

**Statement of Todd E. Gillenwater
President & CEO, California Healthcare Institute (CHI)
Submitted to the House Committee on Energy & Commerce
Subcommittee on Health**

Hearing on “21st Century Cures: Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development”

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CHI - California Healthcare Institute, the statewide public policy organization representing California’s leading biomedical innovators – over 275 research universities and private, nonprofit institutes, venture capital firms, and medical device, diagnostic, biotechnology and pharmaceutical companies – appreciates the opportunity to present our views on the critical need for increased investment and incentives to spur the development of new antibiotics to combat drug-resistant pathogens.

Over the last century, the discovery, development and distribution of antibiotics ranks as one of the most transformative scientific achievements of man. In 1900, the three leading causes of death in the United States were pneumonia, tuberculosis, and enteritis – all infectious diseases. More than a hundred years later, these diseases have by and large been eradicated as a direct result of the anti-microbial drug development that led to therapeutics like penicillin.

Yet, those incredible achievements have led to a level of complacency in the United States 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, 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 and accelerated use, which over time weakened their ability to be effective in treating evolving pathogens. Simply put, as the rate of anti-microbial resistance grew, new research and drug development failed to keep pace with the incredible need for new medicines to treat these increasingly virulent strains.

Alarms were sounded this week when global health experts cautioned that more than 20,000 people worldwide may die from the ongoing Ebola outbreak. In formal statements, the President correctly noted that the time to act on an infectious disease is long before there is an outbreak, because by then, it is too late.

Hospitalizations related to Methicillin-resistant *Staphylococcus aureus* (MRSA) have increased 119 percent according to the Centers for Disease Control and Prevention (CDC) and the Infectious Disease Society of America (IDSA) estimates that 19,000 Americans died last year from MRSA alone – at least that many are expected to succumb to the infection again this year. The President’s statements around the Ebola epidemic ring true for antibiotic-resistant pathogens as well: we cannot wait for MRSA infections to reach epidemic proportions – we must act now.

MRSA represents one of the most compelling case studies of antibiotic resistance in the past decade and clearly illustrates the incredible need for industry and government to work together to encourage the investment and development of new anti-microbial treatments *before there is an outbreak*. 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 by physicians in hospitals. Like all antibiotics, when MRSA had been exposed to vancomycin on a widespread basis, 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, to dire consequences.

In 2012, Congress passed and President Obama signed into law the *Generate Antibiotic Incentives Now (GAIN) Act*. CHI was an early supporter of the GAIN Act, and launched an initiative in March 2012 focused on the growing need for antibiotic discovery and development to combat the emerging threat of antimicrobial resistance and pathogens that are highly resistant to known medicines. The GAIN Act has helped to spur research in the field of antibiotics, encourage investment in development of new antibiotics, and provide regulatory clarity for getting the antibiotics into the hands of physicians. CHI believes the GAIN Act will go down in history as a very important instrument of public policy in the battle against resistant bacteria.

But much more work remains to be done, and this Committee's 21st Century Cures initiative is an incredible opportunity in which to accomplish these goals. The U.S. Food and Drug Administration (FDA) plays a crucial role in turning the tide on antibiotic drug development. We strongly encourage the Committee to work together with FDA to implement a streamlined drug approval process that reduces regulatory barriers and provides the necessary incentives for academic and private research institutions as well as private industry to establish a sustainable R&D infrastructure. Additionally, the Committee must consider strategies to more appropriately reimburse for products targeting bacterial and fungal pathogens associated with high rates of mortality or serious morbidity, and for which we have limited or no alternative treatments. This modification is an important incentive to support enhanced research efforts and could provide sufficient encouragement for manufacturers to remain in or reconsider antimicrobial product development.

The growing epidemic of multidrug-resistant infections knows no borders and the re-establishment of antibiotic development as a viable investment for the biomedical industry is imperative to public health. Academia, industry and the federal government must work together to encourage investment in the development of these drugs.

We would be pleased to provide additional information on the important role Congress can play in creating incentives to spur the development of new antibiotics to combat drug-resistant pathogens, thus promoting venture investment in this field, and creating and retaining jobs in our state. Thank you again for the opportunity to present our views.