

March 29, 2023

Senator Bernard Sanders, Chair
Senate Health, Education, Labor and Pensions Committee
Dirksen Senate Office Building, Room 428
Washington, DC 20510

Senator William Cassidy, Ranking Member
Senate Health, Education, Labor and Pensions Committee
Hart Senate Office Building, Room 833
Washington, DC 20510

Senator Robert P. Casey, Jr., Chair
Senate Health, Education, Labor and Pensions Committee, Subcommittee on
Children and Families
Dirksen Senate Office Building, Room 428
Washington, DC 20510

Senator Mitt Romney, Member
Senate Health, Education, Labor and Pensions Committee
Russell Senate Office Building, Room 354
Washington, DC 20510

Dear Chairman Sanders, Ranking Member Cassidy, Chairman Casey and Senator Romney:

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 need for urgent action to ensure that lifesaving antibiotics are available when Americans need them most. **To fully support U.S. preparedness and enhance our capacity to effectively respond to the next pandemic, we urge the committee to provide critically needed funding for the CDC’s National Healthcare Safety Network, and 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](#) 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—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](#) and [plague](#). These and other diseases are [readily weaponized](#) and could be genetically engineered to resist available antibiotics. 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](#) during the U.S. military conflicts in Iraq and Afghanistan, and a [recent study](#) showed 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](#) 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. According to a [2022 report](#) from the Biotechnology Innovation Organization, 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](#).

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 innovator 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 that delivers a notable clinical impact and succeeds in getting its drug to market. 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, which continues to grow. Earlier this month, Pew joined with more than 230 other organizations, including health care providers, public health professionals, scientists, patients, and the pharmaceutical and diagnostics industries, in a [letter to the committee](#) and other Congressional leaders, urging passage of PASTEUR as part of PAHPA reauthorization.

In addition to PASTEUR—passage of which will be critical to facilitating much needed antibiotic innovation and stewardship—there is also a pressing need to invest in our national infection tracking and biosurveillance systems and tools, like the CDC’s National Healthcare Safety Network (NHSN). NHSN has been a critical tool during the COVID-19 pandemic and in responding to other public health threats such as RSV, influenza, and antibiotic resistance (NHSN being key to ongoing collection of data related to antibiotic use and resistance). However, despite significant increases in the number of health facilities reporting data into NHSN, and a much-needed expansion in the NHSN scope of work (both excellent developments for public health), the annual appropriations to support NHSN’s critical work has remained largely flat for the past eight years. Further, the supplementary funding sources that CDC has used to enable NHSN to meet these expanded responsibilities (including funds from the American Rescue Plan, Data Modernization Initiative and other COVID-19 related funding) will soon be exhausted.

The FY24 President’s budget calls for \$50M in NHSN funding—a significant and needed increase over FY23 funding levels—and we encourage the committee to further assess the role that NHSN can play as part of a broader biosurveillance network that can provide near-real time situational awareness of U.S. health system readiness during a public health emergency. NHSN’s innovative and expanded deployment since the pandemic has included the collection of all-cause, pathogen-agnostic hospital bed occupancy and capacity data, a critical improvement in U.S. biosurveillance capabilities that provides actionable data on all of the nation’s hospital and intensive care unit beds and gives our pandemic planners unparalleled insight into health system response capacity. NHSN remains an essential component of U.S. bio-preparedness and its expanded functionality critically supports CDC’s ongoing collaboration with ASPR and other National Biodefense Strategy stakeholders.

Delays in the passage of PASTEUR and in the funding of essential public health infrastructure like NHSN will erode our preparedness and [put all Americans at risk](#).

We urge you to address the growing threat that antibiotic resistance poses and include PASTEUR and strengthen and expand NHSN in the PAHPA reauthorization. The growing threat of antibiotic-resistant bacteria is simply too salient and serious not to.

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.

Thank you,



Kathy Talkington
Director, Health Programs
The Pew Charitable Trusts

