

November 11, 2019

The Honorable Alex Azar, II
Department of Health and Human Services Secretary
HHS Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar:

We, the undersigned organizations representing clinicians, scientists, public health, patients, veterinary medicine, industry and advocates write to thank you for your leadership in efforts to protect individuals from seasonal influenza and to request additional support for activities to combat a related threat to patients and public health—antimicrobial resistance. Every year, many influenza cases are complicated by secondary bacterial infections like pneumonia which increase risk of hospitalization and death. Such bacterial infections are increasingly difficult to treat due to antibiotic resistance. We greatly appreciate recent steps from the administration to recognize the severe threat of antimicrobial resistance and are eager to work with you on additional progress. Given recent reports that the Administration plans to request emergency supplemental appropriations for influenza, we urge you to include funding to support the antibiotic pipeline and antibiotic stewardship in this funding request.

The antibiotic pipeline is in a state of crisis for which urgent action is essential. We greatly appreciate the administration highlighting this issue at the Biomedical Advanced Research and Development Authority (BARDA) annual Industry Day meeting. The April 2019 bankruptcy of Achaogen following its launch of a new antibiotic shook the antibiotic marketplace and further depressed the already minimal investment interest in supporting antibiotic research and development. Additional companies are likely to face the same fate in the next few months unless the federal government acts now to stabilize the antibiotic marketplace and drive new investment in this area. Additional bankruptcies would jeopardize patient access to existing antibiotics, further weaken the already collapsing pipeline of new antibiotics in development and cause a significant loss of scientific experts that can take many years to recover. Without new antibiotics, modern medical advances such as cancer chemotherapy, organ and bone marrow transplantation, complex and routine surgical procedures and care of immunocompromised patients are all at risk. **We strongly encourage you to request swift new funding from Congress to provide support for new antimicrobial market stabilization and strengthening initiatives by HHS, including potentially a novel pull incentive, to allow for antibiotic innovation.**

It is equally essential that we protect the effectiveness of antimicrobials through stewardship. We applaud the September 2019 action by the Centers for Medicare and Medicaid Services (CMS) to require all hospitals to implement antimicrobial stewardship programs as a Condition of Participation in Medicare. Stewardship programs provide clinicians with the necessary tools and information to optimize antimicrobial prescribing, including education, the use of diagnostic tests, penicillin allergy testing, and surveillance to measure and improve appropriate use. We are eager to work with you to help ensure the success of this important initiative. As you know, the Centers for Disease Control and Prevention (CDC) currently leads activities to promote optimal antimicrobial use. Given the new CMS

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requirement, this is an important time to provide an infusion of funding—particularly to help hospitals (including rural and critical access hospitals) initiate their stewardship programs and begin reporting antibiotic use and resistance data to the CDC National Healthcare Safety Network (NHSN). It is important to collect these data in order to evaluate the impact of stewardship efforts. Both of these activities can require initial funding to launch, and continued operation is far less costly. **We strongly encourage you to couple an emergency supplemental funding request to support the antibiotic pipeline with a request for new funding to support antimicrobial stewardship and NHSN reporting.**

Once again, we thank you for your ongoing leadership on behalf of patients and public health and look forward to working with you to advance investments in policies to combat antimicrobial resistance through innovation and stewardship.

Sincerely,

Accelerate Diagnostics
AdvaMedDx
American Academy of Allergy, Asthma, and Immunology
American Academy of Pediatrics
American Association of Avian Pathologists
American Association of Bovine Practitioners
American Public Health Association
American Society for Microbiology
American Thoracic Society
Antibiotic Resistance Action Center, the George Washington University
Association for Professionals in Infection Control and Epidemiology
Association of Public and Land-grant Universities
Becton Dickinson & Co. (BD)
Biotechnology Innovation Organization (BIO)
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
Merck
National Association of Pediatric Nurse Practitioners
National Institute of Antimicrobial Resistance Research and Education
ONCORD, Inc.
Sepsis Alliance
Small World Initiative
Society of Infectious Disease Pharmacists
Spero Therapeutics

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

The Gerontological Society of America

The Joint Commission

The Tufts Center for Integrated Management of Antimicrobial Resistance

Trust for America's Health