March 12, 2020

The Honorable Roy Blunt
U.S. Senate
260 Russell Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
U.S. Senate
154 Russell Senate Office Building
Washington, DC 20510

The Honorable John Hoeven
U.S. Senate
338 Russell Senate Office Building
Washington, DC 20510

The Honorable Jeff Merkley
U.S. Senate
313 Hart Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
U.S. Senate
290 Russell Senate Office Building
Washington, DC 20510

The Honorable Patrick Leahy
U.S. Senate
437 Russell Senate Office Building
Washington, DC 20510

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 FY2020. The undersigned organizations, representing health care providers, scientists, patients, public health, animal agriculture, and the pharmaceutical and diagnostics industries, 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.

Antibiotic resistance is one of the greatest public health threats of our time. Drug-resistant infections sicken at least 2.8 million each year and kill at least 35,000 people annually in the United States. Antibiotic resistance accounts for direct health-care costs of at least $20 billion. Globally, over 700,000 die each year accounting for a cost as high as $1.2 trillion. If we do not act now, by 2050 antibiotic resistant infections will be the leading cause of death - surpassing cancer - and could cost the world $100 trillion.

Additionally, the pipeline of new antibiotics in development is insufficient to meet patient needs, despite the urgent need for tools to combat AMR. The imminent collapse of the antibiotic market is exacerbating this threat, and small companies that are responsible for nearly all current antibiotic innovation are struggling to stay in business because factors unique to antibiotics, including the need for extremely judicious use, make it challenging for companies to earn a return on investments in antibiotic research and development. 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 FY2021.

Assistant Secretary for Preparedness and Response (ASPR)
We recommend funding of at least $230 million to support Broad Spectrum Antimicrobials and CARB-X at the Biomedical Advanced Research and Development Authority (BARDA). The BARDA broad spectrum antimicrobials program and CARB-X leverage public/private partnerships to develop products that directly support the government-wide *National Action Plan for Combating Antibiotic-Resistant Bacteria* and has been successful in developing new FDA approved antibiotics. Despite this progress, the pipeline of new antibiotics in development is insufficient to meet patient needs, and $230 million in funding is needed to prevent a post-antibiotic era in which we lose many modern medical advances that depend upon the availability of antibiotics, such as cancer chemotherapy, organ transplants and other surgeries.

We recommend $140 million in FY2021 funding for the Project BioShield Special Reserve Fund (SRF). The SRF is positioned to support the response to public health threats, including AMR. BARDA and NIAID efforts have been successful in helping companies bring new antibiotics to market, but those companies now struggle to stay in business and two filed for bankruptcy in 2019. In December 2019, SRF funds supported a contract for a company following approval of its antibiotic—a phase in which small biotechs that develop new antibiotics are particularly vulnerable. Additional funding is needed to expand this approach to better support the antibiotics market.

The Centers for Disease Control and Prevention (CDC)
Antibiotic-resistant infections sicken at least 2.8 million and kill at least 35,000 people annually in the United States, and current CDC resources are not sufficient address AMR. We recommend at least $200 million in FY2021 funding for the Antibiotic Resistance Solutions Initiative would help expansion of efforts at state and local health departments to prevent, detect, contain and respond to multi-drug resistant infections. Increased funding would also support implementation of antimicrobial stewardship programs (newly required by the Centers for Medicare and Medicaid Services at hospitals) to reduce inappropriate antibiotic use and improve patient outcomes.

The Advanced Molecular Detection (AMD) program strengthens CDC's epidemiologic and laboratory expertise to effectively detect and respond to the ever-expanding universe of emerging diseases and deadly pathogens. Recommended FY2021 funding of at least $37.5 million is required to ensure AMD has updated cutting-edge technology to 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. Additional funding in FY2021 would help ensure state and local health departments have enhanced expertise to harness DNA sequencing of pathogens to ramp up early detection and response to surging disease outbreaks.

We recommend funding of at least $25 million in FY2021 to enhance National Healthcare Safety Network (NHSN) reporting at more than 20,000 healthcare facilities, including acute-care hospitals, nursing homes and ambulatory surgical centers. While progress has been made in the number of healthcare facilities voluntarily reporting antibiotic use and resistance data, additional effort is needed to achieve the stated goal in the National Action Plan for Combating Antibiotic Resistant Bacteria for 95% of hospitals to report these data by 2020. FY2021 funding will enable CDC to continue to provide data for national HAI elimination as well as tracking national antibiotic use and resistance data essential to inform and evaluate antibiotic stewardship activities and other efforts to address antibiotic resistance.

Without immediate action, resistant infections will be the leading cause of death by 2050 and could cost the world $100 trillion. We recommend $225 million in FY2021 for programmatic efforts at the CDC's Division of Global Health Protection, would improve health security, capacity and outcomes. This

program helps strengthen laboratory capacities, disease surveillance and field epidemiology in the developing world to stop health threats overseas before they reach the US. CDC is a key implementor of the Global Health Security Agenda (GHSA), which includes preventing AMR as its first action package.

The quick spread of emerging infectious diseases, including resistant infections, makes clear the need for the Infectious Diseases Response Fund. The Fund enables CDC and other federal agencies to rapidly address public health emergencies and infectious disease outbreaks at their source, and before they reach American shores, if possible. An investment of $50 million is needed to ensure agencies, led by the CDC can move forward with initial response activities to contain the spread of infection; treat infected individuals and launch research for vaccines, diagnostics and therapeutics.

National Institutes of Health (NIH)

The National Institute of Allergy and Infectious Diseases (NIAID) is a world leader on research related to AMR. We recommend funding of at least $6.345 billion, including $600 million for AMR research, 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.

US Department of Agriculture (USDA)

We recommend at least an increase of $67 million at USDA for antimicrobial resistance priorities, including support for the Animal and Plant Health Inspection Service (APHIS), the National Agricultural Statistics Service (NASS), and the National Animal Health Laboratory Network (NAHLN) to allow the agency to continue to promote agricultural stewardship, including gathering and evaluating valuable information on antibiotic use practices and provide a national snapshot of antibiotic stewardship practices such as the role of the veterinarian in the decision-making process. Expanded funding for agricultural research at USDA's Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA) Agriculture and Food Research Initiative (AFRI) will enable USDA investigators and scientists working at public universities and other research settings to better understand the factors driving the emergence of pathogen resistance, as well as helping producers find new vaccines and antibiotic alternatives and improved animal management and husbandry practices that can be shared directly to farmers and livestock growers through USDA's Cooperative Extension Service.

Food and Drug Administration (FDA)

We recommend at least an increase of $12 million for FY2021 at FDA for the Combating Antibiotic Resistant Bacteria program. FDA requires support to advance antibiotic stewardship in animals and to protect antibiotic effectiveness for human and animal populations. With suggested resources, FDA can continue to implement Commissioner Gottlieb's 2018 five-year antibiotic stewardship action plan, including plans to continue to strengthen the National Antimicrobial Resistance Monitoring System (NARMS), as well as other initiatives by the FDA Center for Veterinary Medicine to transition the remaining over-the-counter antibiotic products to veterinary supervision, update product labels to fully reflect judicious use principals, identify new ways to encourage the development of antibiotic alternatives, assist academic institutions and other partners in the development of veterinary educational materials, develop strategies to collect and analyze antibiotic use data, and finalize a biomass denominator to contextualize information about antibiotic sales and distribution, and support surveillance capacity building through FDA's Veterinary Laboratory Investigation and Response Network (Vet-LIRN).

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

We recommend $197.5 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 $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 $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 FY2021. 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

AdvaMedDx

Antibiotic Resistance Action Center, George Washington University

American Society of Tropical Medicine & Hygiene

American Veterinary Medical Association

Association of Public and Land-grant Universities

Association of State and Territorial Health Officials

Association of American Veterinary Medical Colleges

bioMerieux

Biotechnology Innovation Organization

Center for Disease Dynamics, Economics & Policy

Center for Integrated Management of Antimicrobial Resistance

Center for Science in the Public Interest

Consumer Federation of America

Cystic Fibrosis Foundation

Food Animal Concerns Trust

Health Care Without Harm

Keep Antibiotics Working Coalition

Making-A-Difference in Infectious Diseases

Microbion Corporation

National Association of County and City Health Officials

National Association of Pediatric Nurse Practitioner

National Athletic Trainers Association

ONCORD, Inc.

Peggy Lillis Foundation

Small World Initiative

Spero

The Antimicrobials Working Group (Amplyx Pharmaceuticals, Cidara Therapeutics Inc., Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., Qpex Biopharma Inc., SCYNEXIS Inc., Summit Therapeutics plc, VenatoRx Pharmaceuticals Inc. and X-Biotix)

The American Society of Transplant Surgeons

The Emory Antibiotic Resistance Center

The Gerontological Society of America

The Johns Hopkins Center for a Livable Future

The Humane Society Veterinary Medical Association

The National Institute for Antimicrobial Resistance Research and Education

The Society of Critical Care Medicine

The Society of Infectious Diseases Pharmacists

The Pew Charitable Trusts

Treatment Action Group

Trust for America's Health