

March 11, 2022

The Honorable Frank Pallone, Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Patty Murray, Chair
Senate Health, Education, Labor and
Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Cathy McMorris Rodgers,
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

The Honorable Richard Burr, Ranking
Member
Senate Health, Education, Labor and
Pensions Committee
833 Hart Senate Office Building
Washington, DC 20510

Dear Chairs Pallone and Murray and Ranking Members McMorris Rodgers and Burr:

The undersigned organizations, representing clinicians, scientists, patients, public health, animal agriculture and the pharmaceutical and diagnostics industries appreciate your leadership on public policy priorities affecting the nation's health. We understand that your committees will soon undertake important legislation to reauthorize the Prescription Drug User Fee Agreement (PDUFA), and we urge you to consider adding bipartisan legislation to address the critical problem of reinvigorating the antibiotic drug development pipeline—the **Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act (H.R. 3932/S. 2076)**).

Antibiotic resistance is one of the greatest public health threats of our time. Drug-resistant infections sicken at least 2.8 million people and kill at least 35,000 people in the United States each year. Global disease burden is significant—new research estimates that 4.95 million deaths worldwide in 2019 were associated with bacterial resistance to current drugs. Antibiotic resistance accounts for direct health care costs of at least \$20 billion and imposes broader economic and health systems costs as high as \$1.2 trillion. If we do not act now, antibiotic resistant infections will be the leading cause of death by 2050 and could cost the world \$100 trillion. And, as we have witnessed throughout the COVID-19 pandemic and the wide utilization of antibiotics to treat secondary bacterial infections, often in medically complex or ventilated patients, it is of the utmost importance that our public health system be prepared for these types of existential threats in the future.

The PASTEUR Act would advance antibiotic drug development through the introduction of subscription-based contracts that will act as economic pull incentives to encourage the production and supply of urgently needed novel antimicrobial products. Unfortunately, the pipeline of new and innovative antimicrobials in development worldwide is woefully insufficient to meet patient needs, a challenge that a senior FDA official recently confirmed at a user fee

oversight hearing.¹ Small companies that are responsible for nearly all current antibiotic innovation are struggling to sustain operations. Factors unique to antibiotics, including the need to use these drugs sparingly, make it challenging for companies to earn a reasonable return on investment. As a result, many companies have either closed their antibiotics research programs voluntarily or gone bankrupt. Targeted incentives, particularly those that address post-market challenges through stable, upfront revenue commitments, are urgently needed to spur antibiotic research and development, revitalize the pipeline, and ultimately curb the spread of antibiotic resistance. In addition, the legislation strengthens antibiotic stewardship programming to preserve the drugs we have for as long as possible, investing directly in small, rural and critical access health care facilities to help stem the burgeoning superbug crisis.

Congress has previously recognized that this vital public health priority is well-suited for inclusion in user fee reauthorization legislation, and enacted the Generating Antibiotic Incentives Now (GAIN) Act as part of the 2012 PDUFA reauthorization bill. The GAIN Act represents an important first step that supported the launch of new small biotechs devoted to antimicrobial R&D, but a robust, market-based subscription model is urgently needed to ensure that these companies can earn a fair return-on-investment and continue to innovate. The sustainability of the antibiotic drug pipeline is absolutely foundational to modern medicine and the PASTEUR Act's unique, 'only pay for success' pull incentive will substantially strengthen U.S. preparedness for future pandemics. We thank you for your attention and we look forward to working with you on this important endeavor in the weeks ahead.

Sincerely,

¹ See, House Energy and Commerce Subcommittee on Health hearing, "FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics," oral testimony by Peter Marks, MD, PhD, Director, FDA Center for Biologics Evaluation and Research (CBER), February 3, 2022.