

Honorable Jack Reed
228 Russell Senate Office Building
Washington, D.C.

Honorable James M. Inhofe
228 Russell Senate Office Building
Washington, D.C.

November 3, 2022

Dear Chairman Reed and Ranking Member Inhofe,

We represent patients, physicians, public health experts, and leading policy experts in antimicrobial resistance, and we are deeply concerned with the potential inclusion of the PASTEUR Act (S.2076) in the National Defense Authorization Act (NDAA).

Given the burden of antimicrobial-resistant infections – infecting three million Americans every year and killing 50,000 – we are all seeking solutions.¹ The PASTEUR Act would award billions in federal funding to pharmaceutical companies for newly developed antimicrobials as a financial incentive. However, it does not address the overarching problem that recent antimicrobials approved by the FDA have not been proven to work against resistant infections or are not more beneficial than other available and less expensive alternative treatments. Under the PASTEUR Act, taxpayer dollars will be wasted as a blank check to pharmaceutical manufacturers for antimicrobials of limited benefit.

Simply put, **the PASTEUR Act is not the answer**, for three reasons:

1. PASTEUR would not benefit members of the armed services.
2. PASTEUR will make the problem of antimicrobial resistant infections worse.
3. An effective solution should improve outcomes for all patients that need antibiotics.

We offer more background on these fatal flaws below and urge you to reject this potential amendment.

1. PASTEUR would not benefit members of the armed services.

The PASTEUR Act as written does not belong as part of the NDAA and would not be beneficial to the U.S. military. We agree that antimicrobial resistance is a threat to readiness, but available evidence from the Department of Defense show that the Department's antimicrobial stewardship efforts are working:

- The occurrence of antimicrobial-resistant bacterial bloodstream infections is less than 1%, and has remained stable or decreased over time within the US Military Health System (MHS).
- Department of Defense researchers found that first-line antibiotics remain clinically available for more than 99% of patients with bloodstream infections.²

¹ CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report 2022. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2022. <https://www.cdc.gov/drugresistance/covid19.html>

² Alexander C. Vostal, MD, Melissa Grance, BSc, John H. Powers, III, MD, M. Leigh Carson, MS, Uzo Chukwuma, MPH, Carlos Morales, MPH, Charlotte Lanteri, PhD, Nicholas Seliga, MPH, Beth T. Poitras, MPH, Edward Parmelee, MS, Katrin Mende, PhD, Longitudinal Changes in Antimicrobial-resistant Bacterial Bloodstream Infections in the US Military Health System from 2010-2019.

Fortunately, this means that there is time to develop better and truly effective products for patients.

2. The bill's premise is fatally flawed and could worsen the problem it's trying to solve.

The PASTEUR Act provides billions of dollars for antimicrobials that are newly developed, but these drugs are not required to demonstrate efficacy on clinically meaningful outcomes (such as survival) or to be more effective than antimicrobials that are already on the market. Studies have shown that most new antimicrobials and antibiotics approved in recent years are not proven to improve patient outcomes compared to older drugs. In fact, new antibiotics may be worse, as they are approved based on studies that include few – if any – patients with resistant infections. Additionally, the studies of new drugs intentionally exclude patients who are older or sicker, who are the exact types of patients for whom the drugs are intended. The World Health Organization found that very few drug candidates in early and late stages of development are truly novel or address the most devastating infections.³ In addition, the bill does not include the stewardship measures necessary to prevent future antimicrobial resistance, instead prioritizing more drugs instead of better drugs. As a result, the bill will contribute to antimicrobial resistance that could significantly worsen the problem we're trying to solve.

3. An effective solution should improve outcomes for all patients that need antimicrobials.

Any legislation pertaining to antimicrobials must focus on better treatments for *all* patients with infections, not just those that are resistant. More patients die from bacteria that could be treated with existing prescription drugs rather than from bacteria that are resistant to prescription drugs. In addition, any financial incentives to strengthen development of new antimicrobials should focus on improving patients' survival, reducing morbidity, and other meaningful patient-level health outcomes. PASTEUR does not do that; instead, it just provides financial incentives to bring more drugs to the market that are not proven to be effective against resistant infections and are not proven to help patients survive and recover more quickly.

We appreciate your attention and consideration and will be reaching out to your staff soon to further discuss the limitations of the PASTEUR Act and how best to address antimicrobial resistance.

Sincerely,

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³ WHO. WHO antibacterial preclinical pipeline review; 2022. Who.int.
<https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/who-antibacterial-preclinical-pipeline-review>

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