

Generating Antibiotic Incentives Now (GAIN) Act

Federal legislation, such as H.R. 2182, the Generating Antibiotic Incentives Now (GAIN) Act of 2011, provides new incentives for the development of products for treating, detecting, and preventing drug resistant bacteria, as well as other significant threats to public health that stem from drug resistance. The bill provides incentives and other provisions including:

- 1) Extending the Hatch-Waxman provisions related to data exclusivity by five years, plus six months of additional exclusivity for products with companion diagnostic tests;
- 2) Providing priority review by the FDA;
- 3) Making products eligible for fast track designation by the FDA; and
- 4) Requiring a review of FDA guidelines regarding requirements for approval of antibiotic drugs.

The GAIN Act, sponsored by Reps. Phil Gingrey (R-GA) and Anna Eshoo (D-CA), provides the necessary incentives and modifications to the FDA regulatory processes that guide response to the threats that drug-resistant pathogens pose to our nation's public health, battlefield readiness and food supply safety. We are pleased to offer our support for this legislation and we look forward to working with its authors to see its enactment into law.

Healthcare-Associated Infections (HAIs)

Healthcare-associated infections (HAIs) are infections that patients develop during the course of receiving healthcare treatment for other conditions. They can happen following treatment in hospitals, as well as outpatient surgery centers, dialysis centers, nursing homes, and community clinics. HAIs are the most common complication of hospital care and are the 10th leading cause of death in the United States, accounting for 2 million infections, and nearly 100,000 deaths per year, as well as nearly \$3.1 billion in excess healthcare costs in acute care hospitals alone. According to the California Department of Public Health, approximately 12,000 people die in the state each year of HAIs.

HAIs are a large and growing challenge. Caused by antibiotic-resistant bacteria, the infections are becoming more prevalent and more deadly, impacting increasing numbers of patients and their healthcare providers every year. A patient with an HAI is about seven times more likely to die than an uninfected patient, and about one in 20 Americans will contract an HAI during a hospital stay in their lifetime.

In addition to the substantial human suffering exacted by HAIs, their financial burden is staggering. Each year, such infections cause an estimated \$28 to \$33 billion in excess healthcare costs. The threat of HAIs in healthcare facilities – including hospitals, acute care centers, outpatient surgical practices and nursing homes – undermines patient confidence and the effectiveness of the healthcare system. By necessity, healthcare providers and biomedical companies are stepping up to combat HAIs.

California Sees Success in Surveillance and Prevention

It is estimated by the California Department of Public Health that approximately 200,000 patients develop infections in California hospitals each year with an annual cost of about \$600 million. The Healthcare Associated Infection (HAI) Program was authorized in December 2009 and is responsible for surveillance and prevention efforts within California's acute care hospitals. Mandated by Senate Bills 739, 1058, and 158, the initiative has been credited with cutting ventilator-associated pneumonia by more than 40 percent; urinary tract infections related to catheters fell 24 percent in 2010; blood poisoning cases dropped by approximately 11 percent. It is estimated that the state has saved approximately \$11 million due to decreased rates. The HAI Program is advised by a committee of healthcare professionals and public advocates from throughout California and who recommend public reporting methods and process measures for preventing the spread of HAIs based on national guidelines.

Several types of bacteria have grown resistant to antibiotics, yet the two most prominent types implicated in HAIs are methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* (C. diff).

MRSA

MRSA comprises about 40 percent of all *Staphylococcus aureus*, a common type of bacteria that lives on the skin and in the nose of many healthy people without effect.

Dangerous infections can occur, however, when the bacteria enter the body through wounds or via surgical instruments. MRSA infections occur most frequently among people who have weakened immune systems in hospitals and healthcare facilities (such as nursing homes and dialysis centers).

An estimated 126,000 Americans are hospitalized with MRSA each year, a number that has more than tripled since 2000 and increased nearly 10-fold since 1995. An estimated 40 percent to 60 percent of hospital MRSA infections are resistant to firstline antibiotics, and the percentage is increasing.

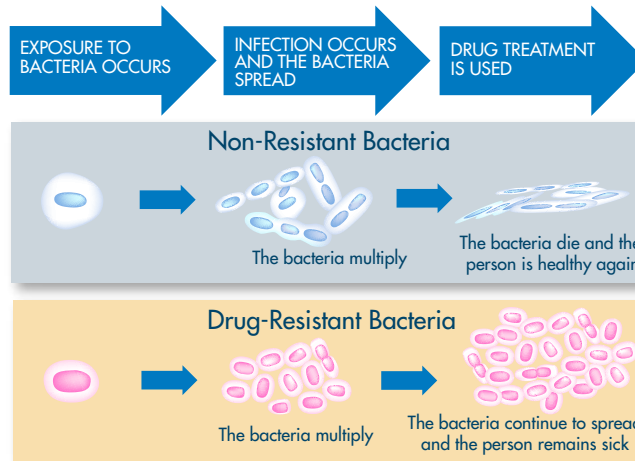
C. diff

Clostridium difficile (pronounced Klo-STRID-ee-um dif-uh-SEEL), also known as "C. diff," is a germ that can cause diarrhea. More than nine out of 10 hospital infections with C. diff occur in people who have received antibiotic treatment. Such regimens kill many different types of pathogens, including the "good" bacteria in the gut that keep C. diff at bay. The resulting overgrowth of the C. diff bacteria produces toxins that can lead to diarrhea, which is often severe; intestinal inflammation known as colitis; sepsis; and, increasingly, death. C. diff sickens about 500,000 Americans annually. Early in this decade, C. diff became four times more lethal, with death rates increasing from 5.7 per million Americans in 1999 to 23.7 per million in 2004.

Source: CDC

WHAT IS DRUG RESISTANCE?

Antimicrobial resistance is the ability of microbes, such as bacteria, viruses, parasites, or fungi, to grow in the presence of a chemical (drug) that would normally kill it or limit its growth.



Non-resistant bacteria multiply, and upon drug treatment, the bacteria die. Drug resistant bacteria multiply as well, but upon drug treatment, the bacteria continue to spread.

the 1940s, antibiotics and other antimicrobials have saved countless lives and blunted serious complications of many feared diseases and infections. The success of antimicrobials against disease-causing microbes is among modern medicine's great achievements.

The Problem

After more than 50 years of widespread use, evolution of disease-causing microbes also has resulted in many antimicrobials losing their effectiveness.

As microbes evolve, they adapt to their environments. If something stops them from growing and spreading – such as an antimicrobial – they evolve new mechanisms to resist the antimicrobials by changing their genetic structure. Changing the genetic structure ensures that the offspring of the resistant microbes also are resistant.

Antimicrobial resistance makes it harder to eliminate infections from the body. As a result of a microbe's ability to survive in spite of antimicrobials, some infectious diseases are now more difficult to treat than they were just a few decades ago.

Diagnosis

Diagnostic tests are designed to determine which microbe is causing infection and to which antimicrobials the microbe might be resistant. This information would be used by a healthcare provider to choose an appropriate antimicrobial. However, current diagnostic tests often take a few days to give results.

Oftentimes, healthcare providers need to make treatment decisions before the results are known. While waiting for test results, healthcare providers may prescribe a broad-spectrum antimicrobial when a more specific treatment might be better. The common practice of treating unknown infections with broad-spectrum antimicrobials is another factor in the emergence of antimicrobial resistance.

The Future of Diagnostics

Efforts are underway to produce rapid diagnostic tests that allow healthcare providers to make more informed healthcare decisions. Timely reporting enables clinicians to administer appropriate therapy, thereby improving patient management and outcomes.

Today's testing methodologies have cut the time it takes to identify infections caused by C. diff and other bacteria down to a matter of minutes. And active surveillance is reducing the number of healthcare-associated MRSA infections.

Source: NIAID

History

In 1928, while working with *Staphylococcus* bacteria, Scottish scientist Alexander Fleming noticed that a type of mold growing by accident on a laboratory plate was protected from, and even repelled, the bacteria. The active substance, which Fleming called penicillin, was literally an antibiotic – it killed living organisms.

Thus began the age of using natural and, later, synthetic drugs to treat people with bacterial infections. Though not widely popular until



Helping all people
live healthy lives

BD is committed to applying its expertise, resources and technologies toward the diagnosis and management of infectious disease worldwide, including the prevention of healthcare-associated infections. BD's portfolio includes rapid molecular diagnostic assays for MRSA, toxigenic *C. difficile* and CT/GC, microbiological methods for the detection, identification and antimicrobial susceptibility of infectious pathogens, and novel device technologies to help prevent bloodstream infections in the healthcare setting.



CareFusion is uniquely positioned to help hospitals improve safety and reduce cost through its systematic and targeted approach, which combines clinically proven products and healthcare-associated infection surveillance to help clinicians reduce the risk

of infection. CareFusion offers a suite of products including ChloroPrep skin prep products, MedMined services for data mining surveillance, MaxGuard needleless IV technology, surgical hand scrubs and patient prep trays.



Cepheid, based in Sunnyvale, Calif., is a leading molecular diagnostics company that is dedicated to improving healthcare by developing, manufacturing, and marketing accurate yet easy-to-use molecular systems and tests. By automating highly complex and time-consuming manual procedures, the company's solutions deliver a better way for institutions of any size to perform sophisticated genetic testing for organisms and genetic-based diseases. Through its strong molecular biology capabilities, the company is focusing on those applications where accurate, rapid, and actionable test results are needed most, such as managing infectious diseases and cancer. Its Xpert MRSA test provides on-demand results in about an hour and has been proven to optimize the effectiveness of any infection control program. Cepheid's 45-minute Xpert *C. difficile* is the first to deliver both speed and accuracy.



Cubist is a biopharmaceutical company focused on the research, development, and commercialization of pharmaceutical products that address significant unmet medical needs in the acute care environment. Cubist markets Cubicin (daptomycin for injection), and has an agreement with Optimer Pharmaceuticals to co-promote Dificid in the U.S. as a treatment of *Clostridium difficile*-associated diarrhea in adults. The company's clinical pipeline includes CXA-201 and CB-183,315 and several pre-clinical programs being developed to address areas of significant medical needs. Cubist is headquartered in Lexington, Mass.



Theravance®

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including COPD and asthma, bacterial infections, and central nervous system/pain. Theravance's first product is Vibativ (telavancin), which is approved for use in the United States, Canada and Europe. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.



Thermo Fisher Scientific is the world leader in serving science. Its mission is to enable its customers to make the world healthier, cleaner and safer. Its products and services help accelerate the pace of scientific discovery, and solve analytical challenges ranging from complex research to routine testing. Thermo Fisher provides a broad range of infectious disease diagnostics, from plated media to cutting-edge biomarkers for diagnosing influenza and healthcare-associated infections. In addition, Thermo Fisher works with the National Institutes of Health to advance the public health field's understanding of a wide array of infectious diseases including AIDS.

Additional Resources:

BD:
www.bd.com

CareFusion:
www.CareFusion.com

C. Diff:
www.cdc.gov/hai/organisms/
cdiff/cdiff_infect.html

Cepheid:
www.Cepheid.com

Cubist:
www.Cubist.com

MRSA:
www.CDC.gov/mrsa/

National Institute of Allergy and Infectious Diseases:
www.niaid.nih.gov/topics/
antimicrobialresistance/Pages/
default.aspx

Theravance:
www.Theravance.com

Thermo Fisher Scientific:
www.ThermoFisher.com

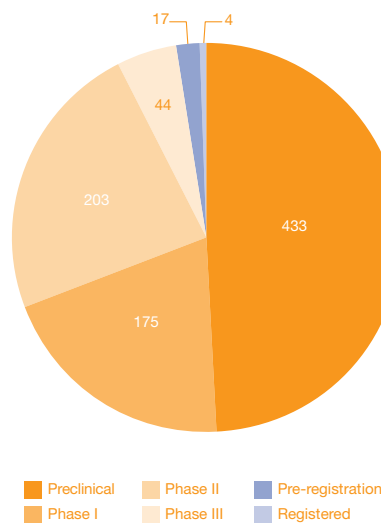
U.S. Department of Health and Human Services Initiatives:
www.hhs.gov/ash/initiatives/hai/
index.html

QUICK FACTS

- Increasing use of antimicrobials in humans, animals, and agriculture has resulted in many microbes developing resistance to these powerful drugs.
- Many infectious diseases are increasingly difficult to treat because of antimicrobial-resistant organisms, including HIV infection, staphylococcal infection, tuberculosis, influenza, gonorrhea, candida infection, and malaria.
- Between 5 percent and 10 percent of all hospital patients develop an infection, leading to an increase of about \$5 billion in annual U.S. healthcare costs.
- About 90,000 of these patients die each year as a result of their infection, up from 13,300 patient deaths in 1992.
- People infected with antimicrobial-resistant organisms are more likely to have longer hospital stays and may require more complicated treatment.

Source: NIAID

California companies are researching and developing 876 pipeline products



California's pipeline is concentrated in six major areas each of which represent significant unmet needs for patients.

Disease focus	Number in CA pipeline
Oncologics	237
Immune system and inflammation	109
Central nervous system	107
Anti-infectives and anti-virals	96
Cardiovascular and blood diseases	56
Diabetes and metabolics	47

CHI-California Healthcare Institute

CHI-California Healthcare Institute is a non-profit public policy research organization for California's biomedical R&D industry. CHI represents more than 275 leading medical device, biotechnology, diagnostics and pharmaceutical companies and public and private academic biomedical research organizations. CHI's mission is to advance responsible public policies that foster medical innovation and promote scientific discovery. CHI's website is www.chi.org. Follow us on Twitter @calhealthcare and Facebook.



Headquarters
888 Prospect Street, Suite 220
La Jolla, California 92037
858-551-6677
858-551-6688 fax

Sacramento
1215 K Street, Suite 940
Sacramento, California 95814
916-233-3497
916-233-3498 fax

Washington, D.C.
1608 Rhode Island Ave. N.W., 2nd Floor
Washington, DC 20036
202-974-6313
202-974-6330 fax