

March 12, 2018

The Honorable Dr. Robert Kadlec
Office of the Assistant Secretary for Preparedness and Response
200 Independence Ave. SW
Washington, DC 20201

Dear Assistant Secretary Kadlec:

The undersigned organizations, representing healthcare providers, hospitals, industry, patients, pharmacists, public health experts, scientists, and advocates are deeply concerned about the serious threat antimicrobial resistant pathogens pose to American health and national security, and are alarmed by the insufficient number of new antimicrobials and diagnostics to combat that threat. We greatly appreciate that the Biomedical Advanced Research and Development Authority (BARDA) is already providing essential support for antimicrobial R&D and urge you to maintain this vital investment. We must also underscore that significant unmet needs persist and new incentives are necessary to ensure that our nation is prepared to respond to the threat of antimicrobial resistance (AMR). We urge you to support inclusion of new antimicrobial research and development (R&D) incentives in the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). We support the allocation of new resources to fund new antimicrobial R&D incentives in order to maintain sufficient investment in ongoing biodefense needs.

Antimicrobial resistance poses a significant threat to our 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 pathogen—*Acinetobacter*, which has become even more resistant to treatment over time. Alarming, resistant pathogens are also a prime candidate for weaponization by our nation's enemies, both state and non-state actors. The former Soviet Union engineered multidrug-resistant strains of both *Yersinia pestis* and *Bacillus anthracis*—plague and anthrax. Studies have concluded that the aerosolized release of a weaponized, resistant pathogen in just a single incident of bioterrorism in the Washington, DC area would result in a death toll of over 3 million. The death toll from a coordinated bioterrorist attack using a weaponized resistant pathogen would be many magnitudes higher. Further, wounds and burns resulting from a mass casualty event can also become quickly infected, and AMR would make those infections much more challenging to treat.

AMR exacerbates influenza complications as well. Even in a typical influenza season, many influenza hospitalizations and deaths are actually due to secondary bacterial pneumonia which is increasingly difficult to treat due to AMR. The impact would be far worse in an influenza pandemic. AMR also puts our health security at risk, both within the US and globally. An outbreak of a serious resistant infection with limited or no treatment options could overwhelm health systems, harm economies and even destabilize communities or entire countries.

The President's Council of Advisors on Science and Technology, CDC, World Health Organization, United Nations, and other expert bodies and individuals have documented the urgent crisis of AMR and called for investment in antimicrobial R&D. Antimicrobial development has dwindled, with most pharmaceutical companies leaving this market. Economic experts agree that incentives are needed to overcome the hurdles that continue to hamper antimicrobial R&D: they are typically inexpensive, used for a short duration, and held in reserve to protect their utility, all of which prevent opportunities to earn a return on R&D investment. Including antimicrobial R&D incentives in PAHPA reauthorization will

March 12, 2018

be critical to ensure that our nation is prepared to respond to threat AMR poses to our health and national security.

We thank you for your leadership on bioemergency preparedness issues, and once again strongly urge you to support inclusion of antimicrobial R&D incentives in PAHPA reauthorization. We look forward to working with you to advance the nation's ability to prepare for and respond to the threat AMR poses to our health and national security.

Sincerely,

Accelerate Diagnostics
Alliance for Aging Research
Alliance for the Prudent Use of Antibiotics
American Academy of Allergy, Asthma, and Immunology
American Academy of Pediatrics
American Gastroenterological Association
American Public Health Association
American Society for Microbiology
American Society of Nephrology
American Society of Tropical Medicine and Hygiene
American Thoracic Society
Antibiotic Resistance Action Center at The George Washington University
Antimicrobial Working Group (Amplix Pharmaceuticals, Aridis
Pharmaceuticals, Arsanis Inc., Cidara Therapeutics Inc., ContraFect
Corporation, Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Nabriva
Therapeutics US Inc., Paratek Pharmaceuticals Inc., SCYNEXIS Inc., Spero
Therapeutics, Inc., T2 Biosystems Inc., Theravance Biopharma U.S. Inc., VPS-3
Inc., Vical Incorporated, and Zavante Therapeutics Inc.)
Association for Professionals in Infection Control and Epidemiology
Center for Foodborne Illness Research and Prevention
Dignity Health
Duke Center for Antimicrobial Stewardship and Infection Prevention
Emory Antibiotic Resistance Center
Foundation to Combat Antimicrobial Resistance
HIV Medicine Association
Infectious Diseases Society of America
Janssen
Johns Hopkins Center for Health Security
Making-A-Difference in Infectious Diseases
March of Dimes
Merck
Musculoskeletal Infection Society
National Association of County and City Health Officials
National Athletic Trainers' Association
NovaDigm Therapeutics

March 12, 2018

Pediatric Infectious Diseases Society
Peggy Lillis Foundation
Sepsis Alliance
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
Spero Therapeutics
The Fecal Transplant Foundation
The Gerontological Society of America
The Veterans Health Council
Trust for America's Health
Vietnam Veterans of America