July 8, 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 Casey and Isakson,

We, the undersigned groups representing health care providers, scientists, patients, public health, advocates and industry, write to offer our support for the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act (S. 1712). We are deeply concerned about the public health crisis of antibiotic resistance and the urgent need for new antibiotics as well as policies to promote and monitor their appropriate use.

Antibiotic resistance is rendering increasing numbers of infections difficult or even impossible to treat. These infections lead to longer hospital stays, increased health care costs, suffering and even death. Some patients can only be treated with decades' old, highly toxic antibiotics that cause severe kidney damage, often requiring long-term dialysis, while others have untreatable infections resistant to all available therapeutic options. Furthermore, the opioid epidemic is driving an increase in serious, hard-to-treat infections, as the Centers for Disease Control (CDC) reported that individuals who inject drugs are 16 times more likely to develop an invasive methicillin-resistant *Staphylococcus aureus* (MRSA) infection. We 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. While resistance impacts increasing numbers of patients, we are failing to develop a sufficient arsenal of new antibiotics.

The antibiotic market is broken. Factors unique to antibiotics make it extremely challenging for companies to earn a return on their investments: 1) antibiotics are typically given for a short duration; 2) the most highly resistant infections are still relatively rare; 3) new antibiotics must be used judiciously to preserve their effectiveness. These factors have resulted in nearly all major pharmaceutical companies exiting the antibiotics market leaving the critical innovation domain of discovering and developing new antibiotics to small biotech companies with limited budgets and R&D capacity. These small biotech firms that are responsible for over 90% of the antibiotics in development worldwide are struggling to stay in business – even those that have launched or are close to launching products. Urgent action is needed to stabilize the antibiotics market.

The complexity of this problem requires a multi-pronged solution. Adjustments to the current Medicare reimbursement structure is one area that can help improve patient access to the most appropriate antibiotics. Many infectious disease physicians report significant challenges in adding a new antibiotic to their hospitals' formularies, attributable in part to the structure of the Medicare bundled payment or diagnosis-related group (DRG). In addition to harming patients with serious and life-threatening infections, this situation further depresses already small revenue opportunities for antibiotic developers. We believe that by carving antibiotics out of the DRG and reimbursing for them separately, the DISARM Act would help level the playing field for new products, allowing physicians to make the best clinical treatment decisions for their patients and helping to stabilize the very tenuous situation innovators currently face.

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In addition to improving patient access to new antibiotics and strengthening the market for innovators, it is equally important to promote 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 ensure the availability of new safe and effective antibiotics for the millions of Americans who need them.

Sincerely,

Accelerate Diagnostics, Inc.

Alliance for Aging Research

American Public Health Association

American Society for Microbiology

Association for Professionals in Infection Control and Epidemiology

Becton Dickinson and Co.

Center for Foodborne Illness Research & Prevention

Council of State and Territorial Epidemiologists

Cystic Fibrosis Foundation

Duke Center for Antimicrobial Stewardship and Infection Prevention

Emory Antibiotic Resistance Center

HIV Medicine Association

Infectious Diseases Society of America

Making-A-Difference in Infectious Diseases

Melinta Therapeutics, Inc.

Merck

NovaDigm Therapeutics, Inc.

Pediatric Infectious Diseases Society

Peggy Lillis Foundation

Qpex Biopharma

Roche Diagnostics Corporation

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Sepsis Alliance

Small World Initiative

Society for Infectious Diseases Pharmacists

The American Academy of Allergy, Asthma & Immunology

The Antimicrobials Working Group (Amplyx Pharmaceuticals, Aridis Pharmaceuticals, Cidara Therapeutics Inc., ContraFect Corporation, Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., Qpex Biopharma Inc., SCYNEXIS Inc., Summit Therapeutics plc and VenatoRx Pharmaceuticals Inc.)

The Foundation to Combat Antimicrobial Resistance

The Gerontological Society of America

The Pew Charitable Trusts

Thermo Fisher Scientific

Trust for America's Health