



IDS

Infectious Diseases Society of America

BAD BUGS, NEED DRUGS **U.S. Regulatory and Economic** **Incentives for Antibiotic R&D**

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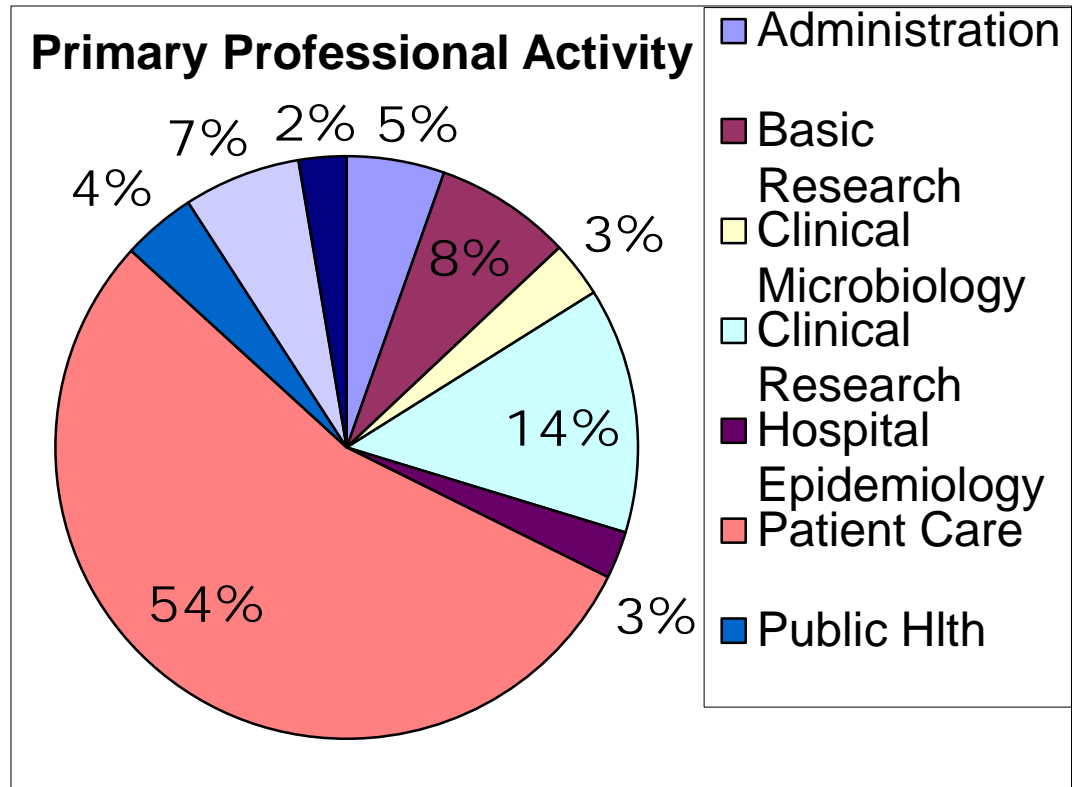
Vice President of Public Policy & Government Relations

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IDSA Membership

10,000+ strong
Majority physicians
providing clinical care



IDSA's Motivation/Perspective

Our patients need new antibiotics and stronger societal response to resistance to stay healthy and alive!

- 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's 2004 Report on AR



BAD BUGS, NO DRUGS



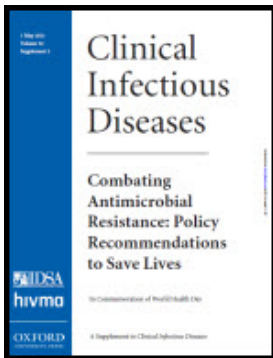
As Antibiotic Discovery Stagnates ...
A Public Health Crisis Advances

**“Bad Bugs, No Drugs:
As Antibiotic Discovery
Stagnates, A Public
Health Crisis Brews”**

Additional IDSA Reports

- “10 × '20 Progress—Development of New Drugs Active Against Gram-Negative Bacilli: An Update From the Infectious Diseases Society of America;” Boucher et al, *CID*, April 17, 2013

- The 10 x 20 Initiative, Global Commitment, April 15, 2010



- Combating Antimicrobial Resistance: Policy Recommendations to Save Lives, Spellberg, Guidos et al, *CID* supp., May 2011

- Numerous position papers focused on FDA clinical trial designs (CAP; cSSSI; HAP/VAP, superiority for MDR organisms)

Challenges to Antibiotic R&D

- **Economic**
 - Antibiotics used for short duration, held in reserve
 - Insufficient research support
 - Pricing
 - Comparisons to lifestyle and chronic disease drugs
- **Scientific**
- **Regulatory**
 - Identifying patients for traditional clinical trials
 - FDA guidance for industry infeasible

New Regulatory Pathway: Limited Population Antibacterial Drug (LPAD)



LPAD: Overview

- Critical new, rapid, voluntary antibacterial drug approval pathway
- Only for products to treat **serious or life-threatening infections** with few or no adequate current treatments
- LPAD drugs would be approved based upon **smaller, faster clinical trials**
- Not intended for products that would treat non-serious infections or infections that already have a satisfactory set of treatment options

LPAD: How It Would Work

- Sponsor would have to seek and FDA would have to approve the designation of eligible LPAD drugs
- LPAD drugs would be approved based upon **smaller, faster clinical trials**
- LPAD would **not alter the standard of evidence** required for approval of a new drug
- The benefits of an LPAD drug must be demonstrated to outweigh the risks for the indicated population
- The LPAD designation, a description of the indicated population, and an **LPAD logo** would appear in the **drug's label**

LPAD: Safeguards for Appropriate Use

- Indicated for a **narrow population** for whom the **benefits** of the drug have been shown to **outweigh the risk**
- Mechanism to collect information re: utility of the pathway (e.g. the CDC's National Healthcare Safety Network)
- Provide for submission and **FDA review of promotional materials** of products approved under this pathway
- Antimicrobial **stewardship** programs
- Opportunity for **higher pricing**
- Clinical decision-making remains in the hands of **physicians**

Antibiotic and Antifungal Drug Transferable Research and Development Tax Credit

- IDSA has always maintained that a combination of push and pull incentives are needed to revitalize antibiotic R&D
- First step: 2012 legislation (Generating Antibiotic Incentives Now/FDA Safety and Innovation Act) provides additional exclusivity for qualifying antibiotic/antifungal drugs
- Additional economic incentives are still needed to increase these drugs' net present value and incentivize R&D

Antibiotic and Antifungal Drug Transferable Research and Development Tax Credit

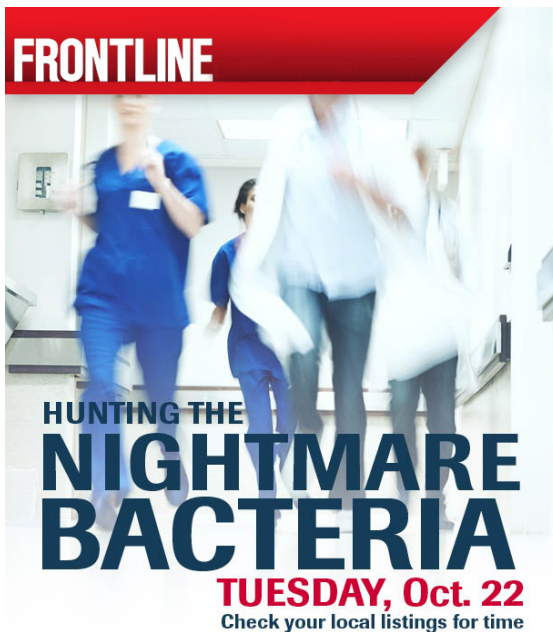
- Modeled after the basic structure of the Orphan Drug Tax Credit
- Provide a credit of **50 percent** of the qualified clinical testing expenses (phases 2 and 3) for the taxable year
- Eligible expenses must relate to a “**qualified infectious disease product**,” defined by FDASIA (antibacterial or antifungal drugs for human use intended to treat serious or life-threatening infections)
- **Unused credits could be transferred** to a qualified pharmaceutical research taxpayer, allowing smaller companies without a tax burden to utilize the credit

Tax Credit Potential Impact

- According to an analysis performed by Ernst & Young for IDSA, the new tax credit would:
 - Result in a federal government revenue loss of \$549 million over 10 years. The revenue loss would be lower if the existing research and experimentation tax credit is extended beyond its expiration date of December 31, 2013, as expected.
 - **Increase R&D spending on antibiotics and antifungals by over \$1 billion** over a 10-year period.
 - Result in **five to six new antibiotic and antifungal drugs** entering the R&D pipeline each year.

Outlook

CDC Report on Antibiotic Resistance Threats and PBS Frontline documentary on Nightmare Bacteria garnered policymaker, media and public attention.



IDSA is working to maintain the momentum and push Congress and the Administration to act.