

September 23, 2020

The Honorable Roy Blunt
United States Senate
260 Russell Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
United States Senate
154 Russell Senate Office Building
Washington, DC 20510

The Honorable John Hoeven
United States Senate
338 Russell Senate Office Building
Washington, DC 20510

The Honorable Jeff Merkley
United States Senate
313 Hart Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
United States Senate
290 Russell Senate Office Building
Washington, DC 20510

The Honorable Patrick Leahy
United States 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:

The undersigned organizations, representing health care providers, scientists, patients, public health, animal agriculture, and the pharmaceutical and diagnostics industries, thank you for support for investments in domestic and global programs to address antimicrobial resistance (AMR). As the work of the Senate Appropriations Committee continues this year on the LHHS, Ag-FDA and SFOP funding bills needed to address this urgent public health threat, we urge you to work with your colleagues in the House to ensure robust funding is included in any final FY2021 appropriations bill.

While there is still much to learn about COVID-19, there is already some evidence of secondary infections among coronavirus patients. It is unclear exactly how significant secondary bacterial infections will be in this pandemic, but serious viral respiratory infections typically pose some risk that increases when patients need to be hospitalized or placed on a ventilator. In study of 191 patients found that 50 percent of those who died had a secondary infection. Further, high levels of inappropriate antibiotic use among COVID-19 patients is likely driving the development of new resistance threats for which we are unprepared.

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. 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 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 final passage of the following funding requests:

Labor-HHS-Education Appropriations

Assistant Secretary for Preparedness and Response (ASPR)

We strongly recommend the Senate Labor-HHS-Education bill include emergency supplemental funding of \$500 million, as included in the House LHHS bill, to support AMR research and development at the Biomedical Advanced Research and Development Authority (BARDA), and \$230 million in funding for the BARDA Broad Spectrum Antimicrobials and CARB-X efforts. 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. \$500 million in emergency funding, and \$230 million in regular appropriations speaks to the urgency of the dwindling antibiotic pipeline and will help 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 that the emergency funding be targeted to provide support in the post-approval phase, as this is where antibiotic innovators are struggling the most. We further urge that this funding be allowed to support all AMR threats, and not limited to traditional biotreats.

Additionally, we recommended \$140 million in regular 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.

The Centers for Disease Control and Prevention (CDC)

We also recommend \$200 million in funding for the Antibiotic Resistance Solutions Initiative in FY2021. This deeper investment will help state and local health departments to prevent, detect, contain and respond to multi-drug resistant infections. This funding will 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.

Our organizations urge at least \$37.5 million in funding for the Advanced Molecular Detection (AMD) program, and \$25 million for the National Healthcare Safety Network in FY2021. Deeper investments for both programs are critical at a time when COVID-19 has underscored urgent needs to detect and respond to emerging pathogens before they are able to spread unchecked.

AMD strengthens CDC's epidemiologic and laboratory expertise and additional funding is needed to help ensure CDC, state and local health departments have enhanced expertise to harness DNA sequencing of pathogens to ramp up outbreak detection and response. Additional resources are also needed to enhance National Healthcare Safety Network (NHSN) which is the most widely used healthcare associated infections tracking system in the country and provides facilities, states, regions,

and the nation with data needed to identify problem areas and best practices, and to measure and drive the progress of prevention and stewardship efforts. NHSN is playing a central role in the COVID-19 response, spurred by new Centers for Medicare and Medicaid Services nursing home COVID-19 case reporting requirements.

Additional funding is needed for the CDC's Center for Global Health to prevent resistant infections from becoming the leading cause of death by 2050. CDC's Division of Global Health Protection requires more resources to strengthen laboratory capacities, disease surveillance and field epidemiology in the developing world to stop health threats overseas before they reach the US, and to help partner countries address growing antimicrobial resistance. CDC is a key implementor of the Global Health Security Agenda (GHSA), which includes preventing AMR as its first action package.

National Institutes of Health (NIH)

We appreciate that the House bill provides \$6.013 billion in funding in FY2021 for the National Institute of Allergy and Infectious Diseases (NIAID), and continued funding of \$511 million for vital research on AMR, and we welcome the opportunity to work with you and the Senate to provide recommended funding of \$6.345 billion overall and \$600 million for AMR funding in a final funding package. This funding will help advance valuable studies into how to combat the ever-evolving threat posed by resistant microbes, and speed the discovery novel antimicrobials, diagnostics and vaccines that are urgently needed to address multi-drug resistant organisms.

Agriculture Appropriations

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. We are pleased that the House bill included \$2 million for USDA's Animal and Plant Health Inspection Service (APHIS) to explore opportunities to develop an antimicrobial resistance data dashboard tool to enhance public health and stakeholder understanding of the emergence and spread of antimicrobial resistant pathogens in livestock production systems and we encourage the Senate to support this initiative.

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 its 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). We are pleased that the House legislation acknowledged the importance of implementing FDA's five-year stewardship plan and provided additional resources to assist the Agency in its efforts to make further progress, and we urge Senate appropriators to support this important initiative with additional funding.

State and Foreign Operations Appropriations

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

While we are pleased that the House State and Foreign Operations bill provides \$800 million in emergency funding for the Global Fund to Fight AIDS, Tuberculosis and Malaria, for the organization's efforts to fight COVID-19 in resource-limited countries, more resources are needed to address growing drug resistance that can result from TB and malaria service disruptions due to the pandemic. We recommend \$1.56 billion in regular appropriations for the Global Fund to allow continued reductions in malaria and TB and help staunch the growth of drug-resistant forms of these infections.

We also recommend \$197.5 million for USAID global health security efforts to strengthen USAID's capacity to invest in health systems strengthening and implement One Health principles 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.

Conclusion

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 Diagnostics, Inc.

AdvaMedDx

American Academy of Allergy, Asthma & Immunology

American Academy of Pediatrics

American Association of Avian Pathologists

American Society of Transplant Surgeons
American Society of Tropical Medicine and Hygiene
Antibiotic Resistance Action Center, George Washington University
Association of American Veterinary Medical Colleges
Association for Professionals in Infection Control and Epidemiology
Association of Public and Land-grant Universities
Association of State and Territorial Health Officials
Center for Disease Dynamics, Economics & Policy
Center for Science in the Public Interest
Cystic Fibrosis Foundation
Food Animal Concerns Trust
Infectious Diseases Society of America
National Athletic Trainers Association
National Institute of Antimicrobial Resistance Research and Education
ONCORD, Inc.
Pediatric Infectious Diseases Society
Peggy Lillis Foundation
Sepsis Alliance
Socially Responsible Agricultural Project
Society of Infectious Diseases Pharmacists
Spero Therapeutics
The Antimicrobials Working Group
(Amplify Pharmaceuticals, Cidara Therapeutics Inc., Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Nabriva Therapeutics US Inc., Melinta Therapeutics, Paratek Pharmaceuticals Inc., Qpex Biopharma Inc., SCYNEXIS Inc., Summit Therapeutics plc, VenatoRx Pharmaceuticals Inc. and X-Biotix)
The Center for Integrated Management of Antimicrobial Resistance
The Emory Antibiotic Resistance Center
The Gerontological Society of America
The Johns Hopkins Center for a Livable Future
The National Association of Pediatric Nurse Practitioners
The Pew Charitable Trusts

Treatment Action Group

cc: The Honorable Mitch McConnell
The Honorable Chuck Schumer
The Honorable Richard Shelby