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IDSA
Infectious Diseases Society of America

November 21, 2019

The Honorable Todd Young
United States Senate
185 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Young,

On behalf of the Infectious Diseases Society of America (IDSA) I am writing to urge you to become a lead cosponsor of the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act, S. 1712. This legislation would provide urgently needed support for the antibiotics market, improve antibiotic use, and strengthen our national approach to antibiotic resistance. While DISARM would take a unique approach to Medicare reimbursement for antibiotics, IDSA asserts that antibiotics provide unique value and face unique challenges that call for an innovative reimbursement mechanism.

IDSA represents over 12,000 infectious diseases physicians, scientists, public health practitioners and other health care providers. Our members care for patients with a wide variety of infectious diseases, including those caused by multidrug-resistant pathogens. They are on the frontlines of the fight against antibiotic resistance, leading antibiotic stewardship programs, informing public health responses, and conducting research to deepen our understanding of resistance and develop new tools, including antibiotics, diagnostics and vaccines.

Antibiotics are unique in many ways. First, they are crucial to modern medicine. Antibiotic resistance impacts patients every day and threatens to undo decades of medical progress. Many procedures—cancer chemotherapy, organ and bone marrow transplants, and other surgeries (joint replacements, Caesarian sections, and many more) are made possible by safe and effective antibiotics. These procedures significantly increase patients' risk of infections by weakening their immune systems or, in the case of surgery, allow invasion of bacteria into the wound. We can only manage that risk with antibiotics.

Second, antibiotics play an important role in national security. Resistant pathogens complicate our soldiers' combat wounds, increasing the risk of limb loss and death, and compromise our military's combat readiness and effectiveness. Between 2004 and 2009, over 3,300 American soldiers in Iraq and Afghanistan became severely ill from a single resistant Gram-negative pathogen—*Acinetobacter*, which has

become even more resistant to treatment over time.[1] Alarmingly, resistant pathogens are also a prime candidate for weaponization by our nation's enemies, both state and non-state actors. The former Soviet Union previously engineered multidrug-resistant strains of both plague and anthrax.[2] Studies have concluded that the aerosolized release of a weaponized, resistant pathogen in just a single incident of bioterrorism in the Washington, DC area could result in a death toll of over 3 million.[3] The death toll from a coordinated bioterrorist attack using a weaponized resistant pathogen would be many magnitudes higher. Any mass casualty event is likely to result in severe wounds and burns, which can quickly become infected and further complicated by resistance.

Third, antibiotics are unique as a class of medicines as they do not directly target the patient but rather a foreign entity, bacteria. Further, bacteria are unique in their ability to mutate and become resistant, and then share their resistance genes with other bacteria. Other classes of drugs beyond antimicrobials do not similarly lose their effectiveness over time.

Antibiotic research and development faces unique challenges due to the nature of these drugs. Antibiotics are typically taken for a short duration and used in a limited fashion—only when necessary—to preserve their effectiveness. Nearly all large pharmaceutical companies have left the antibiotic development field. The small companies that are responsible for most of the antibiotic innovation are struggling to stay in business.

In April 2019, one small antibiotics company—Achaogen—filed for bankruptcy. In June 2019, another small antibiotic company—Tetraphase—announced massive layoffs, including eliminating its research function. The few remaining small antibiotics companies face similar fates. In November 2019, yet another small antibiotic company—Melinta—submitted a filing to the U.S. Securities and Exchange Commission which noted it likely will be necessary for the company to commence proceedings under Chapter 11 of the U.S. Bankruptcy Code. All three of these companies have (or had) important new antibiotics on the market, but were still unable to earn a return on their investments.

Reimbursement reform is an important component of the solution. When new antibiotics are brought to the market, they are used in a highly limited fashion. Infectious diseases physicians reserve these new, novel antibiotics to prevent the development of bacterial resistance to the new drug. Reserving the new antibiotics helps to ensure that they are available for the most severe and already drug-resistant infections. Further, the Medicare reimbursement system can make it challenging for patients to access new antibiotics even when they are clinically appropriate. The Diagnosis Related Group (DRG) payment is too low to cover the costs of new antibiotics, making it difficult in many instances for new antibiotics to be added to hospital formularies or prescribed even when they are medically the best choice for the patient. In addition to harming

[1] Fighting Superbugs: DoD's Response to Multidrug Resistant Infections in Military Treatment Facilities. Hearing before the Subcommittee on Oversight and Investigations of the Committee on Armed Services. US House of Representatives, September 29, 2010.
[2] Microbial Threats to Health: Emergence, Detection, and Response. Smolinski, M.S., Hamburg, M.A., and Lederberg, J. 2003.
[3] Rosen J et al. Cybercare: A System for Confronting Bioterrorism. National Academy of Engineering. Engineering and Homeland Security, December 3, 2008.

patient care, this scenario makes it extremely difficult for antibiotic developers—primarily small companies—to earn a return on their investment.

A recent study estimated that new antibiotics effective against the multi-drug resistant bacteria, carbapenem resistant Enterobacteriaceae (CRE), are currently being used to treat only 35% of CRE infections in which they are the first-line agents physicians should be using.[4] These new antibiotics are actually associated with better cure rates than previously available drugs but may not be used due the higher cost; this reduces the clinical outcomes of patients. Thus, patients may be regrettably deprived of better drugs because of the cost. Of great concern, older antibiotics with high toxicity, such as colistin, are still being used in many cases instead of new, safer antibiotics. Colistin can cause severe kidney damage, sometimes requiring dialysis. Flawed Medicare reimbursement is a key factor in limited uptake of new antibiotics.

The DISARM Act would carve new antibiotics out of the DRG, allowing them to be reimbursed separately and making them more accessible to patients who need them. DISARM also aims to ensure that these drugs are not overused or misused. DISARM would require hospitals receiving higher payments for antibiotics to establish antibiotic stewardship programs and to report their antibiotic use and resistance data to CDC National Healthcare Safety Network (NHSN). The stewardship requirement is aligned with a Medicare Condition of Participation finalized by the Centers for Medicare and Medicaid Services in September 2019. The NHSN reporting mechanism would allow evaluation of the impact of new reimbursement policy on antibiotic utilization and resistance.

IDSA greatly appreciates your consideration of the DISARM Act and would look forward to working with you on the issue of antibiotic resistance.

Sincerely,

Thomas J. File, MD, FIDSA
President, IDSA

[4] Clancy et al. Estimating the Treatment of Carbapenem-Resistant Enterobacteriaceae Infection sin the United States Using Antibiotic Prescription Data. Open Forum Infectious Diseases, Volume 6, Issue 8, August 2019, ofz344, https://doi.org/10.1093/ofid/ofz344 28 July 2019.