



IIDSA

Infectious Diseases Society of America

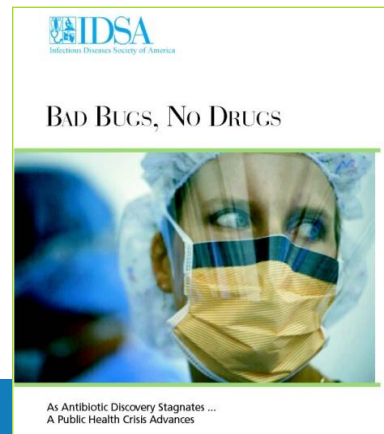
Antibiotic Resistance and the Dry Antibiotic Pipeline: Legislative Solutions



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President

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Key Steps for Congress to Address Antimicrobial Resistance and the Waning Antibiotic Pipeline

Increase funding for CDC and other federal investments

- Surveillance, data collection, antibiotic stewardship

Support the **STAAR Act**: “Strategies to Address Antimicrobial Resistance

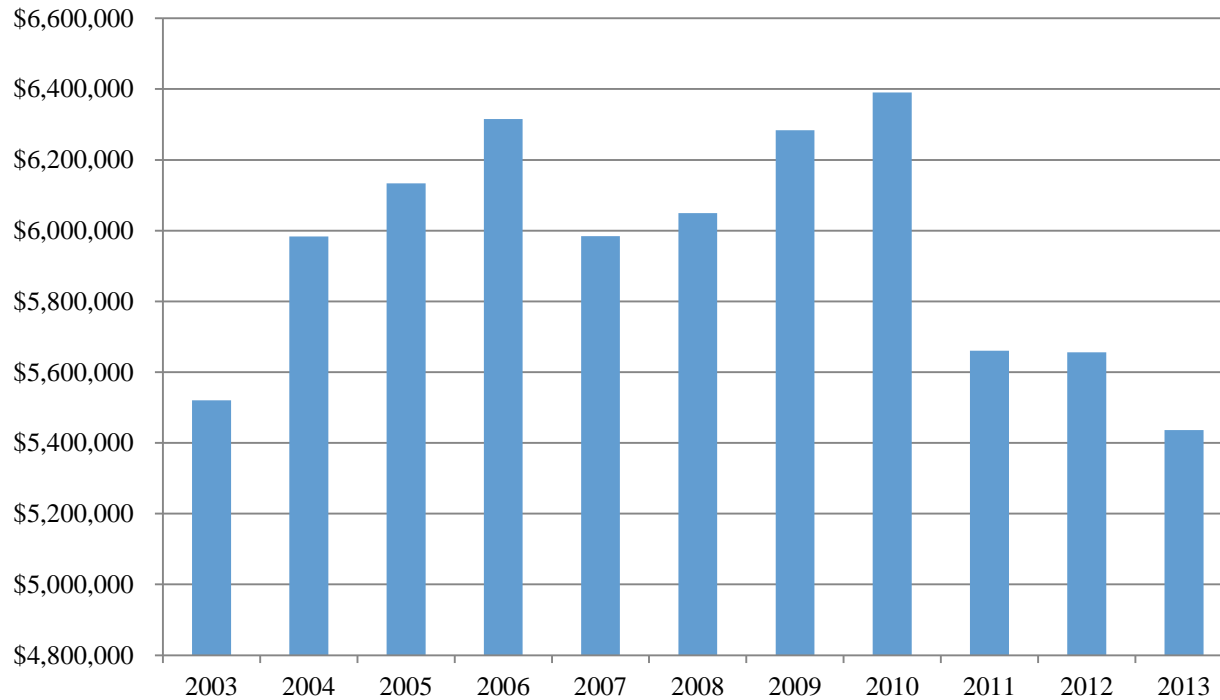
- Will strengthen federal coordination, accountability, leadership as well as support antimicrobial stewardship efforts in health care facilities

Strengthen the antibiotic pipeline

- 2012: **Generating Antibiotics Incentives Now (GAIN, exclusivity)**
- 2013: Still need additional **economic incentives (e.g., R&D tax credits)** and a **new FDA approval pathway (Limited Population Antibacterial Drug—LPAD)**

Increase CDC Funding and Other Federal Investments

- Currently lowest budget level in a decade
- Advanced Molecular Detection
- Diagnostics
- Antibiotic Stewardship



STAAR Act Provisions

Improve **coordination** and **leadership** of federal AR activities

Surveillance

- Authorize an **AR Surveillance and Laboratory Network** and additional CDC efforts to prevent resistance
- Collect **antimicrobial resistance and use data**

Stewardship

- Encourage more **appropriate use** of existing antibiotics
- Develop and test **quality measures** on antimicrobial use

Prevention

- Authorize prevention collaboratives to interrupt and **prevent the transmission of resistant pathogens** across healthcare settings

Challenges to Antibiotic R&D

- **Economic**
 - Antibiotics used for short duration, held in reserve
 - Pricing
 - Lifestyle and chronic disease drugs more profitable
- **Scientific**
- **Regulatory**
 - Identifying patients for traditional clinical trials
 - FDA guidance for industry infeasible

Reinvigorating the Antibiotic Pipeline

- Economic Incentives
- New Regulatory Approval Pathway: **Limited Population Antibacterial Drug (LPAD)**
 - Critical new, rapid approval pathway for products to treat only **serious or life-threatening infections** that currently have inadequate treatments