The 2015 Chatham House Report

Kevin Outterson

DRIVE-AB General Assembly Meeting
Uppsala University, October 15 – 16, 2015
Key question

How is the antibiotic market broken?
Peak antibiotics

EXHIBIT 2


Billions of 2013 constant dollars

12
10
8
6
4
2
0

Total
Oral
Parenteral
Lung
Other

US antibiotic sales peak

SOURCES IMS Health (US manufacturer US dollar sales at ex-manufacturer prices), and St. Louis Federal Gross Domestic Product deflator (2013 = 100).

Outterson K, Powers JH, Daniels GW, McClellan MB. Health Affairs 2015
Private NPV

- Private NPV variable across indications
- CABP has the highest private NPV & HABP/VABP the lowest
- All are relatively small markets

Figure 3: Estimated Private ENPVs by Indication for a New Antibacterial Drug (in $ Million)
Key question

Will it get better soon?
CDC infection strategy

- CRE – 9,000 estimated cases 2011; target 60% decline by 2020 through aggressive measures
- 50% decline in *c. difficile*
- Nosocomial MDR *Pseudomonas* – ↓35%
- MRSA BSI – ↓50%
- Invasive pneumococcal <5 and >65 – ↓25%

National Strategy for Combatting Antibiotic-Resistant Bacteria (White House, Sept. 2014, Table 3)
CDC Rx goals

- 20% reduction in inappropriate inpatient prescription for monitored conditions
- 50% reduction in inappropriate outpatient prescription for monitored conditions

National Strategy for Combatting Antibiotic-Resistant Bacteria (White House, Sept. 2014, at 9)
Bottom line

• Cases may decline
• Volume per case may decline
• Shrinking, unattractive market
Chatham House Working Group on New Antibiotic Business Models
Chatham House WG

• Broad ranging discussion leading to a workshop on new business models Oct. 2013
• Reports were prepared in advance for the workshop, covering all known proposals
Chatham House WG

- March 2014: new *functional* approach
- 6 subgroups, with a broad range of Members and Observers
- Iterative process
- Full day workshop in Geneva Oct. 2014
Towards a New Global Business Model for Antibiotics
Delinking Revenues from Sales

Report from the Chatham House Working Group on New Antibiotic Business Models

• 6 editors responsible for content

• Published October 9, 2015
Strategic alternatives

• Higher Prices
• Delinkage
• Hybrid models
Key Recommendations

1. Delinkage
2. Increased funding across the life cycle
3. Based on a global threat assessment
4. Global access based on medical need
5. Globally coordinated
1. Delinkage

- Delink revenues from sales volume;
- Increase total incentives for antibiotics; and
- Preserve access without regard to ability to pay.

Kesselheim AS Outterson K. Health Affairs 2010; Yale J. Health Policy, Law & Ethics 2011; Chatham House 10.2.13; Outterson. Health Affairs Feb 2015
Analogies

- Prizes
- Insurance
- Defense/Big Science
- Strategic Antibiotic Reserve
2. Life cycle funding

- **Phase**: Preclinical, Clinical, Post-registration
- **Incentives**: Research grants, Tax credits, PPP contracts, Delinkage
- **Standards**: Very broad, QIDP/PR, Threat assessment
3. Global threat assessment

Global threat assessment, data-driven, transparent, and focused on threats posed by resistant pathogens
4. Access

The delinkage business model should guarantee global access to antibiotics together with appropriate use.
Access without conservation and innovation will speed resistance

Conservation constrains access and undermines innovation

Innovation without access is unjust, and without conservation it’s wasteful

Hoffman et al. (2015)
5. Coordination

- Domestic expenditures should be coordinated within a global framework
- Important roles for global coordination, joint funding, secretariat
- Positive incentives for participation
Key question

How much money?
## Magnitude of incentives

<table>
<thead>
<tr>
<th>Model</th>
<th>Payments from Governments</th>
<th>eNPV benchmark at start of R&amp;D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharma &amp; Towse</td>
<td>$2.5 bn ($500m/yr over 5 years)</td>
<td>$300m</td>
</tr>
<tr>
<td>Eastern Research Group</td>
<td>$919m (over R&amp;D cycle)</td>
<td>$100m</td>
</tr>
<tr>
<td>O’Neill</td>
<td>$2-$4 bn</td>
<td>Not stated</td>
</tr>
</tbody>
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Rex & Outterson, 2015 (in review)
Figure 1b. Non-discounted US spending, antibiotics & all prescription drugs, US$ billions, 2009-2013

Source: IMS Health 2014.

Outterson K, Powers JH, Daniels GW, McClellan MB. Health Affairs 2015
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