IDSA Headquarters
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
TEL: (703) 299-0200
FAX: (703) 299-0204
EMAIL ADDRESS:
info@idsociety.org
WEBSITE:
www.idsociety.org

IDSA
Infectious Diseases Society of America

February 5, 2015

The Honorable Peter Roskam
227 Cannon House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Danny Davis
2159 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Representatives Roskam and Davis:

On behalf of the Infectious Diseases Society of America (IDSA), I write to express support for the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act. IDSA is advocating for federal policies to revitalize antimicrobial research and development (R&D) because more and more of our patients are dying from antibiotic resistant infections and we have far too few, in some cases no, safe and effective therapies to treat them. Your bill represents an important facet of the federal response to the public health crisis of antimicrobial resistance and the market failure that is discouraging antimicrobial research and development (R&D). We believe that increased Medicare reimbursement for the most urgently needed new antimicrobial drugs is one of several policies that Congress should enact to prevent a post-antimicrobial era in which we lack the drugs necessary to save patients' lives.

Seniors are one population at heightened risk for contracting a resistant infection. As adults age, their immune systems become less effective at fighting off infections. Seniors are also more likely to experience other health conditions or procedures, such as cancer or various surgeries, which heighten their risk of infection. Unlike death rates from heart disease and stroke, which have fallen in recent years, death rates from infections continue to rise, due in part to antimicrobial drug resistance and a lack of safe and effective new antibiotics to treat resistant infections. In fact, infections now account for nearly one third of deaths among people 65 and older.

In its September 2014 report to the President, the President's Council of Advisors on Science and Technology (PCAST) reiterated the urgent threat posed by increasing antibiotic resistance and the extremely fragile antibiotic pipeline. As more and more patients face deadly infections caused by multidrug resistant pathogens, pharmaceutical companies continue to turn away from antibiotic R&D, in large part due to persisting economic barriers. Antibiotics are typically inexpensive, used for a short duration, and held in reserve to protect their utility. Taken together, these factors create a very low net present value for antibiotics, making them an unattractive, often infeasible investment for many companies. In response to these challenges and the urgent need for new antibiotics, PCAST urged policymakers to advance economic incentives needed to spur antibiotic R&D.

IDSA appreciates that your legislation would target increased reimbursement to new antimicrobial drugs that treat a serious or life-threatening infection with high rates of morbidity or mortality and address an unmet medical need. This narrow focus will appropriately target limited federal resources toward the development of the drugs that patients most urgently need. IDSA also appreciates a new provision that would allow a company to seek a designation for a product as a DISARM drug during the drug's development, rather than requiring a company to wait until its new drug has been approved by the Food and Drug Administration (FDA) in order to apply for increased reimbursement. This approach will give companies the predictability they need in order to target their development programs to the areas of greatest patient need.

In addition to spurring the development of new antimicrobial drugs, it is equally critical that we also take steps to help ensure their appropriate use in order to protect patients and safeguard these precious drugs from the development of resistance caused by misuse. We appreciate that your bill would require prescribing hospitals to participate in the Antimicrobial Use and Resistance (AUR) module of the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) or a similar reporting program to track the use of these important drugs. IDSA is continuing to work with CDC, healthcare institutions, and other key stakeholders to improve data collection on antibiotic use and resistance, and we hope that DISARM can help advance this important effort. We are also working with CDC and related stakeholders to help expand the type of data collected to ultimately include use indication, site of infection, organism, basic patient demographics, treatment duration, and outcomes (efficacy and side effects). These data are crucial for evaluating the effectiveness strategies to address resistance, targeting antimicrobial drug and diagnostic development priorities, and defining clear benchmarks for progress.

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, Ebola virus disease, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), multidrug-resistant *Acinetobacter baumannii*, *Klebsiella pneumoniae,* and *Pseudomonas aeruginosa*, and emerging infections such as that caused by Ebola virus, enterovirus D68, the 2012 fungal meningitis outbreak, the 2009 H1N1 influenza pandemic, and the 2003 SARS epidemic (might add some of these; changed in some other docs).

We thank you for your commitment to addressing antimicrobial resistance, and we look forward to working with you to enact this important legislation and other antimicrobial R&D incentives. Should you have any questions, please contact Jonathan Nurse, Director of Government Relations for the Infectious Diseases Society of America, at 703-299-0202 or jnurse@idsociety.org.

Sincerely,

Stephen B. Calderwood

Stephen B. Calderwood, MD, FIDSA
President