

April 13, 2018

Admiral Brett Giroir
Assistant Secretary for Health
HHS Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Assistant Secretary Giroir,

We, the undersigned organizations, are members of the Stakeholder Forum on Antimicrobial Resistance (S-FAR) and we represent health care providers, scientists, patients, advocates, public health, and pharmaceutical and diagnostics industry representatives. We congratulate you on your appointment as the new Assistant Secretary for Health and look forward to working with you to address the significant threat of antimicrobial resistance (AMR).

Antimicrobial resistance presents a clear and present danger to patient safety, public health and national security. We hope you will work closely with the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), and we encourage you support robust, sustained investment in multi-agency One Health efforts to combat AMR domestically and globally, including prevention, antimicrobial stewardship, surveillance and data collection, research, and development of urgently needed new products including antimicrobial drugs, diagnostics, vaccines and alternative treatments.

The Centers for Disease Control and Prevention (CDC) estimate that at least 2 million individuals in the U.S. are sickened by antibiotic resistant infections annually, resulting in over 23,000 deaths. Congress has demonstrated a strong, bipartisan commitment to this issue, passing the Generating Antibiotic Incentives Now (GAIN) Act in 2012, provisions to reduce regulatory burdens to antibiotic R&D in the 21st Century Cures Act in 2016, providing significant new resources across multiple agencies to address AMR for Fiscal Year (FY) 2016, and building upon that investment in the FY2018 omnibus budget bill. Despite the important progress that has been made, significant unmet needs remain.

Infections caused by drug resistant pathogens are far more difficult and costlier to treat and compromise medical progress in a wide array of areas, including organ and bone marrow transplants, cancer chemotherapy, care of preterm infants and complex surgeries. Resistant pathogens are also a prime candidate for weaponization by our nation's enemies, both state and non-state actors. 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.

The threat of AMR is exacerbated by insufficient innovation. Antibiotics are difficult and expensive to develop and typically provide little to no return on investment for companies because they are used for a short duration and held in reserve to protect their utility. Investments through the National Institutes of Health, the Biomedical Advanced Research and Development Authority (BARDA) Broad Spectrum Antimicrobials program, and CARB-X, along with improvements from the GAIN Act and the 21st Century Cures Act are essential and have yielded

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progress, but the antimicrobial drug pipeline remains fragile and unable to meet current needs, and new incentives are urgently needed.

Diagnostic tests are central to meaningful efforts to address the AMR threat. Such tests have the capacity to reduce inappropriate antibiotic use by identifying non-bacterial infections, expedite diagnosis and treatment decisions, and guide antimicrobial treatment selection. Additionally, diagnostic tests support early detection and diagnosis of drug-resistant infections, enable effective disease surveillance and outbreak monitoring, and help prevent the spread of resistant organisms.

While investments in R&D are essential, we cannot innovate our way out of the problem of AMR. Investments in public health interventions are essential. We urge you to work closely with the Centers for Medicare and Medicaid Services (CMS) and CDC to advance antimicrobial stewardship goals, including the effort to implement antimicrobial stewardship programs that include appropriate use of diagnostics in all health care facilities. We also request your support for CDC's AMR activities. The Antibiotic Resistance Solutions Initiative funds state and local health departments to support surveillance for antibiotic resistant bacteria, as well as rapid outbreak detection and response. The National Healthcare Safety Network tracks antibiotic use and resistance patterns at health care facilities, which is essential for evaluating the impact of efforts to reduce inappropriate prescribing and resistance. Advanced Molecular Detection initiative allows CDC to more precisely identify and track strains of antibiotic resistant bacteria and more rapidly identify pathogens and link them to other potential outbreaks. In addition to CDC, the Agency for Healthcare Research and Quality (AHRQ) supports vital research to improve methods and approaches for combating antibiotic resistance and implementing antibiotic stewardship.

Infectious diseases know no borders, and it is essential that the US maintain global leadership and engagement in combating AMR. We applaud the US participation in G20 and G7 commitments to address AMR. We also urge continued investment in efforts to combat multidrug resistant tuberculosis and global health security. Through both CDC and USAID, global health security funding supports the development of surveillance and laboratory capacity in low resource countries to ensure the ability to detect emerging antibiotic resistance threats where they originate and mount a rapid response.

Finally, effective strategies to combat AMR must maintain a One Health approach. The U.S. Food and Drug Administration (FDA) plays a crucial role in addressing AMR in agricultural settings. We urge your support for FDA efforts to advance antibiotic stewardship in animal agriculture, as well as how to better maintain antibiotic efficacy in both human and animal populations. They also work with the CDC and U.S. Department of Agriculture (USDA) to monitor AMR through the National Antimicrobial Resistance Monitoring System (NARMS). NARMS uses state and local public health departments to track changes in antimicrobial susceptibility of enteric bacteria and conduct epidemiological investigations when needed.

Once again, we thank you for your leadership on this important issue and look forward to working with you to advance a multi-faceted solution to antimicrobial resistance. If you have any

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questions or would like to engage S-FAR members please contact Colin McGoodwin, S-FAR Coordinator at cmcgoodwin@idsociety.org. Thank you for your time and consideration.

Sincerely,

Accelerate Diagnostics, Inc.
AdvaMedDx
Alliance for the Prudent Use of Antibiotics
Alliance for Aging Research
American Academy of Allergy, Asthma, and Immunology
American Association of Avian Pathologists
American Association of Bovine Practitioners
American Association of Immunologists
American Public Health Association
American Society for Microbiology
American Society of Transplant Surgeons
American Society of Tropical Medicine and Hygiene
American Thoracic Society
American Urological Association
American Veterinary Medical Association
Antibiotic Resistance Action Center, The George Washington University
Antimicrobials Working Group (Amplix Pharmaceuticals, Aridis Pharmaceuticals, Arsanis Inc., Cidara Therapeutics Inc., ContraFect Corporation, Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Motif Bio plc, Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., SCYNEXIS Inc., Spero Therapeutics, Inc., T2 Biosystems Inc., Theravance Biopharma U.S. Inc., Viamet, Vical Incorporated, and Zavante Therapeutics Inc.)
Association for Professionals in Infection Control and Epidemiology
Association of American Veterinary Medical Colleges
Association of Public Health Laboratories
BD (Becton, Dickinson, and Company)
BIO (Biotechnology Innovation Organization)
Center for Foodborne Illness Research and Prevention
Clinician Champions in Comprehensive Antibiotic Stewardship
Consumer Federation of America
Duke Center for Antimicrobial Stewardship and Infection Prevention
Emory Antibiotic Resistance Center
Food Animal Concerns Trust
Health Care Without Harm
Infectious Diseases Society of America
Johns Hopkins Center for a Livable Future
Making-A-Difference in Infectious Diseases
March of Dimes
Merck
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners

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National Athletic Trainers' Association
National TB Controllers Association
NovaDigm Therapeutics
ONCORD, Inc.
Pediatric Infectious Diseases Society
Peggy Lillis Foundation
Sepsis Alliance
Society for Healthcare Epidemiology of America
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
Spero Therapeutics
The Fecal Transplant Foundation
The Pew Charitable Trusts
Trust for America's Health