

Optimal Risk-sharing between Developers and Payers for New Medical Technologies

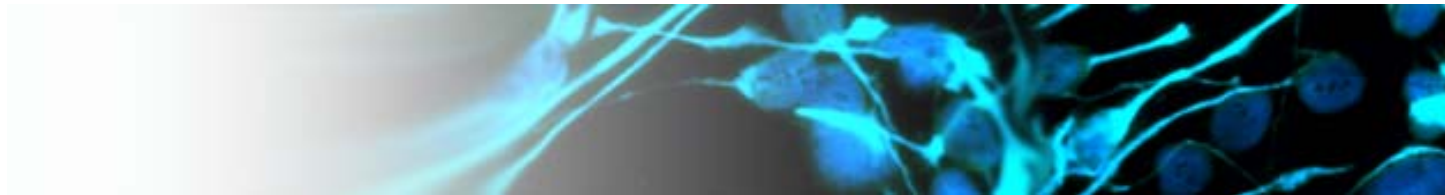
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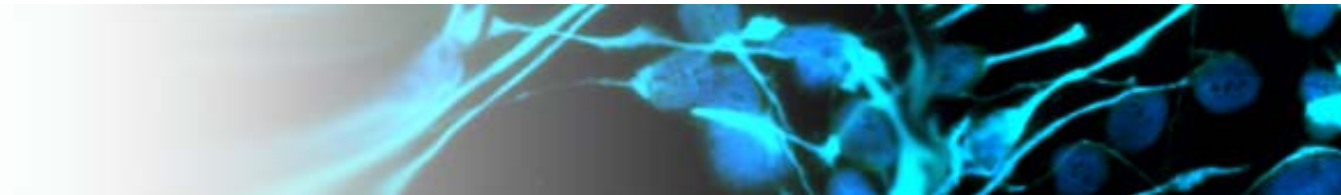
Agenda

- Increasing trend towards use/no use decisions at launch on cost-effectiveness grounds
- Issues at launch
- Expected value of information approaches
- A risk-sharing approach
- Can we bring the two approaches together?
- Experience?



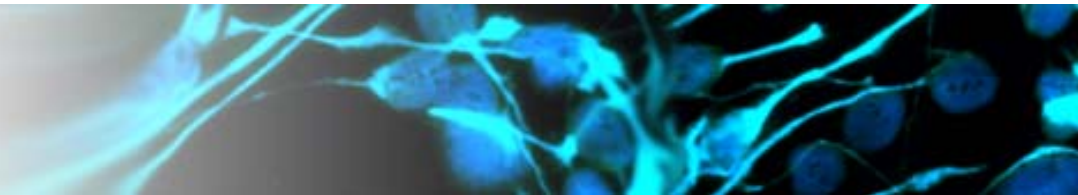
Payer assumptions

- Inefficient to adopt if new technologies are not value for money
- This presupposes:
 - (i) someone to make “cut-off” decisions - there is an agreed value of k
 - (ii) bias against adoption?
 - (iii) evidence is available at launch to make the right decision



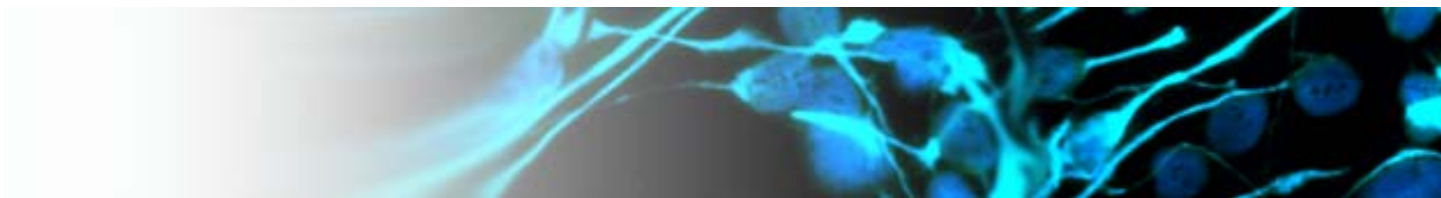
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- Increasing trend towards use/no use decisions at launch on cost-effectiveness grounds
- Issues at launch
 - why the bias against adopting new treatments?
 - problems in measuring cost-effectiveness at launch
- Expected value of information approaches
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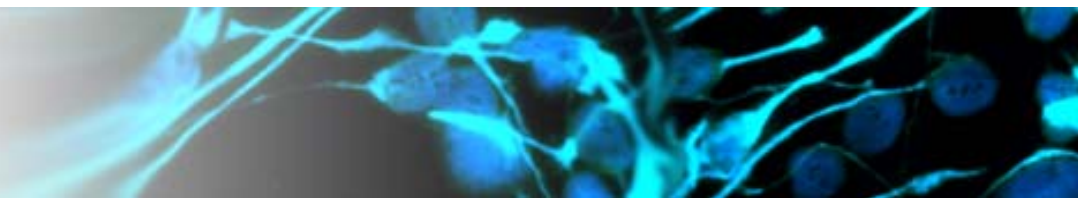
Why the bias against adopting new treatments?

- Bias against adoption - type I errors are of greater concern than type II errors.
- Historical accident of current practice is irrelevant
- Budget impact?
- Problem of irreversibility



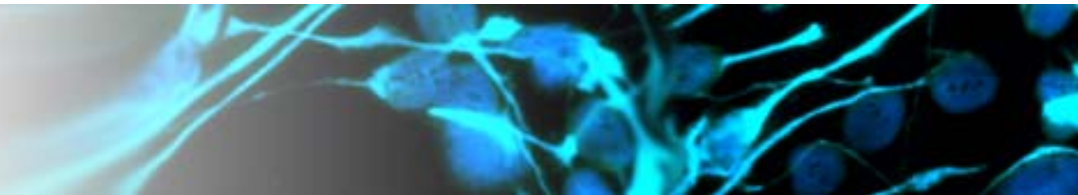
Irreversibility and the use of options (Palmer and Smith, JHE 2000)

- “if there was no such “implementation cost” then policy makers could, if necessary, costlessly switch between technologies as new evidence becomes available. The concern with uncertainty and reversibility suggests that decision-makers are seeking some reassurance that the policy they are implementing is sustainable, because it cannot be reversed without costs.”



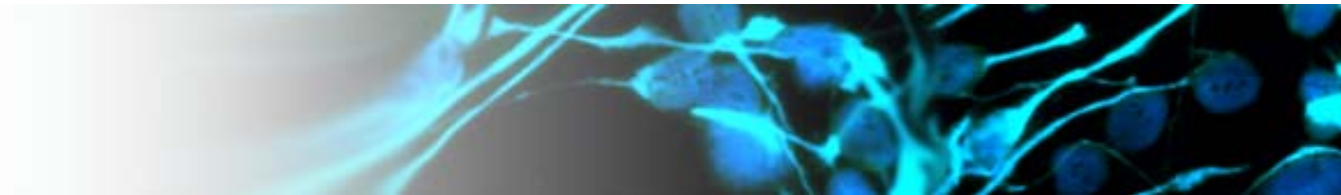
Irreversibility and the use of options (Palmer and Smith) (ii)

- What are the sunk costs?
 - changing service delivery /managing patients
- Are there other (reputational?) costs?
 - conceding that it is the “wrong” treatment?
 - high visibility to a rationing decision?
 - doctors refuse to switch back (value of HTA?)
- Use of real options approaches to value



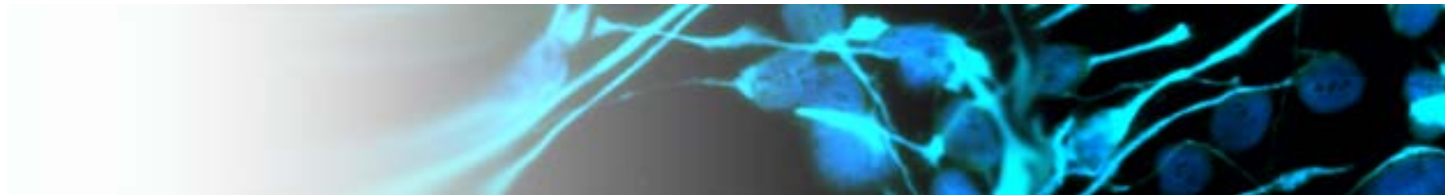
Problems in measuring cost-effectiveness at launch

- Phase III trials plus modelling
 - Real clinical setting
 - Relevant comparators
 - Clinical end point/ bio marker to quality and quantity of life
 - Longer term outcomes
 - Relevant sub-groups
- Asymmetry of information
- Health technologies are “experience goods”



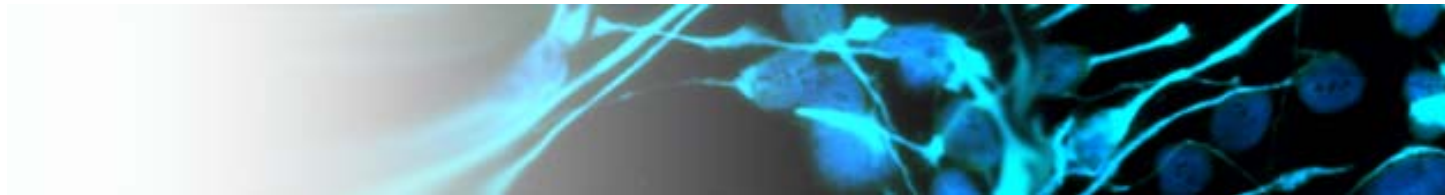
Tackling asymmetry of information

- Payer collection of pre-launch information not feasible
- Detailed guidelines
 - but Hill et al JAMA 2000, Baladi et al, HE 1998, Anis & Gagnon, PE 2000



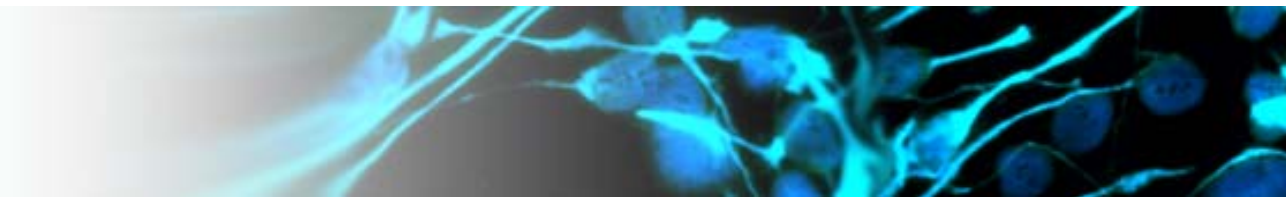
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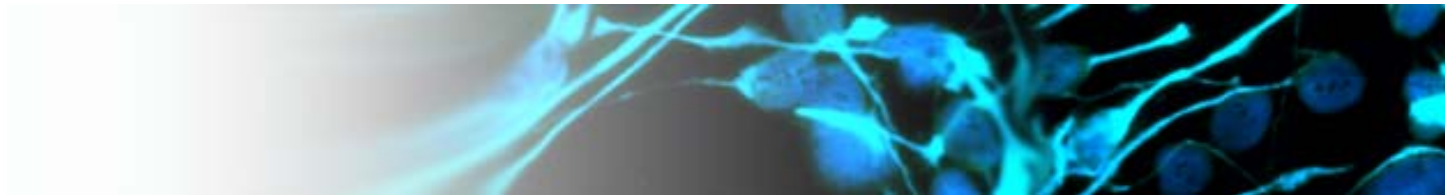
Uncertainty and the Value of Information

- Information helps us know whether we are doing the right thing, i.e. using a cost-effective treatment
- It does this by reducing uncertainty, i.e risk we are not doing the right thing, relative to “something else”
- But collecting information costs money – how much to collect depends on costs versus benefits (reductions in uncertainty)
- Expected opportunity loss = expected value of perfect information (EVPI) provides framework

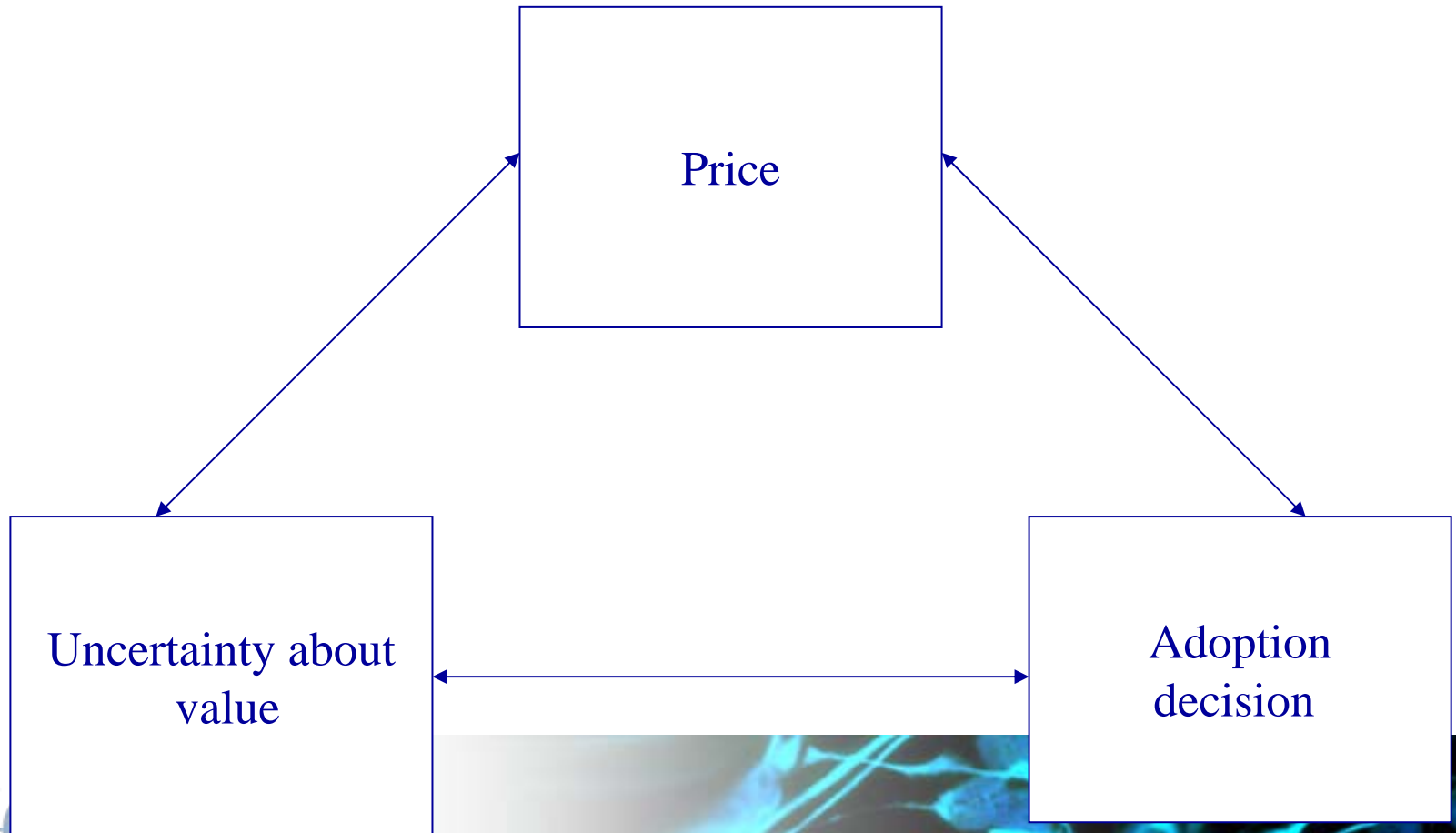


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A risk-sharing approach

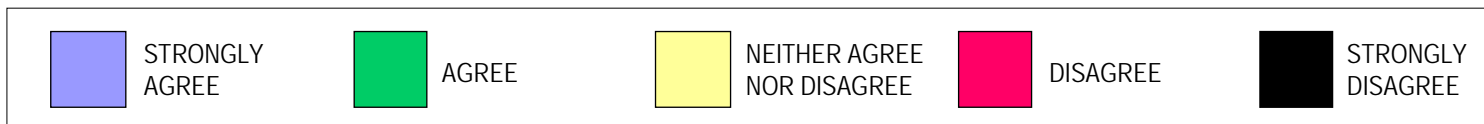
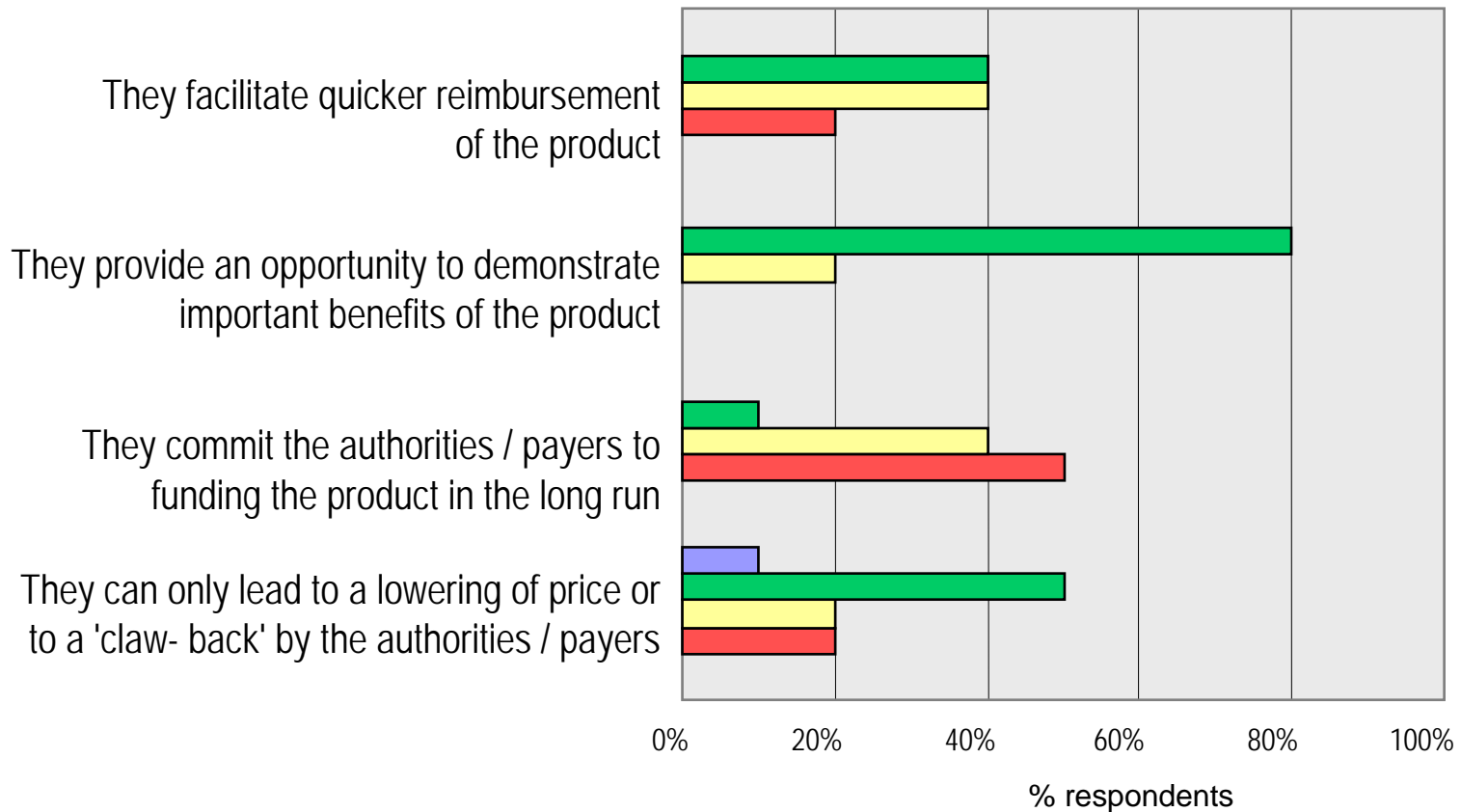


A risk-sharing approach

- Payer and company agree contract to divide up the benefits and costs
 - Bargain about price, one party is price taker (sets cost-effectiveness threshold), or agree price linked to net benefits
- Link uncertainty to performance via this contractual arrangement
 - Post launch monitoring and review
 - Compensation or share of ex post losses / gains

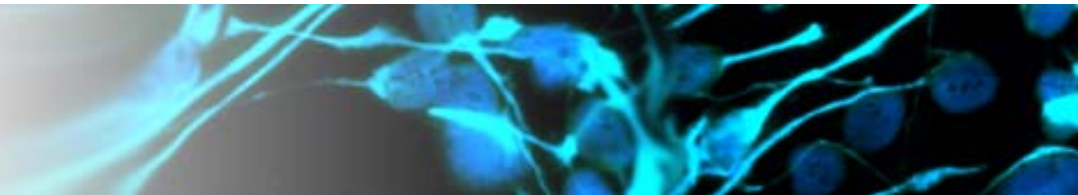


Q. What are your views on risk-sharing schemes, where post launch data collection is explicitly linked to a scheme linking outcomes with price?



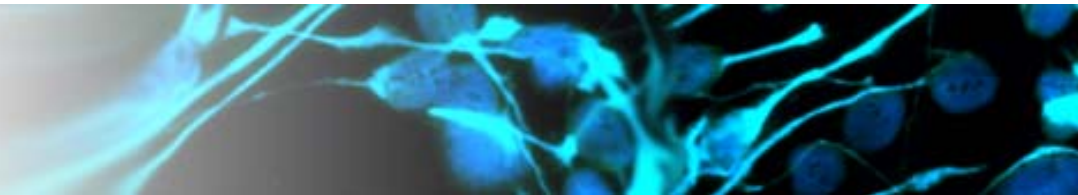
Types of risk-sharing

- Risk-sharing not linked to outcomes
- Free initial use
 - Ex ante approach to problem of non-responder, effectively a form of discounting to focus on cost-effectiveness use in sub groups
- Rebates on “unsuccessful” use
 - Ex post approach to demonstrating cost-effectiveness, again focus on effectiveness in sub groups
- Bonus on successful use



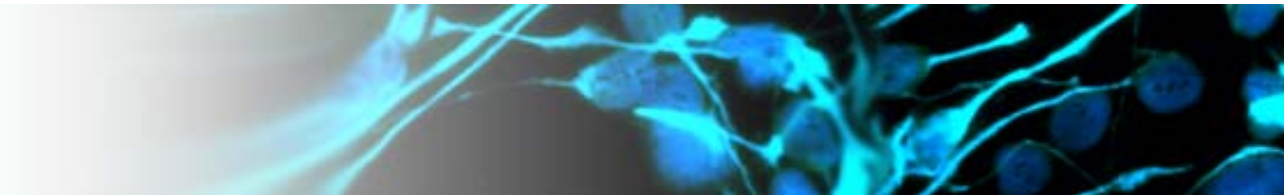
1990s examples of “money back” or “bonus” risk-sharing

- Zocor money back guarantee if cholesterol levels don't fall
- Proscar money back guarantee if compliant patients do not respond after 6 months
- Ortho Procrit replaced if patient does not respond
- More expensive catheter offered at price of conventional one plus shared of savings from avoided UTIs



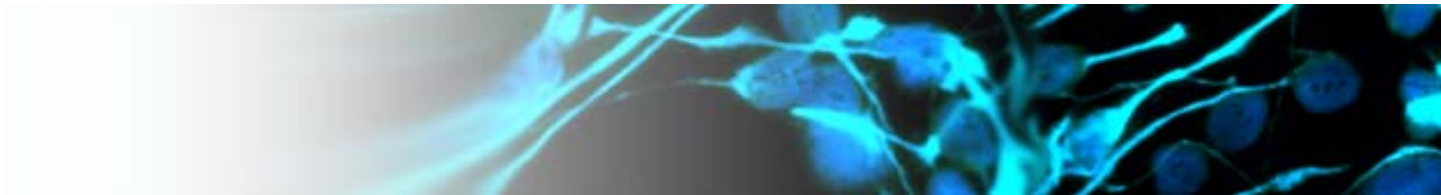
Why is a risk-sharing contract potentially attractive?

- Prior / launch decision become irrelevant for the payer, because of retrospective assessment
- Payer has effective mechanism to overcome information asymmetry through joint post-launch activity
- Company gets product used from launch on the basis of its prior estimate of cost-effectiveness
- Company is able to demonstrate cost-effectiveness in a post-launch environment at a (negotiated) time of its choosing



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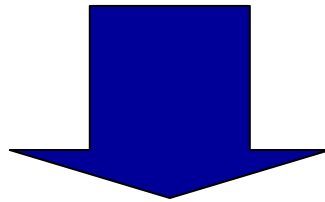


How do the parties agree a risk-sharing contract?

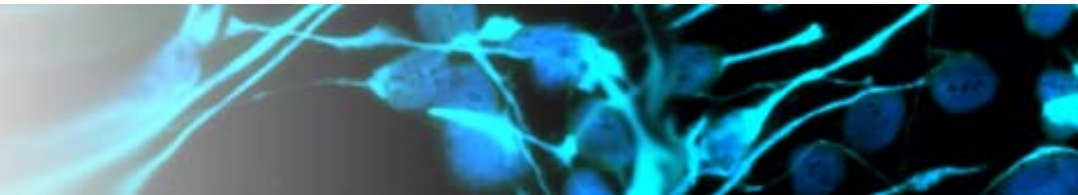
- Company can ensure adoption, but if not cost-effective it faces payback, so it has no incentive to manipulate launch values
- Information asymmetry and compliance issues easier to tackle post launch - effort and external circumstances easier to monitor
- Internalise in contract issues of reversibility costs and use impacting on information collection
- Need arbitration on interpretation of information and other contract provisions

How do the parties agree a risk-sharing contract?

- Where do the values for the contract come from?



- Both payer and company are undertaking EVOI calculations and bargaining around these calculations

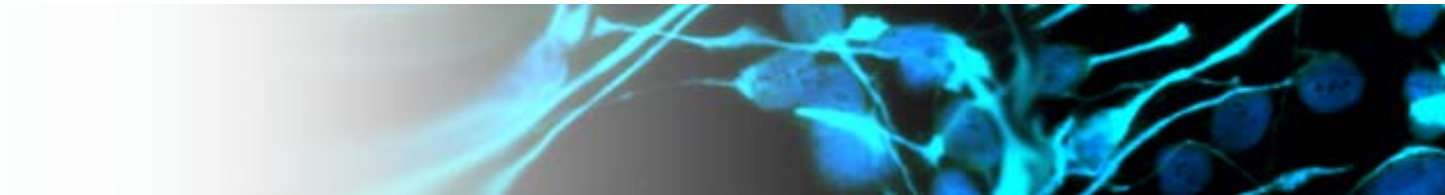


Griffin, Claxton et al

- Difficult to get post launch data collection
 - Lack of incentives on the manufacturer
 - Difficulty of enrolling patients in trial when NHS has sanctioned use
 - Limits of observational research

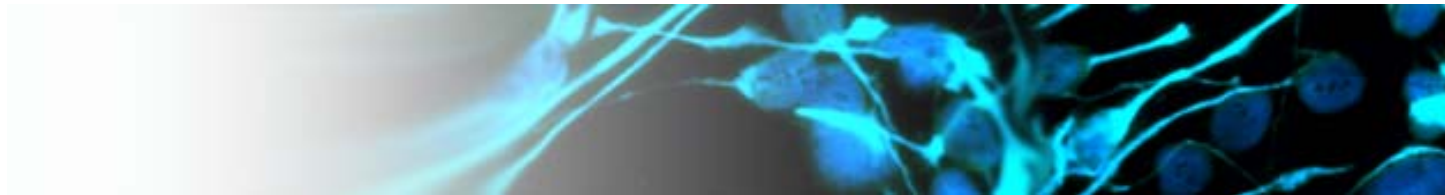


- Need to collect pre-launch or reduce uncertainty through a lower price



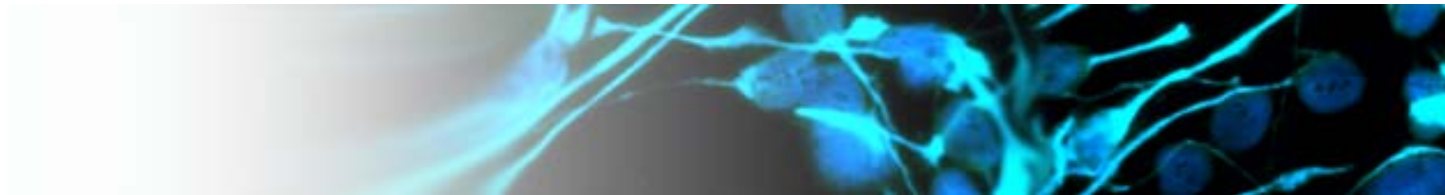
Can we reconcile?

- Information
 - Post launch use does provide information
 - Can conduct RCTs post launch
 - May be some types of RCTs and other studies cannot undertake post launch
- Incentives
 - Risk sharing aligns incentives



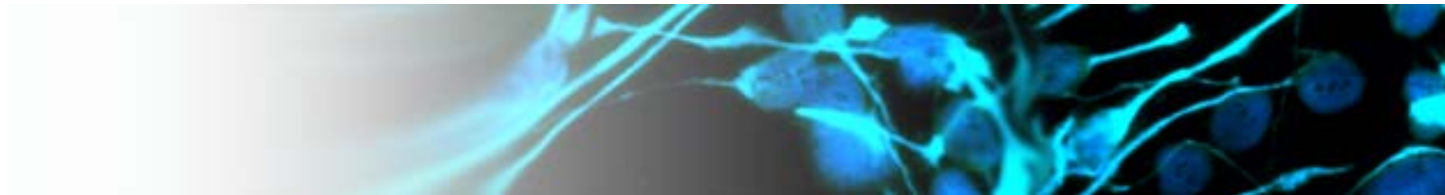
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Experience

- UK Multiple Sclerosis Scheme
- Chapman et al example (BMJ 2003)
- Pfizer and Florida Medicaid
- Alzheimer's disease drugs in Italy

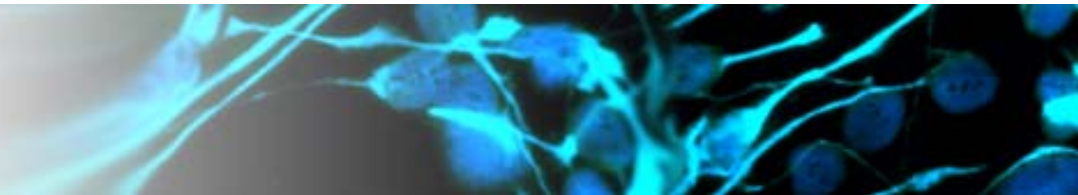


MS Risk-sharing : Key Elements

- Detailed monitoring over 10 years of a cohort of patients to confirm the cost-effectiveness of the MS treatments, various beta interferons and glatiramer.
- Treatments initiated by specialist MS centres based on ABN guidelines; no bar to clinicians prescribing for patients falling outside these guidelines.
- Central features are target outcome measures; agreed NHS price; threshold cost per QALY of £36,000.
- Outcome measure is Expanded Disability Status Score. Actual outcomes reviewed every 2 years against standard MS disease (non-treated) progression model through the EDSS scale.

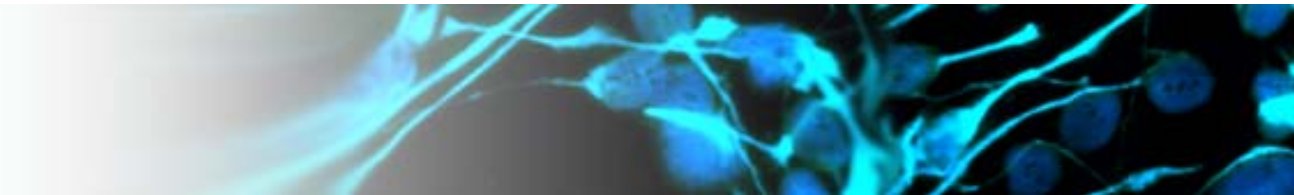
Health Services Circular 2002/004

<http://www.doh.gov.uk/publications/coinh.html>



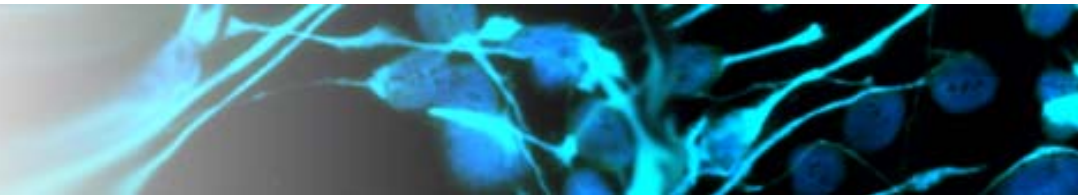
Issues in the MS scheme

- Long negotiation process
- Danger of gold plating data requirements
- Difficulty in recruitment
- Difficulty in monitoring
- Awaiting interim results
- Untried reconciliation process and adjudication group /process
- Is this unique or endemic to risk sharing?



Chapman et al example (BMJ 2003)

- Pfizer's Lipitor
- “Outcomes guarantee” based on CT results
- Rebate to PCTs determined at study end
- Aim to avoid inappropriate prescribing
- Results of audit to appear later
- Project steering group + Keele University



The Risk Arrangement: Savings Guaranty = Rebate



Risk-bearing entity

At risk for:

- Program administration costs
- All medical costs in excess of mutually agreed upon "expected" cost trend

Program Administration

- Executes contracts with hospitals providing care management services
- Disburses grant funds



Upside Potential
Savings beyond guaranty accrue to Pfizer until expenses covered, then 50/50 split



Conclusions

- Review after launch is preferable in principle
- But problem of value-for-money and irreversibility has led to pre-launch hurdle
- Risk sharing offers an alternative route
- But will the data exist, the mechanisms work and what are costs attached?
 - Little evidence to date
- Is pre-launch review more manageable?
 - UK OFT Review puts risk sharing as an option

