Advocacy to Combat Antibiotic Resistance and *C. Diff*

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Antibiotic Resistance: Complex Problem, Requires Multi-Pronged Solution

Advocacy

- Surveillance & Data Collection (Human & Agricultural)
- Antimicrobial Product Development (Antibiotics, Diagnostics, Vaccines)
- Basic & Translational Research (Human & Agricultural)
- Antimicrobial Stewardship; Infection Prevention & Control (Human & Agricultural)
Federal Funding to Combat Resistance

• Congress needs to provide **new funding** for federal agencies to carry forward the National Action Plan for Combating Antibiotic Resistant Bacteria.

• President’s Fiscal Year 2016 Budget Proposal
  – Centers for Disease Control and Prevention: Antibiotic Resistance Solutions Initiative ($264 million); National Healthcare Safety Network (+$14 million)
  – National Institutes of Health (+$100 million)
  – Biomedical Advanced Research and Development Authority (+107 million)

• House and Senate bills each included some, but not all, of the increased funds requested by the President.

• House and Senate must still pass a final budget for 2016, and fiscal constraints are significant.

**Advocacy from constituents—including all of you—is needed to demonstrate to Congress that the public supports funding to address AR.**
Why Do We Need New Antibiotics?

• For *C. Diff*
  – Only one new drug – Fidaxomicin - has been approved in the past 25 years
  – Approximately 20% of *C. diff* patients will have their disease recur
  – At least 29,000 people in the U.S. die as a result of *C. diff*

• Other infections caused by antibiotic resistant bacteria face urgent unmet needs as well.

• Without new antibiotics, physicians and patients increasingly having to turn to drugs of last resort, which pose significant risks for adverse events and toxicity.

• New antibiotics can offer improvements in patient safety and be better targeted (narrower spectrum) which may reduce *C. diff* risk.
New Antibacterial Drug Approvals Are in Decline

Progress in 2014-2015, but Significant Unmet Needs Remain

CID April, 2010; http://www.idsociety.org/10x20/
Challenges to Antibiotic R&D

• Economic
  o Antibiotics used for short duration, held in reserve
  o Insufficient research support
  o Pricing
  o Comparisons to lifestyle and chronic disease drugs

• Scientific
  o Identifying new classes of antibiotics and mechanisms to counter resistance – beyond the “low hanging fruit”

• Regulatory
  o Identifying patients for traditional clinical trials
  o FDA guidance for industry infeasible
## Economic Disincentives to Antibiotic R&D

<table>
<thead>
<tr>
<th>Therapy Area</th>
<th>Development ($$)</th>
<th>Development (years)</th>
<th>Price</th>
<th>Use</th>
<th>Patient pop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculo-skeletal</td>
<td>$$$$</td>
<td>++</td>
<td>↑↑↑↑↑</td>
<td>Chronic</td>
<td>Large</td>
</tr>
<tr>
<td>Neurology</td>
<td>$$$$</td>
<td>++</td>
<td>↑↑↑↑↑</td>
<td>Chronic</td>
<td>Large</td>
</tr>
<tr>
<td>Oncology</td>
<td>$$$</td>
<td>++</td>
<td>↑↑↑↑↑</td>
<td>Acute/Chronic</td>
<td>Medium</td>
</tr>
<tr>
<td>Anti-bacterials</td>
<td>$$$</td>
<td>++</td>
<td>↑</td>
<td>Acute</td>
<td>Small (specialist hospital antibiotics)</td>
</tr>
</tbody>
</table>

*David Payne, GSK, September 2011 IDSA/Pew/PhRMA conference
*Projan 2003
Scientific Challenges: Antibiotics Have High Attrition Rates

**Antibiotics:**
- 72 Leads
- 36 Candidates

**Other areas:**
- 15
- 12

**Discovery to Phase 2 attrition based on real data for 12 novel mechanism antibiotic candidates at GSK**

**Hit to Phase 2 based on novel mechanism AB discovery (GSK) Based on Paul, et al (2010), Nature Reviews Drug Discovery 9: 203-214.**

**David Payne, GSK, September 2011 IDSA/Pew/PhRMA Meeting**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>FDA Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leads</td>
<td>18</td>
<td>6</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Candidates</td>
<td>9</td>
<td>4.6</td>
<td>1.6</td>
<td>1.1</td>
</tr>
</tbody>
</table>

3-10 years 6-7 years

ONE FDA APPROVED DRUG
Congressional Action to Incentivize Antibiotic R&D

- **GAIN** of 2012 an example of success, adds 5 yrs add’l exclusivity for antibiotics treating serious, life-threatening conditions; but just a first step.

- **ADAPT/PATH** would address regulatory barriers by creating a limited population pathway, only for antibiotics filling an unmet medical need; ADAPT included in 21st Century Cures legislation in House.

- **DISARM** would incentivize development by helping improve the reimbursement environment for new antibiotics that treat significant disease threats; included in 21st Century Cures legislation in House.

- **Federal Funding** for the National Institutes of Health (NIH) and Biomedical Advanced Research and Development Authority

- **Tax credits** to support phase 2 and 3 clinical trials for new antibiotics that address an unmet need and new rapid diagnostics.

- = Passed
- = Moving
- = To be introduced
Financial Support Needed Throughout Antibiotic Development

<table>
<thead>
<tr>
<th>Action Needed</th>
<th>Support Already in Place</th>
<th>Pre-Clinical Stage</th>
<th>Phase 2 &amp; 3 Trials</th>
<th>Post-Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Funding from NIH and BARDA</td>
<td>Increased funding</td>
<td>Tax Credits</td>
<td>Increased Reimbursement Transferable Patent Extensions or Exclusivity</td>
</tr>
</tbody>
</table>
Limited Population Antibacterial Drug (LPAD) Approval Pathway (ADAPT/PATH Acts)

- For drugs to treat serious or life-threatening infections where there is an **unmet medical need**

- **Smaller, faster clinical trials;** fewer patients to make trials more feasible

- **Drug label** would clearly indicate drug is approved for a limited population

- Indicated for a narrow population of patients for whom the **benefits of the drug outweigh the risks**

- Mechanism to **monitor** the drugs’ use

- Provide for FDA **pre-review of promotional materials** for products approved under LPAD pathway

- Antibiotic **stewardship** programs
Diagnostics are Critical

New rapid diagnostic tests are crucial for combating resistance and fostering development of new antibiotics

- Guiding appropriate use of antibiotics by lessening the need to treat empirically
- Informing infection control efforts by identifying infectious patients
- Identifying patients eligible for new antibiotic clinical trials in time to impact mortality
Better Tests = New Challenges

New diagnostic face multiple challenges before they can reach patients

• High research and development costs (R&D) with insufficient federal support and financial incentives
• Access to clinical samples during diagnostic clinical trials
• Lack of physician education resources on appropriate use of new innovative diagnostics
Stimulating the Development of New Diagnostics

- Federal funding (NIH/BARDA) and tax credits to support R&D

- Biorepositories to facilitate access to clinical specimens and isolates (similar to existing NIH effort and new CDC effort)

- Federal support research to demonstrate the impact of new ID diagnostics on patient care and outcomes
Stakeholder Forum on Antimicrobial Resistance (S-FAR)

Convene
• Bring partners together to discuss individual policy priorities and to identify mutual areas of interest and collaboration

Inform
• Keep partner organizations informed about developments in federal AR policy

Mobilize
• Encourage and enable partners to engage on U.S. AR policies to drive action and achieve results
S-FAR Activities

- October 2014, inaugural meeting with over 40 S-FAR partners and over 20 guests from the U.S. government, including the White House

- 50+ S-FAR partners joined an October 2014 letter to the President’s Office of Management and Budget (OMB) supporting increased AR funding.

- February 2015 webinar to review the President’s FY2016 budget proposal for AR, with guests speakers from several federal agencies.

- 50+ S-FAR partners joined a March 2015 letter to Congress in support of full funding for the President’s FY2016 budget proposals for AR.

- May 2015 webinar with Senate staff on antibiotics legislation.

- Excel-based tracking tool to analyze progress on the CARB Action Plan milestones.

- 30+ S-FAR partners joined July 2015 letter to Senate in support of antibiotics legislation.

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.

Please join this important effort. Questions? Amanda Jezek, ajezek@idsociety.org
Impact AR and *C. Diff* Policy: Be a Citizen Lobbyist

- Importance of being a constituent
  - Your Senators and Representatives need your vote

- Role of grassroots advocacy in policymaking
  - Connect federal proposals to real people (voters) in each Senator or Representative’s state or district

- Your unique expertise
  - Put a human face on problems of AR and *C. Diff*
Citizen Lobbying—What can you do?

• Meet directly with your Senators or Representatives—or their staff—in their state/local offices or in Washington, DC
• Maintain your relationship with policymakers through relevant emails, phone calls on key policy matters
  – Encourage them to cosponsor or vote for key bills
  – Encourage them to support increased funding to address AR and C. Diff
• Local media (interviews, op-eds, letters to the editor)
• Social media
Tips for meeting with a Member/Congressional Staff

• Schedule your meeting in advance, arrive on time, thank the Member or staff person for their time
• Be concise, organized and relevant—practice and bring talking points
• Do your homework—look at your Senator or Representative’s website to better understand their priorities and positions
• Make local connections
• Consider a “leave behind” with your relevant messages
• Have a clear “ask”—what do you want your Member of Congress to do (cosponsor a bill, vote for/against something, etc.)
• Follow up
2013 Survey of Congressional Staff

Most impactful people (in order)
- Local business owners
- Constituents
- Donors
- Primary voters

Top 3 most valuable sources of information for a Member (in order)
- Local business owners
- Reports from Member’s state or district office
- Local constituents individually contacting an office

What impacts a Members’ decision?
- 85% conversations with staff
- 79% influence from local groups
- 58% constituent contact tally
- 46% local media
Other Opportunities to Get Involved

• Federal regulatory comments

• Food and Drug Administration Advisory Committees
  – Attend meetings re: new drug approvals
  – Apply to serve as a patient representative

• FDA and drug companies are starting to incorporate patients into drug development processes—stay tuned!