



Making Markets for Vaccines

Ideas to Action

7 April 2005

Outline

- The need: toll of infectious disease
- Barriers to more and better immunization
 - Health system and financing
 - Diverging health priorities
 - Low levels of investment, little private sector engagement
- Current solutions
 - Buying existing products
 - Preparing for future products
 - Investing public dollars in R&D
- Possible new solution: advance market commitment
 - Main features
 - Framework and guarantee timeline
 - A market, not a prize
 - Application to “near-term” vaccines

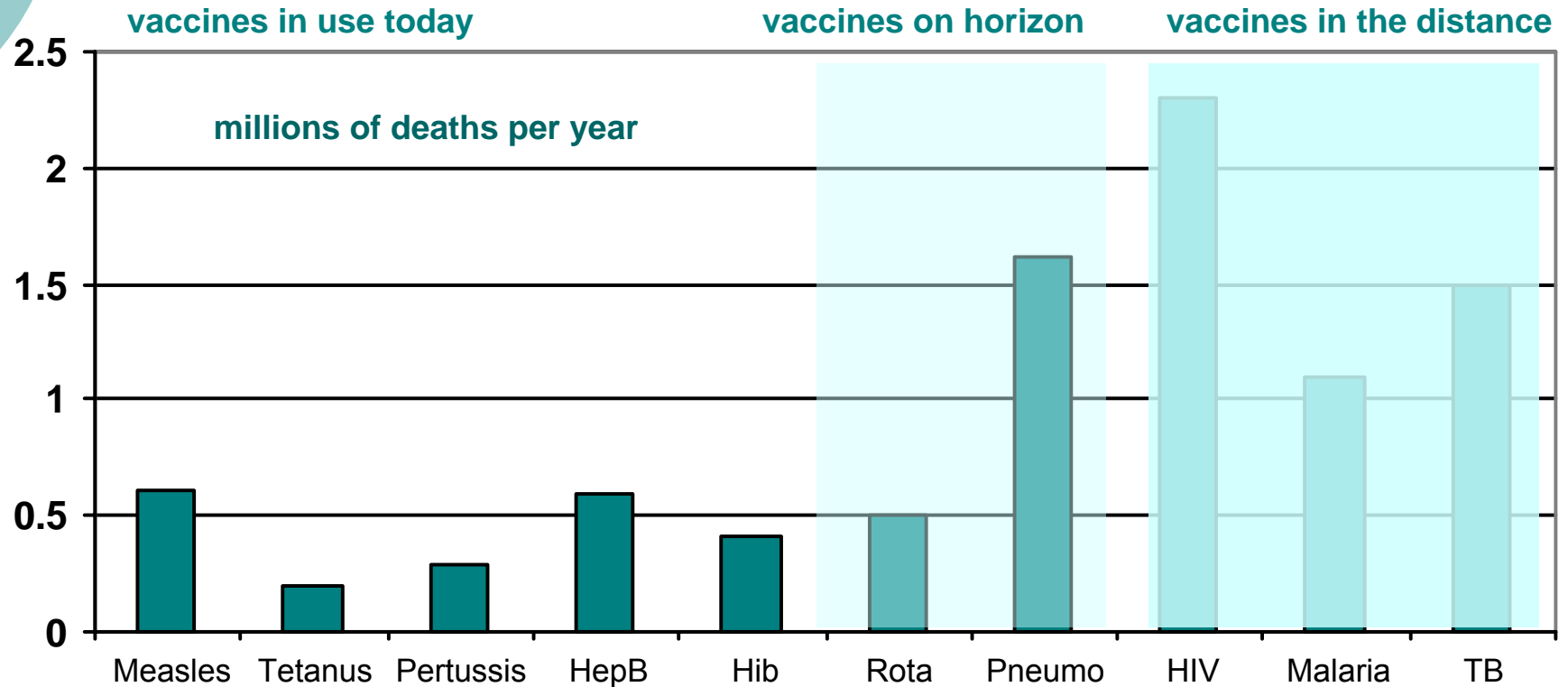
Vocabulary

- Near-term
 - Close to licensure; R&D “done”
- Long-term
 - At least several years pre-licensure, facing scientific hurdles, R&D underway
- Treatment
 - Full course of vaccine to achieve immunity
- Push incentives
 - Direct investment in R&D
- Pull incentives
 - Rewards upon the development of a product
- Advance market commitment
 - Not a quantity guarantee

Deaths from infectious diseases

4.3 million deaths per year

6+ million deaths from
AIDS, TB, malaria



The challenge

The goals

Better health through:

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

The constraints

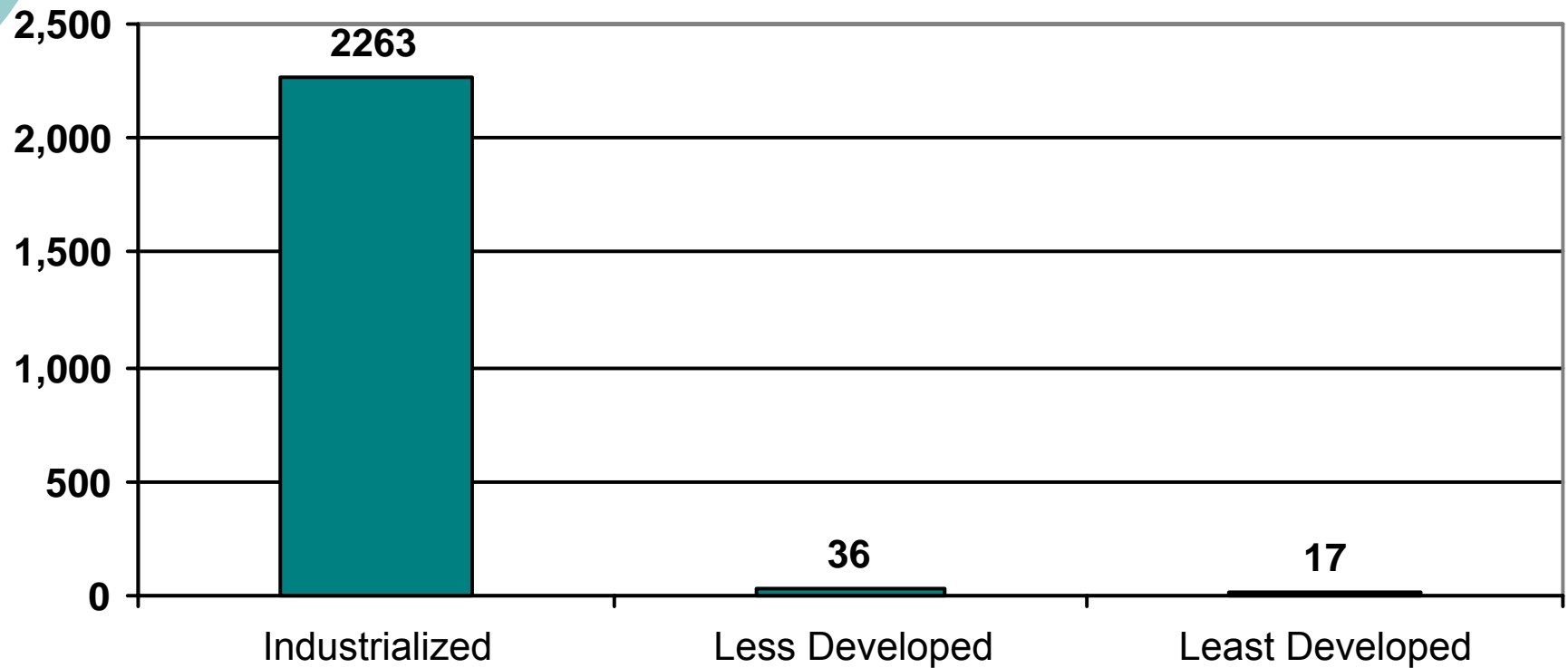
Developing country markets are too small

Government purchasing is unpredictable and prices are low

Disease burden is diverging

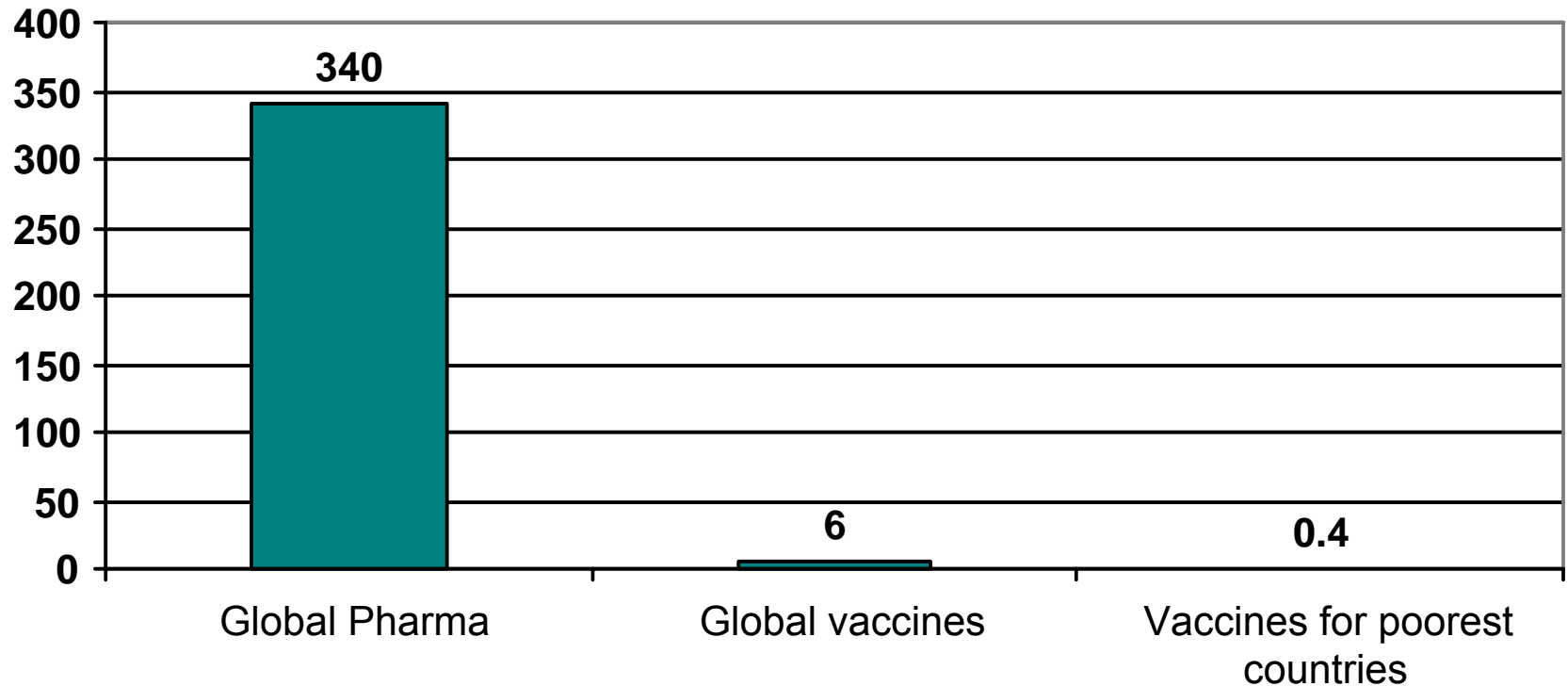
Health spending

\$ per person per year

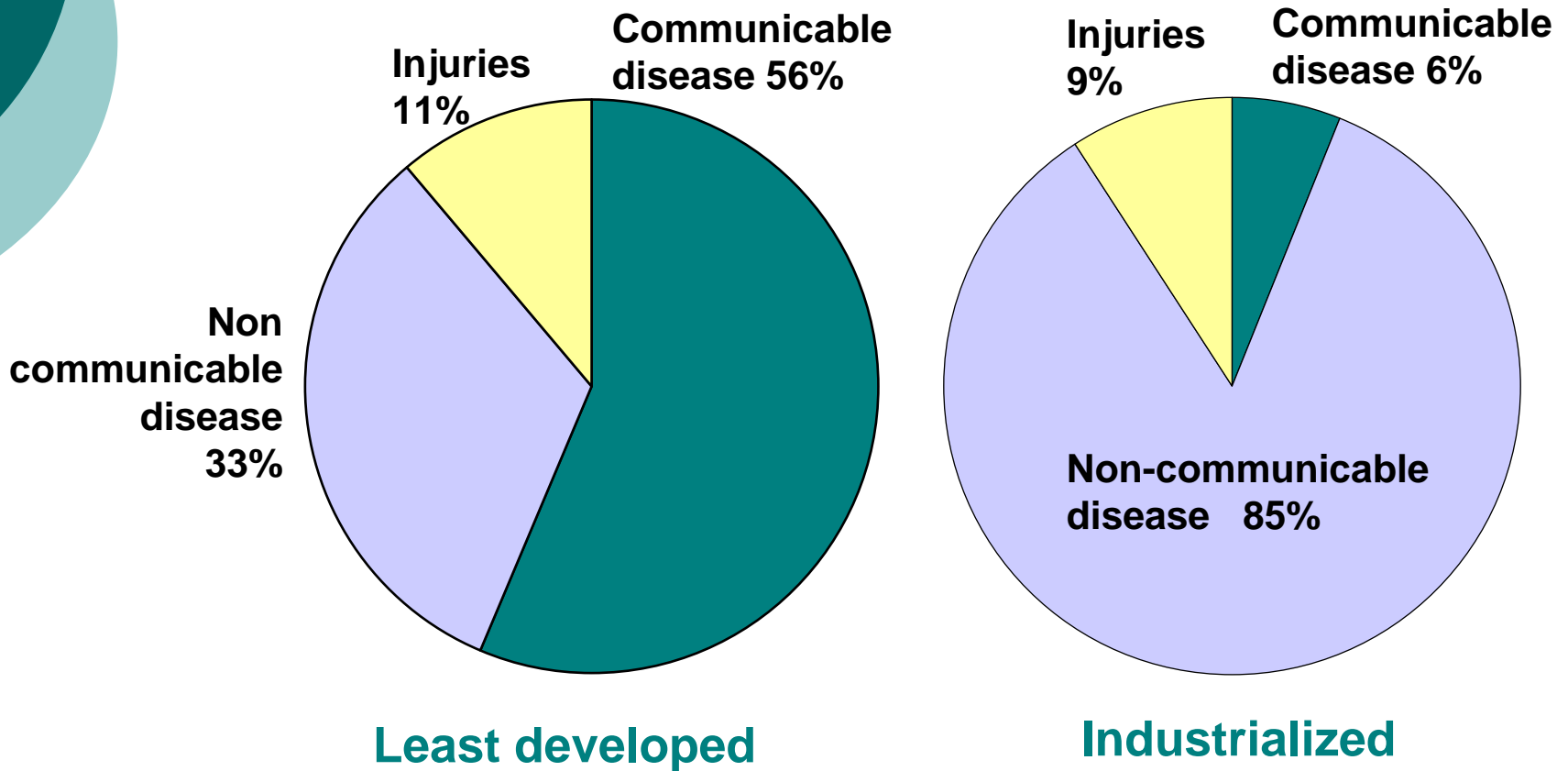


Current markets for pharma products

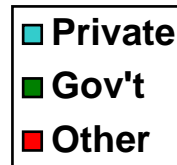
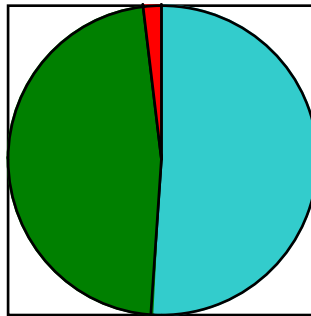
billion \$ per year



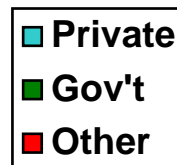
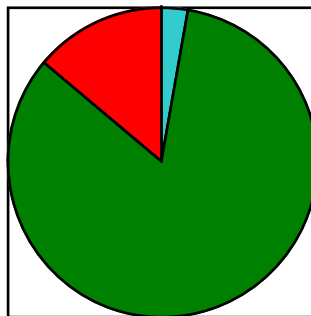
Diverging causes of death



Paying for pharmaceutical R&D



Total R&D: \$106b (2001)



Dev. Country R&D: \$7-8b (2001)

- 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

Problem

- Low investment in R&D relative to social importance
- Missed opportunities for innovation
- Long lag times before introduction and scale-up of use of life-saving products

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

Working Group

- ❖ Convened by Center for Global Development in March 2003, under grant from Bill & Melinda Gates Foundation
- ❖ Started with Michael Kremer's work
- ❖ "Could an advance commitment work?"
- ❖ Industry, governments, lawyers, public health experts, economists ...
- ❖ To identify a practical solution
- ❖ Consulted public health community, industry, sponsors

Assumptions

- More money to R&D -> faster progress
- Firms allocate capital based on risk-reward calculation
- Firms face major opportunity costs that affect R&D investment decisions
- For eventual manufacturing, industry engagement from an early stage is needed

Can market incentives be used to promote speed, quality, low costs of production, rapid scale-up?

Advance market commitment for long-term product

- ❖ 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

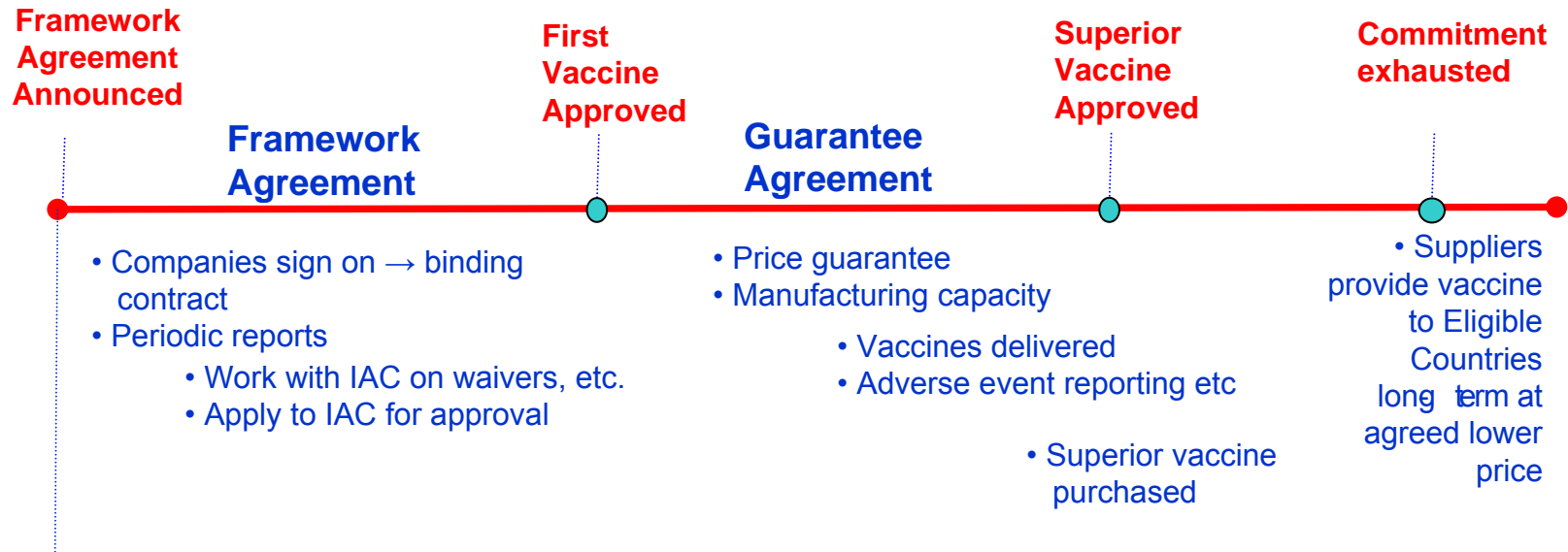
Illustrative example for malaria vaccine

Technical specifications [to be developed with input/under auspices of technical agencies]	Targeted against falciparum, 50% efficacy against clinical malaria, 2-year duration of protection, no more than 4 immunizations, multi-dose vials
Total market value approximately equal to sales revenues earned by average new medicines	Total market size of \$3 billion (NPV 2004 dollars)
Sponsors under-write a specific price	\$15 per treatment (person immunized) (e.g. \$5 per dose for 3 doses)
Price guarantee applies to a maximum number of treatments	Guarantee for first 200 million treatments

Illustrative example for malaria vaccine

Treatments sold in eligible countries	Vaccine Fund eligible countries
In return, the developer guarantees to sell subsequent treatments at a low price	\$1 per treatment
Recipient country makes a co-payment for the vaccines they buy (or asks a donor to do so)	\$1 paid by recipient \$14 paid by sponsors
<p>Subsequent vaccines are also eligible for the guaranteed price, if superior to existing vaccines – as developing countries can switch their demand to these subsequent, superior vaccines.</p>	
<p>An Independent Adjudication Committee oversees the arrangement.</p>	

Timeline



- IAC established
- Rules of competition fixed
- Product specifications set
- Guarantee terms set, e.g.
 - \$3 billion for malaria vaccine
 - 200 million treatments
 - \$15/person immunized

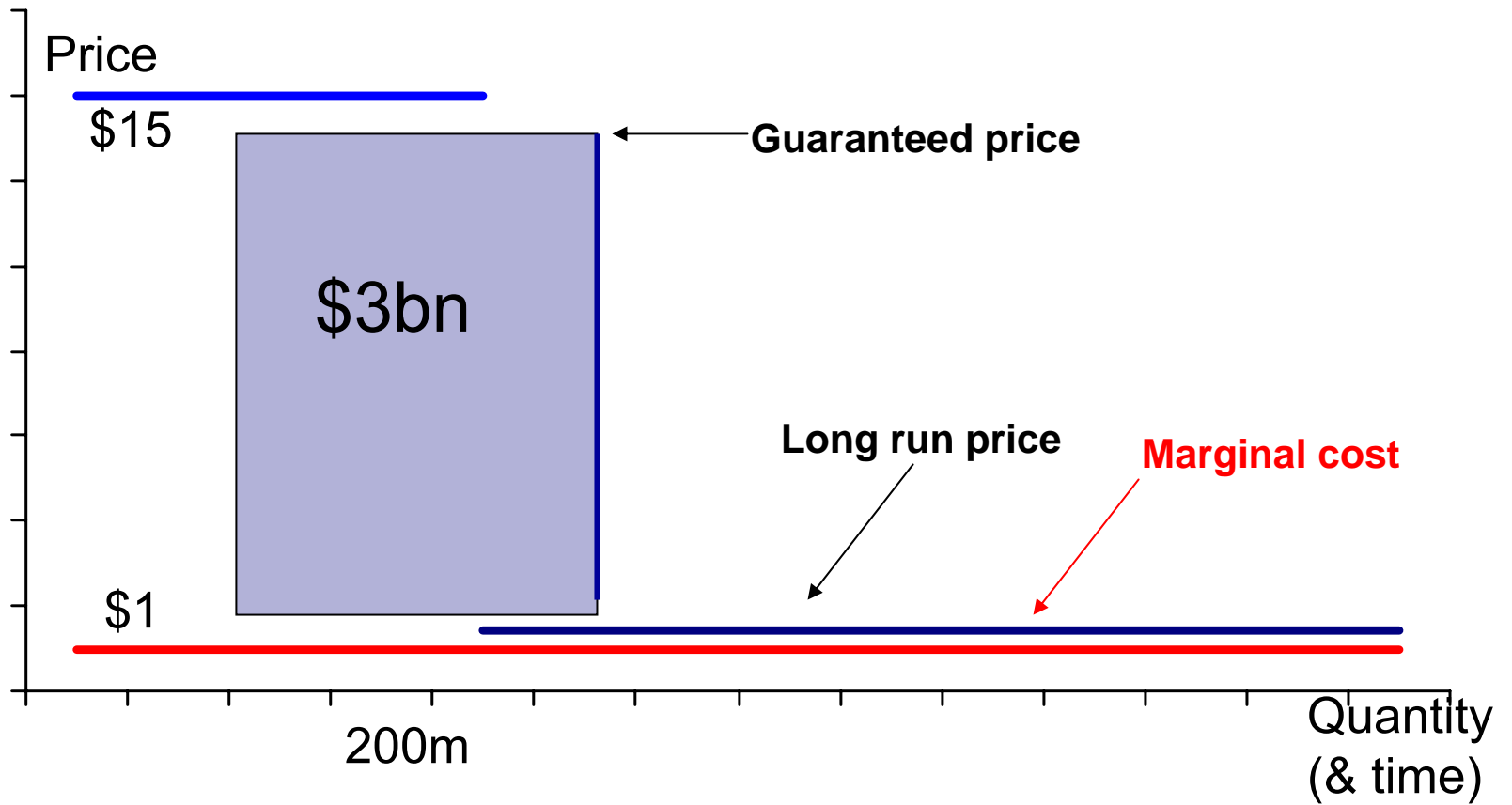
Critical Components of the Commitment

- Approved Vaccine
 - Must meet the technical, usability and approval requirements in the Framework Agreement, unless waived.
- Qualified Sale
 - Sale for to a qualified purchaser (e.g., Ministry of Health, UNICEF, PAHO) for use in an Eligible Country (e.g., a Vaccine Fund eligible country).
 - Must be a reasonable expectation that product will actually be used in Eligible Country.
 - E.g., UNICEF forecast could provide safe harbor.
- Adequate Capacity
 - Must meet demand in all Eligible Countries even after guarantee is exhausted.

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



Independent Adjudication Committee

- Credible and independent
 - Limited review
- Approve qualifying vaccines
 - Use of outside expertise
- Approve “superior” vaccines
- Waivers
- Consultation

Exit Provisions

- Force Majeure
 - Framework Agreement will clearly define objectives and assumptions underlying guarantee
 - Supermajority vote (3/4)
 - Judicial review
- Sunset Provision
 - If no meaningful progress toward an Approved Vaccine

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

Working Group products

- Report
- Policy brief
- FAQ
- Working paper on estimating market size and cost-effectiveness
- Spreadsheet tool
- Website:
<http://www.cgdev.org/vaccine>