BERKELEY CENTER
FOR HEALTH TECHNOLOGY

Current State and Future Outlook for Pharmaceutical Risk Sharing Agreements

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Kimberly MacPherson, MBA, MPH
Program Director, Health Policy & Management
Co-Director, Berkeley Center for Health Technology
University of California, Berkeley

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

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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

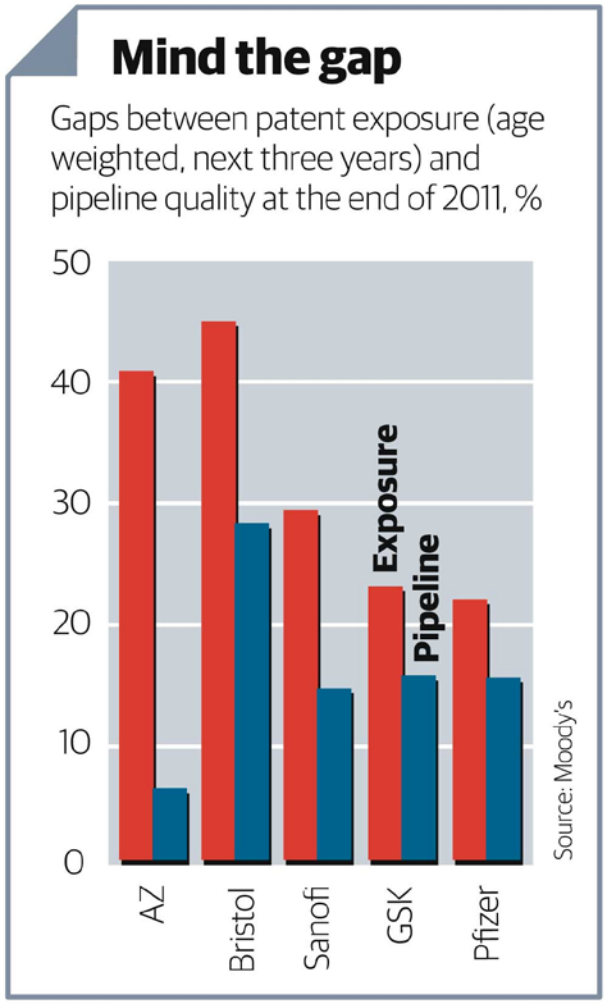
Potential driver for increased focus on pharma-payer risk sharing: Moving toward principled negotiation

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)

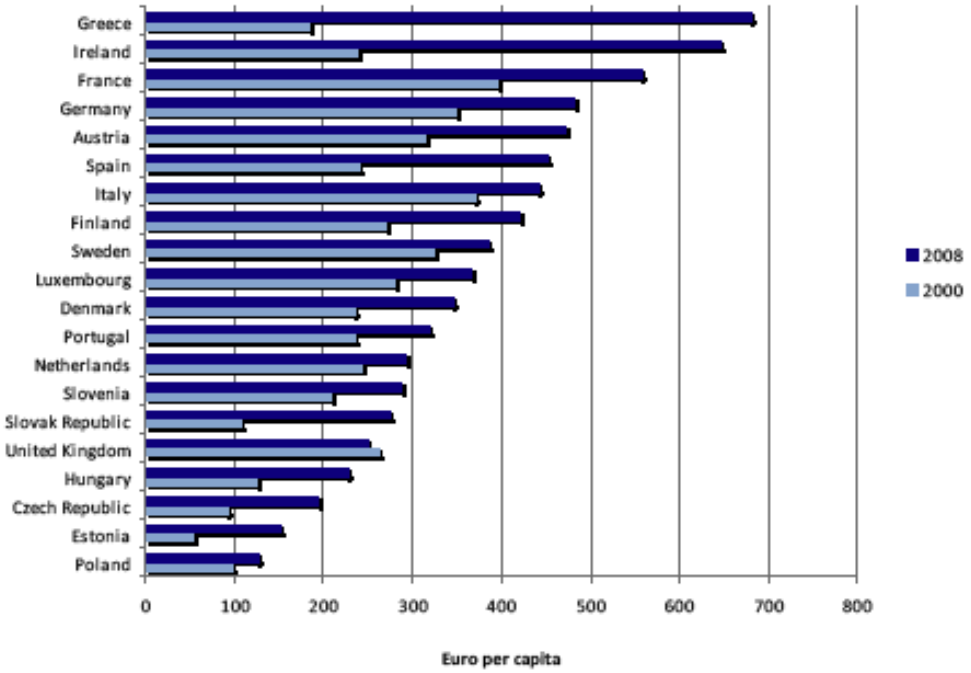
Why Pharma Willing to Change the Conversation

- 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



Why Payers Willing to Change the Conversation

Figure 4: Total Pharmaceutical expenditure per capita (Euro), 2008 compared to 2000



- 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

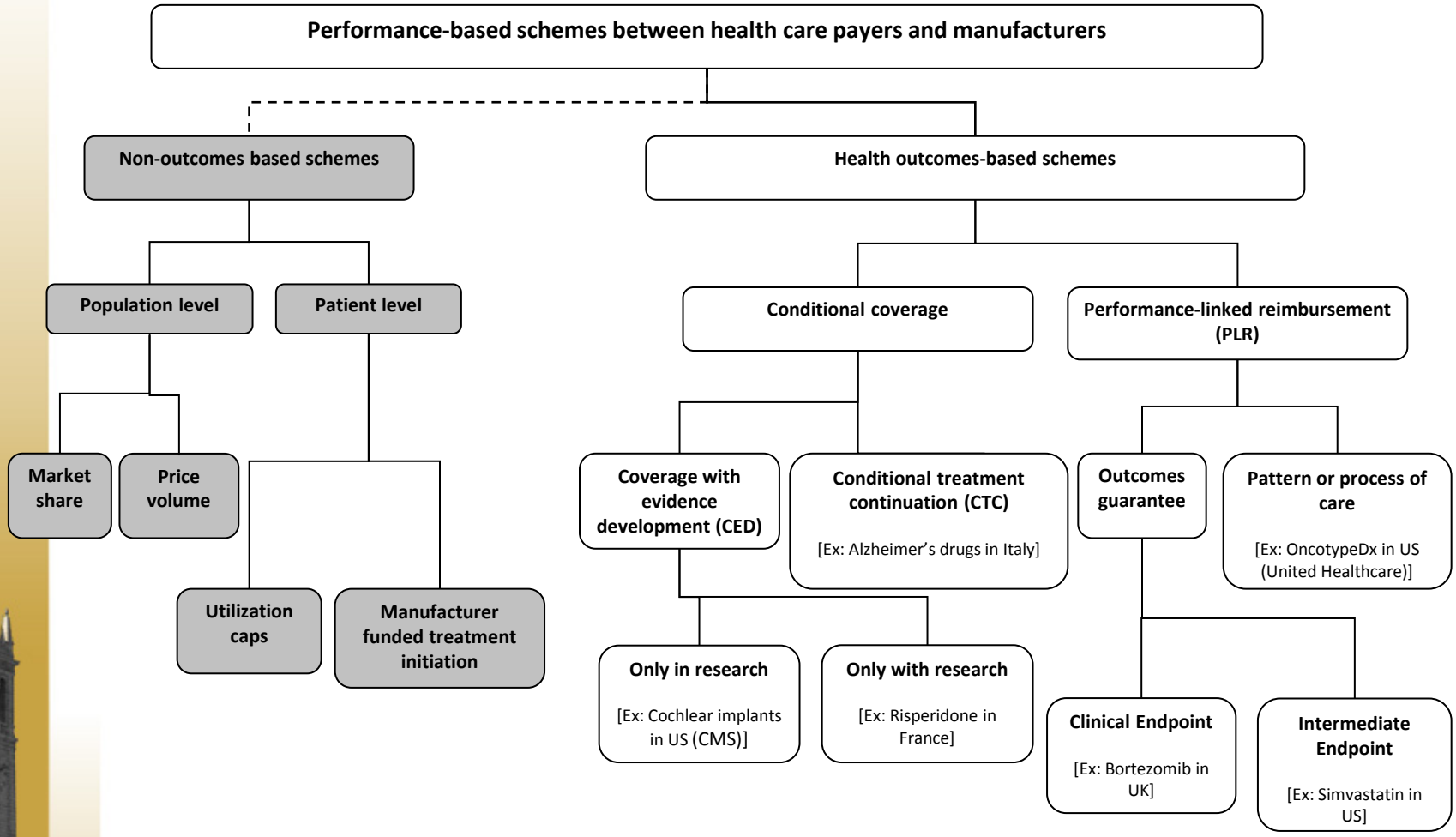
These phenomenon unlikely to reverse so need to explore other ways to interact, collaborate and tackle issues for mutual benefit

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*.

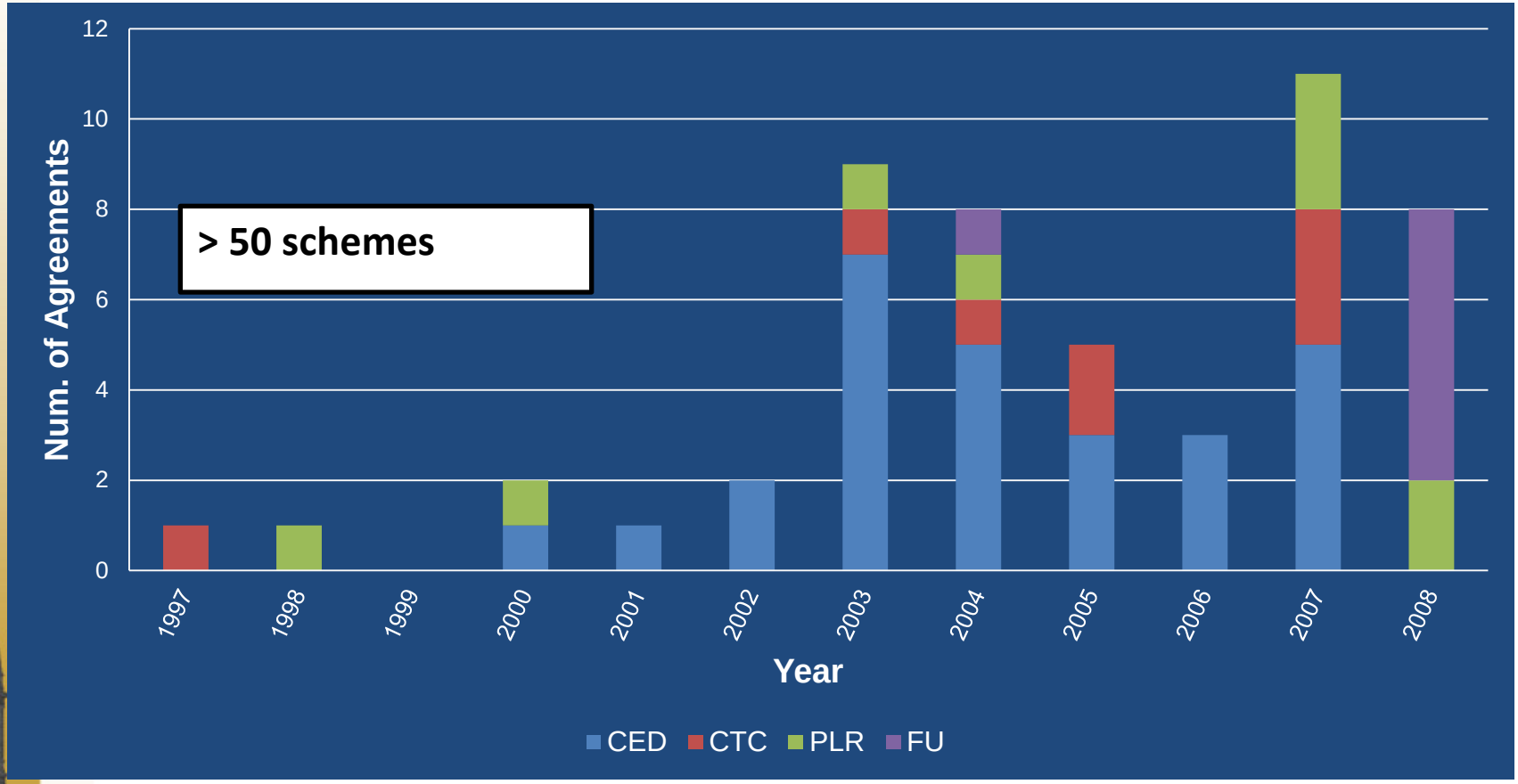
** de Pouvourville EJHE, 2006*

Risk Sharing Arrangements - Really a Suite of Responses



Garrison, et al.

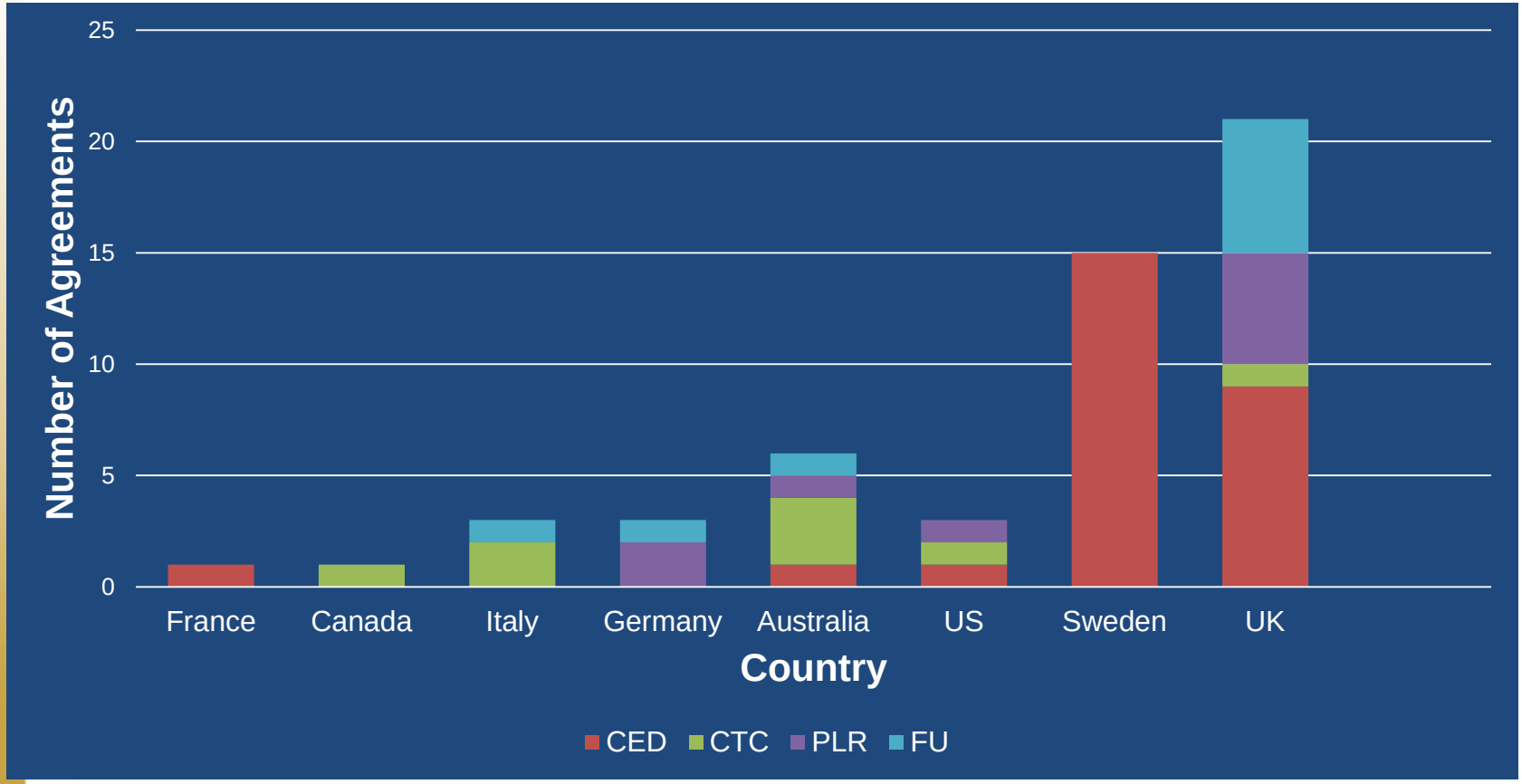
Performance-based schemes by year



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



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Garrison, et al.

Examples in the US

Selected Pay-For-Results Agreements For Biopharmaceuticals *

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

- 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

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?

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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

Berkeley Center for Health Technology
300 Lakeside Drive, Suite 1980, Oakland, CA 94612
510.281.5617 • **bcht.berkeley.edu** • bcht@berkeley.edu

School of Public Health

University of California Berkeley