

November 11, 2019

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

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

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

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

Subject: Antimicrobial Resistance Programs in FY2020 Appropriations Omnibus Bills

Dear Chair Shelby, Vice Chair Leahy, Chair Lowey, and Ranking Member Granger:

The undersigned organizations, representing health care providers, scientists, veterinarians, patients, public health, and industry, appreciate the progress the House and Senate have made on Fiscal Year (FY) 2020 funding legislation, including 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 FY2020, 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.

Infections resistant to multiple drugs kill up to an estimated 162,044 people in the U.S. each year, with the prediction of 10 million people dying globally by 2050 unless change occurs. A sustained and multi-faceted approach is necessary to address antimicrobial resistance. Antibiotic-resistant infections add considerable and avoidable costs to the already overburdened 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 FY2020.

Labor, Health, Human Services, and Related Agencies Appropriations.
Centers for Disease Control and Prevention

Our organizations are deeply appreciative of funding at the Centers for Disease Control and Prevention (CDC) to address AMR. We strongly support \$186 million in funding for the Antibiotic Resistance Solutions Initiative as appropriated in the House LHHS bill to reduce the emergence and spread of AMR pathogens and to improve appropriate antibiotic use through antimicrobial stewardship. A report released in April 2018 by CDC demonstrated that AMR 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 most-deadly bacteria (carbapenem-resistant Enterobacteriaceae 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 for \$12 million for funding for the CDC Healthcare-Associated Infections (HAIs) activities, \$22.75 million for the National Healthcare Safety Network, and \$32.5 million for the Advanced Molecular Detection Initiative (AMD) as provided in the House LHHS bill. The NHSN increase will be essential to help more hospitals report data on antibiotic use and resistance, to help the CDC and other scientists evaluate our efforts to combat AMR and track emerging threats. The additional funding for the AMD Initiative will allow CDC to more rapidly determine where emerging diseases come from, whether microbes are resistant to antibiotics, and how microbes are moving through a population. Each of these steps is essential to prevention of patient morbidity and mortality.

Our organizations urge funding of \$595.84 million for the agency's Global Health Program including \$208.2 million for the CDC Center for Global Health global public health protection program as provided in the Senate LHHS bill. The CDC is a key implementor of the Global Health Security Agenda (GHSA), which includes preventing AMR as its first action package. GHSA focuses on improving surveillance and laboratory capacity and promoting judicious use of antibiotics. Without sustained funding for activities to prevent, detect and respond to AMR threats globally, Americans will be left more vulnerable.

Assistant Secretary for Preparedness and Response (ASPR)

We call for \$567 million in funding for BARDA, as provided in the House LHHS bill to further help the federal effort to combat antibiotic-resistant bacteria. The BARDA Broad Spectrum Antimicrobials 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. CARB-X, supported by BARDA, NIH and other partners, supports the world's largest pre-clinical and early development pipeline of antibiotics and other therapeutics, diagnostics, and vaccines to prevent, diagnose and treat resistant infections. Despite progress in the development of new products, antibiotic research and development continues to face steep economic hurdles. While the first BARDA-supported new antibiotic secured FDA approval in 2017, one of the few small antibiotics companies went bankrupt in 2019 and two others laid-off significant numbers of staff. If more companies are allowed to go bankrupt, the antibiotic pipeline will collapse, depriving patients of lifesaving new antibiotics and putting modern medicine and national security at risk. More, not stagnant, investment in antibiotic research and development through BARDA is essential.

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 \$5.937 billion as provided in the Senate LHHS bill to support this work, including \$600 million 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

Agriculture and Related Agencies

Antibiotics in Agriculture

Experts agree that a One Health approach, addressing both human and animal health, is essential for combating antimicrobial resistance. We urge robust FY2020 funding to enable the Center for Veterinary Medicine (CVM) at US Food and Drug Administration (FDA) to continue to make progress on the Agency's five-year Action Plan for Antibiotic Stewardship in Animal Agriculture. FDA recently announced its proposed Guidance for Industry (GFI) 263 to incorporate veterinary oversight for all remaining medically important antimicrobial drugs administered to animals, but additional funding is needed to enable FDA to advance these and other important priorities identified in the Action Plan, including updating labels for medically important antimicrobials that lack targeted durations of use, the finalization of a biomass adjustment methodology to enhance sales data reporting, updating FDA's list of medically important antimicrobials associated with GFI 152, as well as FDA's commitment to develop a functional and efficient system for collecting antimicrobial use data in food animals. Funding these activities will help ensure that animal antibiotic drug labels reflect judicious use principles and veterinary stewardship, while enhancing the quality and granularity of antibiotic data available to producers, veterinarians and public health stakeholders interested in promoting antibiotic stewardship in agriculture.

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) (we acknowledge and support the increase reflected in the House bill for this work), 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 continue to be prioritized in order to fully meet the 2017 recommendations of the FDA Science Board¹ (we acknowledge and support the increase reflected in the House 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 \$1.56 billion for the Global Fund to Fight AIDS, Tuberculosis and Malaria, as provided in the House and Senate bills. Further, we recommend funding \$310 million for the tuberculosis program through the US Agency for International Development as proposed in the House and Senate bills. 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

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

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 call on Congress to sustain adequate funding for USAID implementation of the Global Health Security Agenda (GHSA). Between 2014 and 2019, USAID has supported GHSA global AMR activities, including training health providers to prevent healthcare-associated infections – which are often resistant to antibiotics – and expanding surveillance of drug-resistant bacteria.

Department of Defense (DoD)

We urge funding of \$33.495 billion provided for the DoD's Defense Health Program in the Senate FY2020 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 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

We are concerned that federal programs to address AMR are currently operating under a continuing resolution (CR), rather than under FY2020 funding levels. To ensure that federal AMR activities receive full funding, and to avoid slowing our progress in addressing the growing domestic and global AMR threat, our organizations urge you to provide meaningful increases in the overall spending allocations for non-discretionary programs and finalize FY2020 appropriations bills by the end of the year.

Once again, we greatly appreciate your leadership in continuing the investments in AMR. As you continue your work to finalize FY2020 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

AdvaMedDx

Alliance for Aging Research

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 Society of Tropical Medicine and Hygiene

American Thoracic Society

Antibiotic Resistance Action Center, the 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 State and Territorial Health Officials
Becton Dickinson & Co. (BD)
bioMerieux
Biotechnology Innovation Organization (BIO)
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
Global Health Technologies Coalition
Health Care Without Harm
HIV Medicine Association
Infectious Diseases Society of America
Making-A-Difference in Infectious Diseases
Melinta Therapeutics, Inc.
Merck
National Association of Pediatric Nurse Practitioners
National Institute of Antimicrobial Resistance Research and Education
ONCORD, Inc.
Roche Diagnostics
Pediatric Infectious Diseases Society
Sepsis Alliance
Small World Initiative
Society for Healthcare Epidemiology of America
Society of Infectious Disease Pharmacists
Spero Therapeutics
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 Pew Charitable Trusts
The Tufts Center for Integrated Management of Antimicrobial Resistance
Trust for America's Health

CC: Majority Leader McConnell, Democratic Leader Schumer
Speaker Pelosi, Republican Leader McCarthy
Senators Blunt, Murray, Graham, Hoeven, Merkley, Durbin
Representatives DeLauro, Cole, Sanford Bishop, Fortenberry, Rogers, Visclosky, Calvert

