

Statement of California Life Sciences Association (CLSA)

Submitted to the House Committee on Oversight and Reform Subcommittee on National Security

Hearing on “U.S. Biodefense, Preparedness, and Implications of Antimicrobial Resistance for National Security”

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California Life Sciences Association (CLSA) – the premier statewide public policy and business leadership organization representing California’s life sciences innovators, including medical device, diagnostic, biotechnology and pharmaceutical companies, research universities and private, non-profit institutes, and venture capital firms – appreciates the opportunity to present our views on the critical need for increased investment and incentives to spur biodefense preparedness and encourage the development of priority antimicrobial products.

As you know, the recent measles outbreaks in California and states across the country, fueled by vaccine hesitancy, illustrate how easily infectious diseases can spread and spiral out of control.¹ Several Ebola and Zika outbreaks and ongoing threats from terrorist organizations have repeatedly exposed our nation’s continued vulnerability to bioterror and pandemic threats, demonstrating the need for robust biodefense preparedness. Robust, long-term funding, and strong and sustained public-private partnerships remain critical in ensuring a well-funded, well-coordinated, swift, and effective response from all stakeholders. This includes, critically, a robust statutory framework for securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI), antimicrobial resistance (AMR), and emerging infectious diseases (EID).

Over the last century, the discovery, development and distribution of antibiotics rank as one of the most transformative scientific achievements in the history of innovation, affecting real change in public health across the world. In 1900, the three leading causes of death in the United States were pneumonia, tuberculosis, and enteritis – all infectious diseases.² More than a hundred years later, deaths from these diseases have by and large been eradicated as a direct result of improvements in sanitation and hygiene, and the implementation of universal childhood vaccination programs, and the discovery of antibiotics and antimicrobial drug development that led to therapeutics, like penicillin.³

Yet, these incredible achievements have led to a level of complacency in the US and around the world with regard to the continued development of these life-saving treatments. Early victories in the antibacterial space led to an explosion of research and investment by government,

¹ Abbott, Brianna. “Measles Outbreaks Strain Local Health Departments.” *Wall Street Journal*, 16 June 2019, www.wsj.com/articles/measles-outbreaks-strain-local-health-departments-11560677401.

² “Achievements in Public Health, 1900-1999: Control of Infectious Diseases.” *Centers for Disease Control and Prevention*, MMWR Weekly, 30 July 1999, www.cdc.gov/mmwr/preview/mmwrhtml/mm4829a1.htm.

³ Ibid.

universities, and industry, producing effective antibiotics that were introduced against many different types of bacteria. The unprecedented successes in the treatment of a range of deadly infectious diseases caused industry and the government to turn its focus to other illnesses and away from the production of new antibiotics. However, many of these effective treatments experienced widespread use, and overuse, which over time weakened their ability to be effective in treating evolving pathogens.

One of the most compelling case studies of antibiotic resistance in the past decade is Methicillin-resistant *Staphylococcus aureus* (MRSA). Beginning in the early 1990's, the rates of MRSA - a gram positive bacterial infection that causes skin infections - began to rise. To treat MRSA infections throughout the 1990's, the antibiotic vancomycin began to be used frequently in hospital settings. Like all antibiotics, once MRSA had been exposed to vancomycin frequently, the bacteria began to develop a resistance to the treatment. A previously effective drug like vancomycin had lost its ability to treat the MRSA infection.⁴

According to the Centers for Disease Control and Prevention (CDC), each year at least two million people in the US are infected with bacteria that cannot be treated with an antibiotic, resulting in roughly 23,000 deaths and health care costs as much as \$20 billion.⁵ These staggering statistics illustrate a dangerous reality: even as the rate of antimicrobial resistance has grown, new research and drug development has failed to keep pace with the incredible need for new medicines to treat these increasingly lethal “superbugs.” Given the threat that these deadly pathogens pose to public health in the US and across the globe, the need for effective public-private partnerships between the government and industry has never been greater.

To that end, CLSA applauds the recent passage of the *Pandemic and All-Hazards Preparedness and Advancing Innovation (PAHPAI) Act of 2019*. This important legislation will strengthen and improve our national preparedness and response for public health emergencies and accelerate medical countermeasure R&D. We were particularly pleased that the law provides new authorities to the Director of the Biomedical Advanced Research and Development Authority (BARDA) to develop strategic initiatives to accelerate and support advanced R&D and procurement for countermeasures to address threats that pose a significant level of risk to our national security, including antimicrobial resistant pathogens. CLSA encourages Congress to work with the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) to ensure that drug approval processes and coverage reimbursement policies provide the necessary incentives for research institutions, universities, and private industry to establish a sustainable R&D infrastructure.

The growing epidemic of multidrug-resistant infections knows no borders and the reestablishment of antibiotic and antifungal development as a viable investment for the life sciences industry is imperative to public health. We thank the Subcommittee for its focus on this

⁴ Borchardt, Roy, and Kenneth Rolston. “MRSA Infections: The Use of Vancomycin and Alternative Drugs.” *Journal of the American Academy of Physician Assistants*, vol. 25, no. 6, June 2012, pp. 22–27.

⁵ *Antibiotic Resistance Threats in the United States, 2013*. U.S. Centers for Disease Control and Prevention, 23 Apr. 2013, www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf.

critical national security issue and look forward to working together on policies to encourage investment in these life-saving therapies.

This statement may be attributed to Jennifer Nieto, Vice President of Federal Government Relations & Alliance Development, California Life Sciences Association - CLSA.