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March 7, 2014

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 (IDSAs), I write to express support for the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act and request a modification to the bill to better track use of these drugs. This legislation would provide a new supplemental payment for certain antimicrobial drugs through the Medicare New Technology Add-on Payment (NTAP) program. Your bill acknowledges that we are in the midst of a public health crisis resulting from an increase in antimicrobial resistant infections and a market failure that is discouraging antimicrobial research and development (R&D). IDSAs has long called for a diverse array of incentives to spur antimicrobial R&D, and we believe that the utilization of NTAP 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.

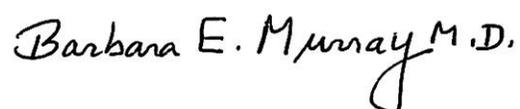
In a report released last fall, [Antibiotic Resistance Threats in the United States, 2013](#), the Centers for Disease Control and Prevention (CDC) for the first time ranked antibiotic-resistant bacterial disease agents according to threat level and outlined policy recommendations, including greater investment in antibiotic R&D. The report conservatively estimates that over 2 million people in the U.S. are sickened every year due to resistant infections and approximately 23,000 die. The actual numbers are likely far greater, as current surveillance and data collection capabilities can't capture the full burden. Antibiotic resistance poses a considerable threat to the Medicare-eligible population. As adults age, their immune systems become less effective in fighting off infections. Additionally, infections can be acquired while patients receive medical or surgical care for other problems in facilities such as nursing homes and hospitals. As an example, more than 90% of *Clostridium difficile* (*C. difficile*) infections, a bacterium that is listed in the highest threat category of the CDC report, occur in individuals over 65 years old. Approximately 75% of *C. difficile* infections begin in health-care facilities. According to the CDC, the incidence of *C. difficile* infections rose by 400% from 2000-2007 and these infections now result in 14,000 deaths in the USA each year and \$1 billion in excess medical costs.

As microbes become increasingly resistant to available drugs, pharmaceutical companies are exiting the antimicrobial market in pursuit of more profitable medications. Antibiotics are typically priced low, generally used for a short duration, and often held in reserve to protect their utility. These economic challenges lead to an extremely low net present value for antibiotics as compared with other drugs. In 1990, there were nearly 20 pharmaceutical companies with large antibiotic research and development programs. Today, there are only 3 large companies with strong and active programs and a few small companies with more limited programs. [An IDSA report issued in April 2013](#) identified only seven new drugs in development for the treatment of infections caused by multidrug-resistant Gram-negative bacilli (GNB).

In addition to spurring the development of new antimicrobial drugs, we must also take steps to help ensure their appropriate use in order to protect patients and safeguard the drugs from the development of resistance caused by misuse. We appreciate that your bill would require prescribing hospitals to participate in the Antimicrobial Use (AU) module of the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) to track the use of these important drugs. However, many hospitals are not prepared to participate in this module. It is our hope that as uptake of the NHSN AU module increases over time, more hospitals will be able to use this mechanism to report pertinent data as envisioned in your bill. In the meantime, to ensure that hospitals are able to participate and report the necessary data right away, we recommend a modification to your bill that calls for participating hospitals to utilize a CDC-based registry of patients using the drugs covered by the bill. We view the registry as a simple electronic database that collects data including use indication, site of infection, organism, basic patient demographics, treatment duration, and outcomes (efficacy and side effects). At this time, we believe that a registry would be simpler for hospitals to use while still providing important data.

We thank you for your commitment to innovation in the area of antimicrobials and ultimately saving lives, and we look forward to working with you to strengthen and 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,

Handwritten signature of Barbara E. Murray M.D. in black ink.

Barbara E. Murray, MD, FIDSA
President, IDSA