

Dear \_\_\_\_\_

On behalf of the undersigned organizations representing health care providers, public health professionals, scientists, patients, and the pharmaceutical and diagnostics industries, **we urge you to include the PASTEUR Act in any moving legislative vehicle this year, including the reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA).** The growing crisis of antimicrobial resistance (AMR) undermines U.S. public health preparedness and significantly hampers our nation's ability to respond to a wide range of threats, including pandemics, outbreaks, natural disasters, and bioterror attacks. PASTEUR would increase our nation's resilience by strengthening the antibacterial and antifungal pipeline to ensure clinicians and other medical professionals have the innovative products they need to treat patients, and ensuring antimicrobials are used appropriately. Every day we wait to address the crisis in the antimicrobial ecosystem is another year patients and providers must wait to have access to life-saving medicines.

In 2019, an estimated 1.27 million deaths worldwide were directly caused by AMR, and AMR played a part in nearly 5 million deaths. This makes AMR a leading cause of death globally.<sup>1</sup> The AMR crisis was further exacerbated by the COVID-19 pandemic. In 2020, U.S. hospitals experienced a 15% increase in AMR infections and deaths, though pandemic-related data gaps suggest that the total national burden of AMR may be much higher. Experts do not expect a return to pre-pandemic levels without concerted action.<sup>2</sup> Any emergency resulting in high levels of hospitalization, particularly high levels of ventilator use, creates a ripe opportunity for the spread of secondary drug resistant infections.

Addressing AMR is important for bioterror preparedness as well, as agents used by bioterrorists may be genetically engineered to resist current therapeutic antimicrobials.<sup>3</sup> World Health Organization (WHO) has estimated that if 50 kg of *Y. pestis* were to be released as an aerosol over a city with a population of 5 million, 150,000 people might fall ill with pneumonic plague, 36,000 of whom would die.<sup>4</sup> Drug resistant strains of *Y. pestis* have been reported, which can increase mortality.<sup>5</sup> As another example, modeling suggests that deliberate release of aerosolized *F. tularensis* over London would result in an estimated 130,000 infections and 24,000 deaths.<sup>6</sup> Natural resistance is already observed in tularemia, and the overuse of fluoroquinolones in the last two decades has led to treatment failure and relapses in tularemia patients.<sup>7</sup>

Hurricanes and other natural disasters can also increase the spread of infections, including drug resistant infections. Loss of electricity increases the risk of food spoilage and foodborne illness. Interrupted access to safe water supplies can lead individuals to turn to rivers or other ad hoc water sources. This approach, along with the presence of floodwaters, can increase the risk of illness caused by waterborne pathogens. Studies have found higher levels of pathogenic bacteria and antibiotic

**Commented [JA1]:** Identical versions of the letter would be sent to the Chairs and Ranking Members of HELP, E&C, W&M as well as the bipartisan co-leads on PAHPA reauthorization.

<sup>1</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext)

<sup>2</sup> <https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf>

<sup>3</sup> [https://books.google.com/books?hl=en&lr=&id=liGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-zSVfBI-1p\\_9TT4#v=onepage&q&f=false](https://books.google.com/books?hl=en&lr=&id=liGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-zSVfBI-1p_9TT4#v=onepage&q&f=false)

<sup>4</sup> <https://apps.who.int/iris/bitstream/handle/10665/39444/24039.pdf>

<sup>5</sup> <https://journals.asm.org/doi/full/10.1128/AAC.00306-06>

<sup>6</sup> <https://www.liebertpub.com/doi/abs/10.1089/bsp.2011.0004>

<sup>7</sup> <https://ami-journals.onlinelibrary.wiley.com/doi/full/10.1111/j.1751-7915.2008.00063.x>

resistance genes in floodwaters and soil in the Houston, TX area following Hurricane Harvey.<sup>89</sup> Conditions in crowded shelters and severely damaged homes can significantly increase the spread of infection as well. All these infections can trigger sepsis among victims and emergency workers.<sup>10</sup> Additionally, during natural disasters, those who are immunocompromised may not only lose access to crucial systems such as infusion or dialysis centers due to the loss of power but are also even more prone to these infections.

Despite the urgent and increasing need for novel antimicrobials to treat superbugs, the antimicrobial ecosystem is broken and unable to meet patient needs. The current pipeline has fewer than 50 antibacterial therapeutics in clinical development worldwide – only a handful of which are for the most threatening gram-negative pathogens – a critical area of need.<sup>11</sup> We know that the pipeline is already inadequate to address current resistant threats, let alone those that will come in the future.

Novel antimicrobials must be used judiciously to limit the development of resistance, so payment based on volume fails to drive innovation. PASTEUR's subscription model is an innovative way to pay for novel antimicrobials that will revitalize the pipeline and support appropriate use. Under PASTEUR, the federal government can enter into contracts with innovators to pay for a reliable supply of novel antimicrobials with payments that are decoupled from the volume of antimicrobials used. Importantly, the federal government only pays once – the subscription payment is all-inclusive, and PASTEUR only pays for success. Furthermore, PASTEUR will only pay for FDA approved treatments that are available to patients and meet unmet AMR needs– those that will have a big impact for patients and public health.

The delinked approach is similar to Project Bioshield, which provides multi-year funding to support procurement of medical countermeasures (MCM) for national security. Antimicrobials, like MCM, have a very limited commercial market. PASTEUR will provide novel antimicrobial innovators with a more predictable return on investment necessary to revitalize the antimicrobial pipeline—just like Project Bioshield has done for MCMs.

PASTEUR would also provide new funding for health facilities including rural, critical access and safety net hospitals to support antimicrobial stewardship, to ensure that antimicrobials are used appropriately to limit the development of resistance, and to ensure that the vulnerable patients served by these hospitals can have access to the benefits of antimicrobial stewardship. 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, 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. At the end of 2022, PASTEUR had over 60 bipartisan cosponsors and the broad support of a diverse array of stakeholders. Delays in the passage of PASTEUR are delays in the development of novel antimicrobials to treat highly resistant, life-threatening infections—delays that

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<sup>8</sup> <https://pubs.acs.org/doi/10.1021/acs.estlett.8b00329>

<sup>9</sup> <https://pubmed.ncbi.nlm.nih.gov/33077230/>

<sup>10</sup> <https://www.sepsis.org/sepsisand/natural-disasters/>

<sup>11</sup> <https://www.who.int/publications/i/item/9789240047655>

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 enact PASTEUR in 2023.

Thank you,

