June 8, 2018

The Honorable Tom Cole
U.S. House of Representatives
2467 Rayburn House Office Building
Washington, DC 20515

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

The Honorable Robert Aderholt
U.S. House of Representatives
235 Cannon House Office Building
Washington, DC 20515

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

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

The Honorable Nina Lowey
U.S. House of Representatives
2365 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 FY2016, FY2017, and FY2018. Regrettably, the President's Fiscal Year 2019 (FY19) budget proposes deep cuts to initiatives that are crucial to combating AMR. The undersigned organizations, representing health care providers, scientists, patients, public health, and the pharmaceutical and diagnostics industry, urge you to reject these proposed reductions, and provide the robust funding needed to address this urgent public health threat through infection prevention, antimicrobial stewardship, surveillance, and innovation.

The Centers for Disease Control and Prevention (CDC) acknowledges that at least 23,000 people in the US die due to antibiotic resistant infections and at least another 2 million are sickened every year. These infections result in an additional $20 billion per year of excess costs to our health care system. In April 2018, a CDC Vital Signs report, Containment of Novel Multidrug-Resistant Organisms and Resistance Mechanisms, showed that early aggressive action does slow the spread of resistant bacteria in health-care settings, thereby reducing such infections. The report confirms the value of investment to combat AMR.

The report also highlights the need for continued and robust funding for AMR given that nationwide testing last year documented 221 cases of so-called "nightmare bacteria," that can spread resistance to last-resort antibiotics. Robust, sustained investment in multi-agency One Health efforts is vital 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.

We are concerned that the gravity and importance of AMR is not reflected in the President's Budget Request (PBR) and would like to bring to your attention several key AMR priority programs that we believe should be fully funded in FY2019.

June 8, 2018

Biomedical Advanced Research and Development Authority (BARDA)
While the PBR proposed level funding for BARDA at $512 million, we recommend funding of at least $700 million given the vital role BARDA plays in leveraging public private partnerships to accelerate research and development of much needed antimicrobials to combat the growing number of resistant organisms. In 2017, BARDA along with the National Institute of Allergy and Infectious Diseases teamed up with other non-profits to launch CARB-X. CARB-X is an initiative that seeks to spur the development of antibiotics through the formation of public-private partnerships for both funding and research and development assistance for promising new antibiotics and other products to combat AMR.

BARDA safeguards our nation's health infrastructure by revitalizing and encouraging antibacterial innovation to ensure that we have a healthy pool of candidate products to address emerging threats. The CARB-X accelerator addresses critical gaps along the early stages of the antibacterial pipeline, and BARDA's Broad Spectrum Antimicrobials program advances therapeutics into late stage clinical development. The two work in tandem to ensure a robust pipeline of novel approaches for highly resistant infections and emerging threat pathogens. 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.

The Centers for Disease Control and Prevention (CDC)
We are extremely concerned that the President's FY2019 budget would cut the CDC's Antibiotic Resistance Solutions Initiative (ARSI) by $31 million below the FY2018 level of $168 million. This proposed cut in funding would greatly weaken our national infrastructure to fight AMR threats and limit CDC 's and state 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 a deeper investment in ARSI for FY2019 of $200 million.

CDC's Advanced Molecular Detection (AMD) program helps to ensure that state and regional laboratories have the most cutting-edge technology to help identify and analyze resistant organisms. Being able to track the spread and mutation using these techniques is a strong tool in the fight against AMR. AMD was funded at $30 million in FY2018 and in the FY2019 PBR, and we recommend funding of at least $30 million in FY2019. Funding for the National Healthcare Safety Network (NHSN) is needed to expand tracking of antibiotic use and resistance patterns in more healthcare facilities. These data are essential for tracking resistance threats and evaluating efforts to limit the development of resistance and reduce inappropriate antibiotic use. We request at least $21 million for NHSN, which is consistent with funding in FY2018 and in the FY2019 PBR.

Globally, approximately 700,000 deaths are attributable to AMR. Multidrug resistant tuberculosis (MDR-TB) accounts for the majority of these deaths and it is expected to become much more common in the countries that already have the bulk of the world's MDR-TB. The CDC's Center for

Global Health has several programs that do significant work to help address our issues in the US by studying the resistance patterns of organisms overseas before they have a chance to get to our shores, and we urge $642 million in funding in FY2019. CDC global health activities are critical for preventing, detecting and responding to infectious disease threats, including rising antimicrobial resistance. Continued funding is needed to support CDC's role as a key implementer of 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 $5.414 billion to support this work. The proposed cut of $468 million in the FY2019 PBR from FY2018 funding of $5.260 billion jeopardizes vast amounts of 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

Experts agree that a One Health approach, including both human and animal health, is essential for combating antimicrobial resistance. We urge funding of $54 million for the Combating Antibiotic Resistant Bacteria initiative at FDA to support FDA's efforts to address public health concerns associated with antimicrobial drug use in animals, and better protect antibiotic effectiveness for both human and animal populations. This funding is needed now more than ever, with estimates that antibiotic use in humans and livestock will rise by 50% before 2030. FDA would be able to better collaborate with consumers, producers, veterinarians, and other agencies to monitor AMR through the National Antimicrobial Resistance Monitoring System (NARMS) as well as other initiatives by the FDA Center for Veterinary Medicine to address AMR.

Additionally, we recommend $15 million in FY2019 funding for NARMS. Both the Department of Agriculture (USDA) and FDA collaborate with the CDC on this national public health surveillance system that tracks changes in the antimicrobial susceptibility of certain enteric (intestinal) bacteria found in ill people (CDC), retail meats (FDA), and food animals (USDA) in the United States. By improving our data collection, FDA would be better able to supply stakeholders with information to improve antimicrobial use and surveillance on farms. The NARMS program helps protect public health by providing information about emerging bacterial resistance, the ways in which resistance is spread, and how resistant infections differ from susceptible infections

Further, $65 million in funding at the UDSA's Animal and Plant Health Inspection Service (APHIS) would support data collection to inform policy related to appropriate antibiotic use in all settings across agriculture and clinical medicine. Funding for agricultural research at USDA's Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA) will provide a better understanding pathogen resistance, and more information about new antibiotic alternatives and improved animal management and husbandry practices through USDA's Cooperative Extension Service.

June 8, 2018

United States Agency for International Development (USAID) and Department of State
The President's budget proposal includes a $83 million cut to the U.S. Agency for International Development'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 in the 10 highest burden countries, strengthen diagnostic and surveillance capacities globally, and accelerate basic and applied research and development to combat MDR-TB. The President's budget also proposes a $425 million cut to the Global Fund to Fight AIDS, TB, and Malaria. Recommended FY2019 funding of $400 million for USAID's TB program and $1.35 billion for the Global Fund will not only allow continued reductions in malaria and TB, but help staunch the growth of drug-resistant forms of these infections, particularly of drug-resistant forms of tuberculosis, which is the only airborne drug resistant disease and the biggest infectious disease killer globally.

Once again, we greatly appreciate your leadership in providing strong investments in AMR in FY2016, FY2017, and FY2018. 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, Inc.
AdvaMedDx
Alliance for Aging Research
Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American Association of Avian Pathologists
American Association of Bovine Practitioners
American Public Health Association
American Society of Transplant Surgeons
American Society of Tropical Medicine & Hygiene
American Thoracic Society
American Veterinary Medical Association
Antibiotic Resistance Action Center, the George Washington University
Antimicrobials Working Group (Amplyx 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 State and Territorial Health Officials
Becton Dickinson and Co. (BD)
bioMerieux

June 8, 2018

Biotechnology Innovation Organization (BIO)
Center for Disease Dynamics, Economics & Policy
Center for Foodborne Illness Research and Prevention
Clinician Champions in Comprehensive Antibiotic Stewardship
Consumer Federation of America
Council of State and Territorial Epidemiologists
Da Volterra
Duke Center for Antimicrobial Stewardship and Infection Prevention
Emory Antibiotic Resistance Center
Food Animal Concerns Trust
GlaxoSmithKline
Global Health Council
Health Care Without Harm
HIV Medicine Association
Immune Deficiency Foundation
Infectious Diseases Society of America
Johns Hopkins Center for a Livable Future
Making-A-Difference in Infectious Diseases
March of Dimes
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
NovaDigm Therapeutics, Inc.
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 Pew Charitable Trusts
The Society for Healthcare Epidemiology of America
The Society of Critical Care Medicine
Treatment Action Group
Trust for America's Health