September 13, 2018

The Honorable Richard Shelby
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

The Honorable Patrick Leahy
Vice Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

The Honorable Rodney Frelinghuysen
Chairman
Committee on Appropriations
United States House of Representatives
Washington, DC 20515

The Honorable Nita Lowey
Ranking Member
Committee on Appropriations
United States House of Representatives
Washington, DC 20515

Subject: Antimicrobial Resistance Programs in FY2019 Appropriations Omnibus Bills

Dear Chairman Shelby, Vice Chairman Leahy, Chairman Frelinghuysen, and Ranking Member Lowey:

The undersigned organizations, representing health care providers, scientists, veterinarians, patients, public health, and industry, appreciate that Fiscal Year (FY) 2019 funding legislation passed by appropriations subcommittees includes investments in domestic and global programs to address the public health crisis of antimicrobial resistance (AMR). As you work to develop a final appropriations agreement for FY2019, we ask that you continue Congress's bipartisan support for AMR that reflects the US commitment to infection prevention, antimicrobial stewardship, surveillance, research and innovation.

The Centers for Disease Control and Prevention (CDC) estimates that at least 23,000 people in the US die due to antibiotic resistant infections and at least 2 million are sickened every year. Antibiotic-resistant infections add considerable and avoidable costs to the already overburdened U.S. healthcare system. In most cases, antibiotic-resistant infections require prolonged and/or costlier treatments, extend hospital stays, necessitate additional doctor visits and healthcare use, and result in greater disability and death compared with infections that are easily treatable with antibiotics. Not only are these infections a threat to public health, but if the patients survive, their lives are often changed forever. We would like to bring to your attention several key AMR priority programs that we believe should be fully funded in FY2019.

Labor, Health, Human Services, and Related Agencies Appropriations
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 $5.506 billion as provided in the Senate LHHS bill to support this work, including a $50 million increase in funding to address AMR. Funding at this level enables NIAID to continue its role as a lead funder of research to discover novel antimicrobials, diagnostics and vaccines that are urgently needed to address multi-drug resistant organisms. This funding also supports the Antibacterial Resistance Leadership Group (ARLG), a scientific team that manages and implements a strategic research agenda by building transformational trials that will change clinical practice and reduce the burden of AMR. Current ARLG efforts aim to support the research and development of urgently

needed new diagnostics and antibiotics, assess the impact of stewardship interventions, and optimize dosing of existing antibiotics to maximize effectiveness and limit the development of resistance.

Centers for Disease Control and Prevention
Our organizations strongly support $168 million in funding for the CDC Antibiotic Resistance Solutions Initiative as appropriated in both the Senate and House LHHS bills to reduce the emergence and spread of AR pathogens and to improve appropriate antibiotic use. A report released in April 2018 by CDC demonstrated that AR is an increasingly dangerous threat, but that CDC containment strategies are effective in preventing its spread. For example, the report found 221 instances of unusual resistance genes in just one of the deadliest bacteria (carbapenem resistant Enterabacteriaceae or CRE) in the US in 2017. CDC further estimated that its aggressive containment strategy could prevent 1600 cases of CRE in a single state in a three-year period. We also advocate funding $12 million for CDC's Healthcare-Associated Infections (HAIs) activities, $21 million for the National Healthcare Safety Network, and $30 million for the Advanced Molecular Detection Initiative as provided in both LHHS bills.

Assistant Secretary for Preparedness and Response (ASPR)
The Biomedical Advancement Research and Development Authority (BARDA) broad spectrum research program leverages partnerships with public and private partners to develop products that directly support the government-wide National Action Plan for Combating Antibiotic-Resistant Bacteria. Last year the first BARDA-supported new antibiotic secured FDA approval, but many more such victories are needed to protect the US against the growing threat of antibiotic resistance. Despite this progress, antibiotic research and development continues to face steep economic hurdles. Federal investment, such as the support provided through BARDA, is essential to stimulate a robust pipeline of antibiotics capable of delivering the new therapies patients urgently need. We call for $586 million in funding for BARDA, as provided in the House LHHS bill to further help the federal effort to combat antibiotic-resistant bacteria.

Agriculture and Related Agencies
Antibiotics in Agriculture
Experts agree that a One Health approach, including both human and animal health, is essential for combating antimicrobial resistance. We urge robust FY2019 funding to enable the Center for Veterinary Medicine (CVM) at US Food and Drug Administration (FDA) to build on the progress achieved with the implementation of guidance related to the labeling of medically important antibiotics and veterinary oversight of their use in animal feed. The Animal Drug and Animal Generic Drug User Fee Amendments of 2018 require FDA to report on how they will incorporate veterinary oversight for all approved medically important antimicrobial drugs administered to animals that are not yet subject to such oversight, including addressing relevant labeling requirements. Funding these activities will help ensure that animal antibiotic drug labels reflect judicious use principals and veterinary stewardship, as will finalizing agency plans to adjust antibiotic sales and distribution data to reflect animal biomass.

We also urge full funding for AMR activities at the US Department of Agriculture (USDA). Funding for the Department's AMR activities would provide continued support for important research in the area of antimicrobials in agriculture, the emergence of resistance and the search for effective antibiotic alternatives. Additional funding would strengthen USDA efforts to promote antibiotic stewardship and support voluntary, on-farm surveillance through the USDA's Animal and Plant Health Inspection Service (APHIS), and essential intramural and extramural research activities underway at the Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA), as well as training

and technical assistance on good stewardship practices provided through USDA's Cooperative Extension Service.

Both the USDA and FDA collaborate with the CDC for an important AMR surveillance system: the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS), and we urge that funding for this multi-agency initiative be increased in order to fully meet the 2017 recommendations of the FDA Science Board[1] (we acknowledge and support the increase reflected in the Senate bill to partially address those recommendations). This national public health surveillance system 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. The NARMS program at CDC 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.

State and Foreign Operations Appropriations
US Agency for International Development
We urge funding of $1.35 billion for the Global Fund to Fight AIDS, Tuberculosis and Malaria, as provided in the House and Senate State and Foreign Operations (SFOP) bills. Further, we recommend funding of $302 million for the tuberculosis program at the US Agency for International Development as provided in the House SFOP bill. Support for the Global Fund and USAID's TB program will drive reductions in the growth of drug-resistant forms of this disease. Funding for these efforts would support 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.

Additionally, we urge $175 million in funding for the USAID's Global Health Security program. USAID global health security funding supports global efforts to combat antimicrobial resistance- efforts. In recent years, some of the deadliest multi-drug resistant threats have been initially discovered in China and India, and quickly made their way to U.S. patients, underscoring the need for a well-resourced, globally coordinated approach to antimicrobial resistance.

Finally, we call on Congress to commit robust funding for the continuation of the Global Health Security Agenda. Across multiple agencies, including CDC and USAID, $1 billion in Global Health Security Agenda funding from 2014 through 2019 has supported global AMR activities, including training health providers to prevent health-care associated infections – which often contribute to AMR – and expanding surveillance of drug-resistant bacteria. Congressional action is needed to extend this funding beyond 2019, or most of these vital global health security activities will cease.

Department of Defense (DoD)
We urge funding of $34.135 billion provided for the DoD's Defense Health Program in the Senate FY2019 DoD Appropriations bill. The Defense Health Program and the Research, Development, Test & Evaluation (RDT&E) budgets support R&D to address key medical challenges to the military including antibiotic resistance. For example, in recent years, projects have been supported to develop strategies to prevent, mitigate, and treat antibiotic resistant bacteria in wounds. The Defense Health Program also

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[1] Science Board to the Food and Drug Administration. Science Board Review of the National Antimicrobial Resistance Monitoring System (NARMS). June 2017.

supports a Multi-Drug Resistant Surveillance Network (MRSN) program that includes development projects for Army service level support. Specifically, the MRSN is the Enterprise effort to collect and characterize bacterial isolates to inform best practice, such as patient management and antibiotic selection.

Conclusion
Once again, we greatly appreciate your leadership in continuing the investments in AMR. As you continue your work to finalize FY2019 funding, we urge you to continue to place a high priority on AMR in order to continue making strides to protect patients and public health and spur needed innovation.

Sincerely,

Accelerate Diagnostics Inc.
AdvaMedDx
Alliance for Aging Research
American Academy of Allergy, Asthma, and Immunology
American Academy of Pediatrics
American Medical Student Association
American Public Health Association
American Society of Tropical Medicine and 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, Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Motif Bio plc, Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., SCYNEXIS Inc., Spero Therapeutics, Inc., Summit Therapeutics plc, 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
Association of State and Territorial Health Officials
BIO (Biotechnology Innovation Organization)
bioMerieux
Center for Disease Dynamics, Economics and Policy
Center for Foodborne Illness Research and Prevention
Clinician Champions in Comprehensive Antibiotic Stewardship Collaborative
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
Health Care Without Harm
HIV Medicine Association
Infectious Diseases Society of America
International Centre for Migration, Health and Development
Making-A-Difference in Infectious Diseases

March of Dimes
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National Tuberculosis Controllers Association
Pediatric Infectious Diseases Society
Peggy Lillis Foundation
Sepsis Alliance
Society for Healthcare Epidemiology of America
Society for Infectious Diseases Pharmacists
Society of Critical Care Medicine
Spero Therapeutics
TB Alliance
The Fecal Transplant Foundation
The Gerontological Society of America
The Johns Hopkins Center for a Livable Future
The Pew Charitable Trusts
Treatment Action Group
Trust for America's Health

CC: Majority Leader McConnell, Democratic Leader Schumer
        Speaker Ryan, Democratic Leader Pelosi
        Senators Blunt, Murray, Graham, Hoeven, Merkley
        Representatives Cole, DeLauro, Rogers, Aderholt, Sanford Bishop