The Honorable Jason Smith
Chair
Committee on Ways and Means
U.S. House of Representatives

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
U.S. House of Representatives

March 8, 2023

Dear Chairman Smith and Ranking Member Neal:

On behalf of the undersigned organizations representing health care providers, public health professionals, scientists, patients, and the pharmaceutical and diagnostics industries, **we urge you to include the PASTEUR Act in any moving legislative vehicle this year, including the reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA).** The growing crisis of antimicrobial resistance (AMR) undermines U.S. public health preparedness and significantly hampers our nation's ability to respond to a wide range of threats, including pandemics, outbreaks, natural disasters, and bioterror attacks. PASTEUR would increase our nation's resilience by strengthening the antibacterial and antifungal pipeline to ensure clinicians and other medical professionals have the innovative products they need to treat patients, and ensuring antimicrobials are used appropriately. Every day we wait to address the crisis in the antimicrobial ecosystem is another year patients and providers must wait to have access to life-saving medicines.

In 2019, an estimated 1.27 million deaths worldwide were directly caused by AMR, and AMR played a part in nearly 5 million deaths. This makes AMR a leading cause of death globally.[1] The AMR crisis was further exacerbated by the COVID-19 pandemic. In 2020, U.S. hospitals experienced a 15% increase in AMR infections and deaths, though pandemic-related data gaps suggest that the total national burden of AMR may be much higher. Experts do not expect a return to pre-pandemic levels without concerted action.[2] Any emergency resulting in high levels of hospitalization, particularly high levels of ventilator use, creates a ripe opportunity for the spread of secondary drug resistant infections.

Addressing AMR is important for bioterror preparedness as well, as agents used by bioterrorists may be genetically engineered to resist current therapeutic antimicrobials.[3] World Health Organization (WHO) has estimated that if 50 kg of *Y. pestis* were to be released as an aerosol over a city with a population of 5 million, 150,000 people might fall ill with pneumonic plague, 36,000 of whom would die.[4] Drug resistant strains of *Y. pestis* have been reported, which can increase mortality.[5] As another example, modeling suggests that deliberate release of aerosolized *F. tularensis* over London would result in an estimated 130,000 infections and 24,000 deaths.[6] Natural resistance is already observed in tularemia,

[1] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext
[2] https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf
[3] https://books.google.com/books?hl=en&lr=&id=IiGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-zSVfBI-1p_9TT4#v=onepage&q&f=false
[4] https://apps.who.int/iris/bitstream/handle/10665/39444/24039.pdf
[5] https://journals.asm.org/doi/full/10.1128/AAC.00306-06
[6] https://www.liebertpub.com/doi/abs/10.1089/bsp.2011.0004

and the overuse of fluoroquinolones in the last two decades has led to treatment failure and relapses in tularemia patients.[7]

Hurricanes and other natural disasters can also increase the spread of infections, including drug resistant infections. Loss of electricity increases the risk of food spoilage and foodborne illness. Interrupted access to safe water supplies can lead individuals to turn to rivers or other ad hoc water sources. This approach, along with the presence of floodwaters, can increase the risk of illness caused by waterborne pathogens. Studies have found higher levels of pathogenic bacteria and antibiotic resistance genes in floodwaters and soil in the Houston, TX area following Hurricane Harvey.[8][9] Conditions in crowded shelters and severely damaged homes can significantly increase the spread of infection as well. All these infections can trigger sepsis among victims and emergency workers.[10] Additionally, during natural disasters, those who are immunocompromised may not only lose access to crucial systems such as infusion or dialysis centers due to the loss of power but are also even more prone to these infections.

Despite the urgent and increasing need for novel antimicrobials to treat superbugs, the antimicrobial ecosystem is broken and unable to meet patient needs. The current pipeline has fewer than 50 antibacterial therapeutics in clinical development worldwide – only a handful of which are for the most threatening gram-negative pathogens – a critical area of need.[11] We know that the pipeline is already inadequate to address current resistant threats, let alone those that will come in the future.

Novel antimicrobials must be used judiciously to limit the development of resistance, so payment based on volume fails to drive innovation. PASTEUR's subscription model is an innovative way to pay for novel antimicrobials that will revitalize the pipeline and support appropriate use. Under PASTEUR, the federal government can enter into contracts with innovators to pay for a reliable supply of novel antimicrobials with payments that are decoupled from the volume of antimicrobials used. Importantly, the federal government only pays once – the subscription payment is all-inclusive, and PASTEUR only pays for success. Furthermore, PASTEUR is designed to pay for FDA approved treatments that are available to patients and meet unmet AMR needs– those that experts agree will likeliest have a big impact for patients and public health.

The delinked approach is similar to Project Bioshield, which provides multi-year funding to support procurement of medical countermeasures (MCM) for national security. Antimicrobials, like MCM, have a very limited commercial market. PASTEUR will provide novel antimicrobial innovators with a more predictable return on investment necessary to revitalize the antimicrobial pipeline—just like Project Bioshield has done for MCMs.

PASTEUR would also provide new funding for health facilities including rural, critical access and safety net hospitals to support antimicrobial stewardship, to ensure that antimicrobials are used appropriately to limit the development of resistance, and to ensure that the vulnerable patients served by these hospitals can have access to the benefits of antimicrobial stewardship. Stewardship teams also typically

---

[7] https://ami-journals.onlinelibrary.wiley.com/doi/full/10.1111/j.1751-7915.2008.00063.x
[8] https://pubs.acs.org/doi/10.1021/acs.estlett.8b00329
[9] https://pubmed.ncbi.nlm.nih.gov/33077230/
[10] https://www.sepsis.org/sepsisand/natural-disasters/
[11] https://www.who.int/publications/i/item/9789240047655

play critical roles in preparedness and response, including managing administration of novel therapeutics during emergencies and managing antimicrobial drug shortages.

In his September 2022 remarks to the World AMR Congress, Secretary Becerra reiterated the Administration's commitment to this issue, as evidenced by the inclusion of a proposal that aligns with PASTEUR in the President's budget request for 2023, which was endorsed in the Consolidated Appropriations Act of 2023. At the end of 2022, PASTEUR had over 60 bipartisan cosponsors and the broad support of a diverse array of stakeholders. Delays in the passage of PASTEUR are delays in the development of novel antimicrobials to treat highly resistant, life-threatening infections—delays that erode our preparedness and that many patients, including those particularly susceptible to infections, such as patients with cystic fibrosis, cancer, or organ transplants, cannot afford.

We urge you to enact PASTEUR in 2023.

Thank you,

Abgenics Life Sciences Pvt Ltd

Acurx Pharmaceuticals, Inc.

Adaptive Phage Therapeutics

AdvaMedDx

Aequor Inc.

AGILeBiotics B.V.

AIDS United

AIIMS

Allegheny Oral and Maxillofacial Surgery

Alliance for Aging Research

Alliance for Biosecurity

Alpha-1 Foundation

American Academy of Allergy, Asthma & Immunology

American Academy of HIV Medicine

American Association for Dental, Oral, and Craniofacial Research

American Association of Bovine Practitioners

American College of Allergy, Asthma & Immunology

American College of Emergency Physicians

American Gastroenterological Association

American Kidney Fund

American Liver Foundation

American Public Health Association

American Society for Biochemistry and Molecular Biology

American Society for Microbiology

American Society of Nephrology

American Society of Plastic Surgeons

American Society of Tropical Medicine and Hygiene

American Urological Association

AMR Insights BV

AMR.Solutions

AN2 Therapeutics

Antibiotic Resistance Action Center, George Washington University

Antimicrobial Development Specialists, LLC

Antimicrobial Innovation Alliance (AIA)

Antimicrobials Working Group

Appili Therapeutics

Aridis Pharmaceuticals Inc.

Arizona Medical Association

ArrePath Inc

Arthritis Foundation

Association for Professionals in Infection Control and Epidemiology

Association of Public Health Laboratories (APHL)

Association of State and Territorial Health Officials

Astellas Pharma Global Development, Inc.

Autoimmune Association

AVAC

Aviva Investors

BD (Becton, Dickinson and Co.)

BEAM Alliance

bioMerieux Inc.

BioPharma Consultants

Biotechnology Innovation Organization (BIO)

BioVersys AG

black, gifted & whole foundation

Blacksmith Medicines

Boehringer Ingelheim Venture Fund USA

Boomer Esiason Foundation

Bugworks Research Inc.

Canadian Antimicrobial Innovation Coalition

Cancer Support Community

CancerCare

Capital Alternatives

Caregiver Action Network

Case Western Reserve University

Clarametyx Biosciences, Inc.

Coalition for Improving Sepsis and Antibiotic Practices (CISAP)

Coalition of Skin Diseases

Colorectal Cancer Alliance

Consumer Federation of America (CFA)

COPD Foundation

Crestone, Inc.

CUBRC, Inc.

Curza, Inc.

Cystic Fibrosis Foundation

Debiopharm International SA

Doodhadhari Burfani Hospital & Research Institute

DRJ Consulting LLC

Duke University School of Medicine

Duke-Margolis Center for Health Policy

Ebright Laboratory, Waksman Institute, Rutgers University

Elizabeth Glaser Pediatric AIDS Foundation

EMH Consulting

Emory Antibiotic Resistance Center

Emory University

Entasis Therapeutics

Ethiopian Public Health Institute

F2G Ltd

Family Voices

Federation of American Hospitals

FHI Clinical

Florida Osteopathic Medical Association

Genentech, a member of the Roche Group

Global Coalition on Aging

Global Health Technologies Coalition

Government College University, Institute of Microbiology

Greater San Diego Biological Solutions

GSK

Half Moon Bay Biotechnology Consulting

Harvard Medical School, Brigham and Women's Hospital

HealthCare Institute of New Jersey (HINJ)

Healthcare Leadership Council

HealthHIV

Healthy Men Inc.

HealthyWomen

Hearts Consulting Group, LLC

Helmholtz Centre for Infection Research

HIV Medicine Association

IAVI

ICAN, International Cancer Advocacy Network

Immune Deficiency Foundation

Incubate

INCubator for Antibiotic Therapies Europe

Infectious Disease Association of California

Infectious Disease Drug Development Consulting, LLC

Infectious Diseases Society of America

Innoviva, Inc

Institute For Life Science Entrepreneurship

International Technology Development Corporation

JMI Laboratories

Johns Hopkins Center for a Livable Future

Kasturba Medical College Manipal

Kathera Bioscience Inc.

Keane Enterprise

Kern Medical

La Jolla Pharmaceuticals

Life Sciences Pennsylvania

LLBarrett Biopharmaceutical Consulting, LLC

Locus Biosciences

LUNGevity Foundation

Lupus and Allied Diseases Association, Inc.

Lymphoma Research Foundation

Lynn interiors

Madam Therapeutics

Mahidol university

Making-A-Difference in Infectious Diseases

Marmion Partnership Ventures

Melinta Therapeutics

Merck

MGB Biopharma

Michigan Antibiotic Resistance Reduction Coalition

Microbion Corporation

Microbiotix, Inc.

Microvioma, India

Musculoskeletal Infection Society

Mutabilis

MyCare

Mycoses Study Group Education and Research Consortium

Mycovia Pharmaceuticals

Nabriva Therapeutics

NASTAD

National Association of Nutrition and Aging Services Programs (NANASP)

National Association of Pediatric Nurse Practitioners

National Athletic Trainers' Association

National Coalition for Cancer Survivorship

National Consumers League

National Grange

National Health Council

National Kidney Foundation

National MS Society

National Organization for Rare Disorders

National Public Health Laboratory

New York State Osteopathic Medical Society

Novo Holdings Equity US Inc.

NTM Info & Research

Oak Ridge Institute for Science Education

Oakrum Pharma

Ohio Osteopathic Association

Oklahoma Academy of Family Physicians

Omniose

Omnix Medical

ONCORD, Inc.

One Health Trust

Opal Biosciences Ltd

Oragenics

Osteopathic Physicians & Surgeons of California

Partnership to Fight Chronic Disease (PFCD)

Partnership to Fight Infectious Disease

Pediatric Infectious Diseases Society

Peggy Lillis Foundation for C.diff Education & Advocacy

Peptilogics

Phagelux Inc.

Phages for Global Health

Phare Bio

PhRMA

Prevent Blindness

Qeen Biotechnologies Inc.

Recombinant Films

Regnum Corp

RNA Medicines, LLC

Sanderling Consulting LLC

SCYNEXIS, INC

Sepsis Alliance

Sequella, Inc.

Seres Therapeutics, Inc.

Shionogi Inc.

Small World Initiative

Social Innovation in Drug Resistance Program - Boston University

Society of Critical Care Medicine

Society of Hospital Medicine

Society of Infectious Diseases Pharmacists (SIDP)

South Dakota State University - Medical Laboratory Sciences Program

Spero Therapeutics

Spina Bifida Association

Stuart B. Levy Center for Integrated Management of Antimicrobial Resistance at Tufts (Levy CIMAR)

Synthetivity

Tanta University

TB Alliance

Terranova Medica, LLC

The American College of Preventive Medicine

The Bonnell Foundation: Living with cystic fibrosis

The Broad Institute of MIT and Harvard

The Gerontological Society of America

The Joint Commission

The Pew Charitable Trusts

Thunder Biotech, Inc.

Treatment Action Group (TAG)

Triage Cancer

Trust for America's Health

UC-Davis Medical Center

UCSB

United Spinal Association

University of Alabama at Birmingham

University of Anbar

University of Colorado Denver School of Medicine

University of New Mexico

University of Port Harcourt Teaching Hospital

University of Texas at San Antonio

VA Boston Healthcare System and BU School of Medicine

Valley Fever Americas Foundation

Valley Fever Institute

Venatorx Pharmaceuticals

Virginia Commonwealth University

Vizient, Inc.

Wayne State Yniversity

Western Ridge

WICN

Zavante Royalty Co