

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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> Drug resistant strains of *Y. pestis* have been reported, which can increase mortality.<sup>5</sup> 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.<sup>6</sup> Natural resistance is already observed in tularemia,

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<sup>1</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext)

<sup>2</sup> <https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf>

<sup>3</sup> [https://books.google.com/books?hl=en&lr=&id=liGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-zSVfBI-1p\\_9TT4#v=onepage&q&f=false](https://books.google.com/books?hl=en&lr=&id=liGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-zSVfBI-1p_9TT4#v=onepage&q&f=false)

<sup>4</sup> <https://apps.who.int/iris/bitstream/handle/10665/39444/24039.pdf>

<sup>5</sup> <https://journals.asm.org/doi/full/10.1128/AAC.00306-06>

<sup>6</sup> <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.<sup>7</sup>

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.<sup>89</sup> 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.<sup>10</sup> 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.<sup>11</sup> 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

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<sup>7</sup> <https://ami-journals.onlinelibrary.wiley.com/doi/full/10.1111/j.1751-7915.2008.00063.x>

<sup>8</sup> <https://pubs.acs.org/doi/10.1021/acs.estlett.8b00329>

<sup>9</sup> <https://pubmed.ncbi.nlm.nih.gov/33077230/>

<sup>10</sup> <https://www.sepsis.org/sepsisand/natural-disasters/>

<sup>11</sup> <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  
Queen 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 University

Western Ridge

WICN

Zavante Royalty Co