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

December 10, 2014

The Honorable Michael Bennet
458 Russell Senate Office Building
Washington, DC 20510

The Honorable Orrin Hatch
104 Hart Senate Office Building
Washington, DC 20510

Dear Senators Bennet and Hatch:

I write to express the Infectious Diseases Society of America's (IDSA) support for the Promise for Antibiotics and Therapeutics for Health (PATH) Act, legislation to establish a new limited population antibacterial drug approval pathway for antibacterial drugs to treat serious or life-threatening infections where there exists an unmet medical need. IDSA greatly appreciates your leadership in authoring this important bill, and we are deeply concerned that without it, the new drugs our patients desperately need in order to stay alive will not be developed and brought to market.

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, 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 the 2009 H1N1 influenza virus.

IDSA is advocating for federal policies to revitalize antibiotic research and development (R&D) because more and more of our patients are dying from drug resistant infections and we have far too few, in some cases no, safe and effective therapies to treat them. A 2013 IDSA report identified only seven new drugs in development for the treatment of infections caused by multidrug-resistant Gram-negative bacilli (GNB), and none of these drugs addresses the complete set of needs associated with these infections.

In September, the President's Council of Advisors on Science and Technology (PCAST) issued a Report to the President on Combating Antibiotic Resistance that explicitly recommended the enactment of legislation to authorize the Food and Drug Administration (FDA) to establish a new approval pathway for antibiotics to be used in limited populations of patients. The PATH Act would implement this important

recommendation and speed patient access to important antibacterial drugs to treat serious or life-threatening infections where there exists an unmet medical need. The PATH Act would allow such drugs to be approved based upon smaller, more rapid clinical trials. It is often not feasible for these antibiotics to be developed using traditional, large clinical trials due to the limited numbers of patients in whom the targeted infections currently occur.

It is important that drugs approved under this pathway be used judiciously, particularly given that they will be approved for limited populations, not the broader population of patients with non-serious infections that can be treated effectively with existing drugs. Appropriate use is critical to deliver optimal patient care and protect these precious drugs from the development of resistance. IDSA strongly supports provisions in your legislation to help guide appropriate use, including clear labeling of drugs approved under this pathway (through a logo or other such means), pre-review of marketing materials, and monitoring the use of drugs approved under this pathway, as well as patterns of resistance.

IDSA greatly appreciates your commitment to strengthening patient care by reinvigorating the antibiotic pipeline. We are extremely pleased to work with you to advance the PATH Act.

Sincerely,

Stephen B. Calderwood

Stephen B. Calderwood, MD, FIDSA
President