

The Honorable Tammy Baldwin
U.S. Senate
Washington, DC 20510

The Honorable Shelly Moore Capito
U.S. Senate
Washington, DC 20510

The Honorable Martin Heinrich
U.S. Senate
Washington, DC 20510

The Honorable John Hoeven
U.S. Senate
Washington, DC 20510

The Honorable Christopher Coons
U.S. Senate
Washington, DC 20510

The Honorable Lindsey Graham
U.S. Senate
Washington, DC 20510

April 13, 2023

Dear Chairs and Ranking Members of the Labor-HHS-Education, Agriculture, and State and Foreign Operations Appropriations Subcommittees:

The undersigned organizations, representing clinicians, scientists, patients, public health, animal agriculture and the pharmaceutical and diagnostics industries, urge you to significantly increase federal funding for domestic and global antimicrobial resistance (AMR) programs. We call for a comprehensive One Health approach that encompasses human, animal and environmental health with increased funding for surveillance, prevention, stewardship, research and innovation.

Antimicrobial resistance is one of the greatest public health threats of our time. Drug-resistant infections sicken at least 2.8 million people and kill at least 35,000 people in the United States each year. Just 6 of the worst resistant pathogens increase U.S. health care costs by \$4.6 billion annually. Infections are a primary or associated cause of death in [50% of patients with cancer](#), as AMR can make these infections difficult or impossible to treat. [Globally](#), resistant infections directly caused 1.27 million deaths in 2019 and played a role in 4.95 million deaths. If we do not act now, antibiotic resistant infections will be the leading cause of death by 2050 and could cost the world \$100 trillion.

AMR has a [disproportionate impact](#) on certain communities due to variance in risk of exposure, susceptibility to infection or treatment received. Rates of several serious antibiotic resistant infections, including community-associated MRSA, are higher incidence in Black populations.

Addressing AMR is central to strengthening our preparedness for future public health emergencies, as patients with respiratory infections, serious wounds or burns, or other conditions requiring hospitalization are all at risk for secondary resistant infections. A 2022 CDC [report](#) found that hospital associated AMR infections and deaths rose 15% in 2020 due to the COVID-19 pandemic, wiping out progress made in 2012-2017 to lower U.S. deaths from AMR.

Safe and effective antimicrobials are essential to enable modern medical advances, including cancer chemotherapy, organ transplantation and other complex surgeries, which all carry a risk of infection. A recent outbreak of [drug resistant eye infections](#) causing blindness due to contaminated eye drops is demonstrating that serious resistant infections are a threat to us all.

Unfortunately, the pipeline of new antibiotics in development is insufficient to meet patient needs. Small companies that are responsible for nearly all current antibiotic innovation are struggling to stay in business. Factors unique to antibiotics, including the need for their judicious use, make it challenging for companies to earn a return on investments in antibiotic research and development. Additionally, new diagnostic tools are needed to help guide appropriate antibiotic use and enable surveillance, and greater investments are needed to support prevention and antibiotic stewardship.

While we are grateful for funding for AMR provided by Congress in FY2023, increased federal appropriations commensurate with the gravity and importance of AMR are urgently needed to improve our defenses against this escalating health crisis. We are encouraged that the President's Budget Request for FY24 prioritizes AMR in multiple ways, including a proposal to strengthen antibiotic research and development through the use of federal contracts that delink payments for novel antimicrobials from their use. For FY24, we recommend:

Labor, Health and Human Services, Education and Related Agencies

The Centers for Disease Control and Prevention (CDC). We recommend \$400 million in funding for the **Antibiotic Resistance Solutions Initiative**. This is needed to expand antibiotic stewardship across the continuum of care; double state and local grant awards; expand the AR Laboratory Network globally and domestically to strengthen the identification, tracking and containment of deadly pathogens; support antimicrobial resistance (AMR) research and epicenters; and increase public and health care professional education and awareness.

We recommend \$175 million for the **Advanced Molecular Detection (AMD) Initiative**. Funding would ensure continued innovation in the detection and tracking of existing and emerging resistant pathogens. Funding would also enable federal, state, and local public health laboratories to expand the use of pathogen genomics, sustain important partnerships with academic research institutions, and bolster training to ensure integration of genomics into AMR surveillance and response.

We recommend \$100 million for the **National Healthcare Safety Network (NHSN)**. Full funding is needed to modernize and automate NHSN to alleviate reporting burden and speed access to actionable data. Funding would bolster data collection on antibiotic use and resistance in healthcare facilities and provide technical support for more than 65,000 users of NHSN.

We recommend \$1.37 billion overall for the **CDC Center for Global Health**, including the **Division of Global Health Protection** (\$842.8 million). Increased resources are needed to improve global health capacity to stop AMR threats before they reach domestic soil as well as address growing drug resistance in developing countries. This Division works to enhance AMR surveillance systems, strengthen laboratory capacity, train health care workers and disease detectives, improve antibiotic use, provide technical assistance to 30 countries and support emergency operations centers. Funding would expand global health capacity address threats in 60 countries.

Assistant Secretary for Preparedness and Response (ASPR)

We recommend funding of \$330 million to support **Broad Spectrum Antimicrobials and CARB- X at the Biomedical Advanced Research and Development Authority (BARDA)**. The BARDA broad spectrum antimicrobials and antifungals program and CARB-X leverage public/private partnerships to develop

innovative products that prevent, detect and treat resistant infections. These efforts have led to new FDA approved antibiotics. Despite this progress, the pipeline of new antibiotics and antifungals in development is insufficient to meet patient needs.

We recommend funding of \$200 million for the **Project BioShield Special Reserve Fund, Broad Spectrum Antimicrobials**. The Project BioShield 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, with others on similar trajectories. In 2019, SRF funds supported a contract for a company following approval of its antibiotic—a phase in which small biotech companies that develop new antibiotics are particularly vulnerable. In October 2022, a second contract was awarded through Project BioShield to support the development and procurement of a novel antimicrobial product that addresses multi-drug resistant infections and supports national preparedness efforts. Full funding is needed to expand this approach.

National Institutes of Health (NIH)

We recommend \$7.060 billion for the **National Institute of Allergy and Infectious Diseases, including \$608 million for AMR Research at NIAID**. Funding at this level would allow NIAID to address AMR while carrying out its broader role in supporting infectious diseases research. Increased funding would support the training of new investigators; enhance basic, translational and clinical research on mechanisms of resistance, therapeutics, vaccines and diagnostics; and support the development of a clinical trials network to reduce barriers to research on difficult-to-treat infections.

Agriculture-FDA

Food and Drug Administration

We recommend \$20 million to support FDA's One Health efforts to combat antibiotic resistance bacteria. This level of support is required to measure changes in antibiotic stewardship in animals and to protect antibiotic effectiveness for human and animal populations. With suggested resources, FDA can complete the remaining goals of its 2018 five-year antibiotic stewardship action plan, including strengthening the National Antimicrobial Resistance Monitoring System (NARMS) to make it consistent with One Health principles, and issuing a draft and final guidance on establishing duration limits to ensure that all current FDA-approved veterinary indications carry duration limits that conform to appropriate and judicious veterinary antibiotic use. These plans were delayed due to the COVID-19 pandemic so additional resources are needed to complete the existing plan and to identify ongoing needs. This funding could also advance FDA's plan to create and implement a functional and efficient system for collecting antimicrobial use data in animals. This additional funding is needed to assist academic institutions and other partners in the development of veterinary educational materials, and support surveillance capacity-building through FDA's Veterinary Laboratory Investigation and Response Network (Vet- LIRN).

US Department of Agriculture (USDA)

We recommend an increase of \$85 million for antimicrobial resistance priorities at USDA. With most emerging diseases and pandemics originating from animals, including food animals, USDA needs more resources to support its work on biodefence to protect both people and animals from resistant infections that are transmitted between humans and animals (zoonosis). An increase of \$25 million for the Animal and Plant Health Inspection Service is needed to strengthen the Zoonotic Disease Management program, which has been chronically underfunded, and to support the and the National Animal Health Laboratory Network (NAHLN). At least \$60 million in additional funding is needed for

Research, Education, and Economics to support agricultural research at USDA's Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA) Agriculture and Food Research Initiative (AFRI). These funds will enable USDA investigators and scientists at public universities, veterinary colleges and other research settings to better understand the factors driving the emergence of resistant pathogens, and help producers find new vaccines, antibiotic alternatives and improved animal management and husbandry practices that can be shared directly with farmers and livestock growers through USDA's Cooperative Extension Service.

Report Language Recommendation

Without updated breakpoints, clinicians are not able to use up-to-date information to treat bacterial infections with the most effective antibiotics. This has serious implications for antibiotic stewardship, as continued use of ineffective antibiotics allows the proliferation of antibiotic resistant bacteria and jeopardizes patient outcomes. Ensuring that FDA updated breakpoints have wide uptake ensures that health care professionals have access to best information available when diagnosing conditions and prescribing antibiotics and antifungals. We therefore recommend the following report language:

Antibiotic Breakpoints.--- The agreement recognizes that the FDA needs to ensure that breakpoints are updated in a timely fashion to promote stronger stewardship efforts. The agreement directs the FDA to convene stakeholders, including manufacturers and laboratories, and report back to the Committee within 180 days of the convening on the barriers to uptake for updating breakpoints.

State and Foreign Operations

US Agency for International Development (USAID) and Department of State

We recommend \$1 billion for **USAID global health security efforts** to enhance technical assistance to partner countries to prevent and respond to rising rates of AMR in resource-limited settings and strengthen global capacities to prevent and respond to outbreaks while improving U.S. and global health security. We also recommend \$1 billion for **USAID's Tuberculosis Program**, which supports high-quality screening, diagnosis and treatment services for patients affected by multidrug-resistant TB. Finally, we recommend \$2 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 including airborne, drug-resistant TB, the biggest infectious disease killer globally in addition to COVID-19.

Conclusion

We greatly appreciate your leadership in providing strong investments in AMR in FY2024. 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,
Abgenics life Sciences Pvt ltd
AdvaMedDx
Aelin Therapeutics
Alliance for Aging Research
Alliance for Biosecurity
Alpha-1 Foundation

American Academy of Allergy, Asthma & Immunology
American Academy of Pediatrics
American Association of Small Ruminant Practitioners
American Association of Veterinary Medical Colleges
American College of Allergy, Asthma & Immunology
American College of Emergency Physicians
American Public Health Association
American Society for Microbiology
American Society of Transplant Surgeons
American Society of Tropical Medicine and Hygiene
AMR.Solutions
AN2 Therapeutics, Inc.
Antibiotic Resistance Action Center, the George Washington University
Appili Therapeutics USA Inc
Arietis Corporation
ArrePath
Association for Professionals in Infection Control and Epidemiology
Association of Public Health Laboratories
Association of State and Territorial Health Officials
Astellas Pharma Global Development, Inc.
AUROBACTHERAPEUTICS
Bactria Pharmaceuticals, LLC
Bazan
BD (Becton Dickinson & Co.)
BEAM Alliance
Beckman Coulter
bioMerieux Inc.
Biotechnology Innovation Organization (BIO)
BioVersys AG
Blacksmith Medicines
Boehringer Ingelheim Venture Fund USA
BUGWORKS RESEARCH INC
Cancer Support Community
CancerCare
Chemical Biology Ventured Ltd
Clarametyx Biosciences, Inc.
Coalition of Skin Diseases
COPD Foundation
CUBRC, Inc.
Cystic Fibrosis Foundation
discoveric bio beta Ltd.
Ebright Laboratory, Waksman Institute, Rutgers University
Emory Antibiotic Resistance Center

Emory University
F2G Inc.
Febris Therapeutics. Inc.
Food Animal Concerns Trust
Genentech
Global Antibiotic Research and Development Partnership (GARDP)
Global Coalition on Aging
Global Health Technologies Coalition
Greater San Diego Biological Solutions
Harvard Medical School/Brigham & Women's Hospital
Health Care Without Harm
HealthCare Institute of New Jersey (HINJ)
Hesed Medical Associates
HIV Medicine Association
HSC College of Pharmacy
ICAN, International Cancer Advocacy Network
Infectious Diseases Society of America
International Immunocompromised Host Society
JMI Laboratories
Johns Hopkins Center for a Livable Future
JU & LMU
Kathera Bioscience, Inc
Kern Medical
Locus Biosciences
Lupus and Allied Diseases Association, Inc.
Making-A-Difference in Infectious Diseases
McCarthy Consultants, Inc.
Michigan Antibiotic Resistance Reduction Coalition
Microbion Corporation
Mosul University
Mycoses Study Group Education and Research Consortium
National Association of Pediatric Nurse Practitioners
National Athletic Trainers' Association
NBCO Inc
Nexys
Novo Holdings Equity U.S. Inc.
NTM Info & Research
Ohio Osteopathic Association
Omnix Medical
Oragenics, Inc
Pediatric Infectious Diseases Society
Peptilogics
Phagelux Canada Inc.
Queen Biotechnologies Inc.
Qpex Biopharma
ReNewVax Ltd
Sepsis Alliance
Sequella, Inc.
Seres Therapeutics

Shionogi Inc
Society for Healthcare Epidemiology of America
Society of Critical Care Medicine
Spina Bifida Association
Stuart B. Levy Center for Integrated Management of Antimicrobial Resistance (Levy CIMAR)
TB Alliance
The Bonnell Foundation: Living with cystic fibrosis
The Ohio State University
The Pew Charitable Trusts
Thunder Biotech, Inc.
Treatment Action Group
Trust for America's Health
University of Edinburgh
University of Mbandaka (UNIMBA)
University of Milano-Bicocca
University of Texas San Antonio (UTSA)
Valley Fever Institute
Vogar Publishing, LLC
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