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Infectious Diseases Society of America

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### IDSAs 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

June 7, 2019

The Honorable Johnny Isakson  
United States Senate  
131 Russell Senate Office Building  
Washington, DC 20510

The Honorable Bob Casey  
United States Senate  
393 Russell Senate Office Building  
Washington, DC 20510

Dear Senators:

The Infectious Diseases Society of America (IDSAs) offers our strong support for the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act. IDSAs represents over 11,000 infectious diseases physicians, scientists, public health practitioners and other health care providers dedicated to the prevention, detection and treatment of infectious diseases, including those caused by multidrug-resistant pathogens. IDSAs members are at the forefront of the battle against antibiotic resistance, caring for patients, leading antibiotic stewardship programs, conducting research to understand resistance better and to develop new therapeutics, and informing public health interventions. IDSAs members see firsthand the urgent need for incentives to develop new antibiotics and for robust stewardship programs to promote appropriate antibiotic use and optimal patient outcomes. We are extremely pleased that your legislation aims to address both of these critical goals.

Our dwindling antibiotic arsenal increasingly leaves us without safe and effective treatment options for patients. Infections that are resistant to antibiotics often result in longer hospital stays, increased health care costs, suffering and even death. In some challenging cases, we are forced to rely upon highly toxic antibiotics that cause severe kidney damage that may require long-term dialysis. We wish to highlight that other patients have untreatable infections resistant to *all* available therapeutic options. Another factor is the opioid epidemic that is driving an increase in serious, hard-to-treat infections. The Centers for Disease Control (CDC) has reported that individuals who inject drugs are 16 times more likely to develop an invasive methicillin-resistant *Staphylococcus aureus* (MRSA) infection. We also risk losing access to a variety of medical advancements currently made possible by safe and effective antibiotics, such as organ and bone marrow transplants, joint replacements and other complex surgeries, and cancer chemotherapy.

The antibiotic market is failing to deliver the innovation needed to save lives because factors unique to antibiotics and their clinical use make it incredibly challenging for companies to earn a return on investments in antibiotic research and development. For instance, antibiotics are typically given for a short

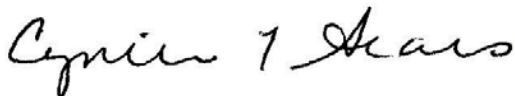
duration and new antibiotics are given to a small number of patients because the most highly resistant infections are still relatively rare. To maintain their effectiveness, new antibiotics must be used judiciously. Nearly all major pharmaceutical companies have exited the antibiotics market. Small biotech firms that are responsible for the majority of current antibiotic R&D are struggling to stay in business. This is aptly demonstrated by the company Achaogen entering bankruptcy in April 2019 despite launching an important new antibiotic, plazomicin, in 2018. Urgent action is needed to prevent the few remaining antibiotics companies from a similar fate, which could doom the antibiotic pipeline.

The current Medicare reimbursement structure prevents some patients who need new antibiotics from accessing them. Many IDSA members report significant challenges in adding a new antibiotic to their hospital formularies, attributable, in part, to the structure of the Medicare bundled payment or diagnosis-related group (DRG). In addition to harming patients, this situation further depresses already small revenue opportunities for antibiotic developers. By carving antibiotics out of the DRG and reimbursing for them separately, the DISARM Act would help level the playing field for new antibiotics, allowing clinicians to make the best treatment decisions for their patients, and creating a fairer market for new antibiotics, with greater opportunity for innovators to earn a return on their investments.

It is equally important to promote the appropriate use of antibiotics to limit the development of resistance. We greatly appreciate that the DISARM Act would require hospitals to: 1) establish antibiotic stewardship programs that are aligned with CDC recommendations, and 2) report antibiotic use and resistance data to the CDC National Healthcare Safety Network. Significant evidence has demonstrated that stewardship programs improve patient outcomes, lower health care costs, and reduce inappropriate antibiotic use. Antibiotic use and resistance data are essential to identify and track emerging threats and evaluate the impact of interventions to address antibiotic resistance.

Once again, we thank you for your leadership in efforts to combat antibiotic resistance and protect the antibiotic pipeline that is necessary to protect the health of all Americans.

Sincerely,

A handwritten signature in cursive script that reads "Cynthia Sears".

Cynthia Sears, MD, FIDSA  
President, IDSA