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December 11, 2020

Representative Mike Doyle 306 Cannon House Office Building Washington, DC 20515 Representative Drew Ferguson 1032 Longworth House Office Building Washington, DC 20515

Dear Representatives Doyle and Ferguson,

I am writing in support of H.R.8920, the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act of 2020, on behalf of the Pew Charitable Trusts – an independent, non-profit research and public policy organization with a number of initiatives focused on addressing the urgent public health threat of antibiotic resistance.

Antibiotics have been fundamental to almost every aspect of modern medicine since their discovery; they have made once-lethal infections into minor treatments and enable the regular medical care and procedures we now rely upon. Unfortunately, the bacteria once routinely killed by antibiotics are now able to fight back, evolving to evade the drugs designed to eliminate them. And Pew's analyses of the global antibiotic pipeline show far too few drugs in development that can treat the most dangerous pathogens.¹ Furthermore, the Centers for Disease Control and Prevention estimates that more than 2.8 million infections and at least 35,000 deaths due to antibiotic-resistant infections occur in the United States each year.² With the insufficient antibiotic pipeline and antibiotic resistance only progressing faster, another public health disaster looms. The current COVID-19 pandemic is a painful reminder of the repercussions of limited preparedness.

The antibiotic market needs a fundamental change to overcome the unique economic challenges confronting it. Pricing and reimbursement, even for new and innovative antibiotics, are considerably lower than other therapies because most current infections are preferentially treated with existing generic drugs to slow emerging resistance to newer drugs. This results in low sales volume for newly-approved antibiotics. Therefore, larger pharmaceutical companies have exited from the antibiotic field due to likely prospects of limited financial returns upon commercialization. The remaining small companies — including those that have already received federal funding — struggle to attract investments as the market continues to retract. But we desperately need to develop new, innovative antibiotics to treat the emerging multi-drug resistant infections.

Recognizing the current market failure for antibiotics, the Centers for Medicare and Medicaid Services updated its Inpatient Prospective Payment System rule in 2019 to allow for higher reimbursement to hospitals using new antibiotics, minimizing consideration of drug prices when selecting an appropriate treatment. The Biomedical Advanced Research and Development Authority has also supported development and commercialization of new antibiotics. These are helpful steps, as the recently released National Action Plan for Combating Antibiotic-Resistant Bacteria highlighted.³ However, these programs are insufficient to truly fix the antibiotic market failure. We need a sustainable ecosystem that enables reinvestment into the pipeline of innovative antibiotics, while ensuring these drugs are used appropriately to prolong their effectiveness.

The PASTEUR Act would help stabilize the antibiotic market by creating a subscription program for critically needed antibiotics that treat the most threatening infections. Successful developers of qualifying antibiotics would receive a subscription contract, thereby providing revenues delinked from the antibiotic sales volume. This approach would deliver improved predictability for return-on-investments for antibiotic innovators, spurring additional investments in antibiotics discovery and development. This policy would also strengthen stewardship of these critical drugs by encouraging and financially supporting establishment of hospital stewardship programs, especially for resource-limited facilities such as rural and critical access hospitals. Recipients of subscription contracts would also be held accountable for guaranteed supply of the antibiotic. In May 2020, Pew, together with the Infectious Diseases Society of America, Trust for America's Health, and U.S. antibiotics companies large and small, called for and laid out key principles for a package of economic incentives to stabilize the antibiotic market.⁴ We are pleased that the PASTEUR Act incorporates these important principles.

Thank you for your leadership and foresight in pioneering the PASTEUR Act. Your work will preserve effectiveness of these life-saving drugs and prevent health crises in the future.

Sincerely,

Larfu J. Hu

Kathy Talkington Director, Health Programs The Pew Charitable Trusts

¹ The Pew Charitable Trusts, "Tracking the Pipeline of Antibiotics in Development" (2020),

https://www.pewtrusts.org/en/research-and-analysis/articles/2016/12/tracking-the-pipeline-of-antibiotics-indevelopment.

² U.S. Centers for Disease Control and Prevention, "Antibiotic Resistance Threats in the United States" (2019), <u>https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf</u>.

³ Assistant Secretary for Planning and Evaluation, "National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025" (2020), <u>https://aspe.hhs.gov/system/files/pdf/264126/CARB-National-Action-Plan-2020-2025.pdf</u>.

⁴ The Pew Charitable Trusts, "Stakeholders Urge Congress to Advance Antibiotic Development" (2020), <u>https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2020/05/08/stakeholders-urge-congress-to-advance-antibiotic-development</u>.