

FACTS ON ANTIBIOTIC RESISTANCE

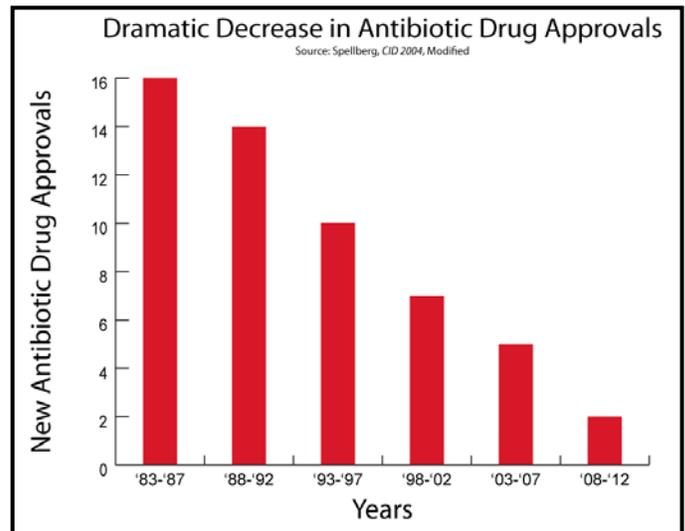
The discovery of antibiotics in the 1930s fundamentally transformed the way physicians care for patients, shifting their approach from a focus on diagnoses without means to help into a treatment-focused approach that saves lives. More than 70 years later, we're at a critical point in treating infectious diseases: the natural ability of bacteria to evolve and defend themselves against antibiotics is occurring at a frightening pace, threatening patient care, public health and national security. At the same time, new antibiotic research and development (R&D) is in steep decline (see chart below). Antibiotic R&D has slowed to a standstill due to market failure, lack of clear regulatory guidance for drug companies, and economic disincentives. Antibiotics aren't as profitable as other drugs, such as those for chronic diseases, because antibiotics are taken for a short course (not for years).

In 2004, the Infectious Diseases Society of America (IDSA) raised the alarm about the dramatic increase in drug-resistant bacteria and the diminishing supply of new antibiotics in its landmark "[Bad Bugs, No Drugs](#)" report. The Society has pursued multiple approaches, including legislation¹, to strengthen federal leadership, public health efforts, research, data collection, surveillance, antimicrobial stewardship (i.e. appropriate use strategies) and efforts to fix the anemic drug pipeline. IDSA has published reports and [policy recommendations](#), including an April 2013 update on the status of antibiotic R&D. In 2010, IDSA launched its [10 x '20 Initiative](#), calling for political leaders, regulators, manufacturers, etc. to work together to create an R&D infrastructure capable of developing 10 new systemic antibiotics by 2020. Only one 10 x '20 antibiotic has been approved to date and that was 30 months ago (see pill bottle image below).

Recognized by the World Health Organization and the U.S. Centers for Disease Control and Prevention (CDC) as one of the greatest threats to human health worldwide, antimicrobial resistance takes a staggering toll in the United States and across the globe:

- Just one organism, methicillin-resistant *Staphylococcus aureus* (MRSA), kills more Americans every year than emphysema, HIV/AIDS, Parkinson's disease, and homicide combined.
- Nearly 2 million Americans per year develop hospital-acquired infections (HAIs), resulting in nearly 100,000 deaths – the vast majority of which are due to pathogens that are at least partially resistant to antibiotics.
- In March 2013, CDC [alerted](#) the public about a four-fold increase in one group of "nightmare bacteria," carbapenem-resistant *Enterobacteriaceae* (CRE), which kills up to 50 percent of the people infected – and is on the rise nationwide. *Enterobacteriaceae* is a large class of bacteria that includes *E. coli*, *Klebsiella*, and others.
- According to CDC, the annual domestic impact to the U.S. health care system of antibiotic-resistant infections is \$20 billion in excess health care costs and more than 8 million additional hospital days.

If we do not act immediately to preserve existing antibiotics and to produce new drugs, we face a future that may resemble the days before these "miracle" drugs were developed; where people die of common infections and many medical interventions we take for granted – including surgery, chemotherapy, organ transplantation and care for premature infants – become impossible. In particular, Congress must enact additional legislation supporting antibiotic development, as well as the STAAR Act (see footnote).



¹ Generating Antibiotics Incentives Now (GAIN; enacted in 2012) as part of the FDA Safety and Innovation Act (FDASIA); and Strategies to Address Antimicrobial Resistance (STAAR) Act (awaiting reintroduction in the U.S. Senate and House).