

March 12, 2019

The Honorable Rosa DeLauro
U.S. House of Representatives
2413 Rayburn House Office Building
Washington, DC 20515

The Honorable Tom Cole
U.S. House of Representatives
2207 Rayburn House Office Building
Washington, DC 20515

The Honorable Sanford Bishop
U.S. House of Representatives
2407 Rayburn House Office Building
Washington, DC 20515

The Honorable Jeff Fortenberry
U.S. House of Representatives
1514 Longworth House Office Building
Washington, DC 20515

The Honorable Nita Lowey
U.S. House of Representatives
2365 Rayburn House Office Building
Washington, DC 20515

The Honorable Hal Rogers
U.S. House of Representatives
2406 Rayburn House Office Building
Washington, DC 20515

Dear Chairs and Ranking Members of the Labor-HHS-Education, Agriculture, and State-Foreign Operations Appropriations Subcommittees:

We greatly appreciate your leadership in providing strong investments in antimicrobial resistance (AMR) in FY2019. The undersigned organizations, representing human and animal health care professionals, scientists, patients, public health, animal agriculture, and the pharmaceutical and diagnostics industry, urge you to provide the robust funding needed to address this urgent public health threat through a One Health approach domestically and globally that includes infection prevention, antimicrobial stewardship, surveillance, research, and innovation, and ask that you work with your colleagues to raise the budget caps to allow for deeper investments.

Antimicrobial resistance is a public health crisis. In November 2018, a report published in the Journal of Infection Control and Hospital Epidemiology found that as many as 162,044 people die in the U.S. each year as a result of antimicrobial resistance, making AMR the third leading cause of death in our country.

Despite the urgent need for tools to combat AMR, current research and development is insufficient. Nearly all large pharmaceutical companies have halted antibiotic R&D and the small companies that provide the bulk of the innovation in this area are struggling to raise the funds necessary to stay in business. New diagnostic tools are needed as well to help guide appropriate antibiotic use and enable surveillance.

We believe that a deeper federal investment commensurate with the gravity and importance of AMR is urgently needed, and we urge your support for the following funding requests for FY2020.

Biomedical Advanced Research and Development Authority (BARDA)

We recommend funding of at least \$750 million for BARDA, with \$230 million for their work on antimicrobial resistance. BARDA plays a vital role in leveraging public private partnerships to

accelerate research and development of much needed antimicrobials to combat the growing number of resistant organisms, and addresses critical gaps in the antibacterial pipeline through the CBRN Countermeasures Division.

In 2016, BARDA along with the National Institute of Allergy and Infectious Diseases (NIAID) teamed up with key stakeholders to launch Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X). CARB-X is working with over 30 companies to support research and development for promising new antibiotics, diagnostics and other products to combat AMR. BARDA's annual contributions to CARB-X total \$55 million, which have been multiplied many-fold with contributions from other CARB-X funders, company cost-share, and follow on private investments. CARB-X is already populating the pipeline, which will give CBRN more competitive options to fund for later stages of clinical development.

These two BARDA programs work in tandem with NIAID to support a pipeline of novel approaches for highly resistant infections and emerging threat, pathogens.

The Centers for Disease Control and Prevention (CDC)

The Antibiotic Resistance Solutions Initiative (ARSI) is a cornerstone of the national infrastructure to fight AMR threats and expand CDC's and state and local health departments' capacity to detect and track resistant threats, respond to and contain outbreaks of resistant pathogens, and support prevention and stewardship activities. We recommend \$200 million in FY2020 funding for ARSI.

The Advanced Molecular Detection (AMD) program helps to ensure that state and regional laboratories have the technology to help identify and analyze resistant organisms. Being able to track the spread and mutation using these techniques is paramount in the fight against AMR. We recommend FY2020 funding of \$32.5 million for AMD.

FY2020 funding of \$22.75 million for the National Healthcare Safety Network will enable CDC to continue to track health care-associated infections, antibiotic use, and antibiotic resistance. These data are essential to inform and evaluate antibiotic stewardship activities and other efforts to address antibiotic resistance. While progress has been made in the number of healthcare facilities voluntarily reporting antibiotic use and resistance data, there is still work to do to achieve the goal in the National Action Plan for Combating Antibiotic Resistant Bacteria for 95% of hospitals to report these data by 2020.

Globally, approximately 700,000 deaths are attributable to AMR. Multidrug resistant tuberculosis (MDR-TB) accounts for the majority of these deaths. We recommend \$642 million for CDC's Center for Global Health to support efforts to prevent antibiotic resistance threats from reaching our shores. Continued funding is also needed for the Global Health Security Agenda, which includes building countries' capacities for surveillance of drug-resistant bacteria, strengthening lab capacity and training health personnel on combating AMR.

National Institutes of Health

The National Institute of Allergy and Infectious Diseases (NIAID) is a world leader on research related to AMR. We recommend funding of at least \$5.761 billion to support this work to continue valuable research into how to combat the ever-evolving threat posed by resistant microbes. NIAID is also a

lead funder of research to discover novel antimicrobials, diagnostics and vaccines that are urgently needed to address multi-drug resistant organisms.

Food and Drug Administration and US Department of Agriculture

With a FY2020 funding increase of \$12 million resources for the Combating Antibiotic Resistant Bacteria initiative and a \$5 million increase for the National Antimicrobial Resistance Monitoring System (NARMS), FDA can begin to implement Commissioner Gottlieb’s 2018 five-year antibiotic stewardship action plan, including plans to modernize and update NARMS and support expanded efforts to monitor antimicrobial resistance and promote effective stewardship.

Further, an increase of \$67 million in funding for USDA for antimicrobial resistance priorities, includes increased funding for the Animal and Plant Health Inspection Service (APHIS) that will strengthen APHIS’ capacity to promote agricultural stewardship through improved surveillance and feedback to growers. Expanded funding for agricultural research at USDA’s Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA) will enable scientists to better understand the factors driving the emergence of resistance, help producers find new antibiotic alternatives and improved animal management practices and better integrate that information throughout production through high-value training and technical assistance provided by USDA cooperative extension agents and veterinarians.

United States Agency for International Development (USAID) and Department of State

We recommend \$400 million for USAID’s global tuberculosis program, which supports high-quality screening, diagnosis and treatment services for patients affected by multidrug-resistant TB. USAID also leads efforts to expand treatment to more patients infected with MDR-TB, strengthen diagnostic and surveillance capacities globally, and accelerate basic and applied research and development to combat MDR-TB. We recommend \$175 million for USAID global health security efforts to strengthen USAID’s capacity to invest in health systems strengthening in low-income countries to combat the spread of AMR. We recommend \$1.56 billion for the Global Fund to Fight AIDS, TB, and Malaria to allow continued reductions in malaria and TB and help staunch the growth of drug-resistant forms of these infections.

Once again, we greatly appreciate your leadership in providing strong investments in AMR in FY2019. We urge you to continue to place a high priority on AMR to continue making strides to protect patients and public health and spur needed innovation.

Signed,

- Accelerate Diagnostics
- AdvaMedDx
- Alliance for the Prudent Use of Antibiotics
- American Academy of Allergy, Asthma & Immunology
- American Academy of Pediatrics
- American Association of Avian Pathologists
- American Association of Bovine Practitioners
- American Association of Small Ruminant Practitioners

American Public Health Association
American Society for Microbiology
American Society of Transplant Surgeons
American Society of Tropical Medicine and Hygiene
American Thoracic Society
American Veterinary Medical Association
Antibiotic Resistance Action Center, George Washington University
Association for Professionals in Infection Control and Epidemiology
Association of American Veterinary Medical Colleges
Association of Public and Land Grant Universities
Association of Public Health Laboratories
BD (Becton Dickinson and Co)
bioMerieux
BIO (Biotechnology Innovation Organization)
Cepheid
Center for Science in the Public Interest
Clinician Champions in Comprehensive Antibiotic Stewardship Collaborative
Council of State and Territorial Epidemiologists
Cystic Fibrosis Foundation
Duke Center for Antimicrobial Stewardship and Infection Prevention
Emory Antibiotic Resistance Center
Food Animal Concerns Trust
Foundation to Combat Antimicrobial Resistance
Health Care Without Harm
HIV Medicine Association
Infectious Diseases Society of America
Making-A-Difference in Infectious Diseases
March of Dimes
Melinta Therapeutics, Inc.
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National Institute of Antimicrobial Resistance Research and Education
ONCORD, Inc.
Pediatric Infectious Diseases Society
Peggy Lillis Foundation
Sepsis Alliance
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
Spero Therapeutics
The Antimicrobials Working Group (Amplifyx 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 Pew Charitable Trusts
The Society for Healthcare Epidemiology of America
Thermo Fisher Scientific

Trust for America's Health