At the Intersection of Payers, Providers and Pharma
Ultimately, It’s About the Data

Roger Longman
IF COST-CONTAINMENT WERE THE CENTER OF THE HEALTHCARE UNIVERSE…

- Forces have been mostly centrifugal…
  - Physicians, providers lived on fee-for-service economy
  - Insurance was largely pass-thru, credit-card business
  - Employers had little influence (particularly when economy was robust and they were afraid employees would resent hc restrictions)
  - Pharmas chased physician decision-makers
  - Insured patients saw few medical consequences to medical decisions
  - Uninsured patients…didn’t get healthcare

- …but are turning centripetal
  - Providers taking on risk for cost and quality
    - Thx to ACA and employers more willing to share costs with employees
  - MDs becoming employees…aligning with goals of provider-employers
  - Payers responding to employers & provider trends by taking on new risk-sharing models; looking for new biz to Medicare and Medicaid
  - More insured patients…and more insured patients in hi-deductible/cost-sharing plans
  - Pharma chasing payer and provider decision-makers…not just physicians
SIGNIFICANT CHALLENGES TO PAYER BUSINESS MODELS

- Large payers trying to simultaneously manage
  - Horizontal consolidations to build Medicare & Medicaid businesses…
    - Aetna/Coventry, Wellpoint/Amerigroup, Cigna/Wellspring
  - Diversifications into new consumer, medical management and data businesses…
    - Payers become providers…e.g., CareMore, Humanicares
    - Payers become consumer companies…1-800-Contacts; Intricon hearing aids; I-Triage; Costco
    - Payers become data companies…Optum, HealthCore, Anvita, Humana’s Competitive Health Analytics

- Providers as payers…with more at stake
  - Indirectly via bundled payments (accountable care, medical home, episodes of care)
    - 221 ACOs as of May 2012 (Levitt Partners)
  - Directly
    - 20% of networks now offer insurance product; 20% considering doing so
Since healthcare costs are theoretically driven by procedures, do drugs count? Yes.

- Total drug spend now >20% of total healthcare spend for commercial insurers
- Most of overall healthcare expenditure increase accounted for by new/specialty drugs
- Specialty drug costs growing 10-15%/year (overall healthcare spending growth 3.5 - 4%)
- Most new drugs are high-cost or specialty drugs (e.g., more than half of approvals in 2012)
- Accurate forecasting of drug spend crucial to managed care economics, customer-attraction and –retention – but very difficult to budget
# The Drug at the Intersection of Payer, Provider, Patient & Pharma

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2015</th>
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<tbody>
<tr>
<td><strong>Payer Definition</strong></td>
<td>Indemnity insurer &amp; benefits mgr, self-insured employer, government</td>
<td>Also risk-sharing providers and insured and uninsured patients</td>
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<tr>
<td><strong>PBM</strong></td>
<td>Lowest ingredient cost, make money on generics, “specialty” meds</td>
<td>Given customer changes, will they have to worry about drug’s effect on total hc cost?</td>
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<tr>
<td><strong>Physician Role</strong></td>
<td>Self-employed free agent incentivized by fee-for-service</td>
<td>Employee incentivized to lower cost, improve quality (MD &amp; payer interests aligned)</td>
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<tr>
<td><strong>Product Launch</strong></td>
<td>Broad after satisfying regulatory requirements</td>
<td>Provisional &amp; incremental as satisfies multiple levels of regulatory and comp. effectiveness requirements</td>
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<td><strong>Unit of Value</strong></td>
<td>Always individual product</td>
<td>Increasingly regimen/pathway</td>
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<tr>
<td><strong>Pricing</strong></td>
<td>Value to MD, patient – neither of whom generally pays for drug.</td>
<td>Value to payer</td>
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<td><strong>Evidence Directed to</strong></td>
<td>Physician</td>
<td>Payers and their vendors</td>
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But...
**GETTING CLOSE**

- MDs less willing to fight formulary restrictions…tho bumps in the road
  - United switches Januvia for Onglyza…with quick, dramatic share loss for former, gain for latter
  - United step-edits Humira behind other TNFs…share loss not as dramatic

- Memorial Sloan Kettering and Zaltrap

- Pathways
  - Virtually equivalent multi-drug regimen outcomes in hep C from Abbott, Gilead
  - Cancer: Most payers feel pathways can reduce oncology costs between 6-20% depending on tumor type
    - How does contracting change when drugs compete to join multi-drug regimen?

- Change physician payment incentives
  - From drug price+% admin fee (higher the drug price, the higher the fee) to fixed admin fee (same $....but no incentive to use high price drug)
Pharma increasingly worried because majority of major launches since 2008 have -- at best -- underperformed expectations

- Lilly (Effient)
- Bristol (Onglyza)
- AstraZeneca (Brilinta)
- Dendreon (Provenge)
- J&J (Simponi)
- Merck (Saphris, Bridion, Victrelis)
- Amgen (Prolia)
- Sanofi (Multaq)
- BI (Tradjenta, Pradaxa)
- Novartis (Fanapt, Gilenya)
- Purdue (Intermezzo)
- GSK/HGS (Benlysta)
The new math for drug company launches

- Regeneron’s Eylea vs. Novartis/Genentech’s Lucentis
  - Eylea total cost is significantly less than Lucentis
  - Regeneron’s post-marketing trial shows Eylea as good as Lucentis
- Regeneron/Sanofi’s Zaltrap vs. Roche/Genentech’s Avastin
  - Zaltrap is significantly more expensive than Avastin
  - No comparative effectiveness trials vs. Avastin in advanced colon CA
- Actelion’s Opsumit vs. Actelion’s Tracleer in PAH
  - Osumit tested against placebo…theoretical dosing advantage vs. Tracleer
  - Product not yet approved…but Actelion needs to replace genericizing Tracleer with product driving greater revenues. Probably no CE trial.
**Theoretically, payers like new technology...**

- When real world evidence/outcomes data supports it
- When it significantly improves patient care
- When it saves total healthcare costs
- If it can do all this within churn period
- And if independent PBMs not dominant formulary decision-makers
THE GOOD NEWS FOR ACCEPTANCE OF NEW DRUGS...

- Churn rates important but probably growing less important...
  - Consolidation at top means fewer plans to churn to
  - More shared-risk health systems with incentives to attack overall health costs & improve quality
  - But most plans we speak with still counting on three-year horizon
- More major PBMs controlled by payers – so theoretically concerned with more than ingredient cost (but market share itself still concentrated among independents)
  - Optum, Prime, Humana Pharmacy
- Employers increasingly interested in pharmacy issues
- Increasing use of IT, EHRs, etc.
  - Or will they just increase the game of up-coding?
IN THE PAST, CE HASN’T OFTEN BEEN VERY EFFECTIVE

- ALLHAT, CATIE, SPORT, COURAGE…little or no change in practice
- Many gored oxes (e.g., interventional cardios hated COURAGE)
- 3 key biases…confirmation ("that’s not what I expected"); pro-intervention ("do something"); pro-technology ("that’s cool")

*SOURCE: Health Affairs 10/2012, “5 Reasons That Many CE Studies Fail to Change Patient Care…”*
The evidence problem

- Even if they wanted to (which they sometimes don’t) pharms often can’t, for regulatory or economic reasons, provide evidence payers want from pivotal trials
  - E.g., standard-of-care (what will SOC be in the future…when drug is on the market?) powered for superiority (higher risk and higher cost) against an endpoint accepted by the FDA
- No evidentiary standards for non-or quasi-randomized observational studies, registries, etc.
- Bureaucratically difficult within payers to agree on definition of total healthcare savings…or how to achieve them
  - Drug/medical benefit split: pharmacy and medical director still often have different budgetary priorities
  - If adopt more cost-effective drug, what is plan giving up relative to rebates?
  - Total cost savings by when?
WHERE WILL CE COME FROM?

- Pharma delivers most of it…
  - Generally can’t promote results thx to “substantial evidence” standard
  - Payers and physicians very skeptical of industry research
  - Why create evidence that can harm sales?
- US government will do considerably more
  - PCORI: $500M/yr until 2019…very broad “condition neutral” research agenda. Time to results…s-l-o-w.
    - Criteria for funding different from AHRQ & NIH (e.g., important to patients)…and can be very different from what payers, pharma might like
    - Any gov’t study on cost-effectiveness is politically challenging
- Academics?
- Commercial payers?
Payers & their vendors? Less likely.

- Major payers themselves…
  - Margins probably don’t permit significant additional R&D expenses
  - Why invest in research that will benefit competitors (free rider effect)?
- PBMs…
  - Have broad customer base over which to leverage investment (and thus minimize free-rider disadvantages)
  - But most are highly focused on price
A CAUTIONARY TALE: MEDCO AND COMPARATIVE EFFECTIVENESS

- Medco Research funds trials on smarter use of existing or soon-to-be generic, e.g.,
  - Warfarin study
  - Effient/Plavix study
- Medco loses United business, other accounts…and lower-cost provider Express Scripts acquires
- Express Scripts shuts down Medco’s research operation
EVEN IF CE DATA CONSISTENTLY AVAILABLE, UNLIKELY IT WILL BE USED IN CONSISTENT AND TIMELY FASHION

- Most P&T Committee processes are slow and inconsistent
  - Many mid-size payers outsource formulary to PBMs
  - Providers haven’t in past had to focus on formularies as essential cost- and quality management tools

- Improved decision-making will require smart vendors focused on solving practical evidence problems allowing plans and providers to take immediate steps to increase likelihood of cutting costs and improving quality
If CE not available at or shortly after launch, what will incentivize development of valuable new technology?
PERSONALIZED MEDICINE COULD ENCOURAGE UPTAKE OF IMPORTANT NEW MEDICINES...
BUT HARDLY STRAIGHTFORWARD

- Payers want to restrict use of new drugs to patients for whom therapy most likely to work
  - Effectively restrict widespread ineffective use of drugs – eg anti-TNFs in RA
  - The Xalkori conundrum: test 100% of patients to use drug in tiny percentage of them
- Rx companies want Dx price low; Dx companies want Dx price high
- Providers/payers not used to paying for information
- Dx companies struggle to find a model in the cost-avoidance market (% of spend averted?) when in fact Dx can increase cost
Pricing incentives

- Getting payers to play: Coverage with evidence development
  - Reimburse at negotiated price if ongoing randomized trial compares drug to standard of care
- Dynamic/segment-specific pricing
  - Price drugs higher for certain situations/indications than others (e.g., higher for late-stage breast cancer than adjuvant setting if drug in late-stage breast has proven significantly better than comparators while merely comparable in adjuvant setting)
WHOLLY NEW INCENTIVES…

- Government increases exclusivity incentives around key development targets for 1st in class products in totally underserved indications (maybe use FDA’s “breakthrough therapy” designation?); drugs would have to meet specified clinical/outcomes hurdles
  - E.g., obesity drug showing weight loss >20%
  - Other areas…antimicrobials, Alzheimer’s, CHF, diabetes…
  - Basis of pricing would have to be pre-agreed
- Commercial payer/pharma collaboration on new product of major potential value
  - Payer pre-agrees to reimburse if drug hits particular endpoints
  - Payer provides claims data, development advice
  - If drug approved, payer gets royalty on total sales