The Honorable Nancy Pelosi Speaker US House of Representatives Washington, DC 20515

The Honorable Kevin McCarthy Republican Leader US House of Representatives Washington, DC 20515 The Honorable Chuck Schumer Majority Leader US Senate Washington, DC 20510

The Honorable Mitch McConnell Republican Leader US Senate Washington, DC 20510

November 16, 2022

Dear Speaker Pelosi and Leaders McCarthy, Schumer and McConnell:

On behalf of the undersigned organizations representing health care providers, public health professionals, scientists, patients, and the pharmaceutical and diagnostics industries, we write to urge you to enact the PASTEUR Act in an end of year package to address the growing crisis of antimicrobial resistance (AMR) by strengthening the antimicrobial pipeline to ensure clinicians 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 It is also clear that the COVID-19 pandemic exacerbated AMR. In 2020, the U.S. experienced a 15% increase in AMR infections and deaths due to COVID-19, and experts do not expect a return to pre-pandemic levels without concerted action.² Because antimicrobials enable modern medicine, growing rates of resistance and a shrinking arsenal of products jeopardize our ability to safely provide organ transplants, cancer chemotherapy and surgeries such as hip and knee replacements and cesarean sections. Additionally, AMR is a significant economic burden here in the U.S.; the direct healthcare costs of treating only six of the most threatening multidrug-resistant pathogens is estimated to be \$4.6 billion per year³.

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 only 43 antibacterial therapeutics in clinical development worldwide – only 19 of which are for the most threatening gramnegative pathogens – a critical area of unmet need.⁴ We know that the pipeline is already inadequate to address current resistant threats, let alone those that will come in the future. This reinforces the need to urgently stimulate investment in novel antimicrobials to quickly bolster the pipeline.

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

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

³ National Academies of Sciences, Engineering, and Medicine. 2022. Combating antimicrobial resistance and protecting the miracle of modern medicine. Washington, DC: The National Academies Press. https://doi. org/10.17226/26350.

⁴ <u>https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/03/tracking-the-global-pipeline-of-antibiotics-in-development</u>

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 will only pay for FDA approved treatments that are available to patients and meet unmet AMR needs– those that will 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 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.

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 Senate released Labor-Health and Human Services appropriations bill for 2023. PASTEUR has 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 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 an end of year package in 2022.

Thank you, Organization (as it will read on the letter) American Academy of Allergy, Asthma & Immunology AdvaMedDx AGILeBiotics BV Alliance for Aging Research Alliance for Biosecurity Alpha-1 Foundation American Association for Dental, Oral, and Craniofacial Research American Association of Bovine Practitioners American Association of Small Ruminant Practitioners American College of Allergy, Asthma & Immunology American College of Emergency Physicians American College of Preventive Medicine American Dental Association American Gastroenterological Association American Kidney Fund American Liver Foundation American Society for Biochemistry and Molecular Biology American Society for Microbiology American Society of Plastic Surgeons American Society of Transplant Surgeons American Urological Association Amputee Coalition **AN2** Therapeutics Antibiotic Resistance Action Center, George Washington University Antimicrobial Innovation Alliance Arizona Medical Association ArrePath Inc Arthritis Foundation Asociación de Oatomizados de Puerto Rico, Inc. Asociación Puertorriqueña de Diabetes Association for Professionals in Infection Control and Epidemiology Autoimmune Association BD (Becton, Dickinson and Co.) BIO Bioomix **BioVersys AG** Black, Gifted & Whole Foundation

Boehringer Ingelheim Venture Fund USA Boomer Esiason Foundation Boston College BUGWORKS CancerCare **Cancer Support Community** CARB-X **Caregiver Action Network** CircaGene **Clarametyx Biosciences** Coalition for Improving Sepsis and Antibiotic Practices (CISAP) Coalition of Skin Diseases Color of Crohn's and Chronic Illness **Colorectal Cancer Alliance Connecticut Plastic Surgery Society COPD** Foundation Crestone CT Association of Ambulatory Surgery Centers Cūrza, Inc **Cystic Fibrosis Foundation Debiopharm International Duke Margolis Health Policy Center Entasis Therapeutics Family Voices** Federation of American Hospitals **FHI Clinical** Florida Academy of Family Physicians Florida Osteopathic Medical Association Forge Therapeutics, Inc.

GARDP North America Genentech Georgia State Medical Association, Inc. **Global Coalition on Aging** Global Health Technologies Coalition (GHTC) GSK HCA Healthcare Healthcare Leadership Council HealthHIV Healthy Men Inc. HealthyWomen Hesed Medical Associates Hezekiah Beardsley Connecticut Chapter of the American Academy of Pediatrics **HIV Medicine Association** ICAN, International Cancer Advocacy Network **Immune Deficiency Foundation** Incubate Infectious Disease Association of California Infectious Diseases Society of America International Foundation for AiArthritis Invitris Johns Hopkins Center for a Livable Future Kathera Bioscience Inc Kentucky Academy of Family Physicians Kern Medical **Kineticos Llfe Sciences** La Jolla Pharmaceuticals/Innoviva Locus Biosciences Louisiana Hemophilia Foundation

LUNGevity Foundation Lymphoma Research Foundation Making-A-Difference in Infectious Diseases Marigold Innovation Medical Association of Georgia Medical Society of Northern Virginia **Melinta Therapeutics** Merck Michigan Antibiotic Resistance Reduction Coalition Michigan State Medical Society **Microbion Corporation** Musculoskeletal Infection Society Mycovia Pharmaceuticals Mycoses Study Group Education and Research Consortium (MSGERC) Nabriva Therapeutics National Association of Nutrition and Aging Services Programs National Coalition for Cancer Survivorship National Consumers League National Grange National Health Council National Kidney Foundation National Organization for Rare Disorders New Mexico Osteopathic Medical Association Novo Holdings Equity US Inc. NTM Info & Research Ohio Osteopathic Association **Oklahoma Academy of Family Physicians** Omniose **Omnix Medical**

ONCORD, Inc. One Health Trust (formerly CDDEP) Oragenics, Inc. **Osteopathic Physicians & Surgeons of California** Partnership to Fight Chronic Disease Partnership to Fight Infectious Disease Peggy Lillis Foundation Peptilogics Inc. Phare Bio Pharmaceutical Research and Manufacturers of America (PhRMA) Prevent Blindness **Qpex Biopharma** SCYNEXIS Sepsis Alliance Seres Therapeutics Shionogi Inc. Social Innovation in Drug Resistance, Boston University Society of Hospital Medicine Society of Infectious Diseases Pharmacists (SIDP) Spexis Spina Bifida Association Stuart B. Levy Center for Integrated Management of Antimicrobial Resistance **TB** Alliance The Bonnell Foundation: Living with cystic fibrosis The Broad Institute of Harvard and MIT The Gerontological Society of America The National Association of Pediatric Nurse Practitioners The Pew Charitable Trusts Triage Cancer

Trust For America's Health

UCSF

United Spinal Association

University of Zurich

Utah Nurse Practitioners

UTILITY therapeutics Ltd

Valanbio Therapeutics

Valley Fever Institute

Venatorx Pharmaceuticals Incorporated

Vizient, Inc.

Vocespr.org