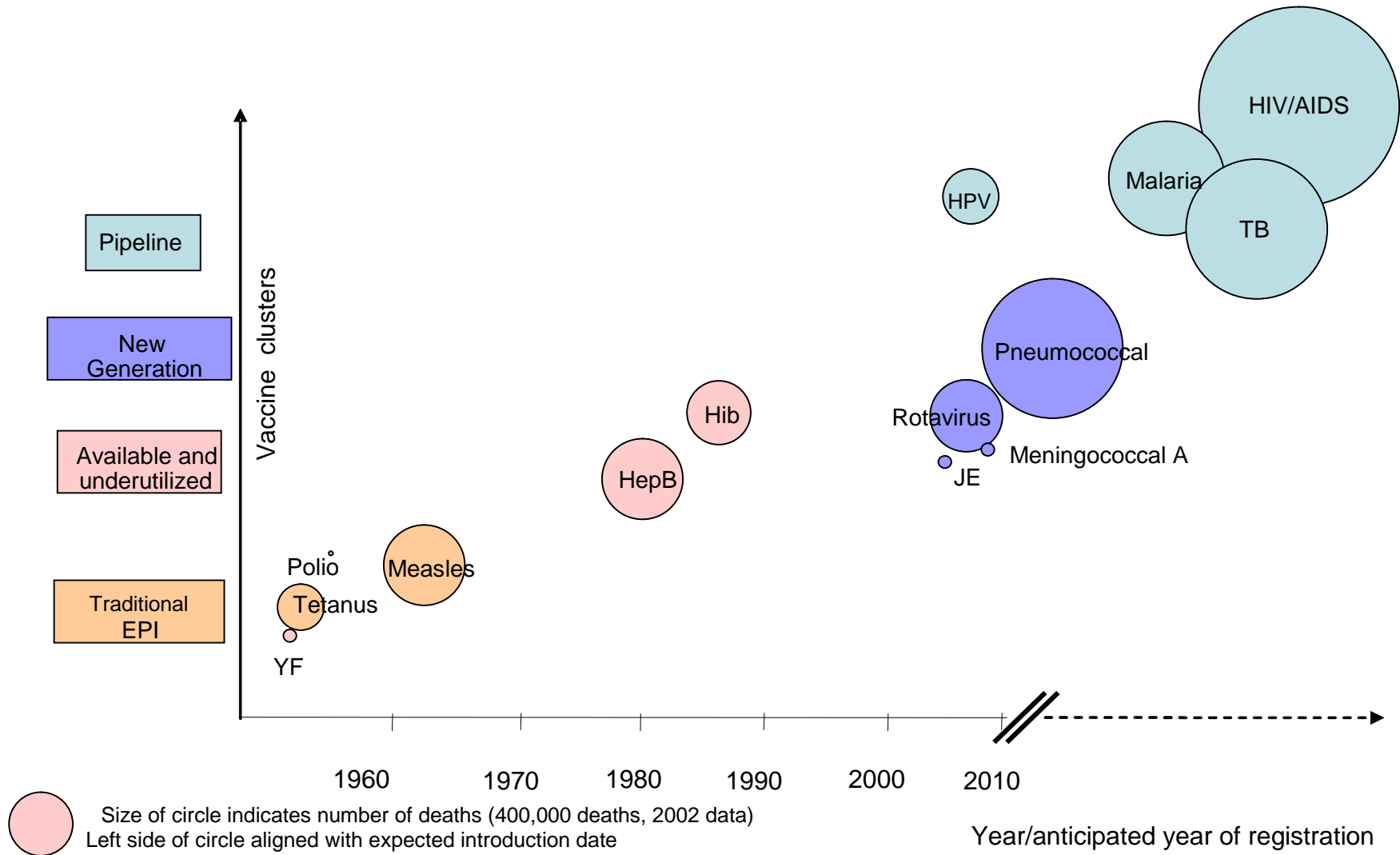


Vaccine Advance-Purchase Agreements for Low-Income Countries: Practical Issues

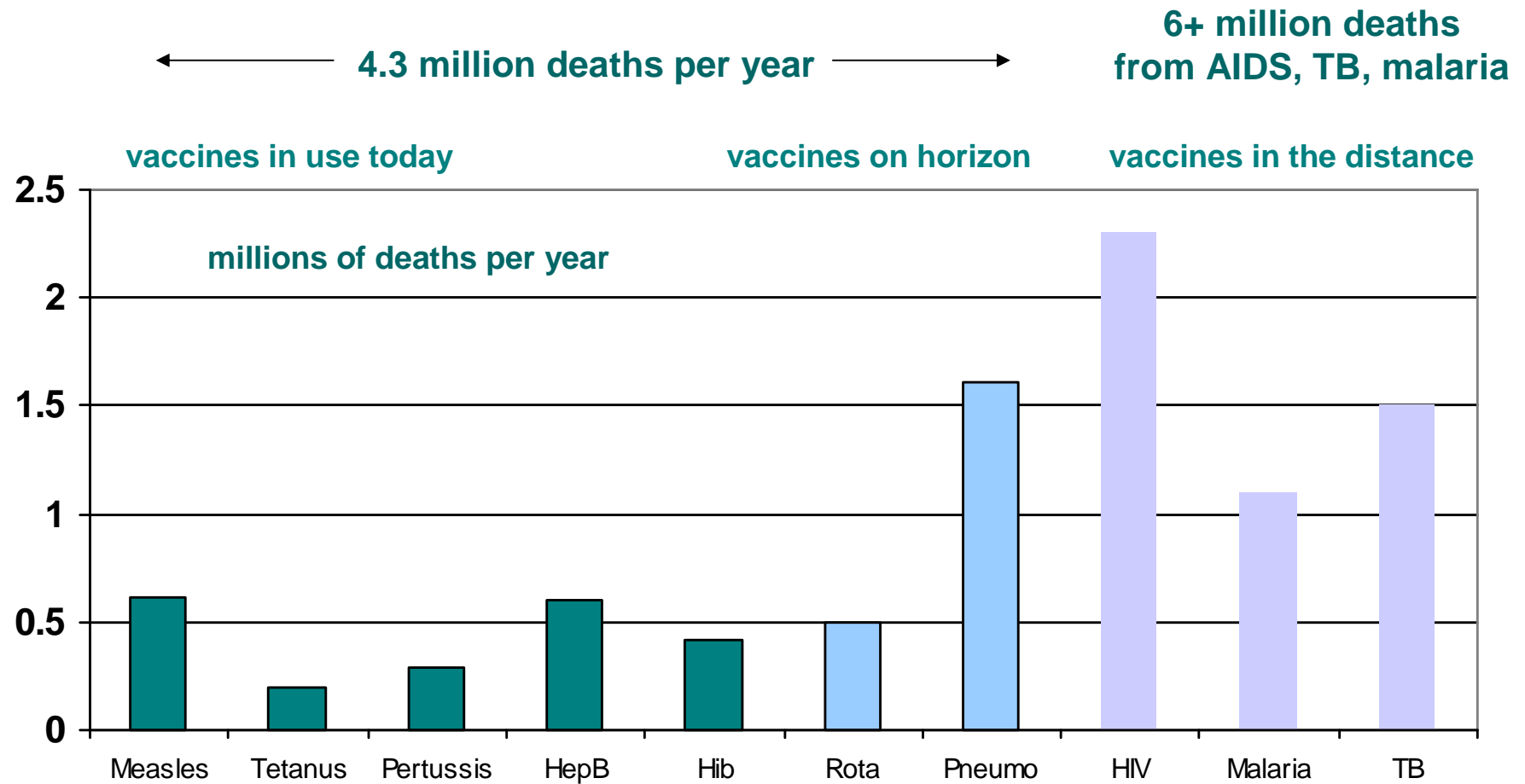
Ernst R. Berndt & John A. Hurvitz
May 23, 2005

COVINGTON & BURLING

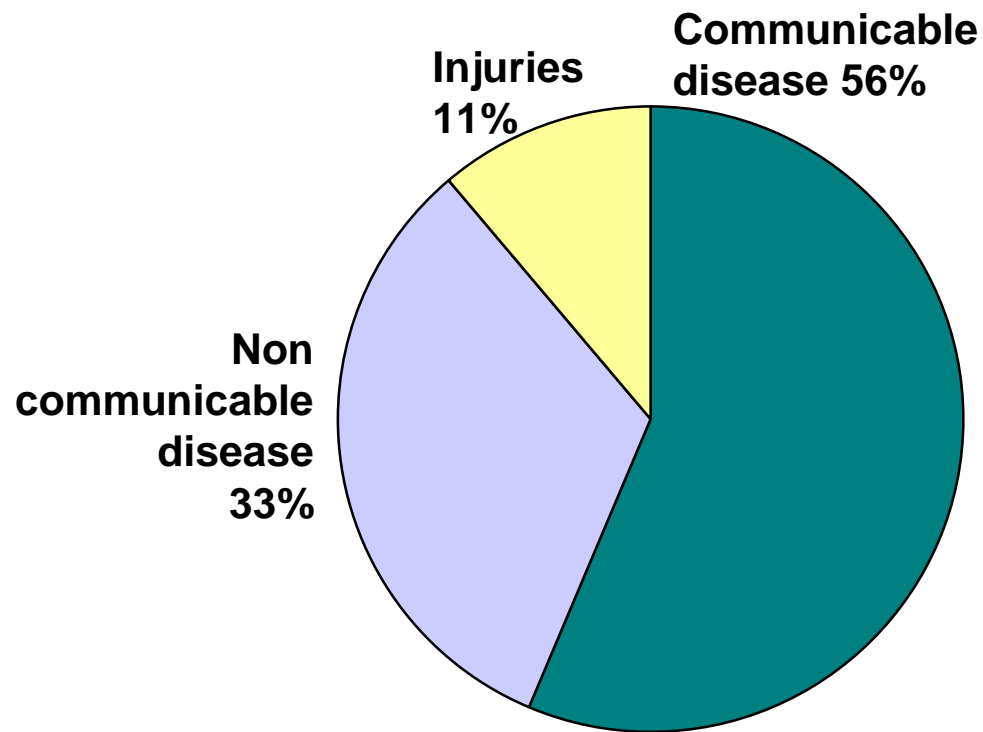
Vaccine Timeline



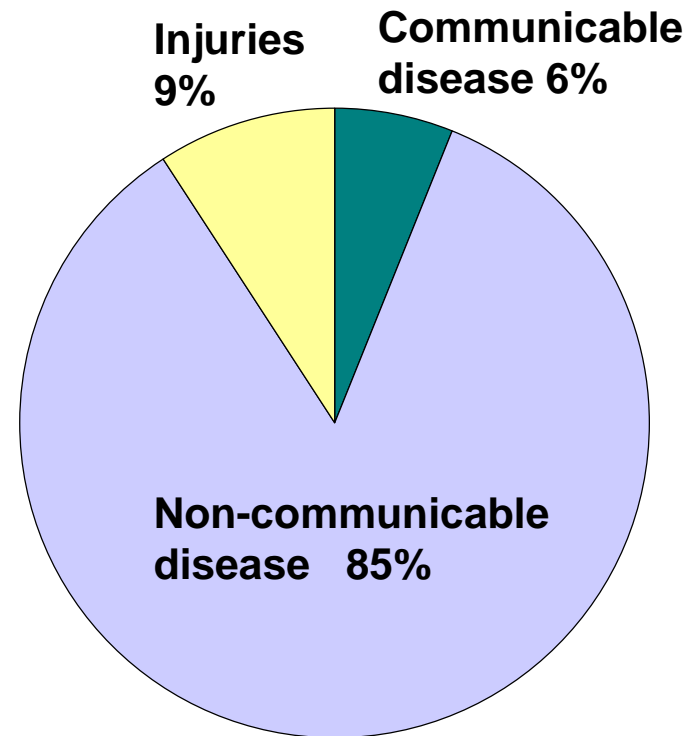
Deaths from Infectious Diseases



Diverging Causes of Death

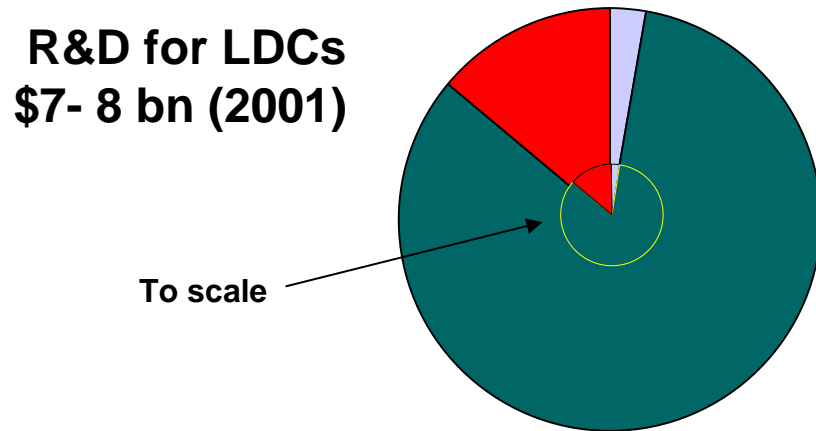
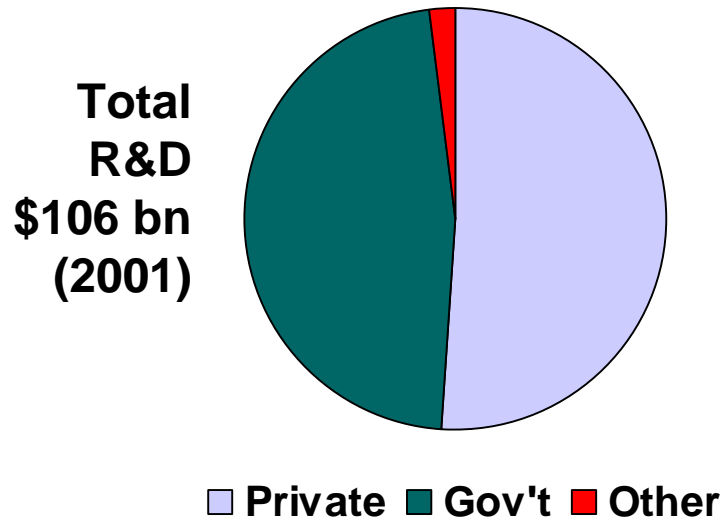


Least developed



Industrialized

Paying for Pharmaceutical R&D



- R&D spending for developing countries is 7-10% of total
- Overall, private dollars are single most important source for pharma R&D
- For products for developing countries, private investment is very low

The Challenge

The goals

Better health through:

- Faster development of new vaccines
- More access to existing and new vaccines

The constraints

Developing country markets are too small

Vaccine purchasing is unpredictable and prices are low

Vaccine priorities are diverging between north & south

Solutions

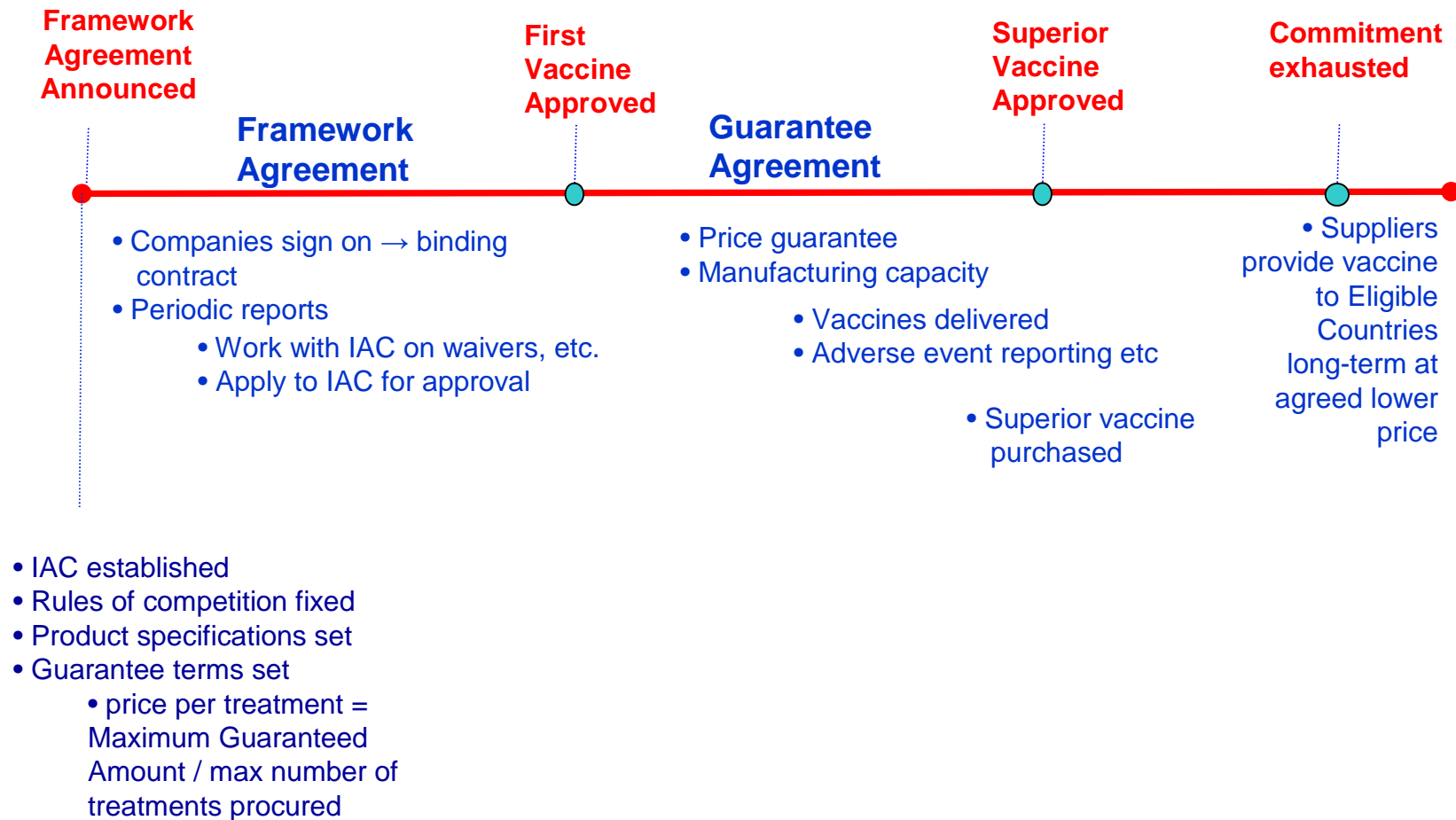
- Buying products today
 - GAVI/VF (and IFFIm)
 - Creates more visible market for existing products
 - Strengthens delivery systems
- Prepare for future products
 - ADIPs and UNICEF
 - Better demand forecasting and creation
 - Negotiation of supply commitments
- Invest public resources in R&D
 - Product-development public-private partnerships
 - “Enterprise” and initiatives to promote greater scientific collaboration

Missing: market for future products

Advance Market Commitment for Early-Stage Products

- ❖ ex ante specification for vaccine
 - ❖ efficacy, duration, target population, presentation
- ❖ sponsors make a legally binding commitment
- ❖ underwriting a guaranteed price
- ❖ for a max number of treatments
 - ❖ based on demand – no demand, no payout
 - ❖ procured through normal channels
- ❖ providing a return to suppliers
 - ❖ taking into consideration opportunity cost of capital, and alternative markets
- ❖ in exchange for affordable price afterwards

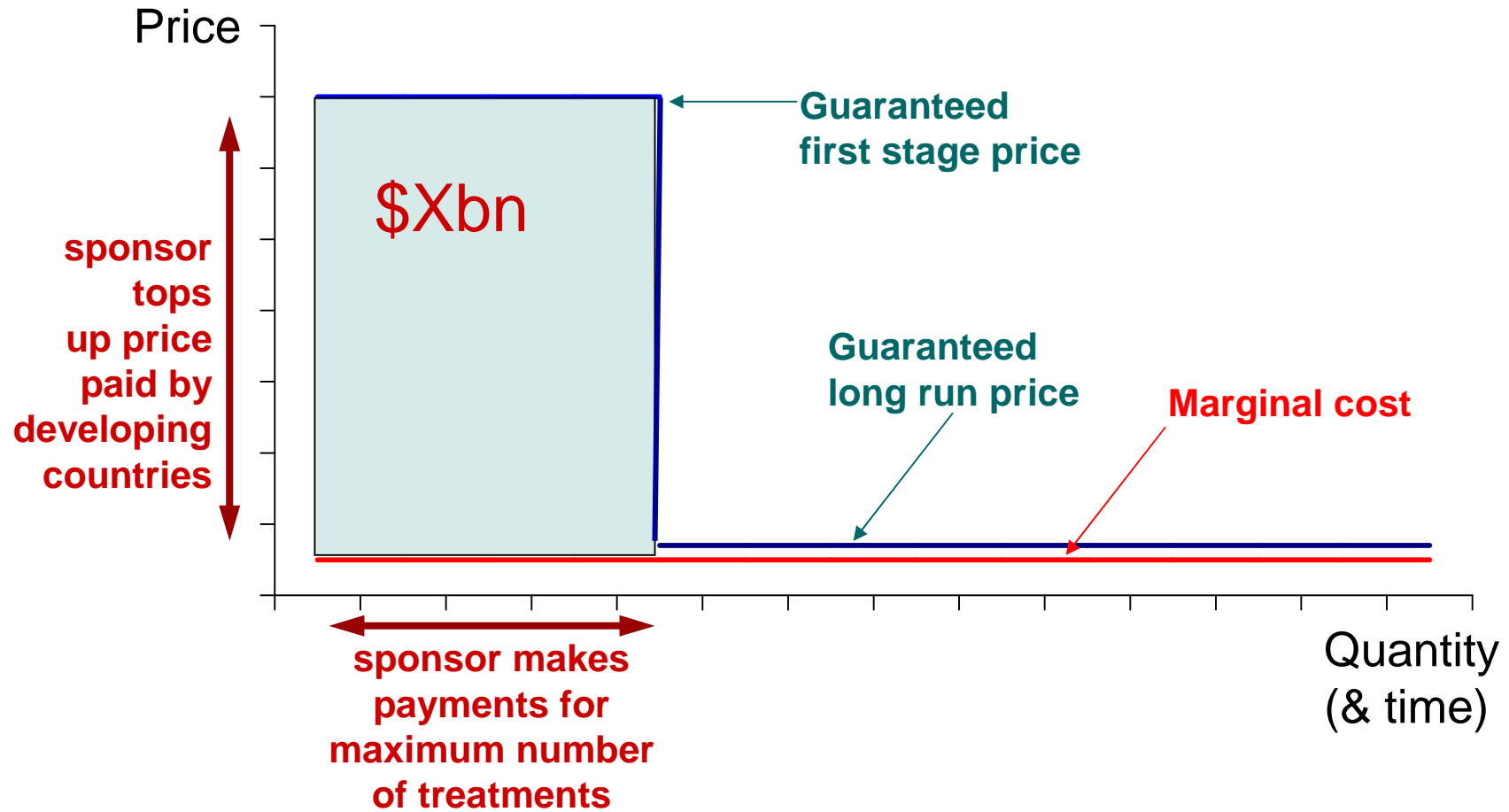
Timeline



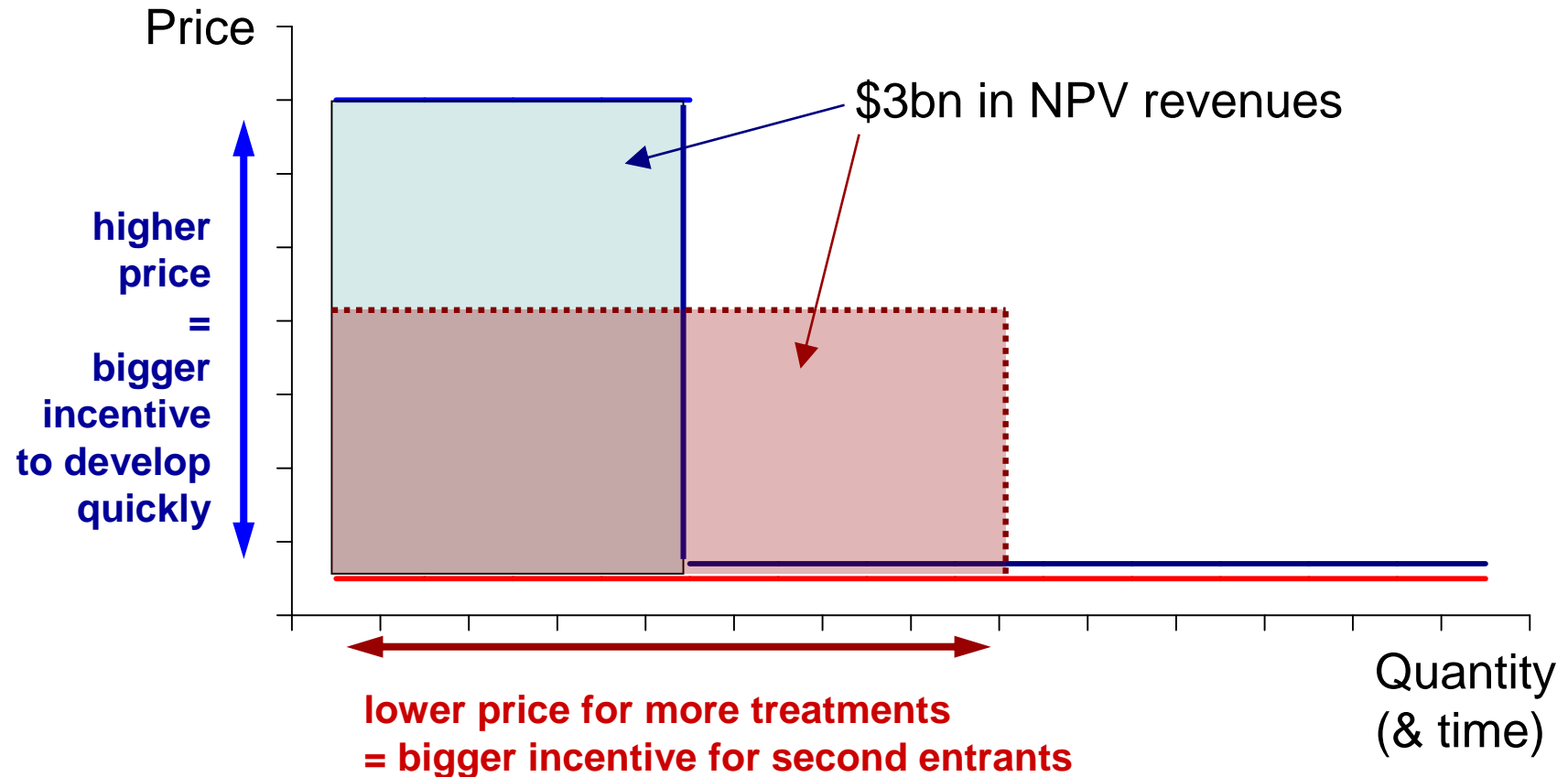
A Market not a Prize

- No quantity guarantee
- Incentives for innovation
- Allows less exhaustive specifications
 - Lower risk for donors
- Some demand risk with manufacturers
 - Removes risks of certain market failures
 - Incentives to develop optimal products
- Allows developing countries to choose
 - Co-payment helps ensure efficient procurement and distribution
- Advance Market Commitment

Two-Stage Pricing



Choice of Price and Quantity



Late-Stage Vaccine Candidates

- Market uncertainty may still affect investment decisions
 - Process and plant capacity
 - Specifications and presentations
 - Development and approval
- Negotiated bilateral agreements rather than open framework agreement
 - Allows donors to influence specific activities of known Developers for known products
 - Single agreement
- Benefits
 - Accelerate availability of, and access to, new vaccines, modified as necessary, to meet specific needs of developing countries
 - Ensure continuity of supply at affordable prices
 - Enhance credibility of advance market commitments