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Infectious Diseases Society of America

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October 18, 2013

The Honorable Barack H. Obama
President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

On behalf of the Infectious Diseases Society of America (IDSAs), which represents more than 10,000 physicians and scientists, thank you for your administration's focus on the increasing public health threat posed by antimicrobial resistance. On September 16, 2013, the Centers for Disease Control and Prevention (CDC) released the report: *Antibiotic Resistance Threats in the United States, 2013*. CDC's conservative estimates revealed that more than 2 million Americans suffer antibiotic resistant infections each year, which result in approximately 23,000 deaths. The actual numbers are likely far higher, as surveillance and data collection capabilities cannot yet capture the full disease burden. Additionally, according to CDC, the annual domestic impact includes \$20 billion in excess health care costs and more than 8 million additional hospital days. The CDC report recommended four core actions to address this crisis: prevention, surveillance, appropriate use of antibiotics, and the development of new antibiotics and diagnostics. IDSAs respectfully requests your leadership in urging Congress to advance legislation to address these issues.

Last year, IDSAs worked closely with Congress to advance new incentives in the FDA Safety and Innovation Act (FDASIA) in an effort to spur industry to reengage in the development of antibiotics. This legislation's bipartisan enactment demonstrated policymakers' commitment to addressing our diminishing arsenal of effective antibiotics. However, more work is needed in order to provide a comprehensive federal policy response that will both impact the trend of increasing resistance and further promote the development of new lifesaving drugs. Specifically, IDSAs proposes the following:

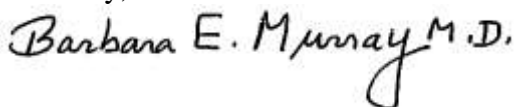
- **Limited Population Antibacterial Drug (LPAD) Pathway** – LPAD legislation would provide a faster approval mechanism for antibacterial drugs for patients with serious or life-threatening infections and few or no treatment options. LPAD drugs would be approved based upon smaller clinical trials, as these infections typically occur in too few patients to populate a large traditional trial. LPAD drugs would be clearly labeled and monitored to guide their appropriate use in the limited indicated population for whom the benefits have been shown to outweigh the risks. The President's Council of Advisors on Science and Technology recommended this type of approval mechanism in its 2012 report *Propelling Innovation in Drug Discovery, Development, and Evaluation*.

- **Targeted and Transferable R&D Tax Credits for Antibiotic/Antifungal Drugs and Diagnostics** – While the antibiotic/antifungal incentives in FDASIA were an important first step, experts agree that additional incentives will be necessary to revitalize the antibiotic and antifungal pipelines and help make these drugs, which typically have high development costs and low profitability, more attractive to companies and investors. IDSA supports proposals for targeted and transferrable R&D tax credits to further stimulate drug development. IDSA also supports a new federal tax credit for rapid (less than four (4) hours) diagnostic tests that detect serious or life-threatening infectious diseases, which would strengthen patient care, enable more precise use of antimicrobials and improve capacity for identifying participants for clinical trials.
- **Strategies to Address Antimicrobial Resistance (STAAR) Act, H.R. 2285** – While investment in the development of new drugs and diagnostics is crucial, steps must also be taken to combat antibiotic resistance and preserve the utility of new and existing antimicrobial drugs. The STAAR Act would increase federal coordination and leadership, and build upon existing federal programs and activities to enhance efforts to limit resistance and prevent the spread of antibiotic-resistant infections, improve surveillance and data collection, strengthen research, and promote antibiotic stewardship.
- **Federal Investments in Biomedical Research and Public Health Activities** – The federal government must be a strong partner to industry, academia, medical professionals, and the general public in slowing the development of antimicrobial resistance. Support for the National Institutes of Health should be a top budget priority. It is particularly imperative that the National Institute of Allergy and Infectious Diseases invest more vigorously in antibacterial resistance research and diagnostics. Robust support must also be provided for the Biomedical Advanced Research and Development Authority, which is an important source of funding for public-private collaborations in these areas. Finally, the federal government must also provide the CDC the resources necessary to track resistance, understand its driving factors, respond to outbreaks, and promote and measure the impact of efforts to limit resistance and prevent the spread of antibiotic-resistant infections.

IDSA requests that you endorse the aforementioned proposals through a public statement that heightens public awareness and calls for action, and that you and your staff work with us to advance these initiatives.

Once again, we thank you for your many efforts on behalf of the health of the American people. IDSA remains committed to advocacy on behalf of our patients. Please let us know if we can be of additional assistance to your administration in this regard.

Sincerely,



Barbara Murray, MD, FIDSA
President, IDSA

cc: Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services
Thomas Frieden, MD, MPH, Director, Centers for Disease Control and Prevention
Anthony Fauci, MD, Director, National Institute of Allergy and Infectious Diseases
Margaret Hamburg, MD, Commissioner, U.S. Food and Drug Administration