The Need for New Antibiotics

Amanda Jezek
Vice President of Public Policy & Government Relations

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IDSA Membership

10,000+ strong

Majority physicians providing clinical care
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

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

Tom Dukes: colostomy, lost 8” colon

www.AntibioticsNow.org
Declining New Antibacterial Drug Approvals, U.S.

 Spellberg, CID  2004, Modified
“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
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.
Carbapenem-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 bacterial infections result in:

• Additional $21-34 billion cost annually to US healthcare system
• Additional 8 million hospital days
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?”
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.