March 8, 2023

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. 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. 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.

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1 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext
Addressing AMR is important for bioterror preparedness as well, as agents used by bioterrorists may be genetically engineered to resist current therapeutic antimicrobials. 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. Drug resistant strains of Y. pestis have been reported, which can increase mortality. 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. Natural resistance is already observed in tularemia, and the overuse of fluoroquinolones in the last two decades has led to treatment failure and relapses in tularemia patients.

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. 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. 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. 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

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3 https://books.google.com/books?hl=en&lr=&id=IiGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-ZVFbI-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
8 https://pubs.acs.org/doi/10.1021/acs.estimate.8b00329
10 https://www.sepsis.org/sepsisand/natural-disasters/
11 https://www.who.int/publications/i/item/9789240047655
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 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
Crestone, Inc.
CUBRC, Inc.
Curza, Inc.
Cystic Fibrosis Foundation
Debiopharm International SA
Doodhadhari Burhani 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 (PFID)
Pediatric Infectious Diseases Society
Peggy Lillis Foundation for C.diff Education & Advocacy
Peptilogics
Phagelux Inc.
Phages for Global Health
Phare Bio
Pharmaceutical Research and Manufacturers of America
Prevent Blindness
Qeen Biotechnologies Inc.
Recombinant Films
Regnum Corp
RNA Medicines, LLC
Sanderling Consulting LLC
SCYNEXIS
SCYNEXIS, INC
Sepsis Alliance
Sequella, Inc.
Seresc 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