

### ANTIBIOTIC RESISTANT INFECTIONS

Mr. BURR Mr. President, I rise today to speak about legislation passed by the Senate yesterday, S. 3560. Antibiotic resistant infections are a serious and growing threat to public health in the United States, and I am pleased that S. 3560 contains a provision to address this threat.

The Institute of Medicine and the Infectious Disease Society of America, among others, have been warning us about antibiotic resistance for decades. We all know the therapeutics that work today against infections will be less effective over time as bacteria mutate into new resistant strains—and the pipeline of new antibiotics is nearly empty. My colleagues and I in Congress have been talking about the importance of developing new antibiotics for years, yet little has been done to create incentives to bring these anti-infectives to market.

In 2000, Senator KENNEDY stated on the Senate floor, “We are in a race against time to find new antibiotics before microbes become resistant to those already in use.” He could not have been more correct. That year, the Centers for Disease Control and Prevention estimated that methicillin-resistant *Staphylococcus aureus*, MRSA, was the cause of 126,000 hospitalizations in the United States. Today, that rate has tripled to nearly 400,000 hospitalizations per year and MRSA is the cause of an estimated 19,000 deaths every year.

The number of MRSA infections in hospitals has increased 10-fold since 1993. The University of North Carolina hospital systems reported earlier this year that 55 percent of patients with skin infections had a resistant strain.

Perhaps more frightening than hospital-acquired infections are those infections acquired in the community, including our elementary schools, athletic teams, and offices.

These numbers are more than statistics. Every Senator in Congress has constituents who have been impacted by MRSA. These super bugs are attacking and in several cases, killing healthy children and adults.

Earlier this year, six otherwise healthy high school football players at East Forsyth High School in Winston-Salem were diagnosed with MRSA. As the father of two boys who grew up in Winston-Salem and a former football player myself, this story hits close to home. Unfortunately, this outbreak was far from isolated.

According to the National Institute for Allergy and Infectious Diseases, antimicrobial resistance is driving up health care costs, contributing to the severity of disease, and increasing death rates from certain infections. In 2003, the economic burden for staph aureus associated hospital stays in the United States was \$14.5 billion.

As you may know, many pharmaceutical companies are abandoning or scaling back antibiotic research and

development in favor of more profitable drugs that treat chronic conditions. This is a regrettable, but understandable, development as market forces that would lead companies to consider investing in new antibiotic development are weak. Because antibiotics work so well and quickly in most cases, they are prescribed for only one or two weeks. That means antibiotics do not have as large a market as drugs that patients take for years. Bottom line—increasing the number of safe and effective antibiotics available in the United States is crucial to protecting the public health.

Section 4 of S. 3560, entitled “Incentives for the Development of and Access to Certain Antibiotics,” is an important step forward to help spur research on new antibiotics and provide incentives for the creation of additional generic antibiotics.

In the Food and Drug Administration Modernization Act of 1997, FDAMA, legislation I sponsored in the House, Congress moved antibiotics from section 507 to section 505 of the Food, Drug and Cosmetic Act because it did not make sense to have antibiotics separate from other drugs in the statute. Congress added language in FDAMA to ensure that antibiotics approved under section 507 would not be able to double dip on Hatch-Waxman benefits due to their new status under section 505. Those benefits include 3-year and 5-year data exclusivity and patent term extension for drugs. The FDAMA language said that any application for an antibiotic that was submitted to the Secretary could not “double dip.” As a result, companies have no access to Hatch-Waxman incentives to develop drugs based on active ingredients of the old 507 antibiotics submitted to, but not approved by, the Food and Drug Administration, FDA.

Equally important, the FDAMA language also negatively impacted generic drug companies’ ability to gain approval of and market generic equivalents of antibiotics approved under section 507.

Section 4 of S. 3560 says that any antibiotic that was the subject of an application submitted to the FDA, but not approved before FDAMA, can get the 3 year and/or 5 year Hatch-Waxman exclusivity or a patent term extension. According to the FDA, approximately 10 antibiotics fit this category of submitted but not approved and about half of those could never be approved because of issues with the active ingredients. According to a Congressional Research Service legal expert, the Patent Act would apply to this language, and it would be legally confusing if it did not mention the available Hatch-Waxman patent term extensions. For that reason, the provision authors added language providing the option of data exclusivity or a patent term extension.

This provision also addresses the negative consequences of the FDAMA language on generic drugs. Section 4 of S. 3560 includes language clarifying the

ability of generic drug companies to gain approval of and market generic equivalents of antibiotics approved under section 507.

This provision was included in Senate-passed S. 1082, the Food and Drug Administration Revitalization Act, and was agreed upon in Senate-House conference negotiations. Due to a lack of funding in H.R. 3580, the Food and Drug Administration Amendments Act, the House pulled this provision before passage of H.R. 3580, Public Law 110–85.

I commend Senators BAUCUS, GRASSLEY, KENNEDY, ENZI, and BROWN for making antibiotic incentives a priority at this time. It is important to encourage more treatments for the increasing number of resistant microbes we face.

### IMPROVING ACCESS TO MAINSTREAM FINANCIAL INSTITUTIONAL ACT

Mr. AKAKA Mr. President, too many Americans are left out of our mainstream financial institutions. Millions of working families do not have a bank or credit union account. The unbanked rely on alternative financial service providers to obtain cash from checks, pay bills, and send remittances. Many of the unbanked are low-and moderate-income families that can ill afford having their earnings diminished by reliance on these high-cost and often predatory financial services. In addition, the unbanked are unable to save securely to prepare for the loss of a job, a family illness, a down payment on a first home, or education expenses. There are few affordable alternatives for consumers who need small loans quickly.

We need to enact S. 3410, the Improving Access to Mainstream Financial Institutions Act of 2008. This legislation authorizes grants intended to help low-and moderate-income unbanked individuals establish credit union or bank accounts. The legislation also authorizes a grant program to encourage the development of affordable small loans at banks and credit unions.

Mr. President, I ask unanimous consent to have a letter of support from the Credit Union National Association, CUNA, for S. 3410 printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

AUGUST 1, 2008.

Hon. DANIEL AKAKA,  
*U.S. Senate,*  
*Washington, DC.*

DEAR SENATOR AKAKA: On behalf of the Credit Union National Association (CUNA), I am writing in regards to S. 3410, the “Improving Access to Mainstream Financial Institutions Act of 2008.” CUNA is the nation’s largest credit union advocacy organization, representing nearly 90 percent of our nation’s 8,300 state and federally chartered credit unions, their state credit union leagues, and their more than 90 million credit union members.