

# Thresholds to Invest: Manufacturers' Elasticities for Sponsoring Real World Comparative Trials

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# Introduction & Goal

- Comparative effectiveness research (CER) emerges on the center stage for health care reform in the United States.



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- 2009 ARRA dedicates \$1.1 billion for head-to-head research



# Comparative effectiveness research

- Potential to deliver timely and crucial information to physicians and improve efficiency and quality of care
- Economic incentives for different stakeholders to invest in CER is less clearly understood
  - Public versus private
  - Cost/duration of trials



# Outline

- Understand role of comparative effectiveness information
- The value of CE information to patients, payers and manufacturers and their incentives to invest
- Lay out a framework for understanding the role of trial durations on private investments

# Role of comparative effectiveness information

- Focus on drugs & head-to-head trials
- FDA approves drug based on placebo control trials, direct head to head comparison are seldom available
- Uncertainty exist about the which drug is more efficacious (will ignore all issues regarding heterogeneity)
- Resolving this uncertainty will allow patients to receive the more efficacious treatment thereby enhancing welfare



# Role of comparative effectiveness information

- Question: When is evidence sufficient?
- Claxton et al. (2005)
  - used value of information arguments
  - Invest if  $E(\text{value of information}) > E(\text{costs of investment})$
- However, who appropriates this value has implications for understanding who has the incentive to invest in CER.



Bo – First Dog

# Value of CE information to Stakeholders & Incentives to Invest

(Meltzer, Basu and Conti, IOM White Paper)

- Consider two drugs, A & B, on which CE study is required
- The truth can be any of these three possibilities:  $A > B$ ,  $A < B$  &  $A = B$
- Prior belief about the likelihood of these possibilities :
  - Is not degenerate-> representing uncertainty about the truth.
  - would be partly reflected in the utilization of these drugs and therefore their market shares and their prices



# Values & Incentives (contd..)

- Assume, both drugs are on patent → market is split but prices remain high.
- With perfect information (the extreme case) the posterior distribution of beliefs will shift to  $(1,0,0)$  OR  $(0,1,0)$  OR  $(0,0,1)$ ;
  - $(1,0,0)$ : maximum consumer value for the CE information will be the gain in efficacy for those who were consuming B before.
  - $(0,1,0)$ : maximum consumer value for the CE information will be the gain in efficacy for those who were consuming A before.
  - $(0,0,1)$ : maximum consumer value for the CE information will be driven by reduction in prices



# Values & Incentives (contd..)

- Expected social value of CE information is the weighted average of these values that is often very high
- Public investments in CER
  - High social value may not warrant public investments in CER
  - Not if such spending will only crowd-out private investments



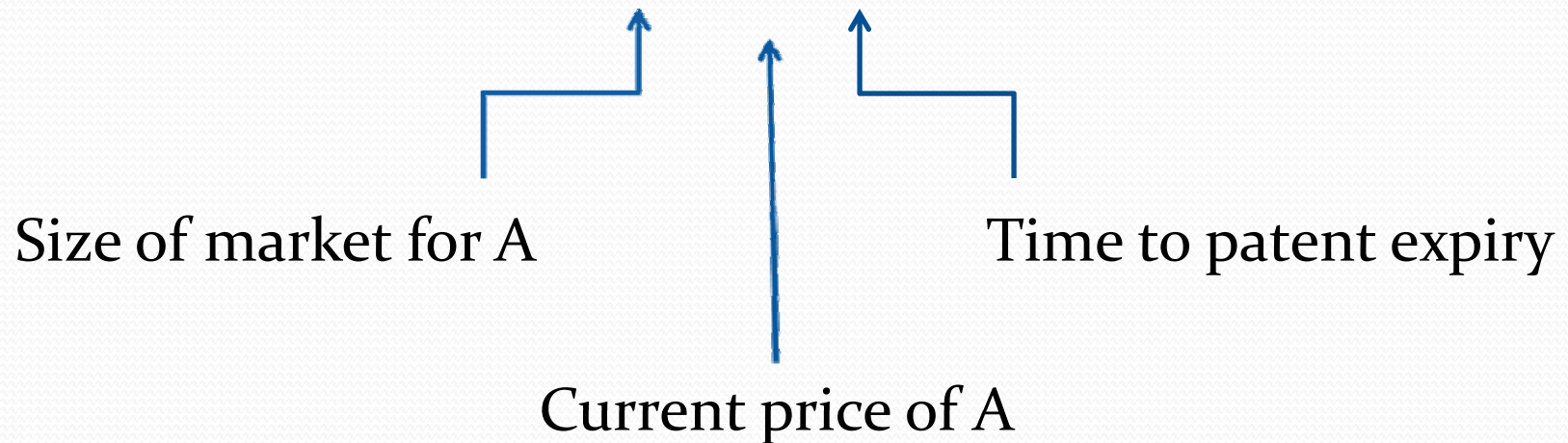
# Values & Incentives (contd..)

- Private investments in CER
- Value to the private payer is small as CER information will be public
- Value to manufacturer
  - reduces if they are risk averse -portfolio of investments helps to spread risk
  - increases with appropriation of value through prices and market share

# Manufacturer's Value & Incentive

- Let's consider manufacturer's value and incentives to invest assuming they are risk neutral
- Expected revenue for manufacturer A without CE:

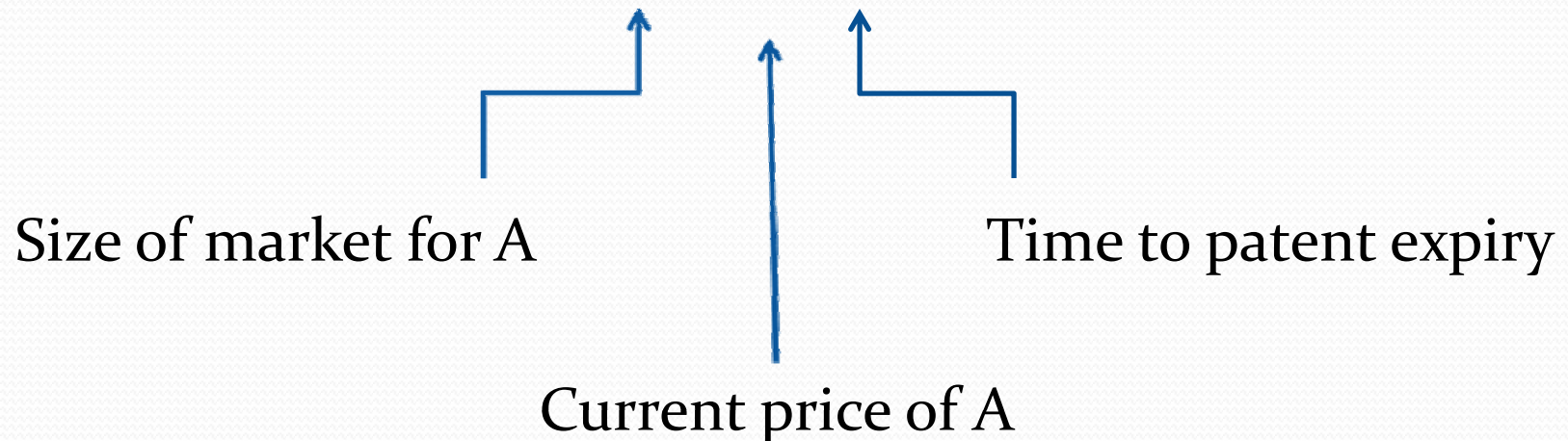
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# Manufacturer's Value & Incentive

- Assume:
  - A trial of length  $T$  and costs  $C(T)$  could reveal perfect information.
  - For the duration of the trial, status-quo will persist
- At time  $T$ , if it is revealed that  $A > B$ :
  - Firm A will set an adjusted price for the whole market.
  - Number of A units sold will decrease based on price elasticity of demand

# Manufacturer's Value & Incentives

- At time T, if it is revealed that  $A < B$ :
  - Firm A prices will be based on units sold to the residual market after B capture the rest.
- At time T, if it is revealed that  $A = B$ :
  - Firm A prices equate to zero (marginal costs).
- Expected revenue for manufacturer A **with** CE:

$$E\{R_A^1\} = \underbrace{s_A^0 \cdot p_A^0 \cdot T}_{\text{Status-quo till trial results are revealed}} + \underbrace{\sum_{k=1}^3 \{w_k \cdot s_{A,k}^1 \cdot p_{A,k}^1 \cdot (T_A - T)\}}_{\text{New revenue stream after trial results are revealed}} - C(T)$$



# Manufacturer's Value & Incentives

- The manufacturer will invest in a CE trial of length  $T$ :

$$\Delta(T) = E\{R_A^1\} - E\{R_A^0\} > 0$$

- Manipulating parameters in a comparative -static analysis will help us understand thresholds to invest
- A Bayesian trial will usually help the manufacturers “agree” to invest as it can reduce duration of trial
  - Reduces costs
  - Increase time over which benefits of a favorable result can be enjoyed

# Conclusions

- Prior distribution matters!!
- A manufacturer is less likely to invest if prior information “ambiguously” shows equivalence between its own and competitor’s drugs
- A manufacturer is more likely to invest if prior information either “ambiguously” favors or opposes the superiority of its drug
  - If manufacturer’s competitor has incentives to invest, then manufacturer might as well invest to control design points
- Interesting implications for public investments



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