IDSA
Infectious Diseases Society of America

# Why Patients Need New Antibiotics

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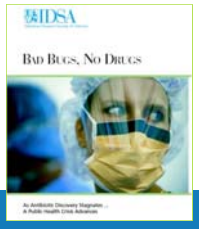


## Agenda for This Talk

- Overview of IDSA
- What Antibiotic Resistance Means for Patients
- The Antibiotic Pipeline Crisis
- IDSA's Strategy to Combat Resistance and Stimulate Antibiotic R&D

## IDSA's Motivation/Perspective

**Our patients need new antibiotics to survive**

- IDSA represents 10,000+ physicians, scientists, public health practitioners – most provide clinical care
- Unlike other disease areas (cancer, HIV/AIDS, etc.), there are **no easily identifiable patient advocacy groups** to push for change and to put a human face on the antibiotic resistance problem
- IDSA decided it must step in to advocate on our patients' behalf
- We have not taken any pharmaceutical funding to support these advocacy efforts

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## Antibiotic Resistance Threats Grow

- Conservative estimates indicate that over 2 million Americans are sickened every year by antibiotic resistant infections and at least 23,000 die.
  - The actual numbers are likely far higher.
- One example of an "urgent threat" according to CDC: Carbapanem-Resistant Enterbacteriaceae
  - The actual numbers are likely far higher.
  - 9,000 drug resistant infections per year, 600 deaths
  - resistant to all or nearly all current antibiotics
  - at least one type of CRE in in 44 states.
- Up to half of all bloodstream infections caused by CRE result in death.


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## Lives Devastated/Lost Due to Antibiotic Resistant Infections

### Premature Death

**Rebecca Lohsen (17 yr)--Dead**

**Mariana Bridi da Costa (22 yr)--Dead**


**Carlos Don (12 yr)--Dead**

**Ricky Lannetti (21 yr)--Dead**

### Life-altering Disability

**Tom Dukes: colostomy, lost 8" colon**

**Addie Rereich, 11yo**
**Double lung transplant**
**Stroke, nearly blind**
**$6 million hospital bill**

www.AntibioticsNow.org

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## One Patient's Story: María Julia

Dear Dr. Benjamin:

My name is Mario Manzanares. I'm neonatologist and work at the Pereira Rossell Hospital in Montevideo, Uruguay. I wrote you in january 2010, asking you for help in the treatment of a very ill preterm that was born with a gestational age of 25 weeks and weight of 650 grams.

Her name was María Julia. When she left our NICU her brother said that she looked like E.T. Then I sent you a photograph.

**A Good Ending**

It's a pleasure for me to send you now another photograph of her.

She is now 3 1/2 years old and lives in Rivera, Uruguay. She is a completely normal girl. I really enjoy sharing this with you.

Once more time, thank you very much.

Yours sincerely

Dr.M.Manzanares

## Two forthcoming papers illustrate the direct relationship between resistance and mortality:

*Bergen, et al. Antimicrobial resistant Escherichia coli sepsis: Clinical outcomes and impact of initial antibiotic therapy*.

- Increased mortality with Gram-negative rod bloodstream infections that are resistant to Ampicillin in premature and term infants

*Thaden, et al. Survival Benefit of Empirical Vancomycin Therapy for* Staphylococcus aureus *Bloodstream Infections (BSI) in Infants.*

- Shows that, among hospitalized infants, greater mortality for MRSA bloodstream infections compared to MSSA BSI.

## Antibiotic Resistance: Realities for Patients and Physicians

- The only antibiotic remaining to treat many Gram negative bacterial infections is Colistin.
- Colistin is toxic; it causes kidney failure; its efficacy is questionable.
  - Colistin had not been used in 30 years, but has been pulled off the shelves because there is nothing else.
- Gram negative bacteria are now developing resistance to Colistin.
- Economic burden on U.S. health care system: **$21-34 billion cost annually; 8 million add'l hospital stays**

**Current alternatives for these patients: "Do you want to die, or to be on dialysis for the rest of your life or until you can get a kidney transplant?"**

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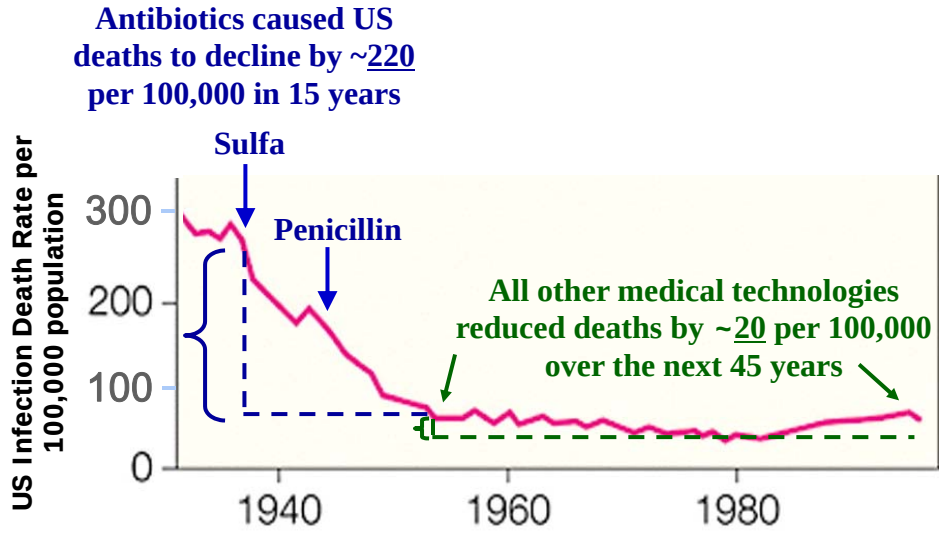
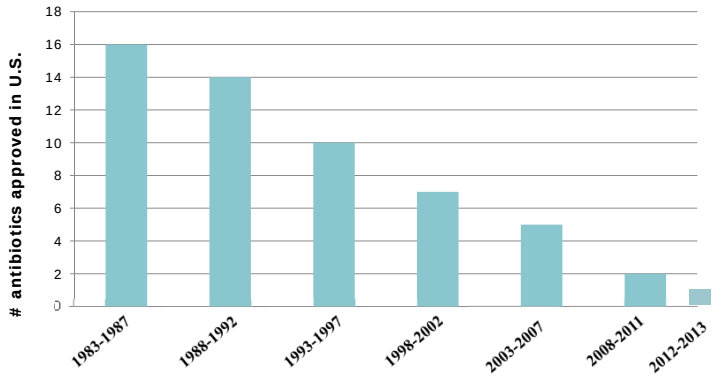
## Antibiotic Effectiveness is Also Declining




Armstrong, G. L. et al. JAMA 1999;281:61-66.

## New Antibacterial Drug Approvals Are in Decline




Modified from: Rice LB. Federal funding for the study of antimicrobial resistance in nosocomial pathogens: no ESKAPE. J Infect Dis 2008; 197:1079–81; Spellberg B, Guidos R, Gilbert D, et al. The epidemic of antibiotic resistant infections: a call to action for the medical community from the Infectious Diseases Society of America. Clin Infect Dis 2008; 46:155–64.

## Status of the 10 x '20 Initiative

- Global commitment to develop **10 new systemic antibacterial drugs by 2020** (CID; April 2010)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## Variety of Incentives Needed to Spur Antibiotic R&D

- **Economic**
  - **Generating Antibiotic Incentives Now (GAIN)** Act—Enacted 2012
  - Improving reimbursement such as through the **DISARM Act**
  - **Stronger funding** for federal agencies to support antibiotic R&D, including the National Institute for Allergy and Infectious Diseases **(NIAID)** and the Biomedical Research and Development Authority **(BARDA)**
  - **Tax Credits**

## Regulatory solution: Antibiotic Development to Advance Patient Treatment (ADAPT) Act

- Establishes a limited population antibacterial drug (LPAD) approval pathway to address serious or life-threatening infections where an unmet medical need exists
- ADAPT/LPAD drugs would be approved based upon smaller, faster, and less expensive clinical trials; drugs must still be demonstrated to be safe and effective for indicated population based upon current FDA evidentiary standards
- ADAPT/LPAD drugs' labeling must make clear to the healthcare community that these drugs are approved for a limited population and must be used appropriately
- ADAPT/LPAD drugs' use would be monitored by CDC's National Healthcare Safety Network (NHSN)

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## Increased Federal Funding for AR is Desperately Needed

To strengthen the U.S. federal response to resistance, IDSA recommends robust funding for the following agencies and initiatives:

- CDC Detect and Protect Against Antibiotic Resistance initiative
- CDC National Healthcare Safety Network (NHSN)
- CDC Advanced Molecular Detection (AMD)
- National Institute of Allergy and Infectious Diseases (NIAID)

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## Stewardship Protects the Effectiveness of Antibiotics and Improves Patient Care

- **Antibiotic stewardship** programs in every healthcare facility as a condition of Medicare/Medicaid participation
- Increased **research on the optimal ways to use current antibiotics** to improve patient care and protect the drugs' utility
- Improved **surveillance** to rapidly identify and respond to emerging threats
- Enhanced antibiotic use and resistance **data collection** to help us better understand the scope of the problem and evaluate interventions
- Better **infection control** practices

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## The Global Response is Gaining Momentum; It's Time for the U.S. to Help Lead the Way

- April 2014: The World Health Organization (WHO) Releases "Antimicrobial Resistance: Global Report on Surveillance."
  - Highlights major gaps in resistance data in both developed and developing countries
- May 2014: The 67th World Health Assembly (WHA) approves a resolution urging Member States to:
  - strengthen drug management systems;
  - support research to extend the lifespan of existing drugs; and
  - encourage the development of new diagnostics and treatment options.


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## Thank You.

Prior generations gave us the gift of antibiotics. Today, we have a moral obligation to ensure this global treasure is available for our children and future generations.

IDSA

10x'20

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