Current State and Future Outlook for Pharmaceutical Risk Sharing Agreements

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AGENDA

- Rationale for New Ways for Manufacturers and Payers to Relate – *the quest for value*
- Overview of “Risk-Sharing” Arrangements – *what is the “suite” of tools and where are they happening?*
- Challenges with Risk-Sharing Agreements – *where might they flourish and where is it a bad approach?*
First, some important acknowledgments

- Key work being done in US and EU by many academics and industry experts
- Special thanks to
  - Lou Garrison and his team at University of Washington
  - Peter Neumann at Tufts University
  - Adrian Towse in UK at the Office of Health Economics
  - EU-wide team (Adamksi et al) behind 2010 BMC article
Why Are Risk Sharing Agreements Springing Up?

Two Avenues to Explore

Quest for Value

Desire to Change the Way Two Powerhouses Relate – “Expanding the Pie”
Driving the Quest for Value

- Soaring health care costs; well beyond ability to manage and projected to continue trend
  - Aging population
  - Increasing innovation
  - Demands for choice; sense of entitlement (in US)
  - Administrative hurdles to reining costs in
- Specialty pharma is especially difficult to manage (as we heard from Dr. Robinson earlier)
- Resources limited and under microscope
  - Austerity programs
  - Linkage to national budget deficits and debt loads
  - Crowding out of other key social programs (education, social security)
So it is a Noble Quest

But, What is Value & How Do We Know it When We See It?

Can be very hard to find – much like the legend of the mythical Fountain of Youth
Challenges with Focusing on Purchasing Value

- Myriad of definitions; subjective
- Stakeholder perspectives may never easily align to come to simple agreement
- Evolving with increasing innovation, evidence base (biomarkers?)
- Non-transparent
- Requires a more complex interaction and higher degree of trust
  - In both product and capabilities/patient outcomes
  - In predictability of sales/volume, adherence, physician behavior
  - In the future market and economic context

*So, both sides must consider a change in the conversation*
Old Pharma-Payer Paradigm: Positional Bargaining

Parties as adversaries

Goal = victory

Push for concessions

Dig into position

Apply pressure

Look for one-sided win
Downsides to Positional Negotiating

- Inefficient
- May produce unwise agreements
- Potentially endanger ongoing relationships
- Takes many potentially interesting ideas/topics off the table
- May not even lead to a conclusion
Potential driver for increased focus on pharma-payer risk sharing: Moving toward principled negotiation

1. Focus on interests not positions
   - negotiating positions obscures what you actually need
   - focusing on interests avoids being forced to compromise

2. Identify solutions for mutual gain

3. Insist on objective criteria

4. Know best alternative to an agreement

5. Analyze bargaining power carefully

(Fisher & Ury)
Why Pharma Willing to Change the Conversation

- Sales at risk due to patent expiry
- Harder line by payers – cost pressures increase
- Weak R&D pipelines
- Push to keep list prices at certain level and some elements of agreements confidential
- Net result: Decline in portfolio regeneration

![Mind the gap chart](chart.png)

Gaps between patent exposure (age weighted, next three years) and pipeline quality at the end of 2011, %
Why Payers Willing to Change the Conversation

- Seek new ways to both hold down/reduce costs AND maintain access for patients to innovative therapies
- Seeking to shift some risk to manufacturer and increase predictability
- Gain visibility and transparency; decrease uncertainty
These phenomenon unlikely to reverse so need to explore other ways to interact, collaborate and tackle issues for mutual benefit
Key Elements of Performance-Based Risk-Sharing Arrangements, (Garrison et. al)

1. There is an agreement about a program of data collection to reduce uncertainty about the expected cost-effectiveness of the drug (or device or diagnostic).

2. The coverage, price, and/or revenue is linked to the outcome of this program of data collection. This may be prospective or retrospective.

3. It can be about health outcomes and cost-effectiveness or about budgets.

4. These arrangements provide a different distribution of risk as between the payer and the manufacturer than “conventional” arrangements*.

* de Pouvourville EJHE, 2006
Risk Sharing Arrangements - Really a Suite of Responses

Performance-based schemes between health care payers and manufacturers

Non-outcomes based schemes

- Population level
  - Market share
  - Price volume
  - Utilization caps
  - Manufacturer funded treatment initiation

Patient level

Health outcomes-based schemes

- Conditional coverage
  - Coverage with evidence development (CED)
    - Only in research
      - Ex: Cochlear implants in US (CMS)
  - Conditional treatment continuation (CTC)
    - Only with research
      - Ex: Risperidone in France
  - Outcomes guarantee

- Performance-linked reimbursement (PLR)
  - Pattern or process of care
    - Ex: OncotypeDx in US (United Healthcare)
  - Clinical Endpoint
    - Ex: Bortezomib in UK
  - Intermediate Endpoint
    - Ex: Simvastatin in US

Garrison, et al.
Performance-based schemes by year

CED: Coverage with evidence development; CTC: Conditional treatment continuation; PLR: Performance linked reimbursement; FU: Financial or utilization based agreements

Garrison, et al.
Performance-based schemes by country

CED: Coverage with evidence development; CTC: Conditional treatment continuation; PLR: Performance linked reimbursement; FU: Financial or utilization based agreements

Garrison, et al.
Examples in the US

- More limited vs. what is seen in EU
- Also facing highest drug prices; powerful forces to maintain them

* Peter Neumann, et al.  Health Affairs Dec 2011

<table>
<thead>
<tr>
<th>Program</th>
<th>Partners</th>
<th>Year</th>
<th>Agreement type</th>
<th>Outcome metric</th>
<th>Notes/challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lucentis (ranibizumab) for macular degeneration</td>
<td>Novartis/National Health Service (UK)</td>
<td>2008</td>
<td>Dose cap at 14 injections, after which drug company pays for product</td>
<td>Visual acuity</td>
<td>Clear criteria for reimbursement</td>
</tr>
<tr>
<td>Actonel (risedronate) for osteoporosis</td>
<td>Warner Chilcott/Health Alliance (US)</td>
<td>2008</td>
<td>Drug company gives rebate to health plan based on fractures incurred while patients are on the drug</td>
<td>Fractures confirmed with x-ray</td>
<td>Need for data collection and coordination by health plan</td>
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<tr>
<td>Januvia/Janumet (sitagliptin/sitagliptin with metformin) for diabetes</td>
<td>Merck/Cigna (US)</td>
<td>2009</td>
<td>Drug company discount is increased if HbA1c values improve in 1 year for patients on any oral diabetes therapy</td>
<td>Blood glucose control plus adherence to therapy</td>
<td>Outcomes cannot be attributed solely to Januvia/Janumet</td>
</tr>
<tr>
<td>Velcade (bortezomib) in multiple myeloma</td>
<td>Johnson &amp; Johnson/National Health Service (UK)</td>
<td>2006</td>
<td>Drug company reimburses insurer for the first 4 cycles of treatment if there is no patient response</td>
<td>25% or greater reduction in serum M protein</td>
<td>Valid biomarker has helped, but administrative complexity remains</td>
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<tr>
<td>Beta-interferons for multiple sclerosis</td>
<td>4 firms/National Health Service (UK)</td>
<td>2003</td>
<td>Initial discount plus price adjustments if results are 20% more or less than initially projected over 10 years</td>
<td>Expanded Disability Status Score</td>
<td>Long time frame; administrative burden and cost; low adherence</td>
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Challenges for risk sharing arrangements

- To share risk, you have to really understand it
- Can be difficult to effectively map out then model all the flows and eventualities; define what is success for a particular therapy
  - Especially when it comes to off-label usage of high cost specialty drugs
- High degree of administrative complexity
- The agreement itself could change behavior – all the unintended consequences that can alter outcomes (financial and performance)
- Needs to move beyond “creative discounting” to true sharing of risk – that requires a more open, interest based dialogue or partnership could be damaged
- Can have “free rider” issues
“The policy of being too cautious is the greatest risk of all”

Jawaharlal Nehru
THANK YOU

QUESTIONS?
Core Research Areas:
- Payment Reform and Benefit Design for High Cost Services
- Consumer Cost Sharing
- Coverage Policies for Specialty Drugs and Devices

Educational Programs:
- Academic Content for UC Berkeley Graduate Students
- Professional Development Programs for Industry