

Lifesaving antibiotics face doubtful future

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To head off a health care disaster, the Infectious Diseases Society of America (IDSA) has developed a plan to combat deadly antibiotic-resistant "super bugs" and is rolling out the multi-pronged plan today, on World Health Day 2011.

Infections are becoming increasingly resistant to existing [antibiotics](#), while the number of [new antibiotics](#) being developed has plummeted. IDSA warns that unless sweeping actions are taken now, the future could resemble the days before these miracle drugs were developed. People will die of common infections and many medical interventions we take for granted – surgery, chemotherapy, organ transplantation, and premature infant care – will no longer be possible.

IDSA's new policy paper, "Combating Antimicrobial Resistance: Policy Recommendations to Save Lives," is being released at a press conference and published in the journal *Clinical [Infectious Diseases](#)*. The paper is available online.

"The way we've managed our antibiotics for the past 70 years has failed. Antibiotics are a precious resource, like energy, and we have a moral obligation to ensure they are available for future generations," said IDSA President James M. Hughes, MD, FIDSA. "IDSA has a comprehensive, multifaceted plan to address this crisis, but time is running out. If such measures are not implemented now by Congress, federal agencies and [health care](#) providers across the country an increasing number of lives will be devastated and lost."

The incidence of antibiotic-resistant bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), *Acinetobacter baumannii*, *Klebsiella*, and others has skyrocketed over the past two decades. Each year, these infections kill nearly 100,000 U.S. hospital patients and are increasingly affecting healthy people as well. But while 16 new antibiotics were approved between 1983 and 1987, only two have been approved since 2008. The crisis is so dire, the World Health Organization has made antibiotic resistance the central focus of this year's World Health Day, a day held each year to highlight a global public health issue of critical concern.

The complex problem is caused by several factors. Antibiotics are becoming less effective due to over-prescription and improper use (up to half of antibiotic use is unnecessary or inappropriate) as well as bacteria's natural ability to evolve and develop resistance to antibiotics. Treating these resistant bugs costs the U.S. health care system an estimated \$21 billion to \$34 billion annually. Just when we most urgently need new drugs, a market failure coupled with lack of clear guidance from the Food and Drug Administration (FDA) about how to design studies for new antibiotics has caused research and development (R&D) efforts to slow to a standstill. Drug companies now are shifting their research dollars to developing drugs that treat chronic conditions, such as diabetes and high blood pressure. These drugs are less challenging to bring to market than antibiotics from a regulatory standpoint and are much more lucrative because they are used for years, rather than days or weeks, as antibiotics are.

In 1990, there were nearly 20 pharmaceutical companies with large, strong and active antibiotic R&D programs. Today, there are just two, and only a small number of companies have more limited programs.

IDSA supports legislative and administrative action to address the problem, and two bills, the Strategies to Address Antimicrobial

Resistance (STAAR) Act and the Generating Antibiotic Incentives Now (GAIN) Act, are good first steps, but IDSA believes they can do more. To turn the tide, IDSA recommends:

- Creating incentives (and removing economic and regulatory disincentives) for antibiotic R&D so companies find developing new antibiotics a viable business endeavor. IDSA's goal is to have 10 new systemic antibiotics by 2020, known as the 10 x '20 initiative. Since the initiative was launched in April 2010, one new antibiotic has been approved.
- Recalibrating and better communicating FDA's requirements for new antibiotic approvals.
- Funding antibiotic R&D efforts under the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) and proposed independent strategic investment firm.
- Supporting R&D for rapid diagnostic tests for use at the point of care to identify the cause of infections more quickly.
- Designating a leader within HHS to facilitate coordination of federal agencies' efforts and better utilize outside experts.
- Promoting the judicious use of available antibiotics in all settings (human and agricultural) through better stewardship programs and infection control practices.
- Creating an Antimicrobial Innovation and Conservation (AIC) Fee to help pay for drug development and stewardship. The fee would be charged against the wholesale purchase of antibiotics

used in humans, animals, plants, and aquaculture.

- Strengthening public health measures (e.g., surveillance, data collection, immunization) and research that lead to new interventions to limit the spread of resistant organisms.
- Establishing non-profit Public Private Partnerships to invest in bringing new antibiotics to market even though the market may be a small one.

"Infectious diseases specialists around the country can tell you stories about formerly healthy patients who died because physicians ran out of antibiotics that worked," said Brad Spellberg, MD, FIDSA, associate professor of medicine at the Geffen School of Medicine at the University of California at Los Angeles, Los Angeles Biomedical Research Institute. "We're facing a day in the not-too-distant future where people will be outraged with our inability to treat infectious diseases, and wonder why something wasn't done earlier. The IDSA plan lays out innovative approaches that can and should be enacted, but they must be done now. The longer we wait, the bigger and more costly the problem will become both in terms of lives lost and health care expenditures."

Provided by Infectious Diseases Society of America

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