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IDSA
Infectious Diseases Society of America

December 12, 2013

The Honorable Phil Gingrey, MD
442 Cannon House Office Building
Washington, DC 20515

The Honorable Gene Green
2470 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Gingrey and Green:

On behalf of the Infectious Diseases Society of America (IDSA), I write to thank you for introducing the Antibiotic Development to Address Patient Treatment (ADAPT) Act, legislation to establish a new limited population antibacterial and antifungal drug approval pathway for antibacterial and antifungal drugs to treat serious or life-threatening infections where there exists an unmet medical need. IDSA strongly supports the establishment of this pathway, 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 began advocating for federal policies to revitalize antimicrobial drug research and development (R&D) because we are seeing more and more of our patients succumb to drug resistant infections and we have far too few, in some cases no, safe and effective therapies to treat them. Most recently, an IDSA report issued in April 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 Centers for Disease Control and Prevention (CDC) issued a report on antibiotic resistance threats which conservatively estimated that over 2 million people in the U.S. are sickened every year due to resistant infections, and approximately 23,000 die. The real numbers are likely far higher, as our current surveillance and data collection capabilities cannot capture the full burden. CDC specifically recommends the development of new antibiotics to address this public

health crisis, and your legislation is a critical step in that effort.

The proposed limited population antibacterial and antifungal drug pathway would speed patient access to important antibacterial and antifungal drugs to treat serious or life-threatening infections where there exists an unmet medical need by allowing them to be approved based upon smaller, more rapid clinical trials. It is often not feasible for these drugs to be developed using traditional, large clinical trials due to the limited numbers of patients in whom these infections currently occur. Importantly, any drug approved under this new pathway must still meet the Food and Drug Administration's (FDA) standards of evidence for safety and effectiveness for the limited indicated population.

It is important that drugs approved under this pathway be used judiciously, particularly given that they will be approved for limited populations, not the broad population of patients suffering non-serious infections that can be treated effectively with existing drugs. Appropriate use is critical for optimal patient care and public health efforts to protect these precious drugs from the development of resistance. IDSA strongly supports provisions in your legislation regarding the monitoring of antimicrobial drug use and patterns of resistance as well as the requirement that these data be made publicly available.

The labeling of drugs approved under this pathway must send a strong signal to the health care community about the need to use these drugs prudently. Specifically, the drug's labeling should reflect the patient population for which the drug is approved and should also summarize the limitations of available data that supported the approval. Physicians need this information in order to use these drugs appropriately. IDSA appreciates the language in your legislation that seeks to address this important point, and we look forward to continuing to work with you on this issue. In particular, IDSA supports the inclusion of a logo or other such visual means to clearly mark drugs approved under this pathway.

IDSA also supports provisions in your legislation designed to ensure that susceptibility test interpretive criteria (commonly referred to as "breakpoints") for antimicrobial drugs are regularly updated in a timely fashion, and that updated breakpoints are made publicly available via FDA's website. A breakpoint provides information that helps to predict whether a patient infected with a specific pathogen will have a good clinical response to standard doses of a drug. Given the ongoing development of drug resistance, it is critical that breakpoints be regularly updated to provide physicians with accurate information to guide the optimal use of drugs in patients.

IDSA greatly appreciates your longstanding commitment to strengthening patient care by reinvigorating the antibacterial and antifungal drug pipeline, as evidenced by your successful effort last year to enact the Generating Antibiotic Incentives Now (GAIN) Act. While the GAIN Act was an important first step, we agree that additional federal action is needed and are extremely pleased to work with you to advance the establishment of a limited population antibacterial and antifungal drug pathway.

Sincerely,

Barbara E. Murray M.D.

Barbara E. Murray, MD, FIDSA
President, IDSA