



March 31, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Frank Pallone
Chair
Member Committee on Energy and Commerce
U.S. House of Representatives

Dear Chairwoman McMorris Rodgers and Ranking Member Pallone:

The Pew Charitable Trusts is pleased to respond to the committee's request for insights and perspective on improving our nation's biosecurity and preparedness infrastructure through the upcoming reauthorization of The Pandemic and All-Hazards Preparedness Act (PAHPA).

Pew is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of health care and strengthening the public health system. Our comments in response to this RFI focus on the growing threat posed by antibiotic-resistant bacteria and the urgent need for new types of antimicrobial drug products with antibacterial or antifungal properties to combat this threat. **To fully support U.S. preparedness and enhance our capacity to effectively respond to the next pandemic, we urge the committee to include the bipartisan PASTEUR Act as part of PAHPA reauthorization.**

Antibiotic-resistant bacteria are one of the greatest public health threats of our time. In 2019, an estimated 1.27 million deaths worldwide were directly caused by resistant bacteria, and that number is expected to soar to 10 million deaths by 2050. COVID-19 has further exacerbated this threat, with U.S. hospitals experiencing a 15% increase in both infections and deaths from drug-resistant bacteria (1) in just the first year of the pandemic.

Ultimately, any future pandemic resulting in high levels of hospitalization, particularly one involving high levels of ventilator use associated with medically complex respiratory disorders, will put patients at an increased risk of deadly secondary bacterial infections. But antibiotics aren't just important tools in a public health emergency; they're also vital to our nation's ability

to respond to a wide range of threats, including natural disasters, zoonotic transmission of highly pathogenic illnesses, and bioterror attacks.

“There are no walls high enough or oceans wide enough to keep out biothreats and protect our communities,” the Biden administration warned in October 2022, echoing themes raised by Presidents of both parties that the risks from a deliberate attack with bioweapons (2)—the weaponization of biological agents, in other words—are expanding. Antibiotics are essential for the treatment of a wide array of biodefense threats, including anthrax (3) and plague (4). These and other diseases are readily weaponized and could be genetically engineered to resist available antibiotics (5). Even if an attack isn’t intentional—in the case of an accidental leak of dangerous material, for instance—antibiotics can help avert disaster.

Antibiotics also help protect military, security forces, and civilians in war zones. Combat injuries often require ready access to antibiotics and can be exacerbated when bacteria are resistant to existing antibiotics. There were more than 53,000 wounded in action (6) during the U.S. military conflicts in Iraq and Afghanistan, and a recent study showed (7) that more than a quarter of combat wound infections during those wars were caused by multidrug-resistant bacteria. And the usefulness of antibiotics in war goes beyond battlefield injuries: Military conflict often damages or destroys public health infrastructure in war zones, rendering it unable to meet patient needs and creating an environment in which infectious diseases can thrive. Hurricanes and other domestic and international natural disasters can present similar infectious disease risks.

Unfortunately, when it comes to antibiotics, U.S. preparedness does not meet the magnitude of the current threat. Despite the vital need for these lifesaving drugs as part of virtually any pandemic or public health emergency response, the medicines we rely on to treat serious infections are increasingly ineffective against quickly evolving bacteria.

The urgently needed new antibiotics that can combat multidrug-resistant bugs are not being developed—in large part because the market for antibiotics is fundamentally broken. The latest data from the World Health Organization (8) shows a stagnant antibiotic pipeline, with fewer than 50 antibiotics in global clinical development. Alarming, just a handful of those drugs are targeted against the pathogens that present the most urgent threats, and based on historical data, most will likely never make it to FDA approval.

Why this dearth of urgently needed antibiotic innovation? In short: There is a stark financial disincentive to invest in the development of these drugs (9). According to a 2022 report from the Biotechnology Innovation Organization (10), the average annual revenue from an antibiotic’s sale is just \$16 million—a figure that pales in comparison to the more than \$1 billion

average investment needed to bring such a drug to market (estimated at \$1.3 billion on average).

As a result, major pharmaceutical companies have shifted their focus away from antibiotic development, and the biotech companies remaining in the space are struggling to sustain their operations. Today, small companies and nonprofit organizations are responsible for nearly 90% of the antibiotic candidates in global clinical development, and over the past several years, a number of those startups have already gone belly-up (11).

This categorical market failure puts us all at risk, and the market is not going to fix itself.

The Pioneering Antimicrobial Subscriptions to End Up Surging Resistance (PASTEUR) Act—introduced in the last Congress by Senators Michael Bennet (D-CO) and Todd Young (R-IN) in the Senate, and Reps. Mike Doyle (D-PA) and Drew Ferguson (R-GA) in the House—supports both antibiotic development and stewardship to help ensure that lifesaving antibiotics are available when Americans need them most. PASTEUR is designed to provide a carefully targeted lifeline to companies with promising, medically important new antibiotic candidates through an upfront funding commitment that will give small companies and their investors a strong incentive to stay committed to developing these lifesaving drugs. And crucially, PASTEUR only pays for success: The PASTEUR Act will fund contracts only when a company successfully demonstrates that its drug addresses an unmet need and delivers a notable clinical impact. It's a win-win for patients and U.S. preparedness.

PASTEUR would also provide new grant funding for health facilities including rural, critical access and safety net hospitals to support antibiotic stewardship programming, designed to ensure that these essential, life-saving drugs are used appropriately. Stewardship not only slows the development of resistance, it also is proven to improve patient outcomes and lower health care costs. 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, HHS 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 (the administration request was also included in the recently released FY2024 budget). At the end of 2022, PASTEUR had over 60 bipartisan cosponsors and the broad support of a diverse array of stakeholders, including health care providers, public health professionals, scientists, patients, and the pharmaceutical and

diagnostics industries. (An accompanying letter of support from 237 organizations has been transmitted to the committee under separate cover).

Delays in the passage of PASTEUR will inevitably delay the development of novel antimicrobials needed 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 address the growing threat that antibiotic resistance poses and include PASTEUR in the PAHPA reauthorization. Antibiotics are simply too important to our nation's health and security to leave this essential bill behind.

Thank you for your leadership to improve our public health infrastructure and medical preparedness and response programs. We appreciate the opportunity to inform this important process.

A handwritten signature in black ink, which appears to read "Kathy L. Talkington".

Kathy Talkington
Director, Health Programs
The Pew Charitable Trusts