Antibiotic Resistance and the Dry Antibiotic Pipeline: Legislative Solutions

David Relman, MD, FIDSA
President

September 17, 2013
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