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June 23, 2015

Dear Representative,

On behalf of the Infectious Diseases Society of America, I am writing to strongly urge you to vote in favor of the bipartisan 21st Century Cures Act, H.R. 6, when it is brought to the House floor for a vote in July. The legislation, which was unanimously approved in May by the Energy and Commerce Committee, is an important step forward in making the investments and policy changes necessary to spur research and development (R&D) leading to new immunizations, diagnostics, and therapeutics, including antibiotics.

The Cures bill provides desperately needed new resources to the National Institutes of Health (NIH) by establishing an NIH Innovation Fund that would provide a mandatory \$2 billion per year for 5 years to support priority areas such as infectious diseases. The NIH base budget has been in decline (adjusted for inflation) since Fiscal Year 2004, even as patient needs for research have increased and new infectious diseases threats — such as infections caused by antibiotic resistant pathogens, Ebola virus disease, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), and others — continue to grow.

The Cures bill would also increase the NIH loan repayment maximum to \$50,000 — providing important assistance to young people entering careers in research. Given that fewer and fewer individuals are pursuing this career path, due largely to financial concerns, this provision is critical and a step in the right direction to help ensure adequate recruitment of our nation's next generation of biomedical researchers who will be needed to discover the new preventive measures and treatments for tomorrow's infectious diseases threats.

Lastly, the Cures bill would help revitalize antibiotic development — an urgent need identified by a wide variety of leaders and public health experts including the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and the President's Council of Advisors on Science and Technology (PCAST). As infectious diseases physicians, IDSociety members are seeing increasing numbers of patients whose infections cannot be satisfactorily treated with existing antibiotics due to resistance to currently available antimicrobials, while the number of new antibiotics in development has plummeted during the last decade. Each year, at least 23,000 Americans die from antibiotic-resistant infections. This is a conservative estimate due to limited surveillance and data collection capabilities and the real number may be much higher.

One key barrier to antibiotic development is that it is often not possible to populate traditional, large scale clinical trials for antibiotics that treat the most deadly infections due to the small number of patients in which each of these infections

currently occurs. The Cures bill would allow these promising specific new antibiotics to be studied in smaller human clinical trials and approved for the limited population of patients who need them. Any drug approved under this new pathway would still have to meet the existing rigorous Food and Drug Administration (FDA) standards for safety and effectiveness for the limited indicated population. The legislation also contains provisions to foster appropriate use of antibiotics approved under the new pathway, including monitoring the drugs' use, FDA pre-review of promotional materials, and prominent "limited population" product labeling.

Once again, I ask that you vote in favor of the 21st Century Cures bill, H.R. 6. If you have any questions about this legislation or any other infectious diseases issues, please contact Jonathan Nurse, IDSA's Director of Government Relations, at jnurse@idsociety.org or 703-299-0202. Thank you for your consideration of this important legislation.

Sincerely,

A handwritten signature in cursive script that reads "Stephen B. Calderwood".

Stephen B. Calderwood, MD, FIDSA
President, IDSA

About IDSA

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease 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, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA) vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, and, finally, emerging infections such as Ebola virus, enterovirus D68, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), and bacteria containing the New Delhi metallo-beta-lactamase (NDM) enzyme that makes them resistant to a broad range of antibacterial drugs.