrobial Resistance Strategic Research Plan to define high-priority research needs, and address scientific challenges. As no strategic research plan exists, key research areas remain unaddressed. For example, basic science research should be expanded to further study antibiotic resistance mechanisms and epidemiology, identify new lead compounds, and develop vaccines and immunotherapies to prevent and treat infections in humans and animals. Studies that help to translate promising compounds from pre-clinical research into clinical trials should be expanded. We also need to better define optimal components and goals of antimicrobial stewardship programs in different health care settings, to define clinically relevant patient outcomes, and to develop national metrics to monitor program success. Clinical and health outcomes research is needed to study infections and interventions to improve outcomes and reduce antibiotic exposure. New funding is needed to expand NIAID support in each of these critical areas of research.

Conclusion

IDSA understands the need to get the nation's fiscal house in order. But as infectious diseases experts, we know that today's investment in infectious disease research, public health and prevention, and new treatments will pay significant dividends in the future by preventing needless deaths, dramatically reducing health care costs and improving the quality of life for millions of Americans. In addition, U.S. leadership in antibiotic resistance research and product R&D will translate into worldwide health benefits. We urge the Subcommittee to continue to demonstrate leadership and foresight in this area by appropriating the much-needed resources outlined above in recognition of the lives and dollars that ultimately will be saved.