September 11, 2024

The Honorable Cathy McMorris Rodgers Chair Energy & Commerce Committee The United States House of Representatives 2188 Rayburn House Office Building Washington, DC 20515

The Honorable Brett Guthrie Chair Energy & Commerce Health Subcommittee The United States House of Representatives 2434 Rayburn House Office Building Washington, DC 20515 The Honorable Frank Pallone Ranking Member Energy & Commerce Committee The United States House of Representatives 2107 Rayburn House Office Building Washington, DC 20515

The Honorable Anna Eshoo Ranking Member Energy & Commerce Health Subcommittee The United States House of Representatives 272 Cannon House Office Building Washington, DC 20515

Dear Committee Chairs McMorris Rodgers and Guthrie and Ranking Members Pallone and Eshoo:

On behalf of the undersigned organizations representing millions of patients who face serious acute and chronic health conditions, we urge you to address the growing crisis of antimicrobial resistance by prioritizing the passage of the Pioneering Antimicrobial Subscriptions To End Upsurging Resistance (PASTEUR) Act (H.R. 2940 / S. 1355) this year. Addressing antimicrobial resistance (AMR) through this important legislation simply cannot wait any longer.

AMR poses a rapidly growing threat to the United States and the world. According to the 2019 CDC *Antibiotic Resistance Threats in the United States* report¹, over 2.8 million AMR infections occur in the United States each year, with over 35,000 people dying as a result. In 2019, 1.27 million deaths were directly caused by resistant infections around the world, and played a role in 4.95 million deaths²; without action, antimicrobial resistance is predicted to be a leading cause of death by 2050³. Every day we wait to address the AMR crisis is another day that lives are lost.

The economic toll of AMR is also staggering – annually, only six of the worst resistant pathogens increase U.S. health care costs by \$4.6 billion annually. Notably, antimicrobial resistance increases a patient's risk for developing sepsis, the body's overwhelming response to infection, which already impacts 1.7 million patients in the U.S. and costs Medicare more than \$41 billion in sepsis-related inpatient and skilled nursing facility admission costs each year. As resistance worsens, the financial and human costs of sepsis will only increase.

¹ CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

² Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis [published correction appears in Lancet. 2022 Oct 1;400(10358):1102. doi: 10.1016/S0140-6736(21)02653-2]. Lancet. 2022;399(10325):629-655. doi:10.1016/S0140-6736(21)02724-0

³ The Review on Antimicrobial Resistance. TACKLING DRUG-RESISTANT INFECTIONS GLOBALLY: FINAL REPORT AND RECOMMENDATIONS. 2016.

Along with patients experiencing sepsis, data from the Centers for Medicare and Medicaid Services published in 2021 found that Medicare beneficiaries account for the majority of cases of both new diagnoses of AMR infections and resulting deaths in United States hospitals, spending hundreds of thousands of additional days in hospitals each year due to AMR and costing taxpayers billions in extra heath care costs annually.⁴ These data indicate that efforts to address AMR will not only improve patient outcomes for Medicare beneficiaries but may also yield net savings to the federal government.

As patients and providers wait to access life-saving treatments, these delays put the entire country – particularly individuals with cystic fibrosis, Valley Fever, cancer, organ transplants, and other conditions—at risk. The PASTEUR Act is targeted legislation that directly addresses these patients most at risk for AMR. As you may know, the necessary and frequently routine use of antimicrobials to treat patients with chronic conditions associated with infections, including combat veterans who have sustained traumatic injuries, too often leads to patients battling antimicrobial-resistant infections. For example, the highly contagious methicillin-resistant *Staphylococcus aureus* (MRSA), which can cause invasive infections, sepsis, and death, is found in 2% of the total United States population⁵ but 14% of people with CF, highlighting the risk for AMR among chronically ill patients.

Despite the magnitude of the AMR crisis and the increasingly urgent need for antimicrobial products, the antimicrobial ecosystem is remarkably weak. Fewer than 50 antibacterial therapeutics are currently in clinical development worldwide, only a handful of which are for the most threatening gram-negative pathogens.⁶ Antimicrobials are incredibly expensive and time-consuming to develop, typically command a lower price and need to be used sparingly to minimize resistance. These factors make it difficult for new products to stay on the market and for their developers to stay in business.

That's why the PASTEUR Act is so important. Under PASTEUR's subscription model, the federal government can enter into contracts with developers to pay for a reliable supply of product of innovative antimicrobials that have been approved by the FDA and meet established innovation criteria. Payments are decoupled from the volume of antimicrobials used, thereby removing the incentive for companies to promote the widespread use that often results in the development of drug-resistant pathogens. The subscription contract is all-inclusive, and the federal government only pays once. Economic modeling performed by the Center for Global Development suggests that a subscription-based approach to incentivizing antimicrobial development, such as that authorized by the PASTEUR Act, would generate a significant return on investment (ROI) in both the short- and long-term.⁷

Importantly, bill sponsors are pursuing the authorization of this bill without funding attached as a critical first step to set up a PASTEUR office. Removing funding from the bill allows it to abide by regular order and determine funding levels through the appropriations process.

The time to address the threat of AMR is now. Without innovative, cost-effective strategies for tackling this crisis, the tremendous impact of AMR on patients who face serious, acute, and chronic health

⁴ <u>Aligning Payment And Prevention To Drive Antibiotic Innovation For Medicare Beneficiaries | Health Affairs</u> ⁵<u>https://www.cdc.gov/mrsa/healthcare/index.html#:~:text=Studies%20show%20that%20about%20one,not%20develop%20serious%20MRSA%20infections</u>.

⁶ 2021 antibacterial agents in clinical and preclinical development: an overview and analysis (who.int)

⁷ Adrian Towse and Rachel Silverman Bonnifield. 2022. "An Ambitious USG Advanced Commitment for Subscription-Based Purchasing of Novel Antimicrobials and Its Expected Return on Investment." CGD Policy Paper 277. Washington, DC: Center for Global Development.

conditions and for the broader United State population will continue to worsen. The millions of patients we represent know all too well how underprepared we are to meet their AMR treatment needs today.

Please include the PASTEUR Act in a future mark up so that it can be included in any moving vehicle to ensure its passage this year – our patients and all Americans simply cannot wait any longer.

Respectfully,

American Kidney Fund Autoimmune Association **Boomer Esiason Foundation** CancerCare **Coalition of Skin Diseases Colorectal Cancer Alliance COPD** Foundation **Cystic Fibrosis Foundation Elizabeth Glaser Pediatric AIDS Foundation** Foundation for Sarcoidosis Research **Global Liver Institute** HealthHIV HealthyWomen **Immune Deficiency Foundation** MyCARE Foundation National Organization for Rare Disorders NTM Info & Research Peggy Lillis Foundation Sepsis Alliance Spina Bifida Association Stop TB USA The Bonnell Foundation: Living with cystic fibrosis We Are TB

CC:

The Honorable Speaker Johnson The Honorable Minority Leader Jeffries