Infectious Diseases Society of America

Anti-Infective Drugs Advisory Committee
U.S. Food and Drug Administration

The Need for New Antibiotics

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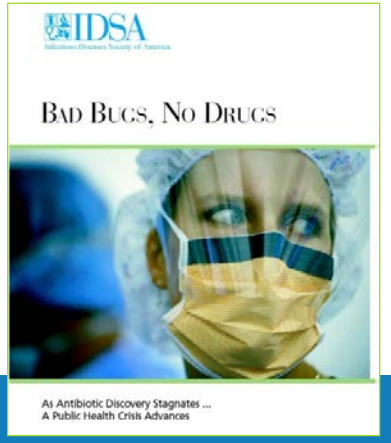
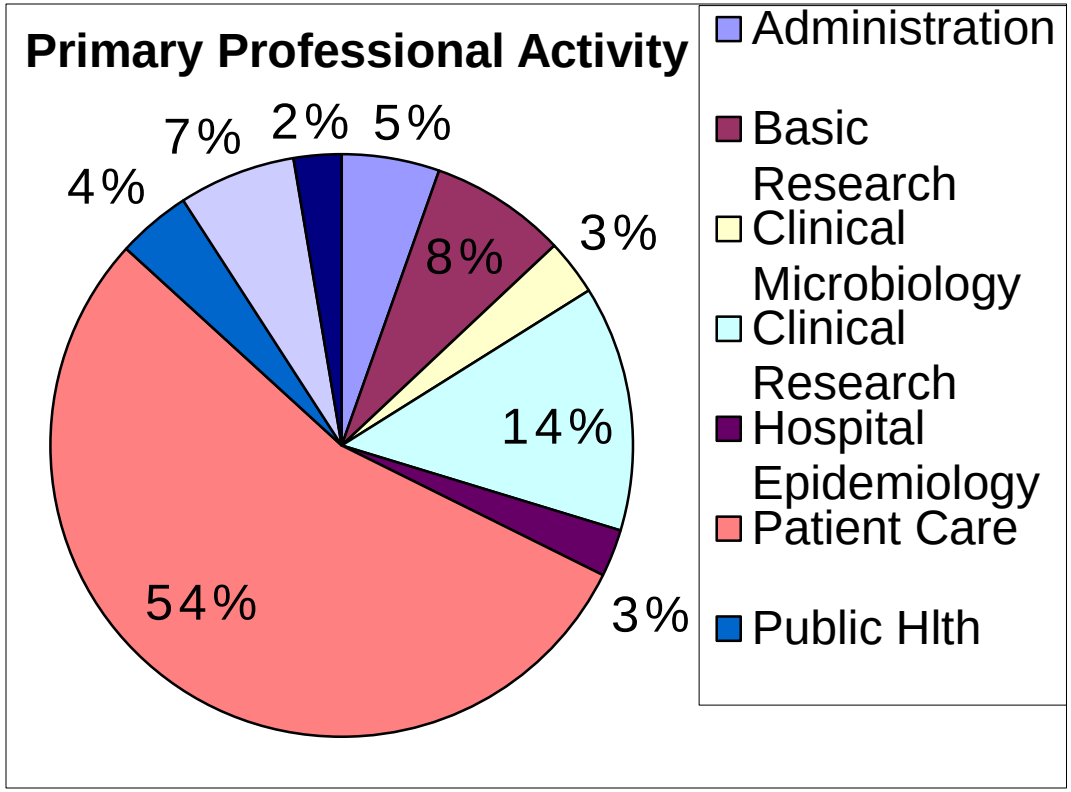


IDSA Membership

10,000+ strong

Majority physicians providing clinical care



IDSA's Motivation/Perspective

Our patients need new antibiotics to survive!

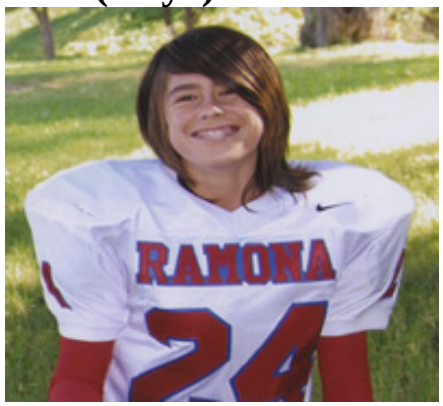
- Unlike other disease areas (cancer, HIV/AIDS, etc.), there are **no easily identifiable patient advocacy groups** to push for change and to put a human face on the antibiotic resistance problem
- IDSA decided it must step in to advocate on our patients' behalf
- We have not taken any pharmaceutical funding to support these advocacy efforts
- **IDSA does not take a position on the potential FDA approval of any specific product.**

Physician Perspective: Why Patients Need New Antibiotics Now

Premature Death

Rebecca Lohsen (17 yr)--Dead

Mariana Bridi da Costa (22 yr)--Dead



Carlos Don (12 yr)--Dead

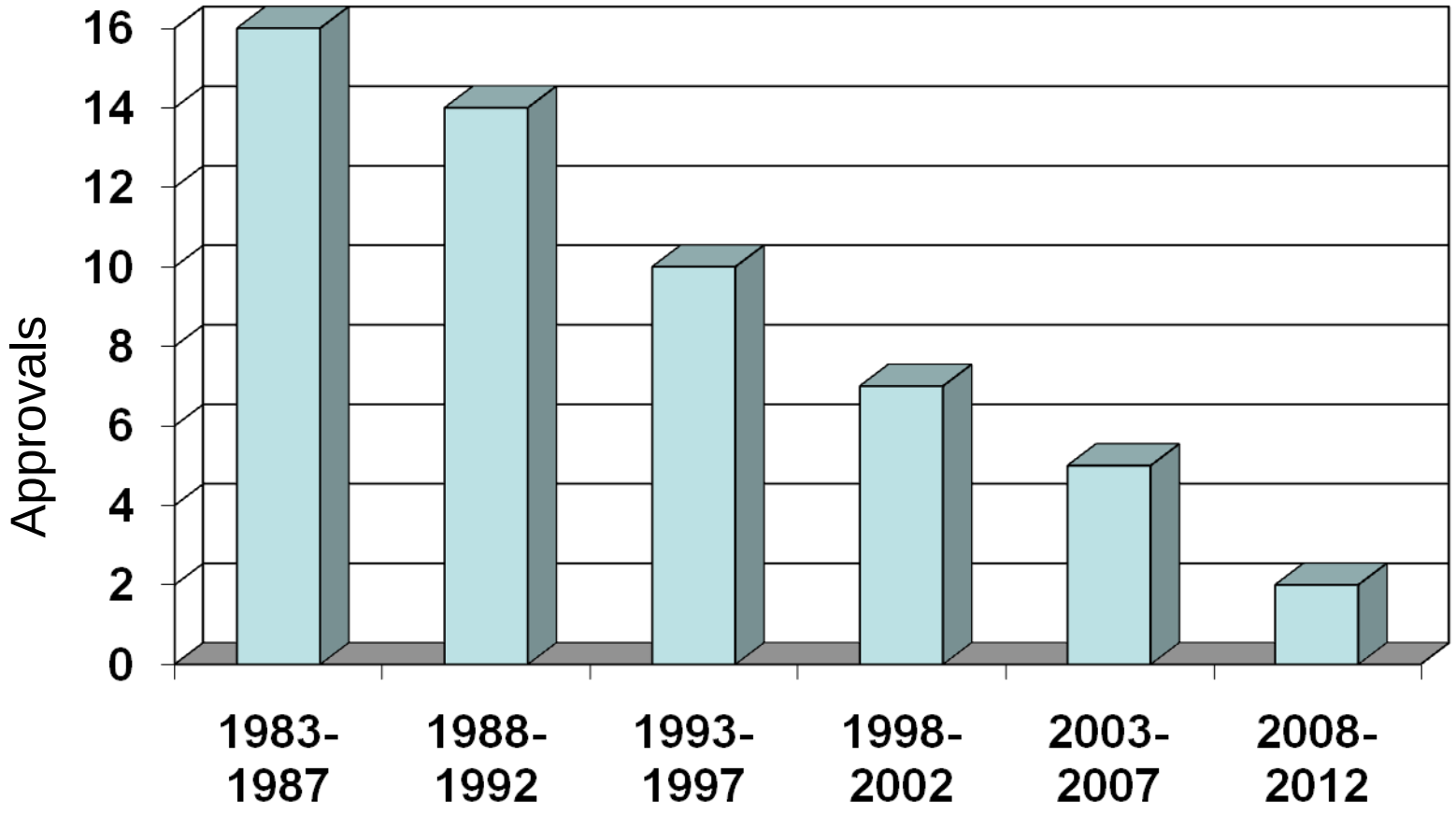
Ricky Lannetti (21 yr)--Dead

Life-altering Disability

Tom Dukes: colostomy, lost 8” colon

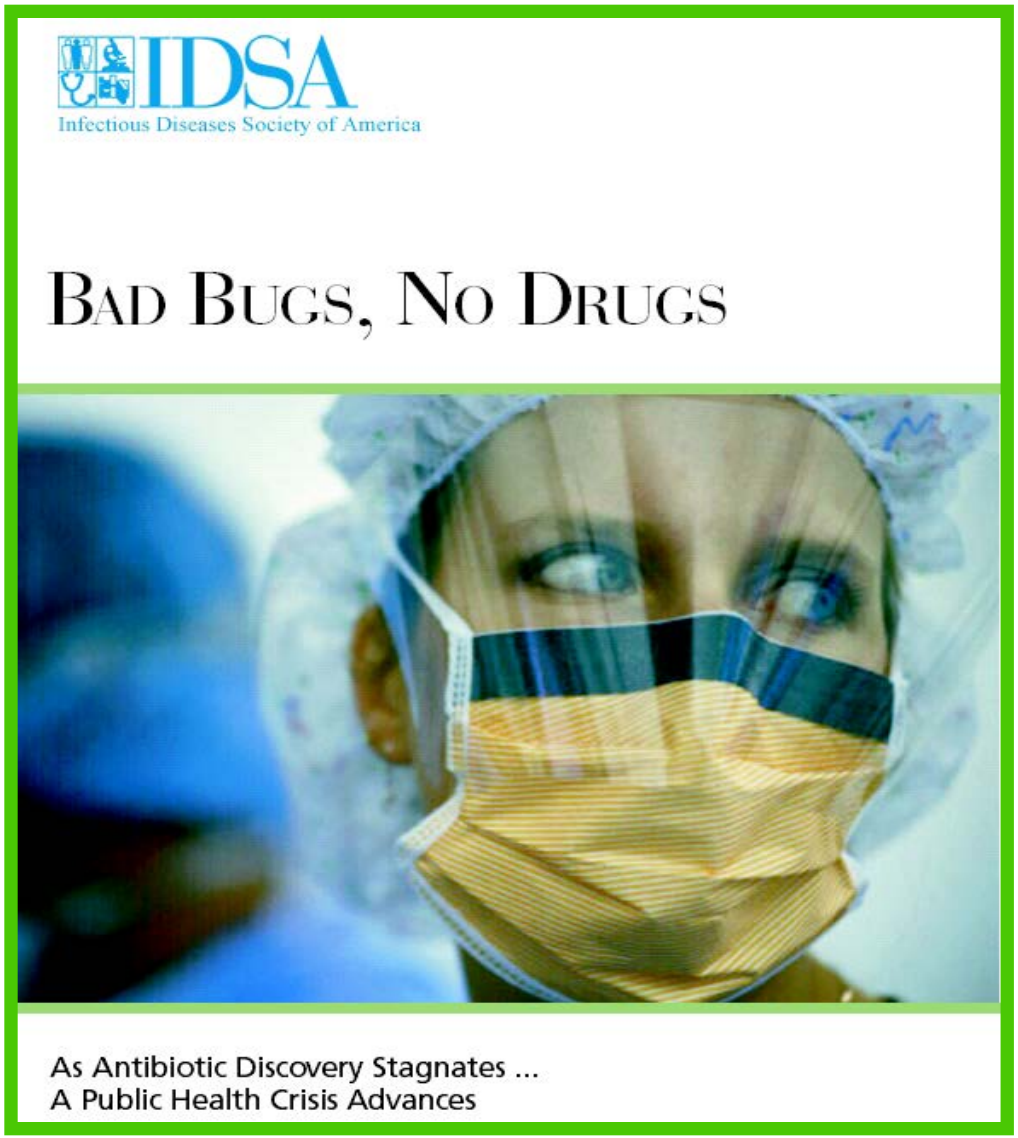
Addie Rereich, 11yo
Double lung transplant
Stroke, nearly blind
$6 million hospital bill

Declining New Antibacterial Drug Approvals, U.S.



Spellberg, CID 2004, Modified

IDSA's 2004 Report on AR



"Bad Bugs, No Drugs: As Antibiotic Discovery Stagnates, A Public Health Crisis Brews"

Bad Bugs, No Drugs: No ESKAPE 2009 IDSA Update

- Growing resistance among gram-positive and gram-negative pathogens that cause infection in the hospital and in the community
- “ESKAPE” pathogens *Enterococcus faecium*,*Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumanii*, *Pseudomonas aeruginosa*, and*Enterobacter* species)
- ESKAPE pathogens cause the majority of US hospital infections and effectively “escape” the effects of antibacterial drugs
- Antibiotic pipeline remains unacceptably lean

The 10 x ‘20 Initiative

- Global commitment to develop **10 new systemic antibacterial drugs by 2020** (CID; April 2010)

- Bring together essential leaders: global political, scientific, industrial, economic, intellectual property, policy, medical and philanthropic leaders to determine the right combination of incentives necessary to establish a sustainable R&D enterprise

State of Antibiotic R&D Remains Dire

April 2013 analysis by IDSA:

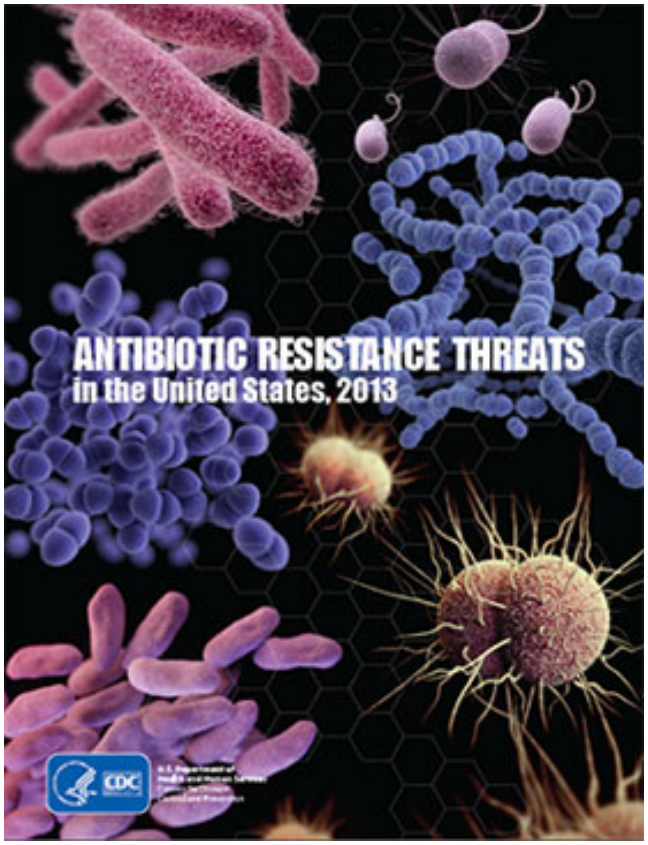
- Only seven new drugs in development for the treatment of infections caused by multidrug-resistant Gram-negative bacilli (GNB) bacteria.
- There is no guarantee that any of these will make it across the finish line to FDA approval
- None of them will work against the pan-resistant pathogens (those resistant to all current antibiotics)

Boucher et al. Clinical Infectious Diseases 2013

Status of the 10 x ‘20 Initiative

Antibiotic Resistance Threats Grow

Centers for Disease Control and Prevention (CDC) Report



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.

Carbapanem-Resistant Enterbacteriaceae

- One example of an “urgent threat” according to CDC.
- 9,000 drug resistant infections per year.
- 600 deaths per year.
- CRE bacteria have become **resistant to all or nearly all currently available antibiotics**.
- CDC laboratories have confirmed at least one type of CRE in healthcare facilities in 44 states.
- About 4% of U.S. short-stay hospitals had at least one patient with a serious CRE infection during the first half of 2012. About 18% of long-term acute care hospitals had one.
- Up to half of all bloodstream infections caused by CRE result in death.

Antibiotic-Resistant Bacteria: Economic Burden

Antibiotic resistant bacterial infections result in:

- Additional **$21-34 billion** cost annually to US healthcare system
- Additional 8 million hospital days

RR Roberts, CID 2009:49, 1175-1184;
PD Maudlin, AAC 2010:54, 109-115

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.
- Soon there will be no alternatives for these patients.

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?"

IDSA's Goal: New Antibiotics to Save Lives

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.