Understanding the vaccine market and its economics

Obstacles and potential solutions

Amie Batson – Presentation to Out of the Box Group

26 July 2001

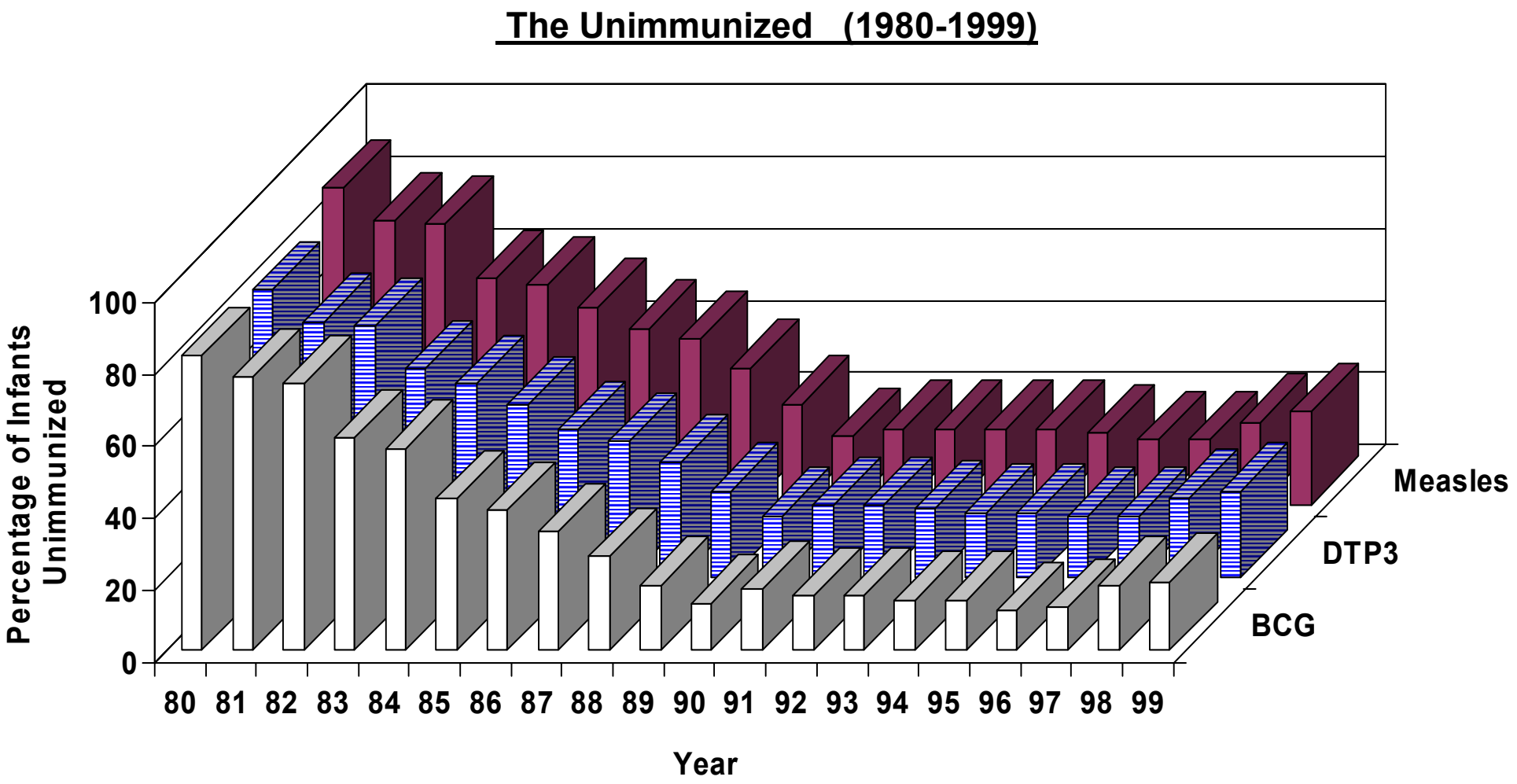
What are our goals?

- Investment to ensure a delivery system capable of reaching infants and other target groups with priority vaccines
- Investment to rapidly develop priority vaccines targeting the diseases of the developing world
- Investment in production capacity to ensure the supply of global vaccines to the developing world
- Pricing which is affordable to the developing world
- Funding to purchase vaccines as soon as they are technically available

Agenda

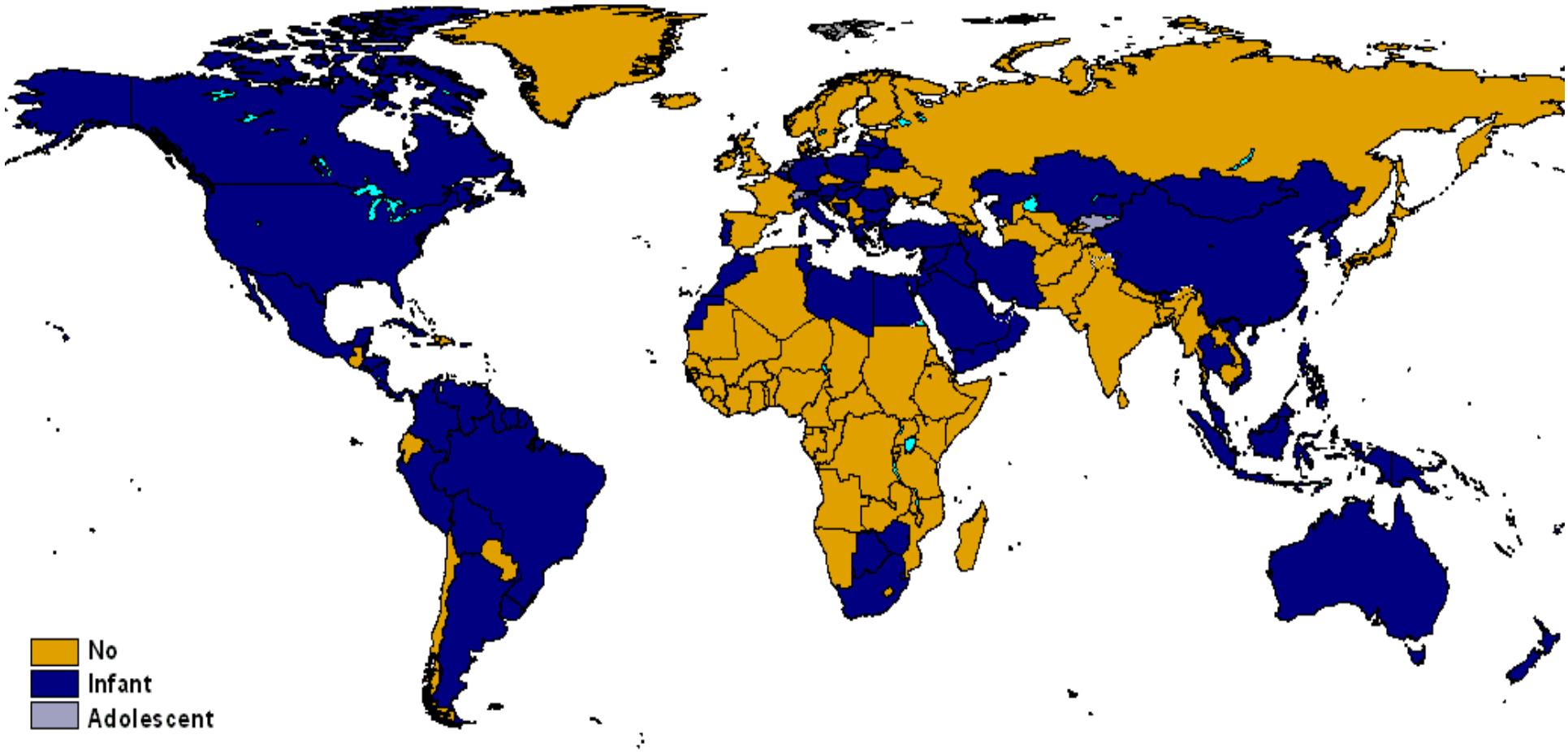
- Immunization and vaccine customer
- Vaccine industry:
  - Players
  - Market Size
  - Changing environment
- Vaccine Economics and the role of partnerships

Immunization is success story, reaching roughly 70% of infants globally – however, the delivery system only consistently reaches infants and 30% of infants are still unimmunized



Data as of 15 th May 2000

However, global coverage data masks disparities between countries.

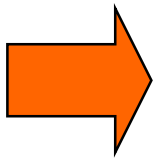


Extensive investment is needed to maintain a complex delivery system to reach infants and other target populations

- **Logistics** to transport vaccine from capital city, to province, to district to town/village/remote areas
- **Cold chain** to maintain temperature of vaccines within narrow range to avoid freezing or heat exposure
- **Trained staff** to properly handle vaccine, check child records, safely administer vaccine, safely dispose of injection devise
- **Surveillance and reporting systems** to track and report diseases, vaccine coverage, and adverse events

It costs roughly $25 to "fully" immunize a child with the basic package of recommended vaccines --- most of the cost comes from the delivery system.

Infrastructure	**20%**
Buildings	9%
Cold Chain	8%
Other Logistics	3%
Labor	**60%**
Vaccines	**20%**
TOTAL	**100%**



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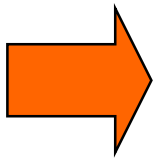
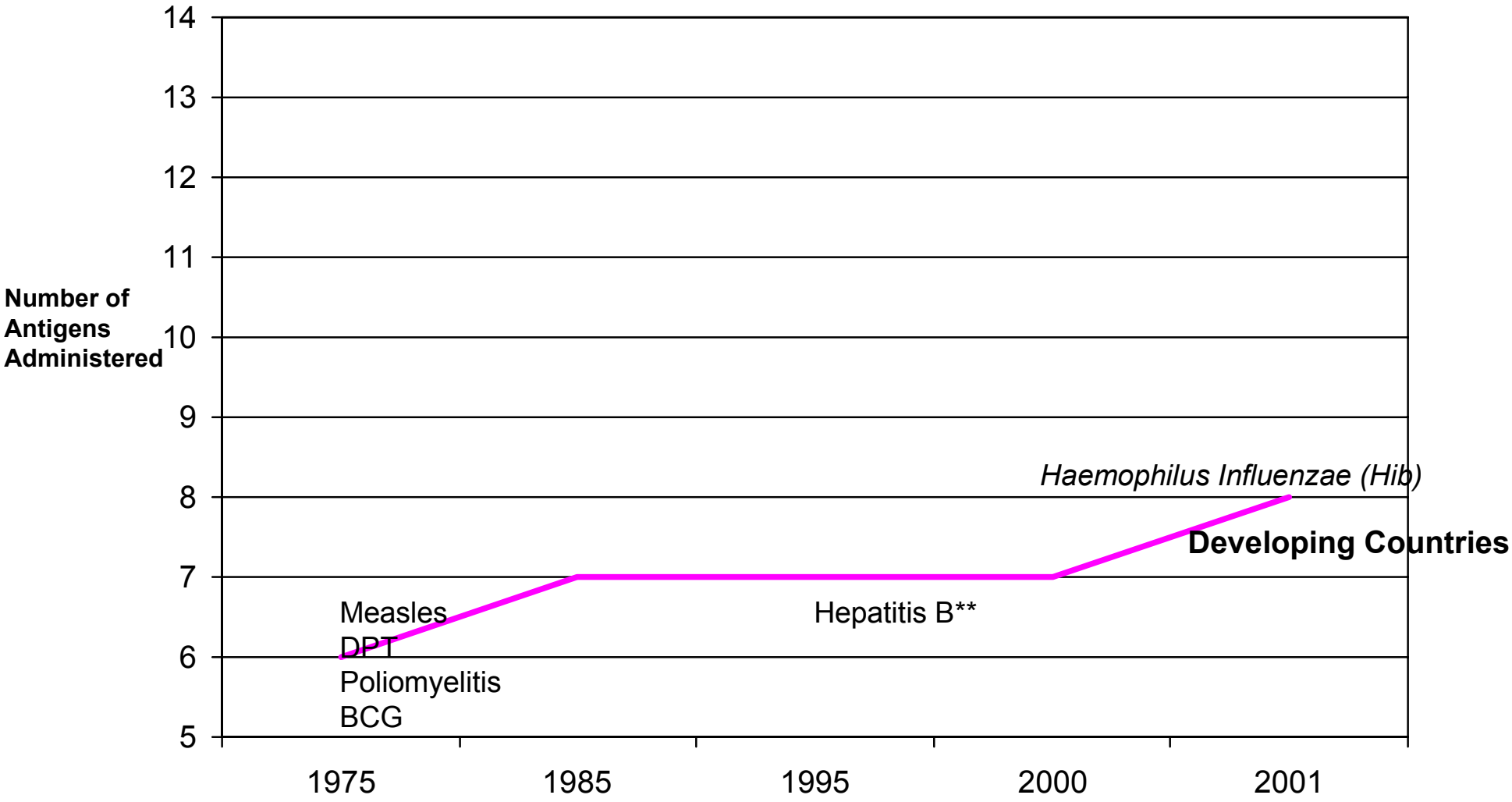
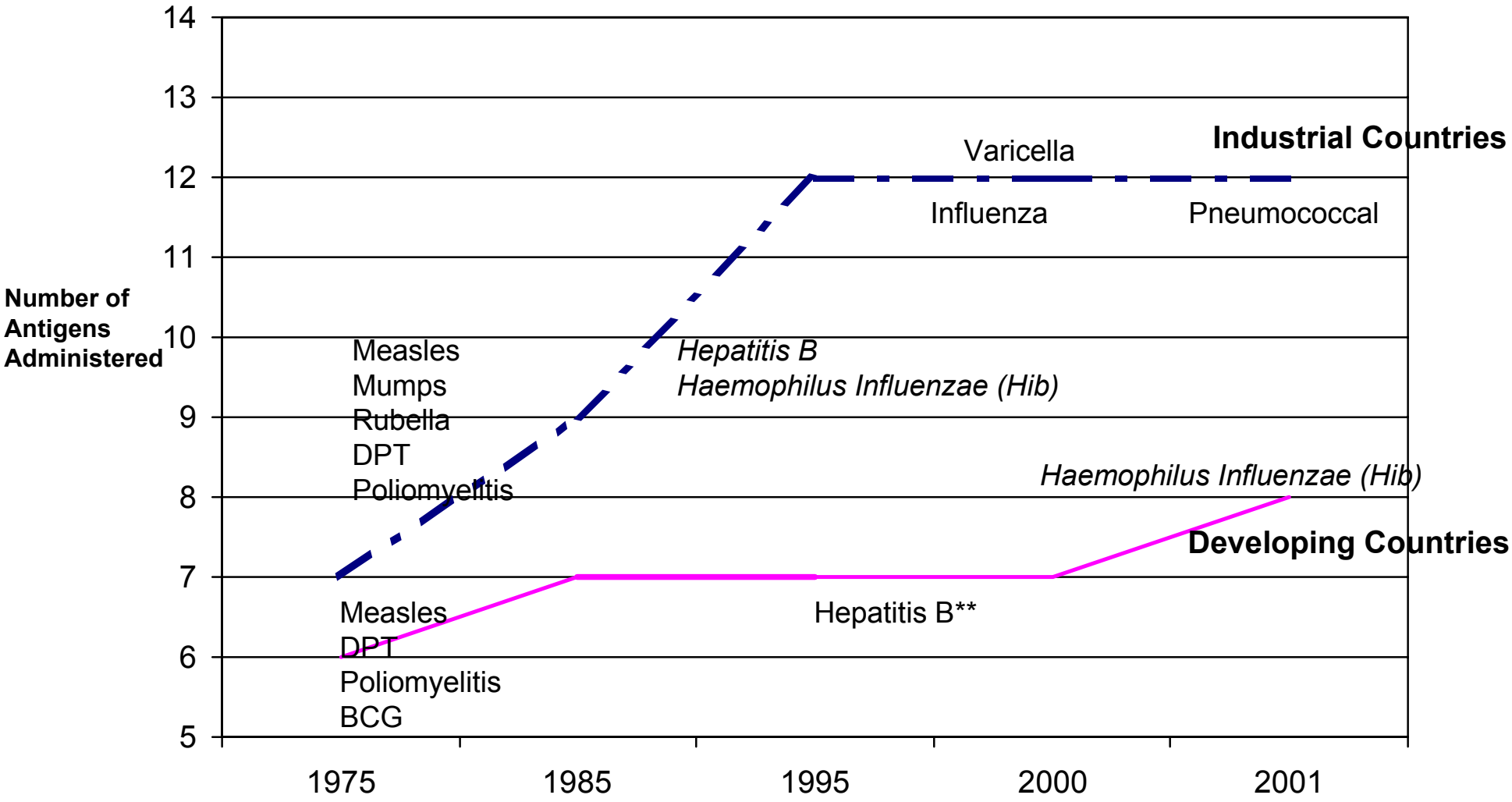


Cost per Fully-Immunized Child: $25

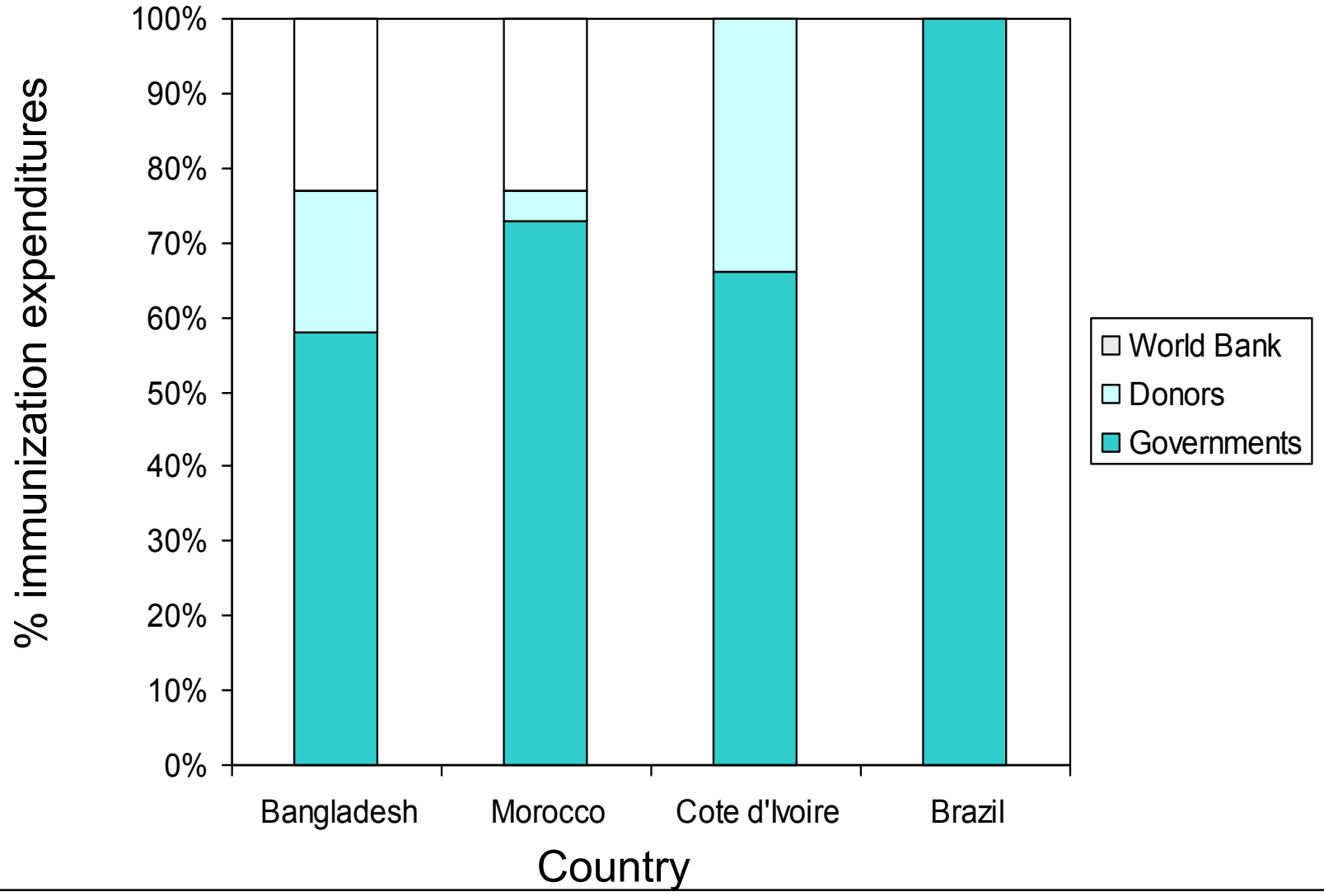
This system is currently allowing the average child in a developing country to receive 8 antigens



However, children in industrialized countries receive 12.



The immunization system and vaccines are financed first by national governments, supplemented by bilaterals, foundations and the development banks.



Vaccines are unique in large part because of their status as global public goods.

- Benefit all countries and people no matter who pays
  - **Child**: individually protected
  - **Family**: reduces the risk of transmission to and from siblings/friends
  - **National governments**: reduces transmission nationally
  - **International governments**: reduces cross border infections

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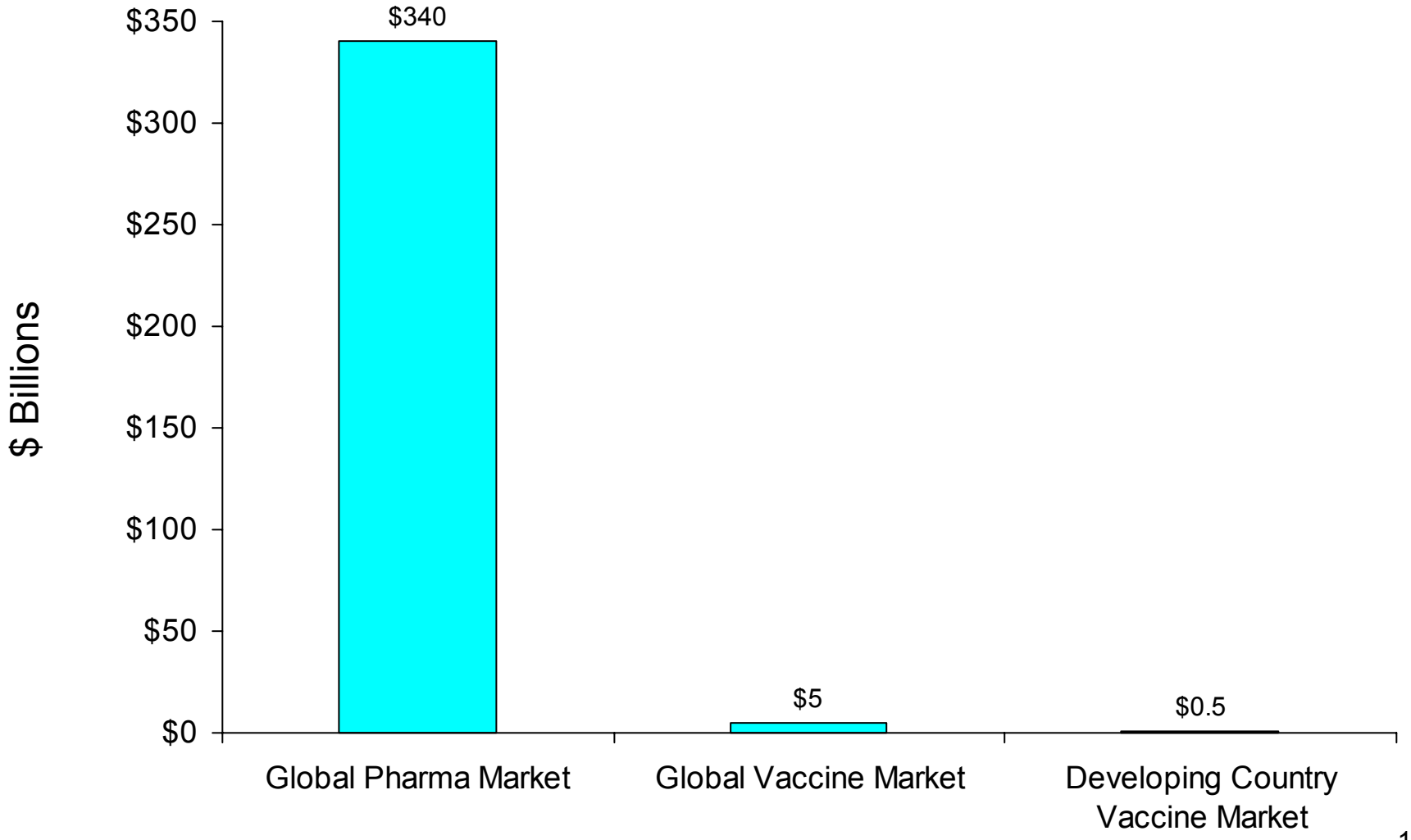
Vaccines represent a tiny percentage of global pharmaceutical sales.



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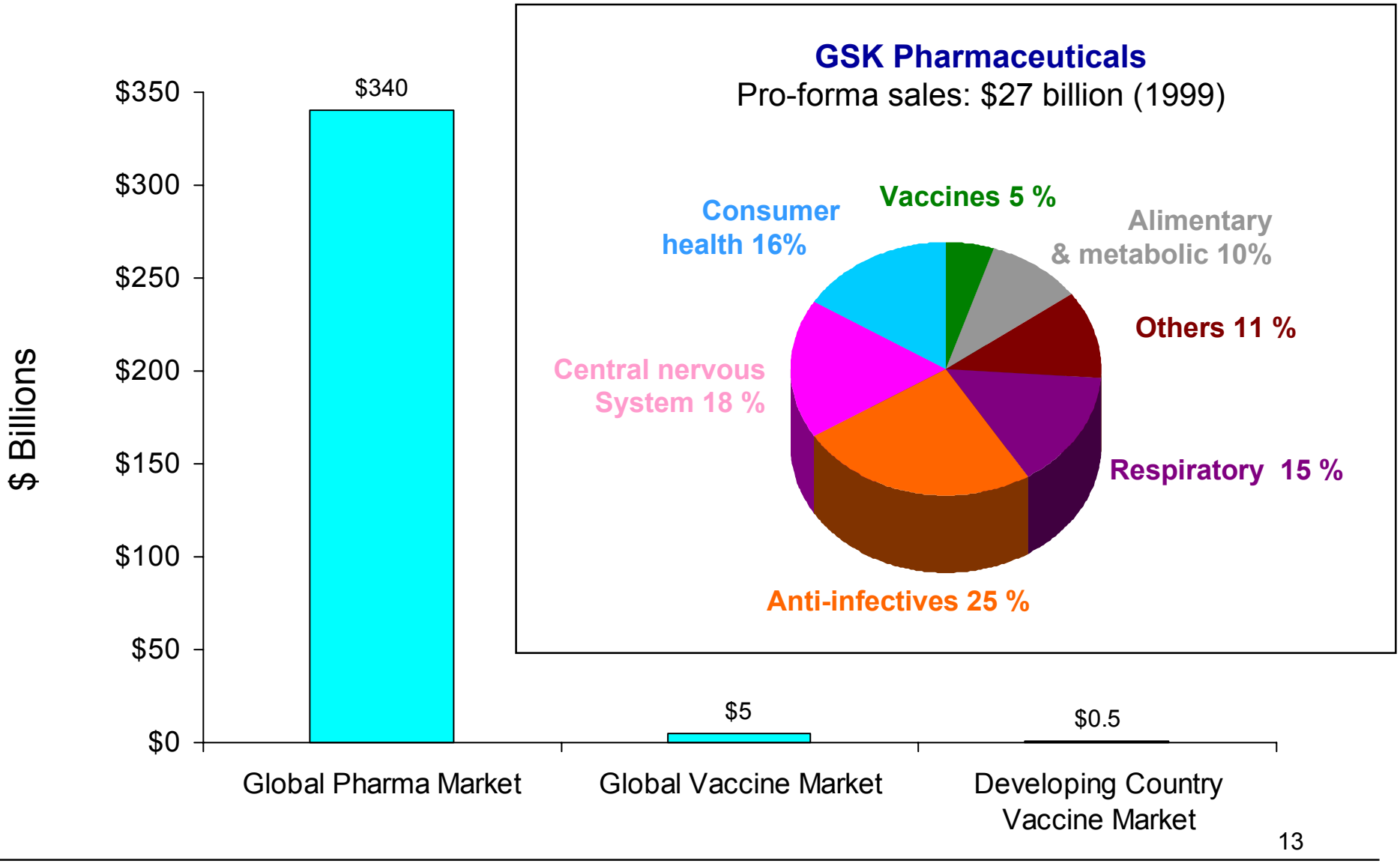
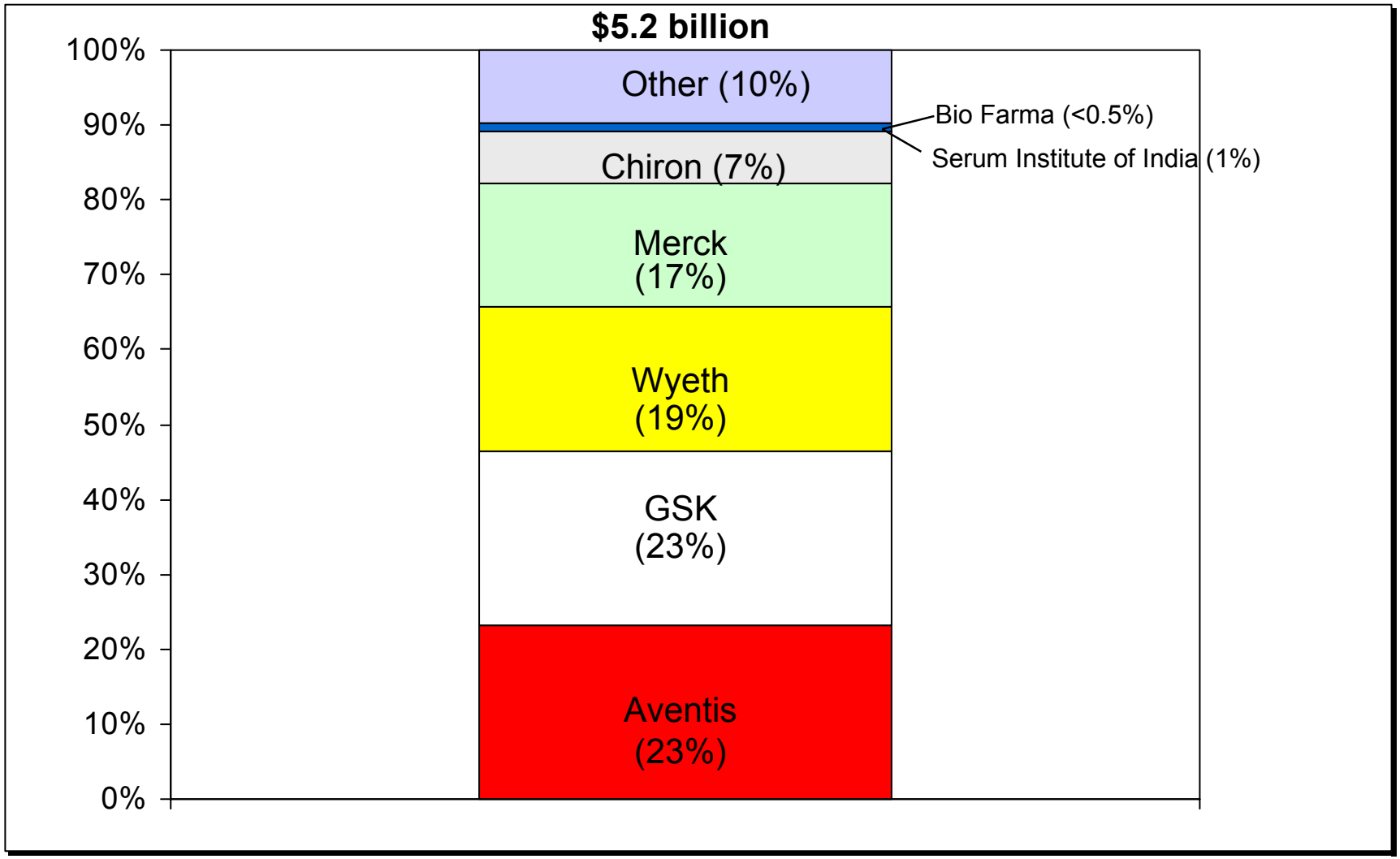
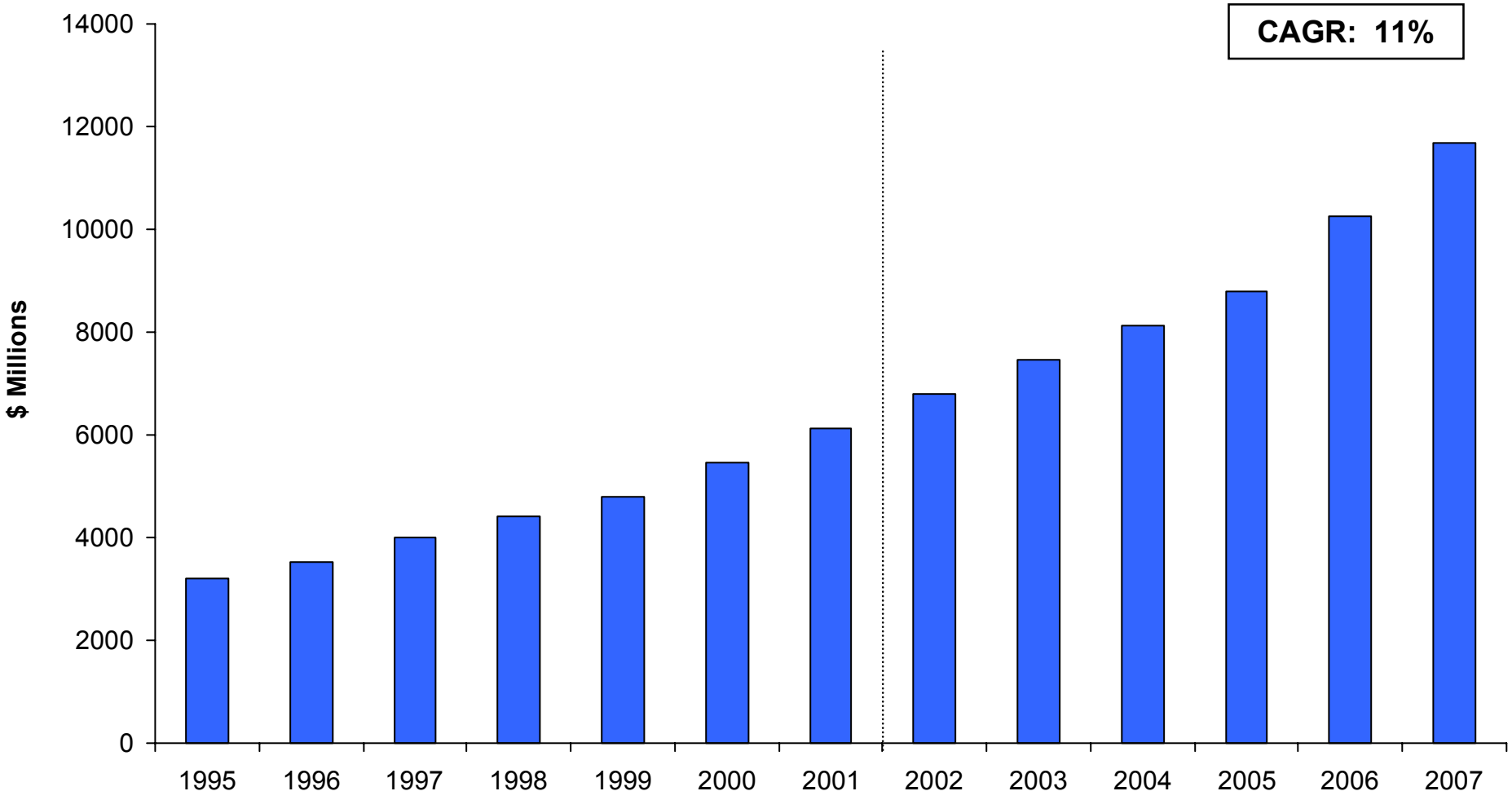


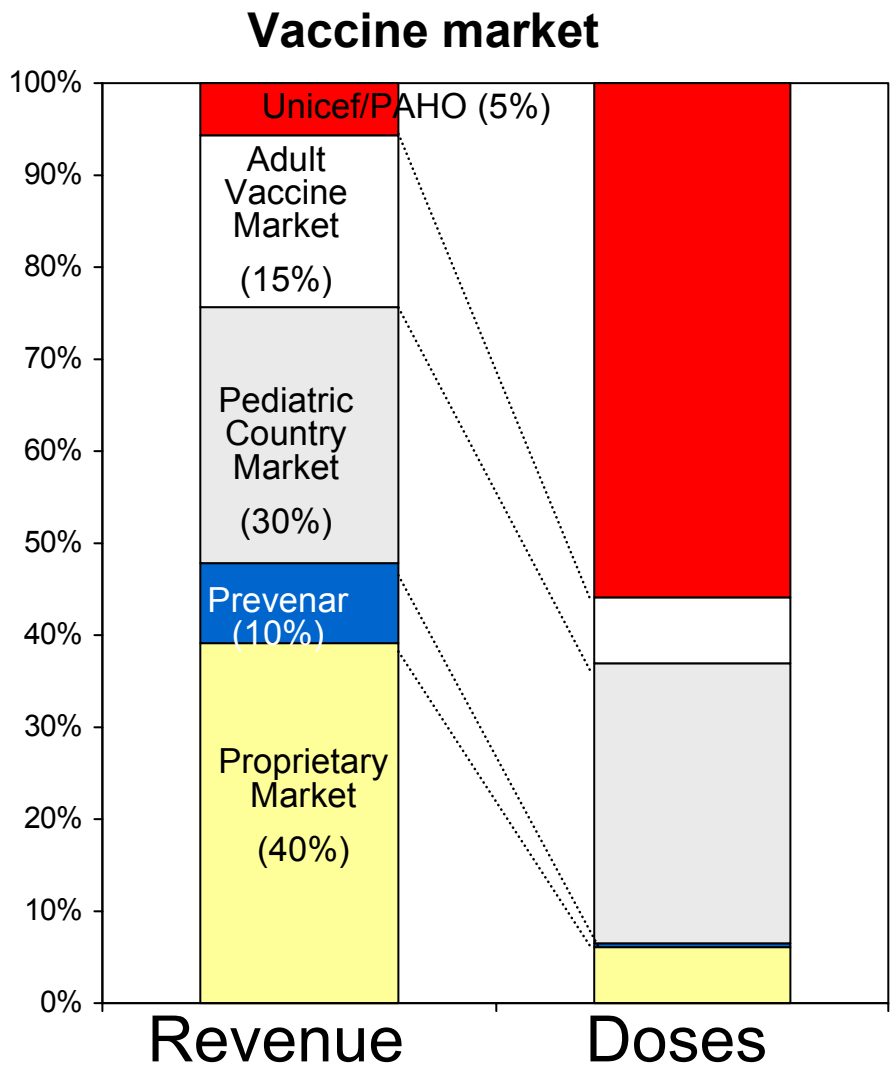
Despite changes in the biotechnology and pharmaceutical markets, 5 vaccine manufacturers still control the vaccine market.



Market projections show robust and steady growth



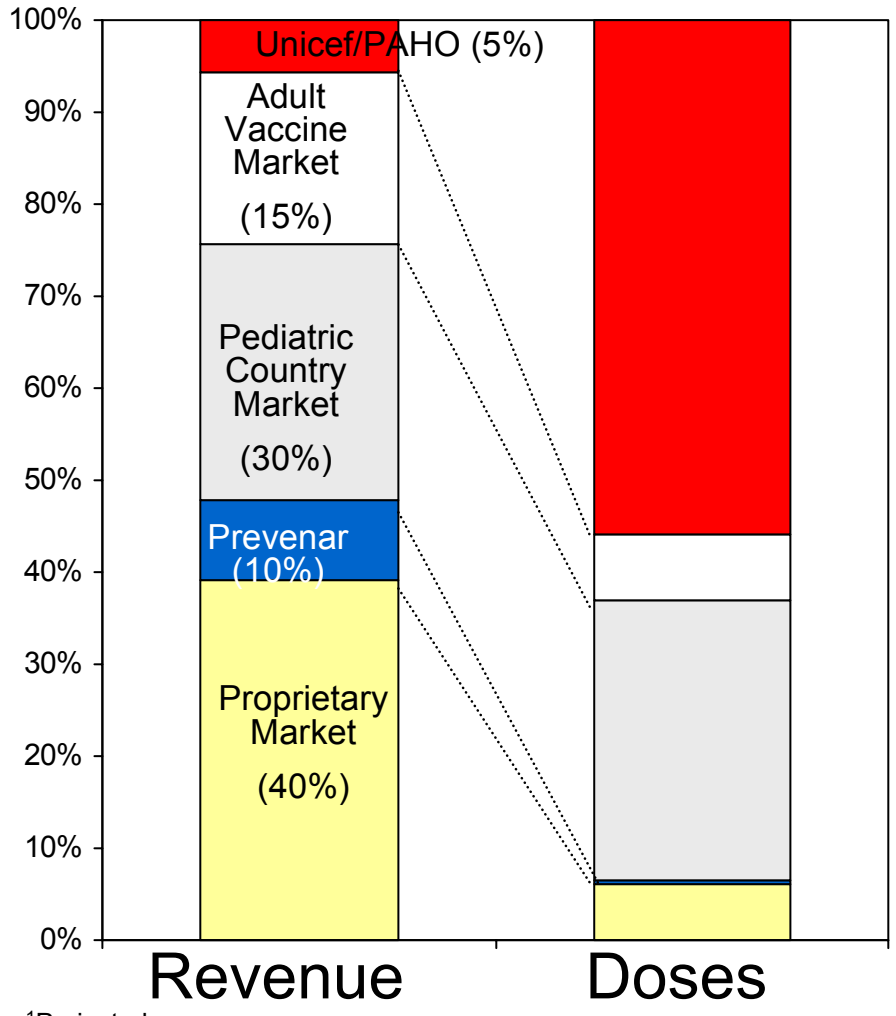
The vaccine market is comprised of a number of distinct product and customer groups.



UNICEF and PAHO account for 5% of the revenues and roughly 50% of the volume

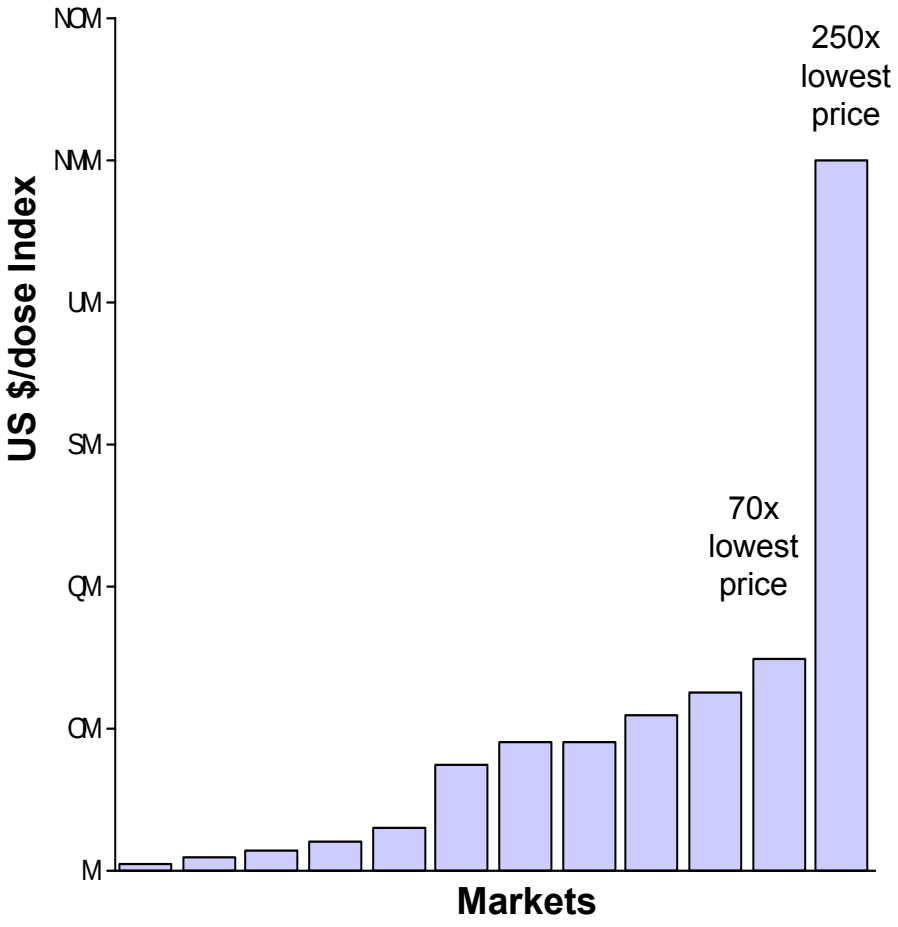
This extreme difference between volumes and revenues is made possible by differential pricing.

Vaccine market

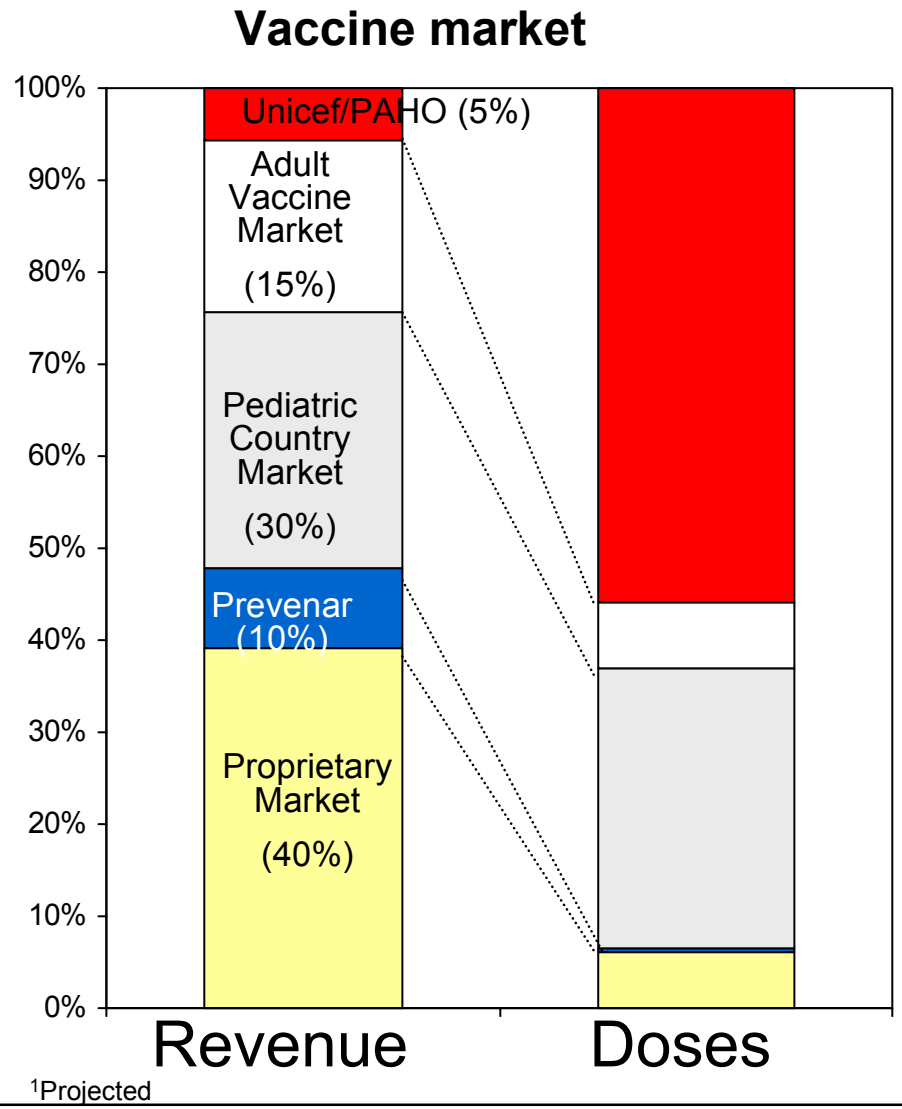


[1]Projected

Differential pricing: OPV



The market's growth is fuelled by new vaccines. Prevenar, introduced into the US in 2000 already has sales of nearly $500.



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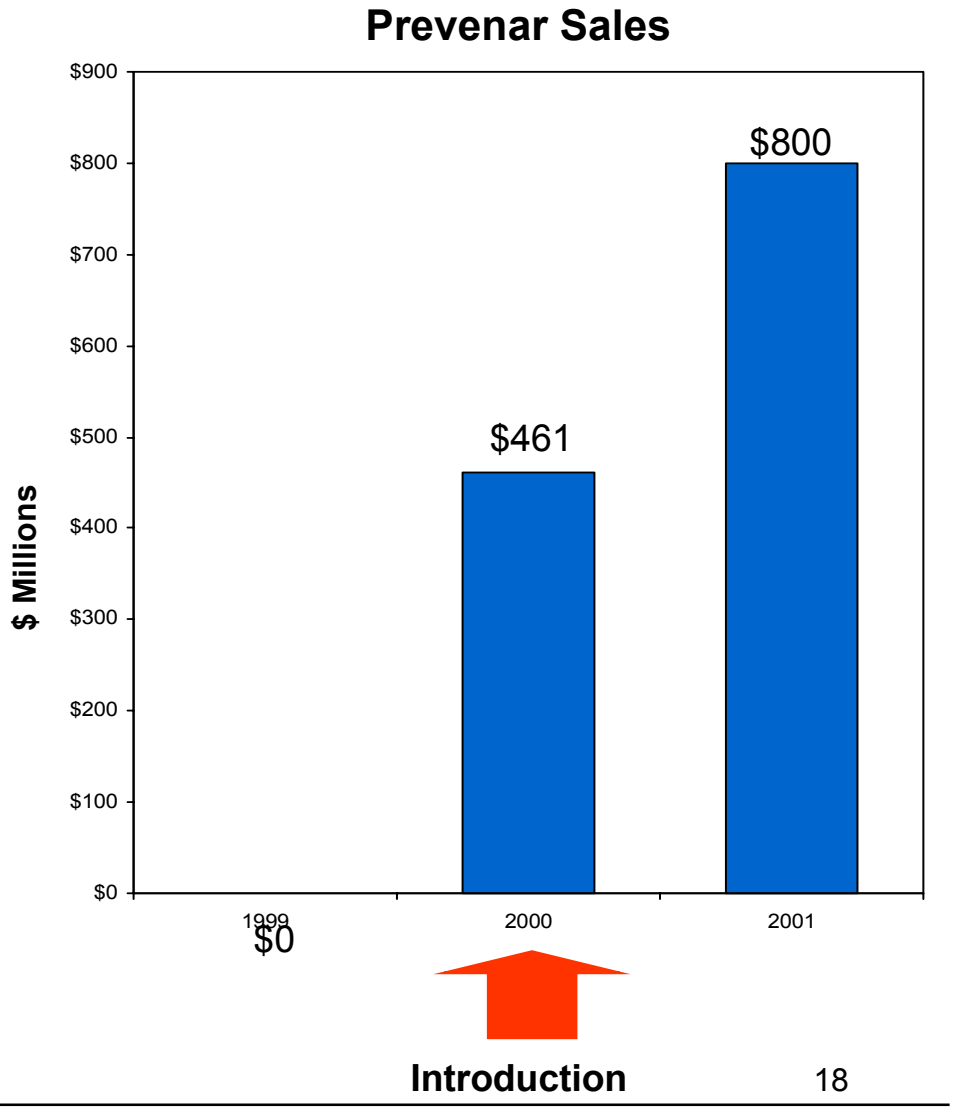
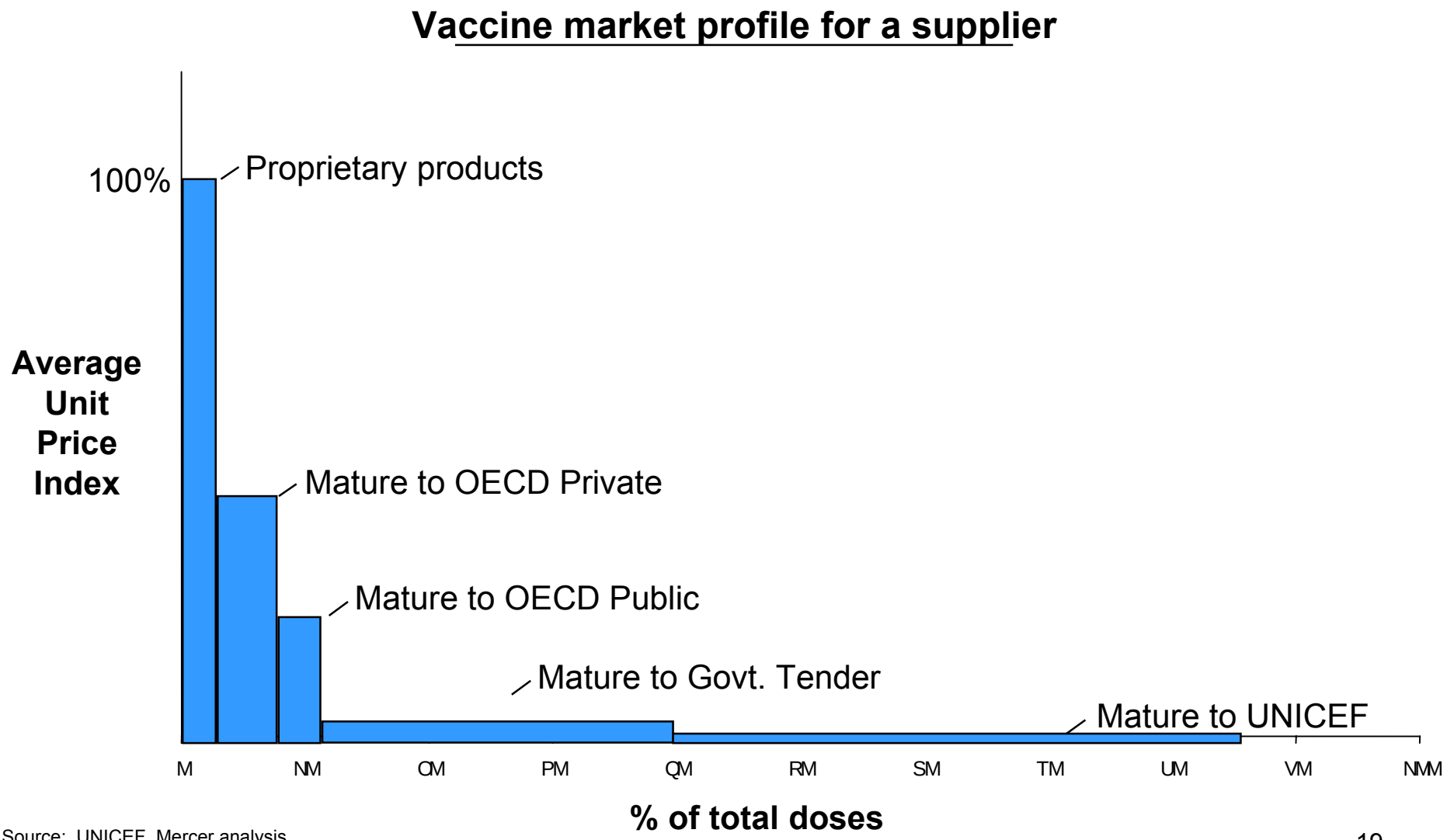
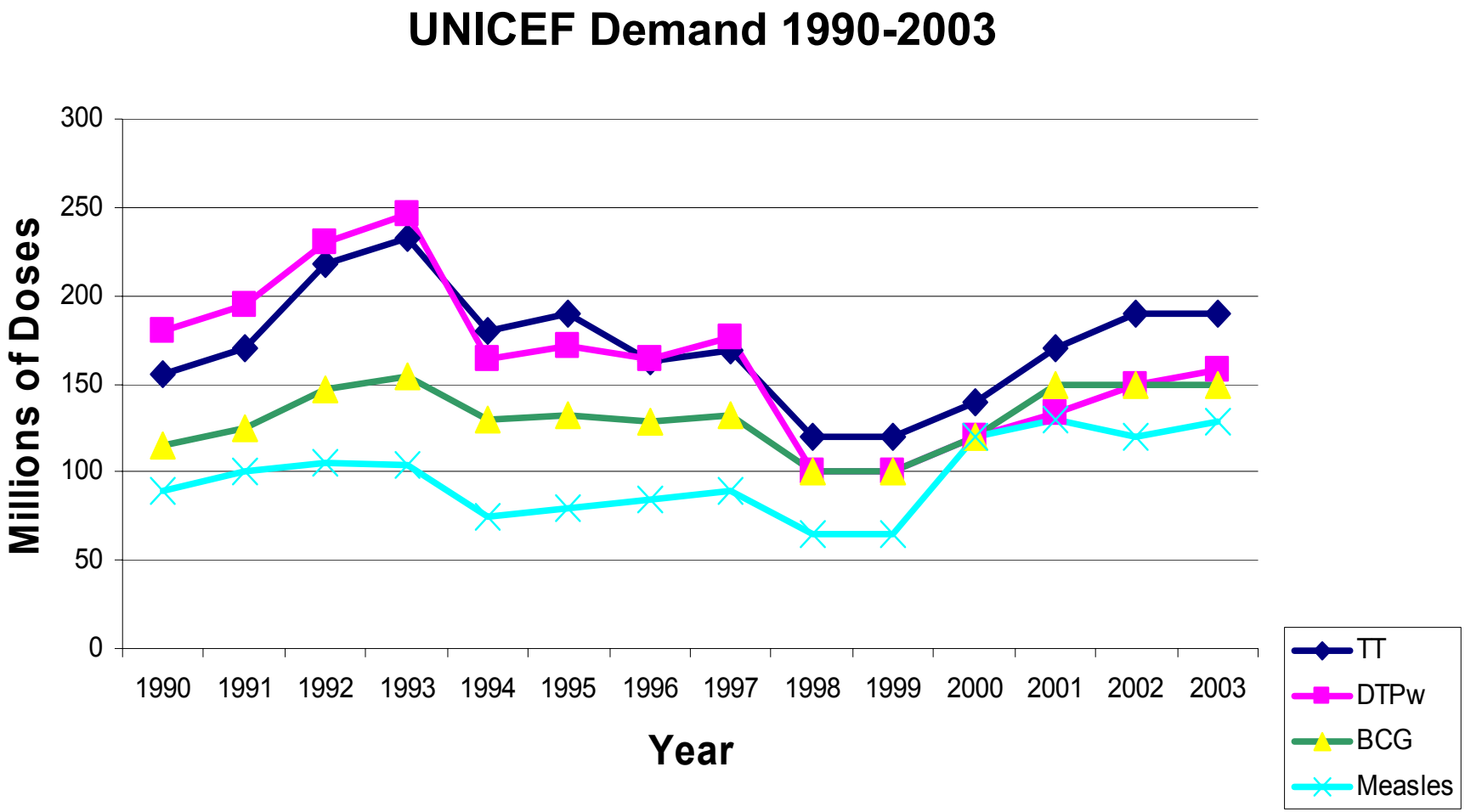


Differential pricing has resulted in strong volume/value skews for individual manufacturers.



Source: UNICEF, Mercer analysis

The large volumes demanded by UNICEF and PAHO have historically been unpredictable.



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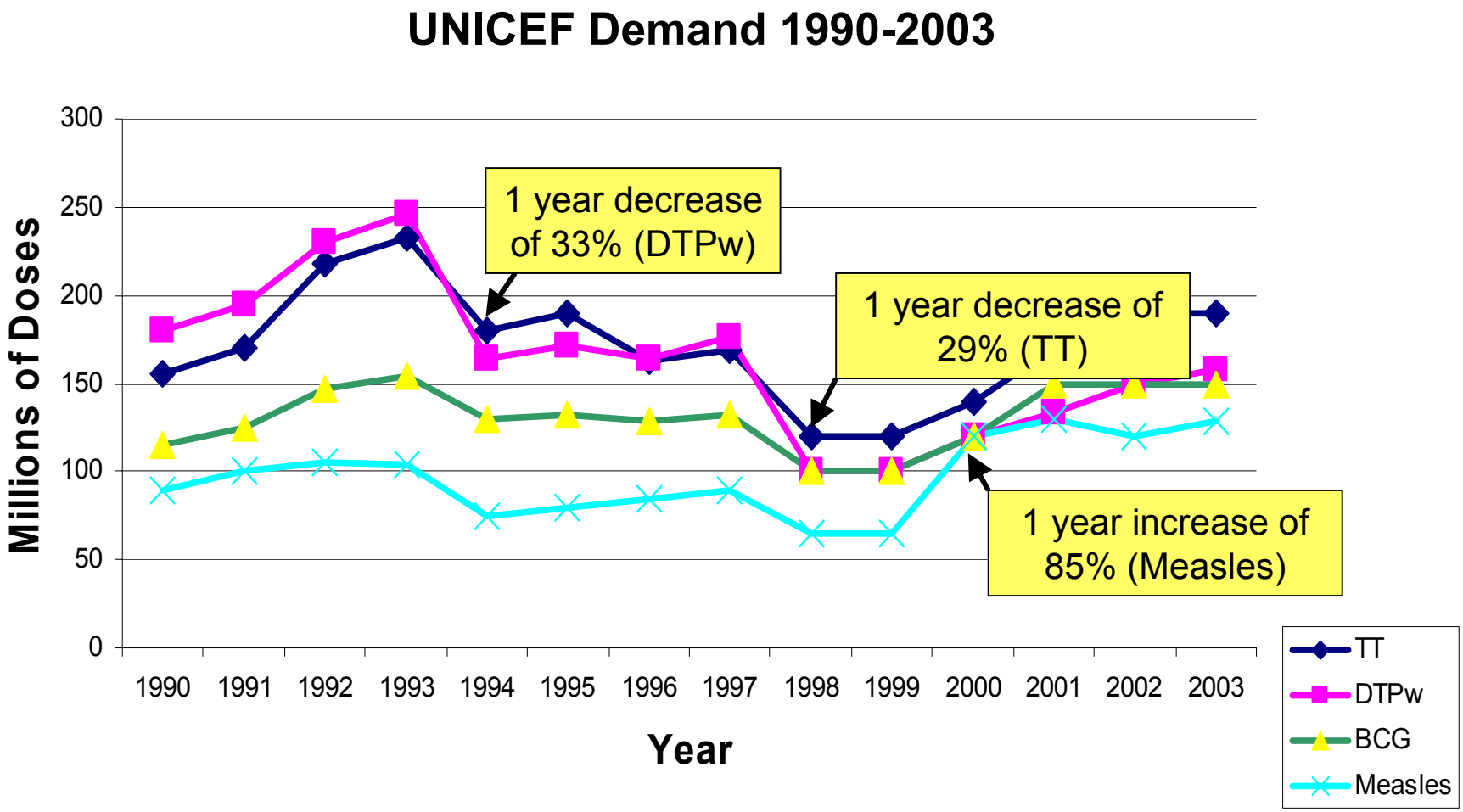
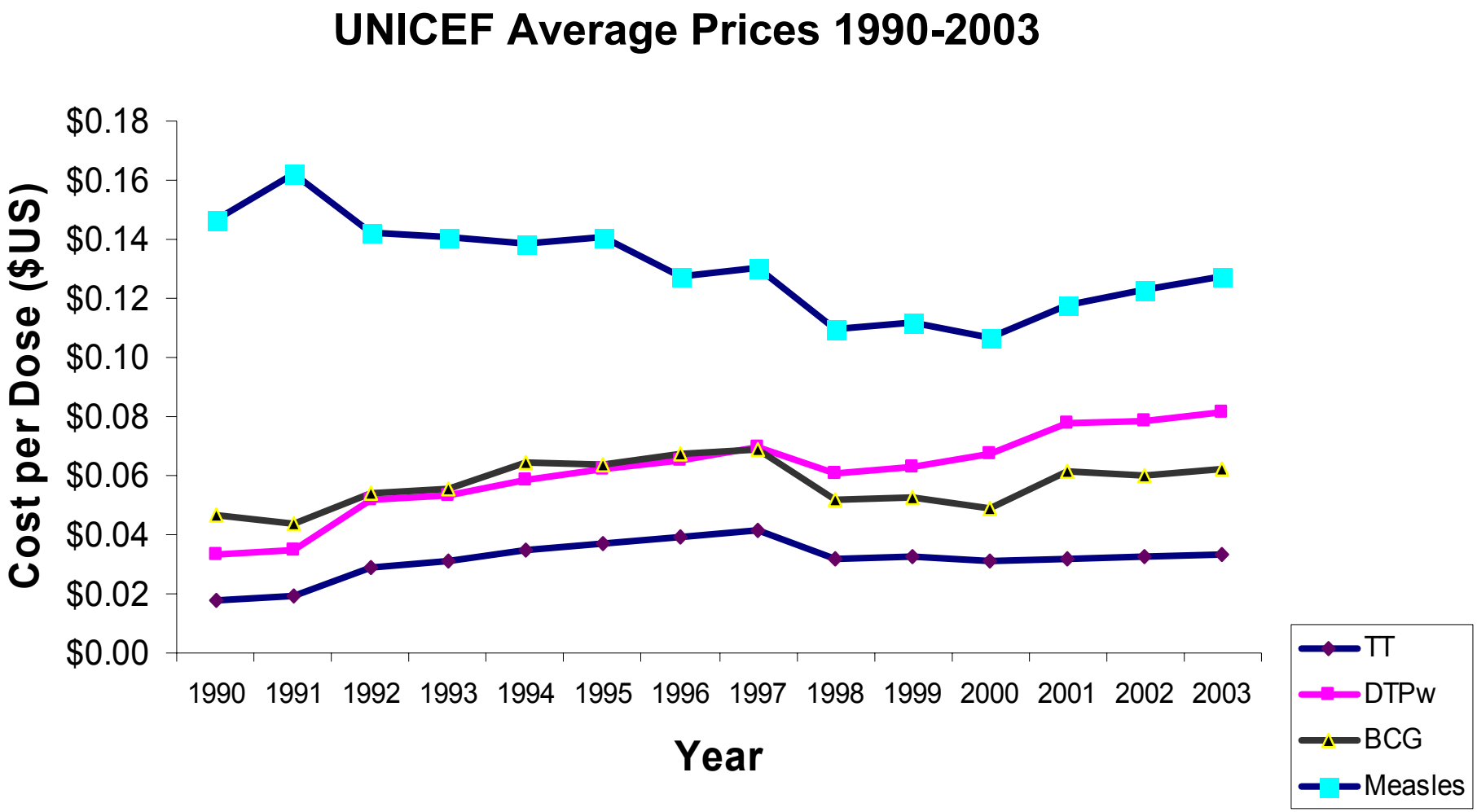
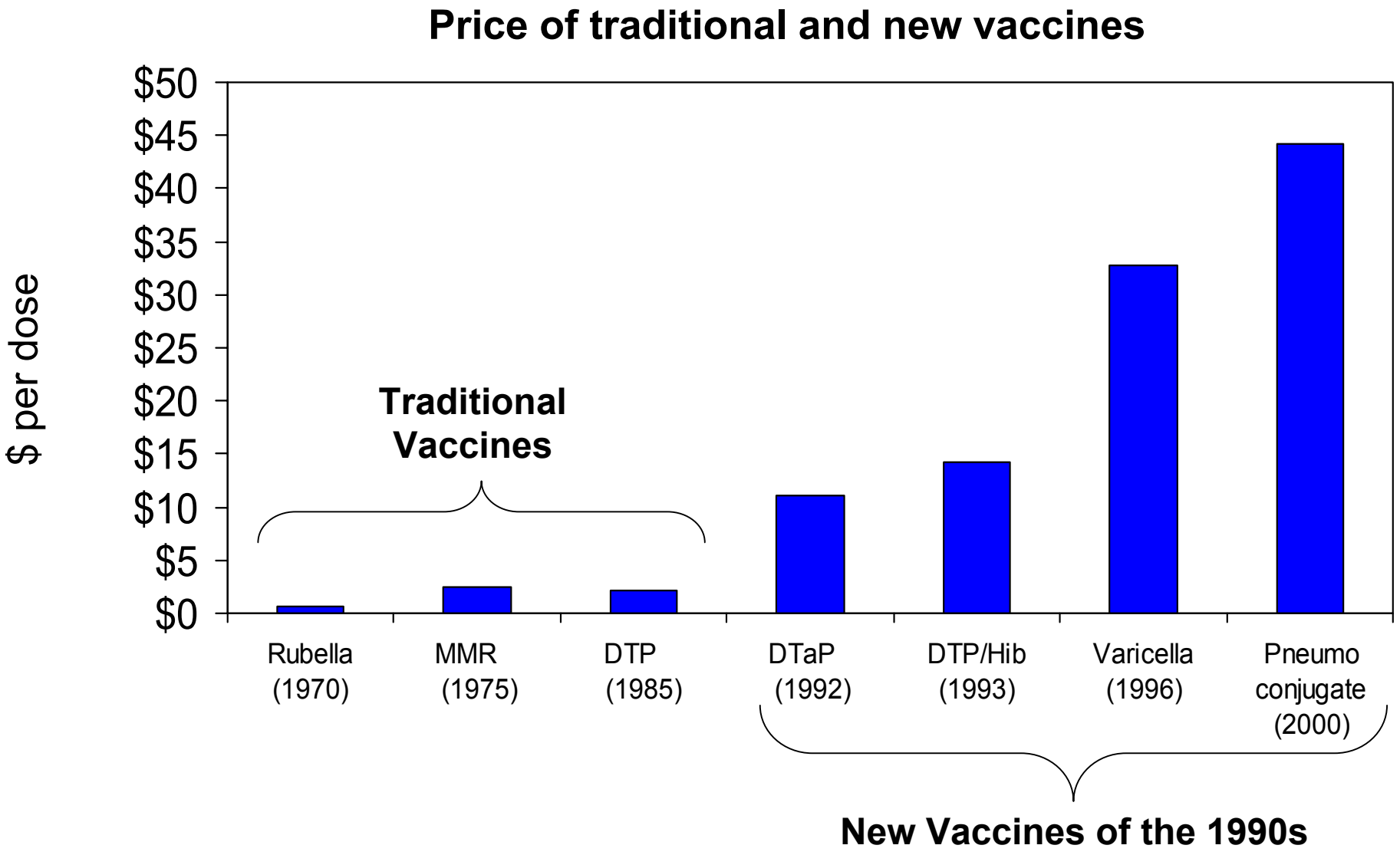


Despite unpredictable demand, manufacturer prices for traditional vaccines have remained extremely stable.



Source: UNICEF

However, prices for newer vaccines are orders of magnitude larger than prices for the traditional vaccines.



Source: CDC contract prices, 1970-2000

New forces are impacting the vaccine industry.

- Increased visibility of global health issues
- Pressure from pharmaceutical parents company to meet financial targets
- Emerging competitors
- Changes in regulation
- Emergence of many combination products
- Increased range of new and complex technologies
- Bio tech “revolution”
  - More products
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- **India**: Serum Institute of India, Bhara Biotech
- **Indonesia**: Bio Farma
- **Cuba**: CIGB, and the Finlay Institute
- **Brazil**: Biomanguinhos
- **Others**: ?

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One manufacturer estimates that costs/sq m have risen 3 fold in the past 5 years because of increased regulatory requirements

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- DTP-Hep B
- DT-IPV
- DTP-IPV-Hib
- DTPa-IPV
- DTPwHB+Hib
- DTwP-Hep B-Hib

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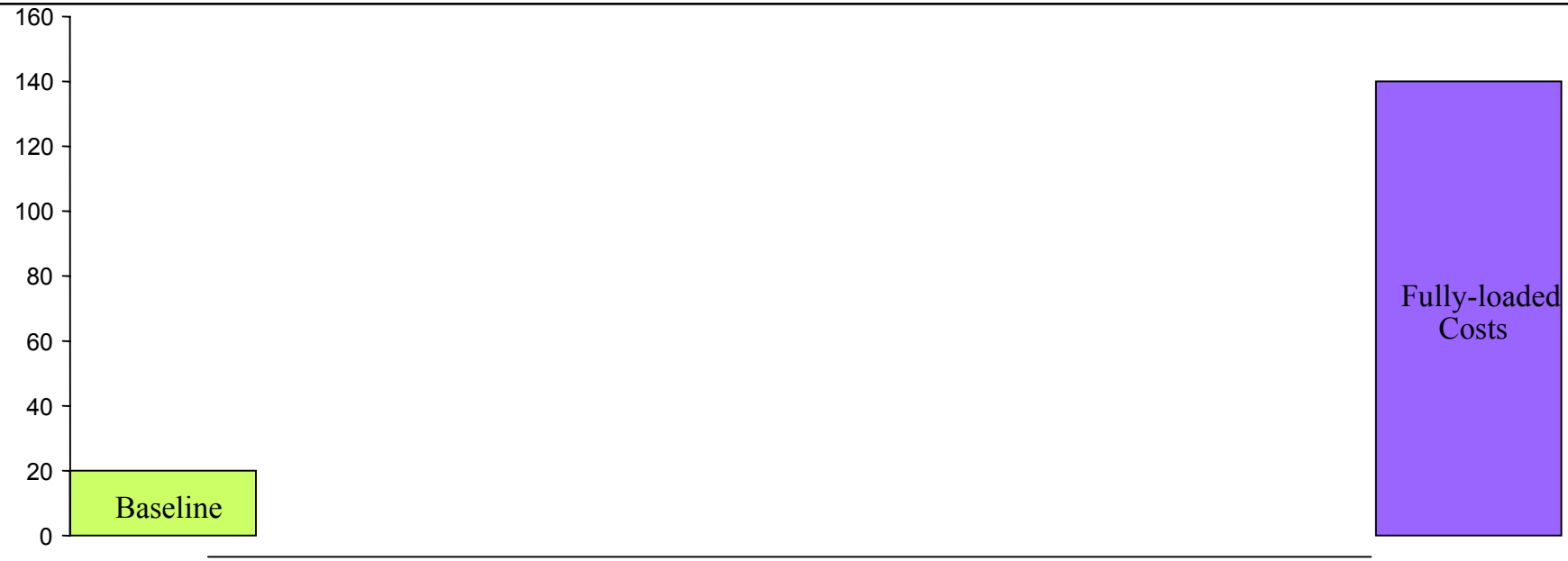
In addition to the baseline, a number of risks contribute to the total cost of the product



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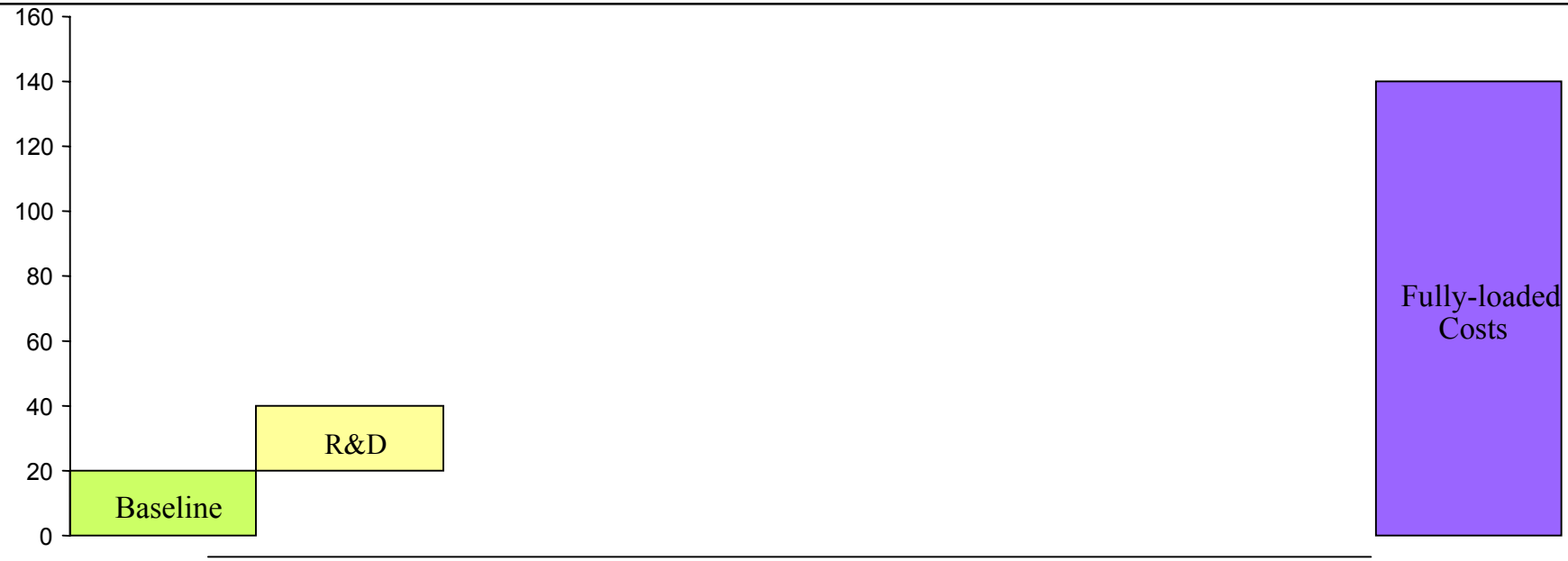

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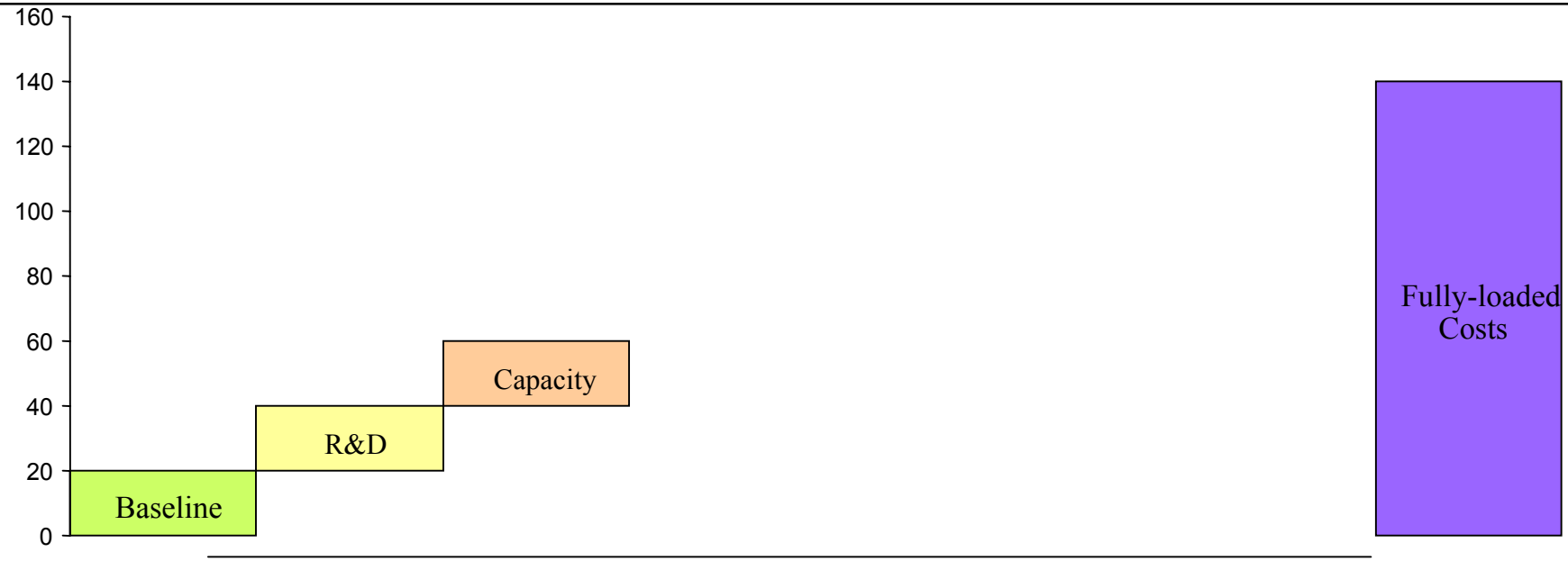

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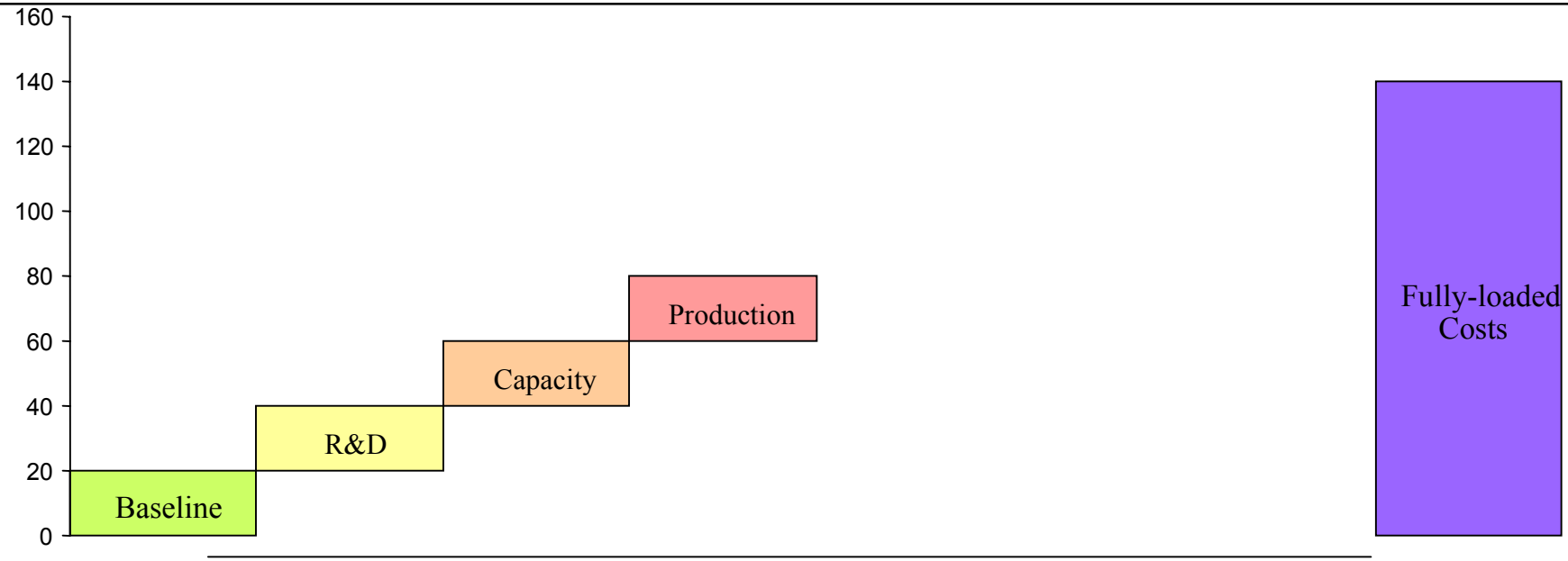

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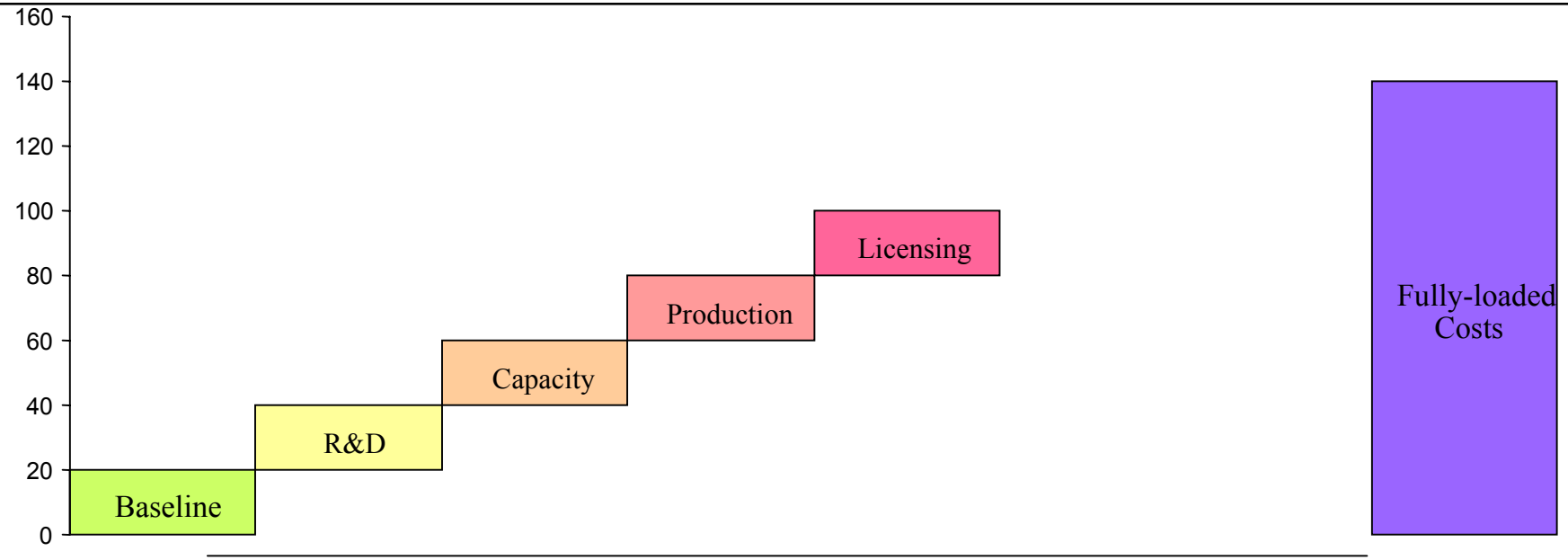

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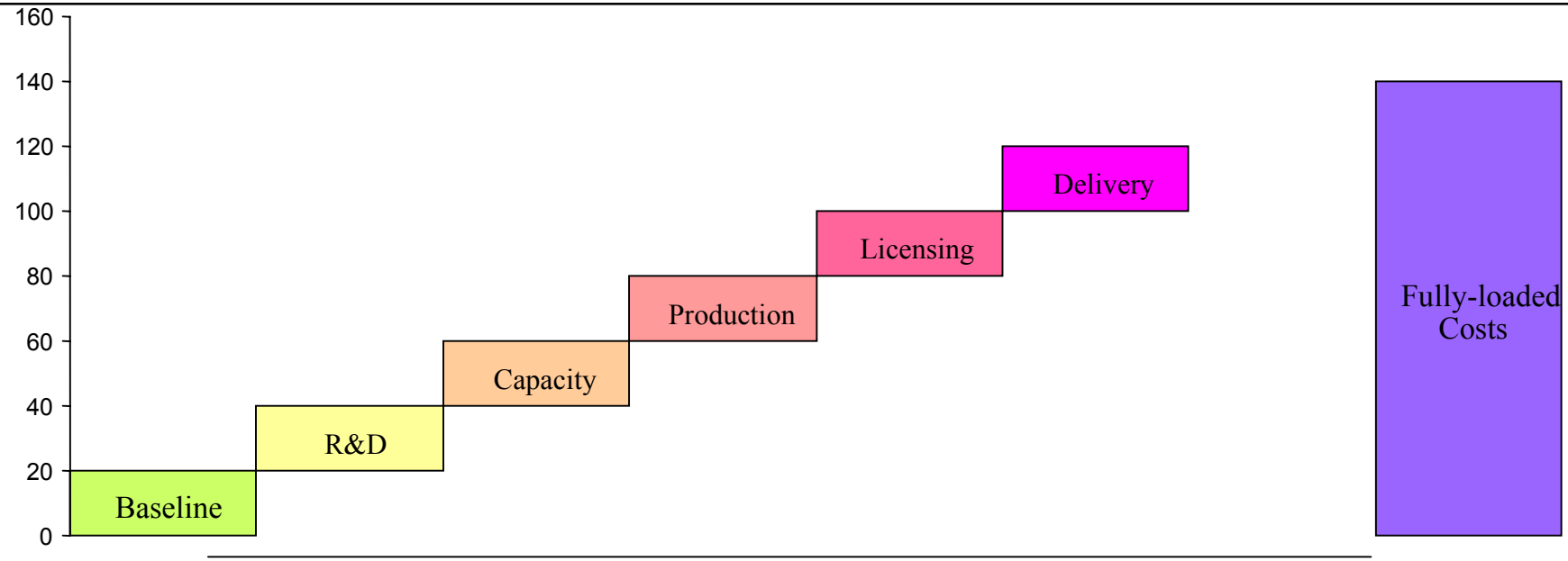

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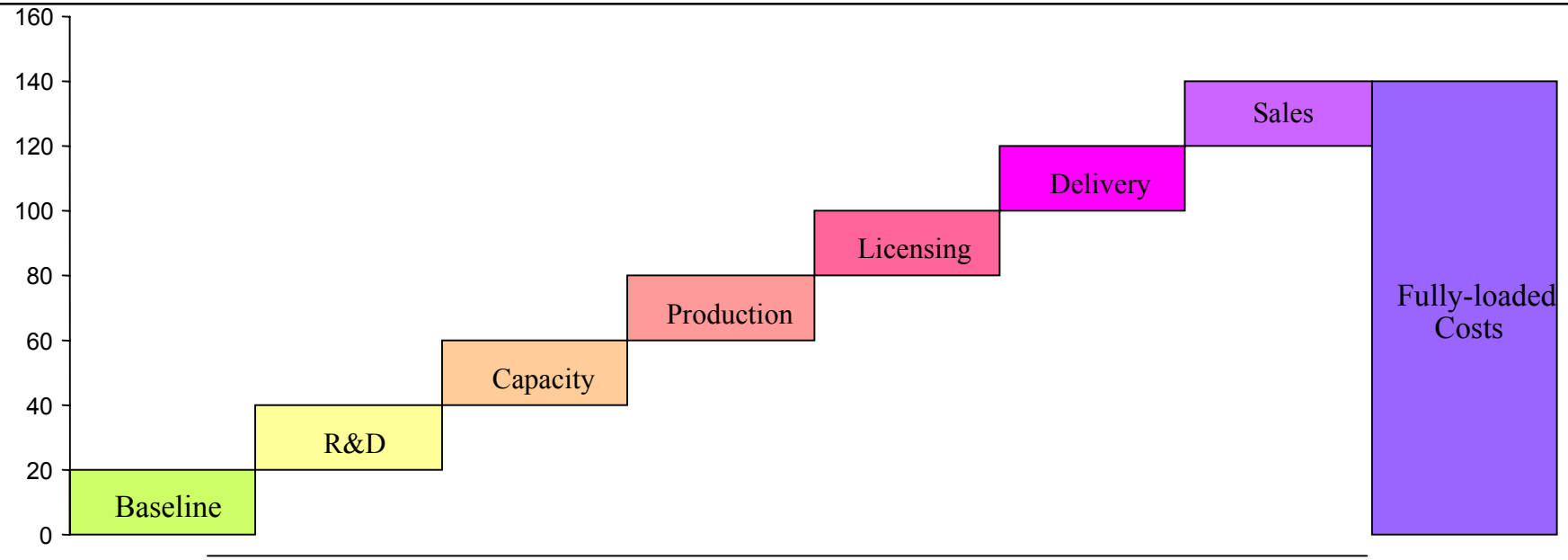

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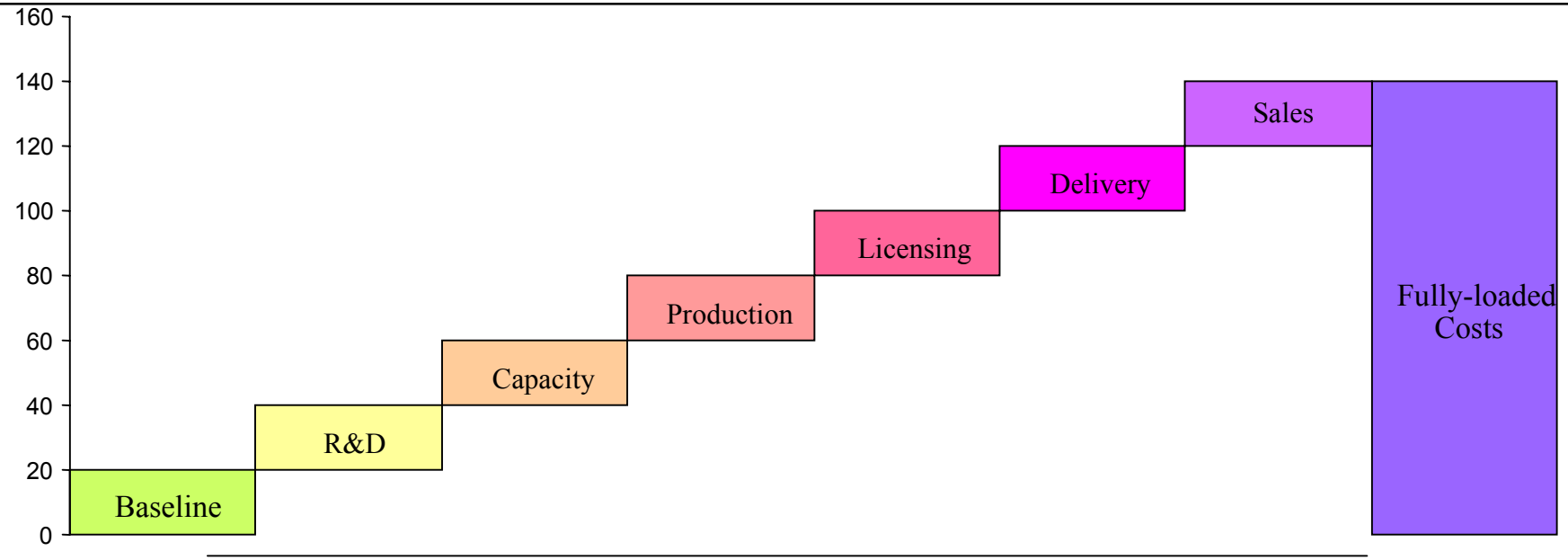

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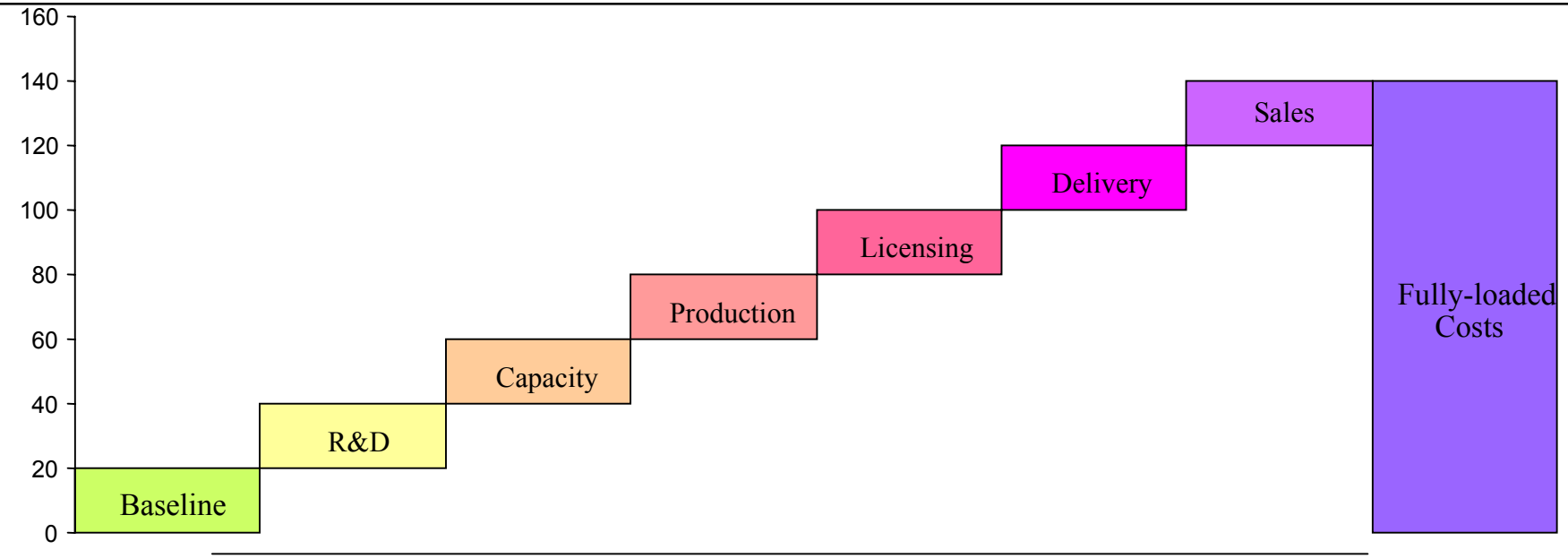

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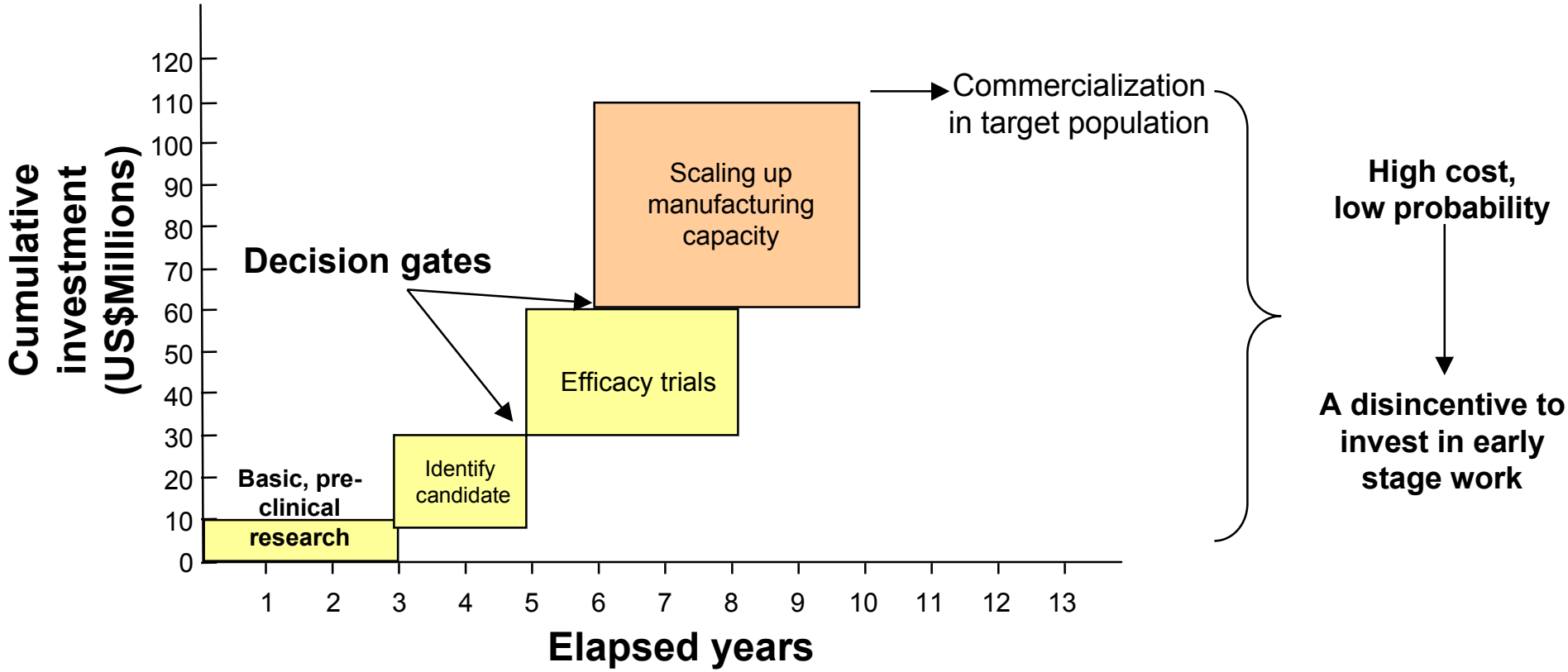
Baseline: Costs and decision gates in vaccine development for a single population

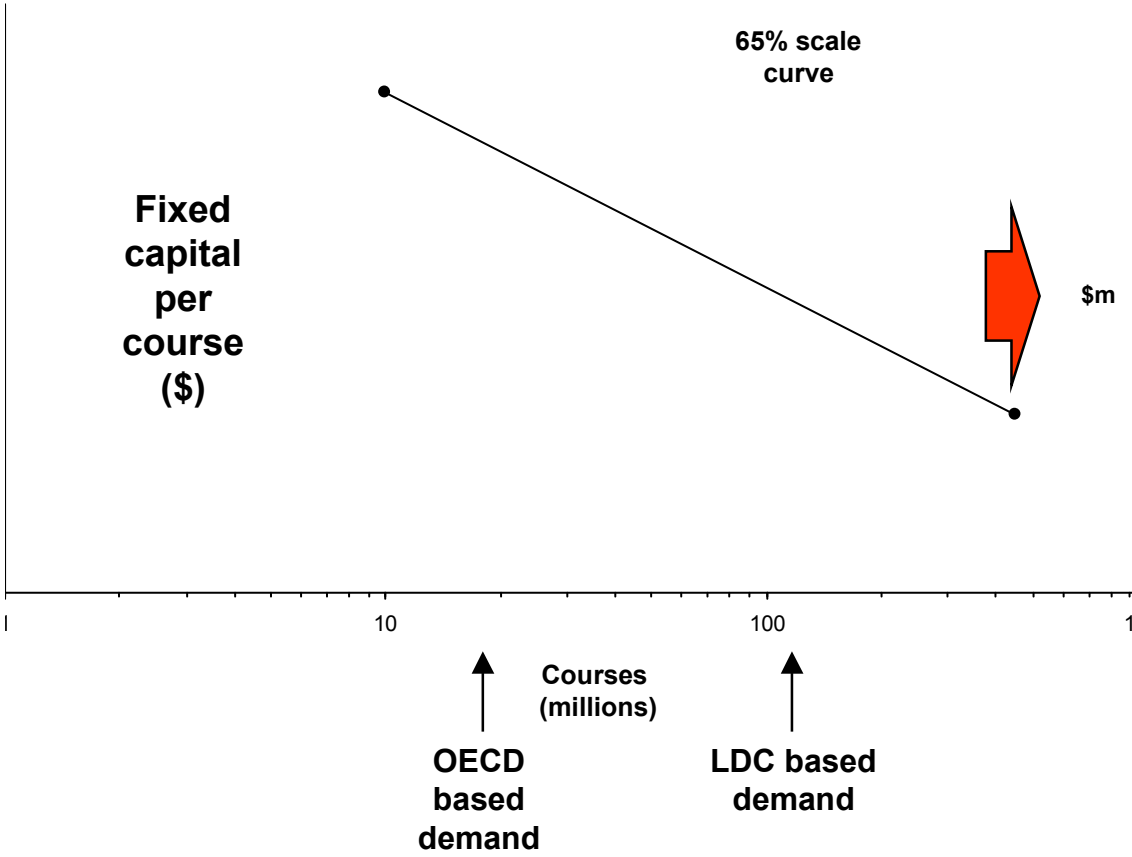


Source: Mercer Management Consultants

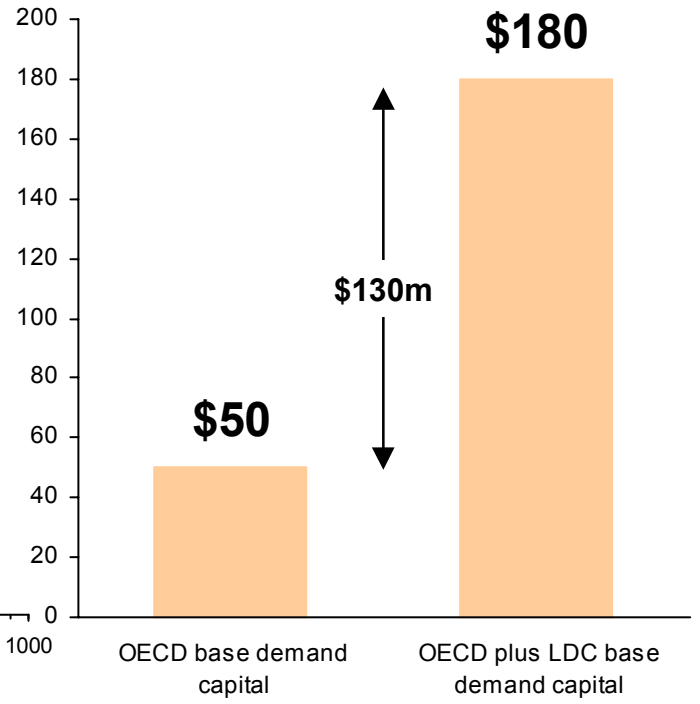
Despite significant economies of scale, sizing a facility for global supp expensive

Illustrative

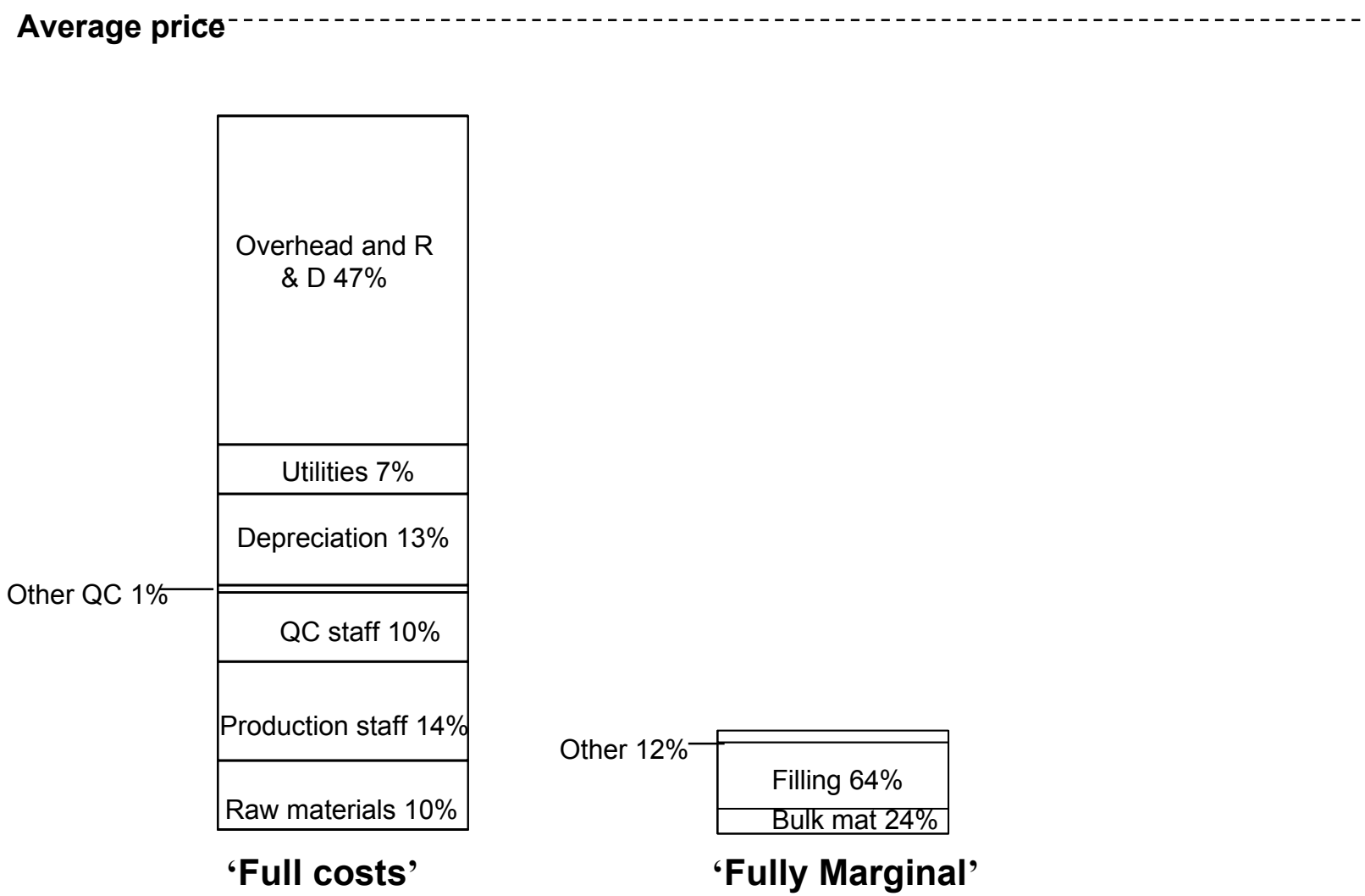
Capital costs are highly scale sensitive



Incremental cost of global production capacity

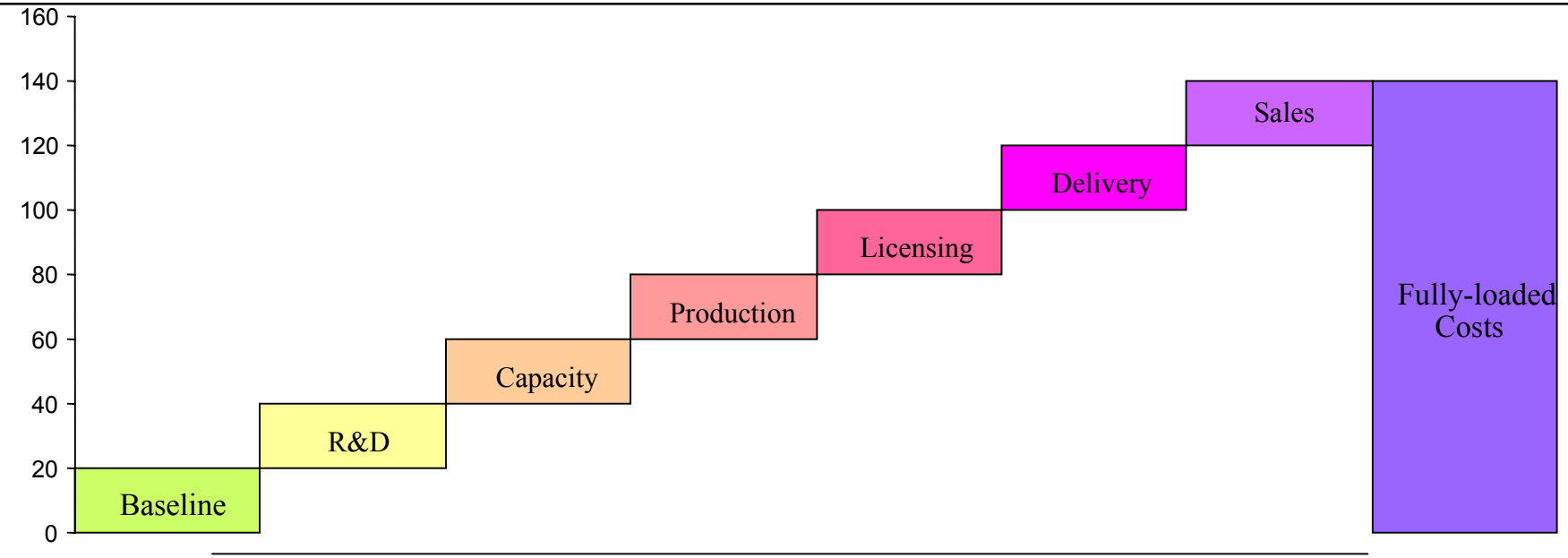


These price differentials between markets can exist because of marginal costing.



Source: Company visits and data, interviews, Mercer analysis

Different risks and costs occur at each step of the value added chain



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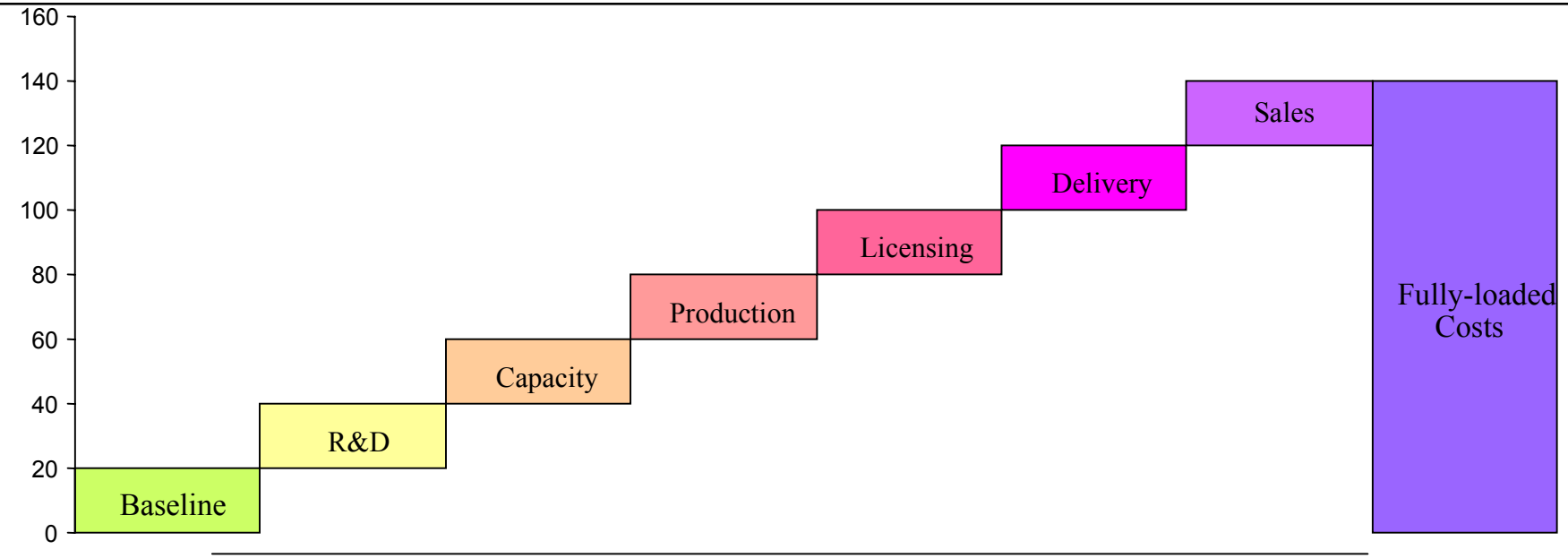

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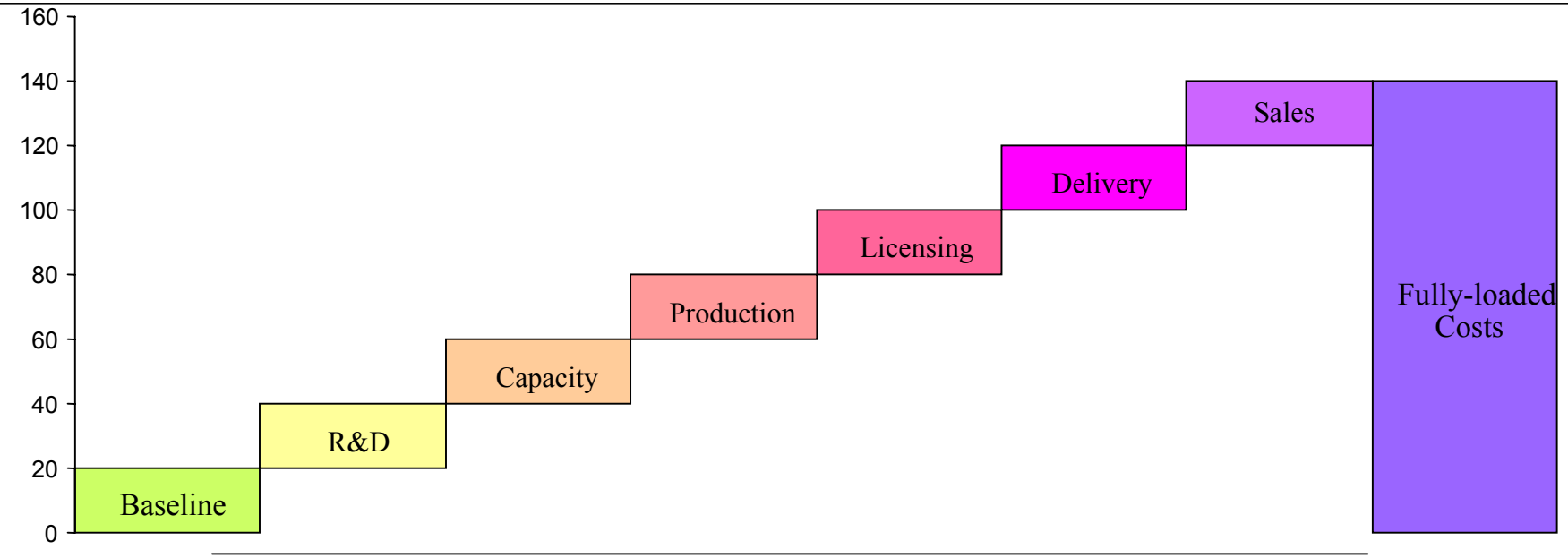

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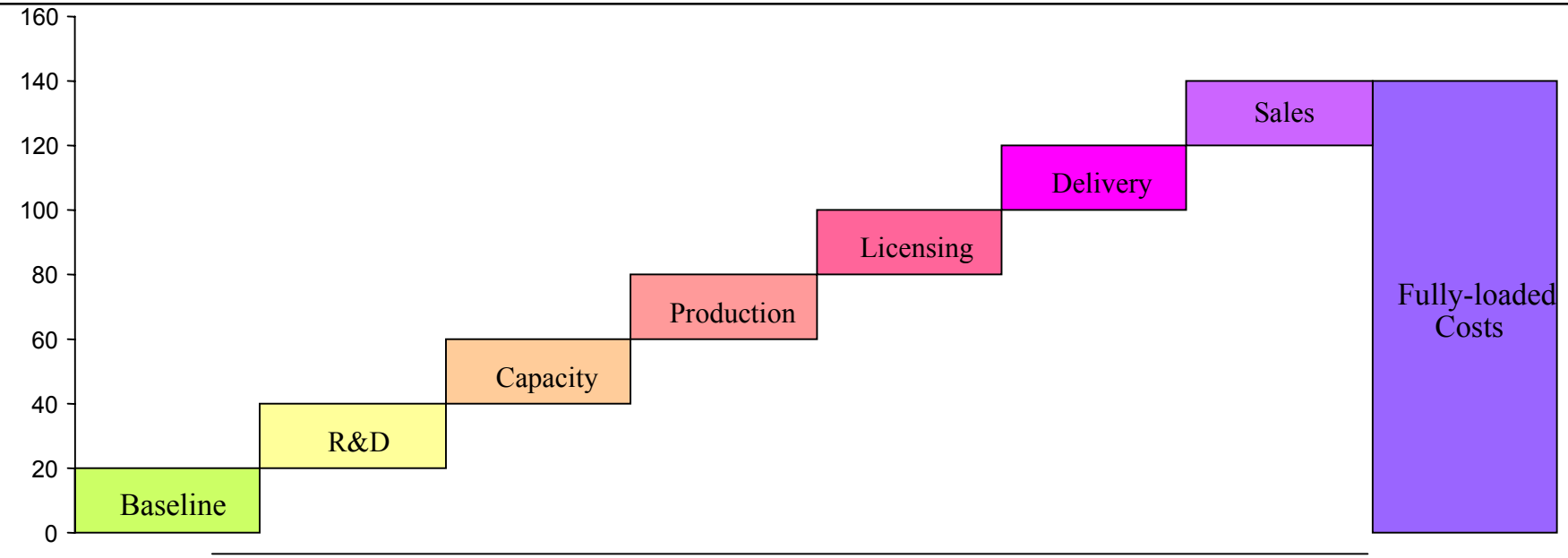

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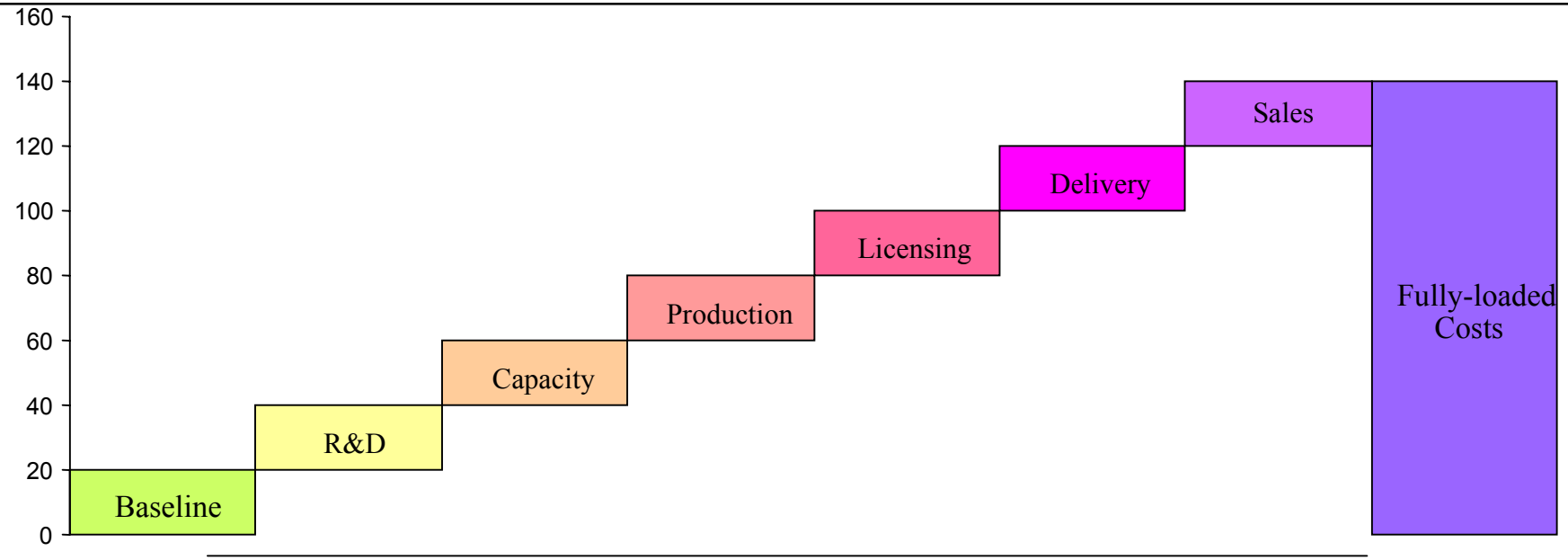

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- Absorbs management time
- Government delays
- License denied
- Complaints/ adverse event

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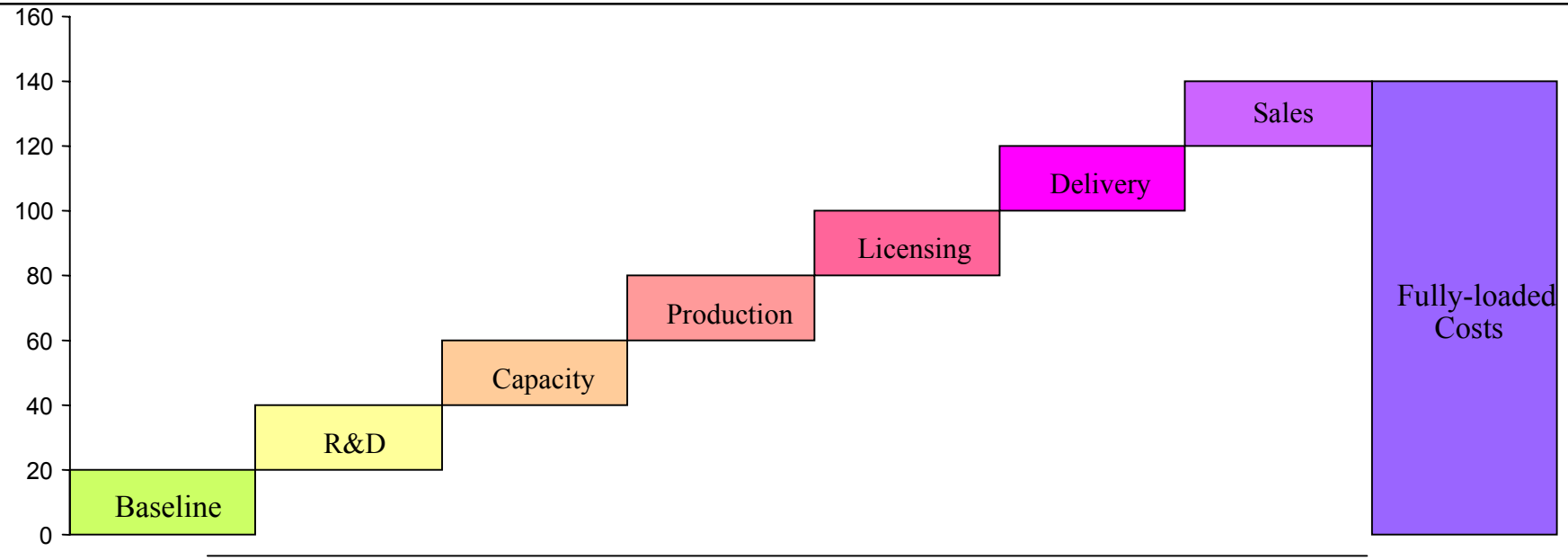

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  - –delays
- Promised product after trial over
- Parallel trials
- Different data hurts licensing

- Difficulty with
  - – plans
  - – facility
  - – equipment
  - – validation
  - – staff
- Degree of dedication
- Management over-runs

- Mgmt problems
- Equipment overruns
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- Supply overruns
- Batch failures
- Scale-up failure
- Raw materials failure
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- Complaints/ adverse event

- Slow uptake
- Can't reach infants
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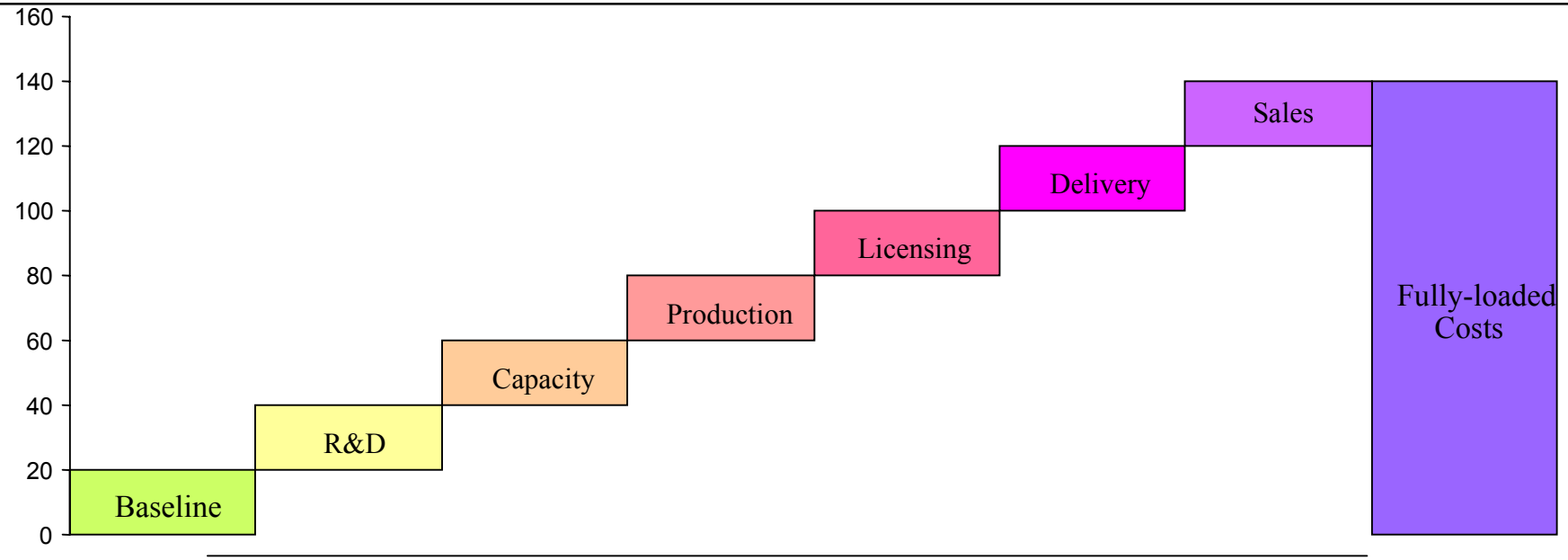
- All baseline costs
- Incremental opportunity costs/risk

Different risks and costs occur at each step of the value added chain



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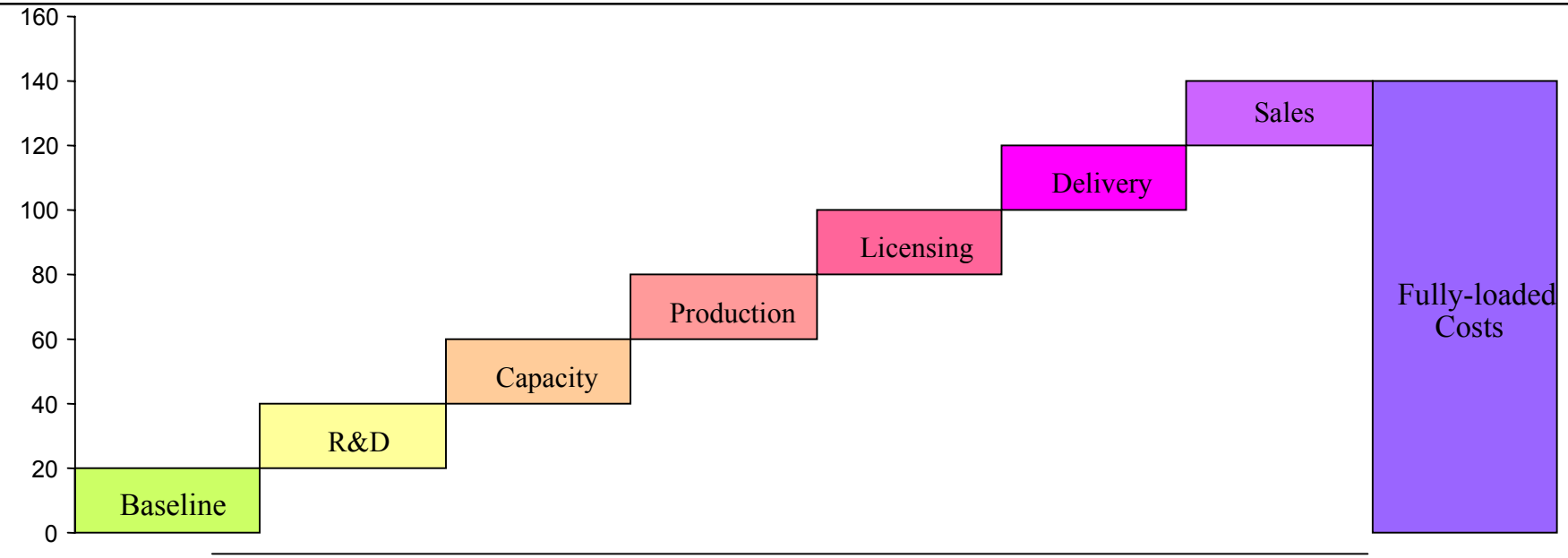

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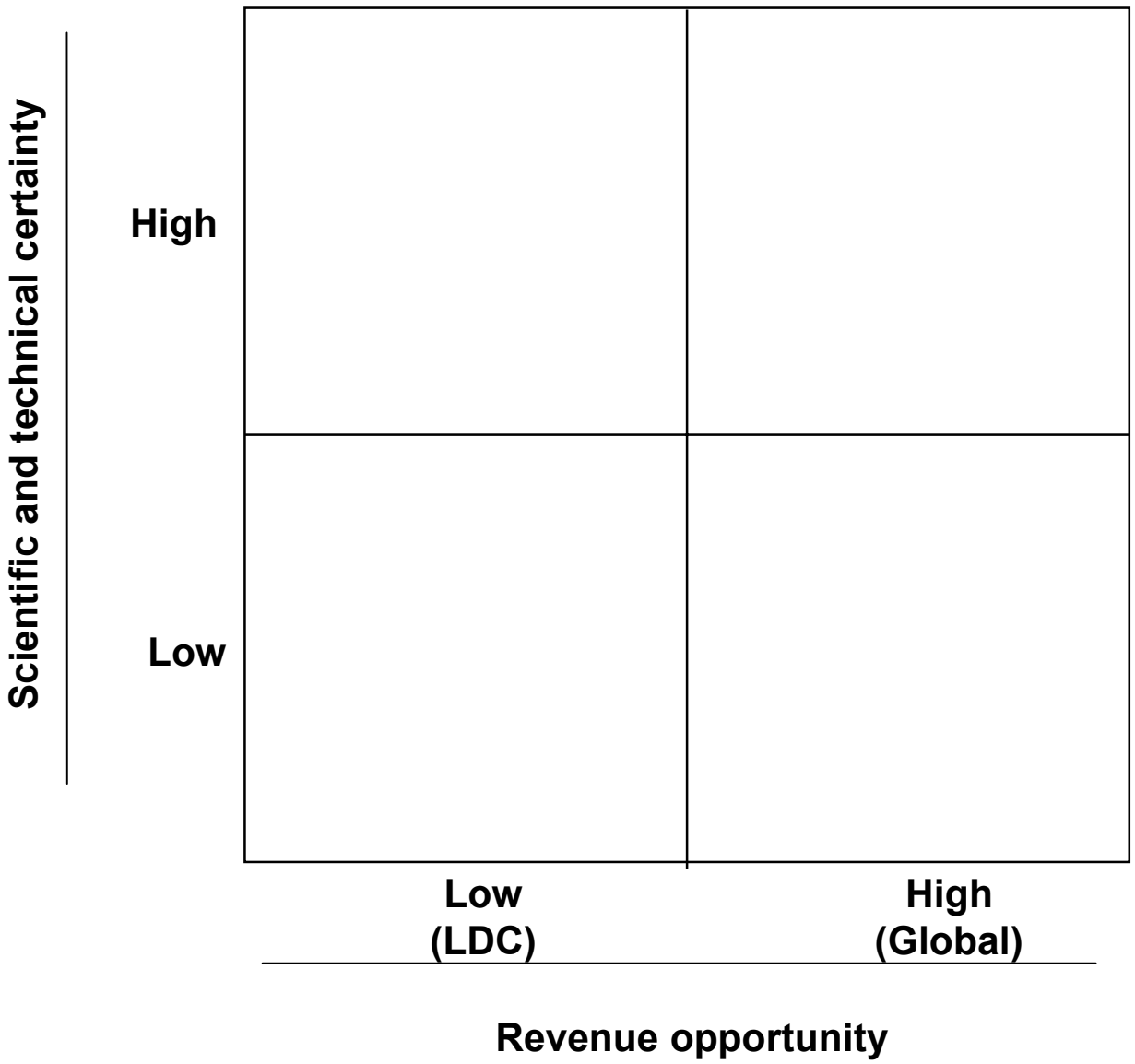
Public Sector Assumes ALL Risk **Private Sector Assumes ALL Risk**

However, the relative importance of each barrier depends on the type of vaccine.



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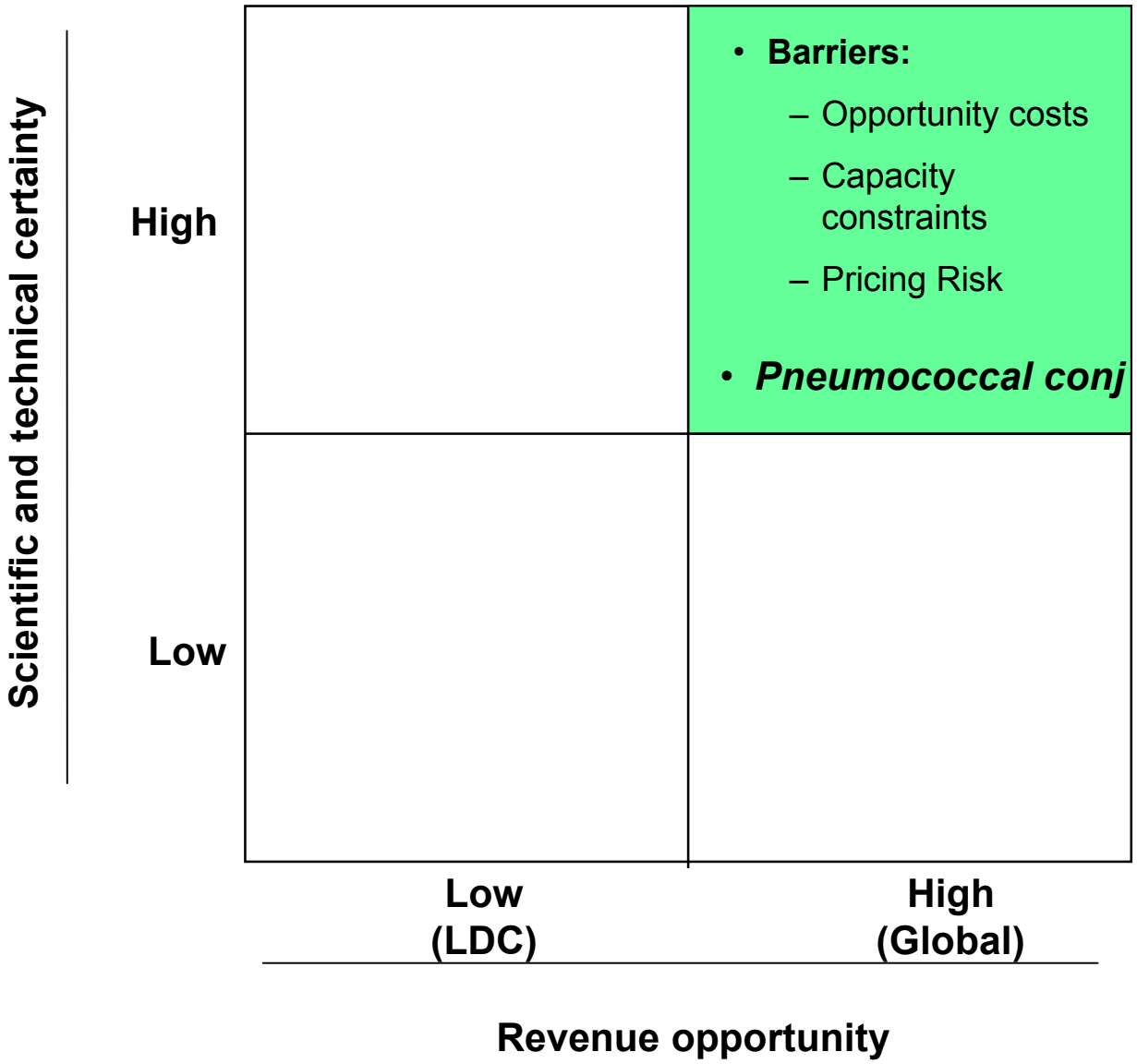

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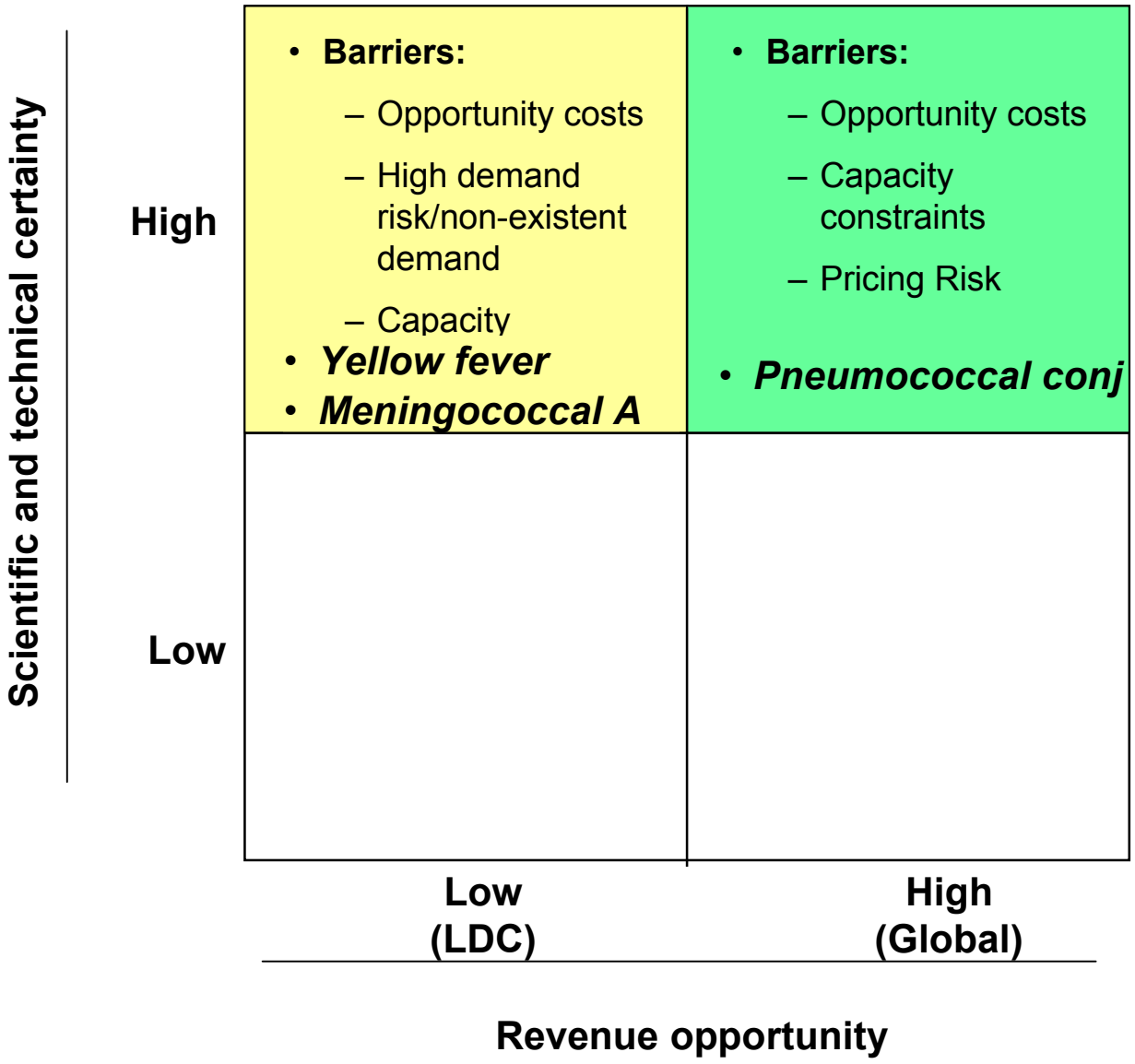

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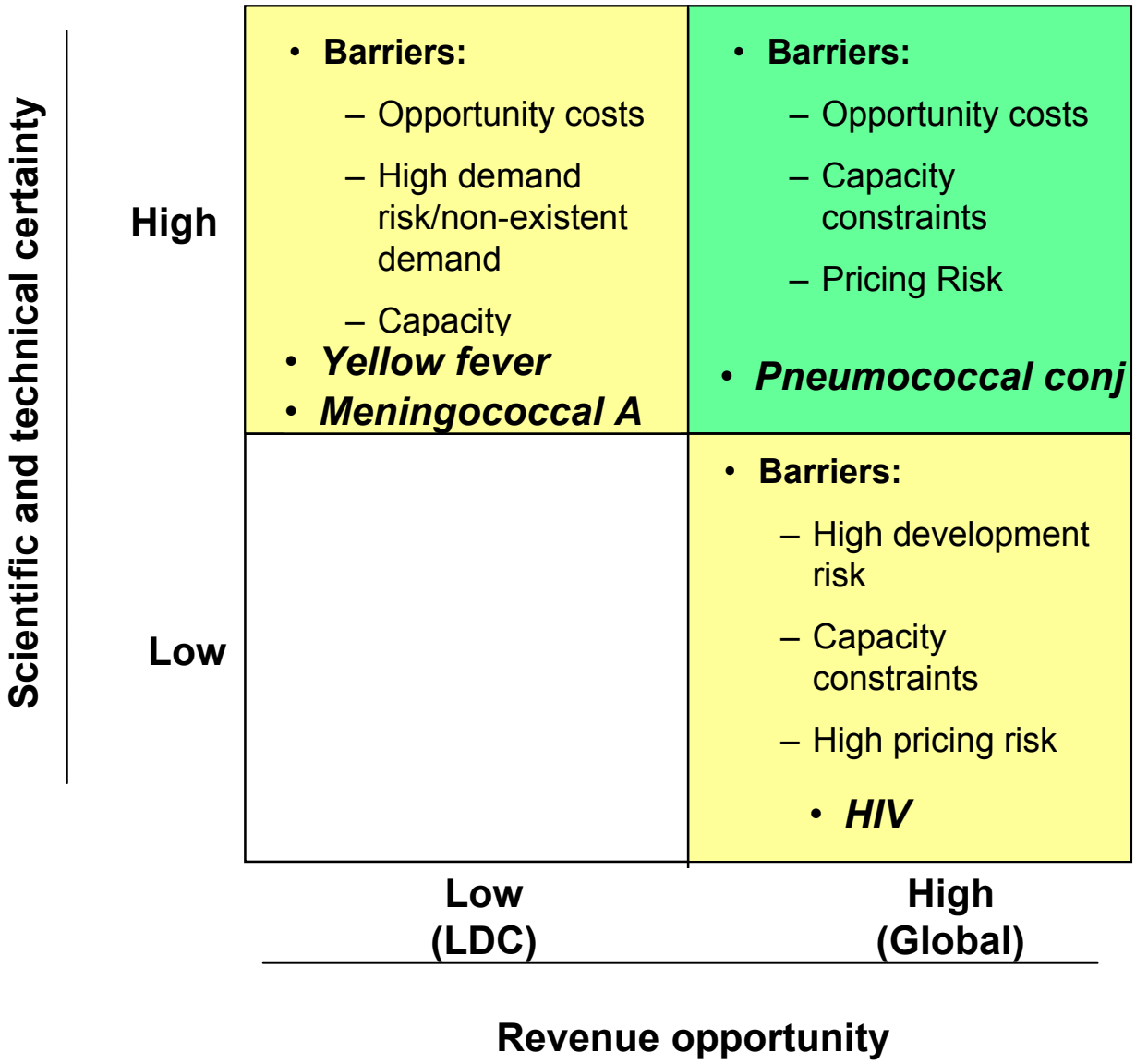

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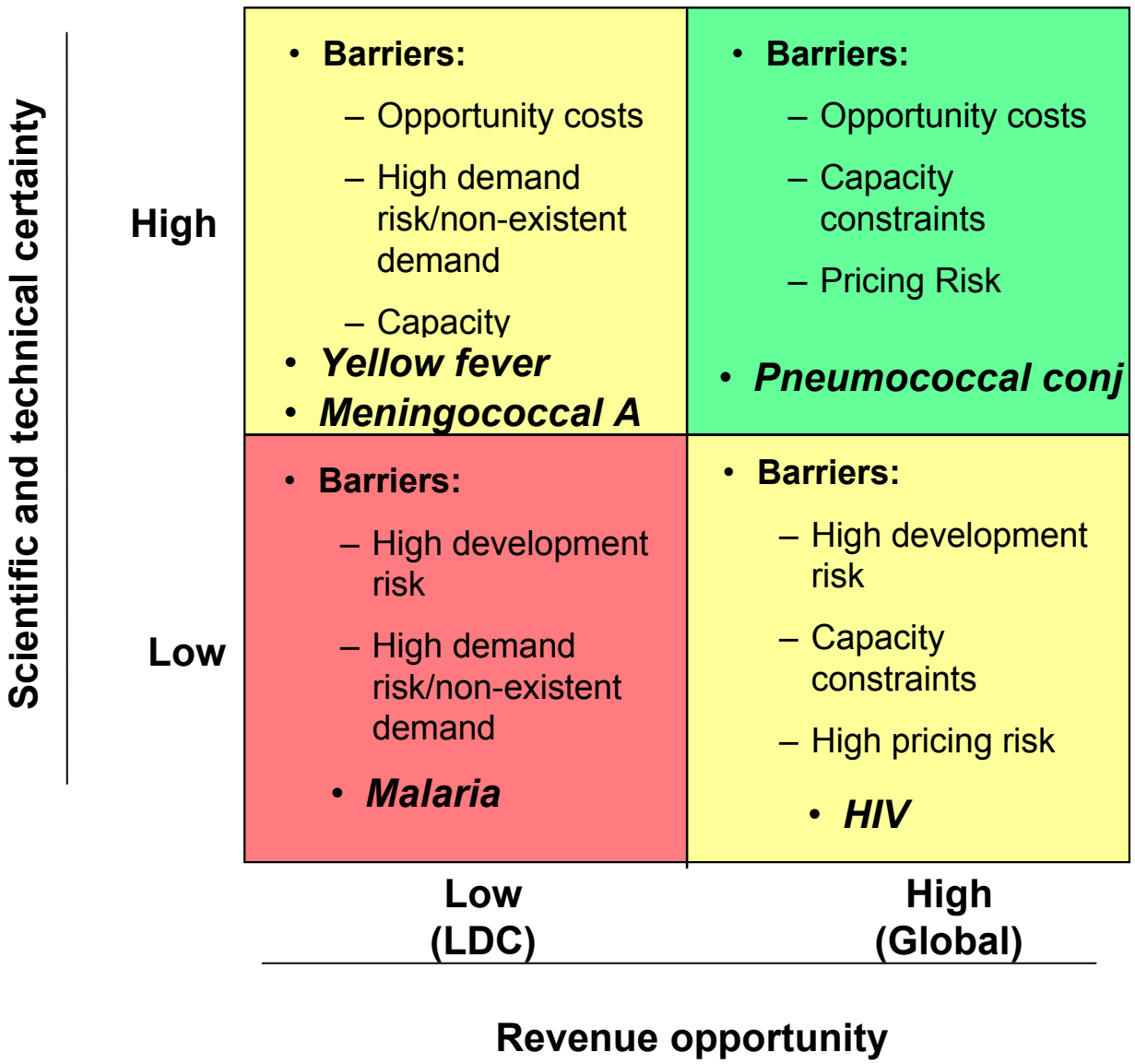

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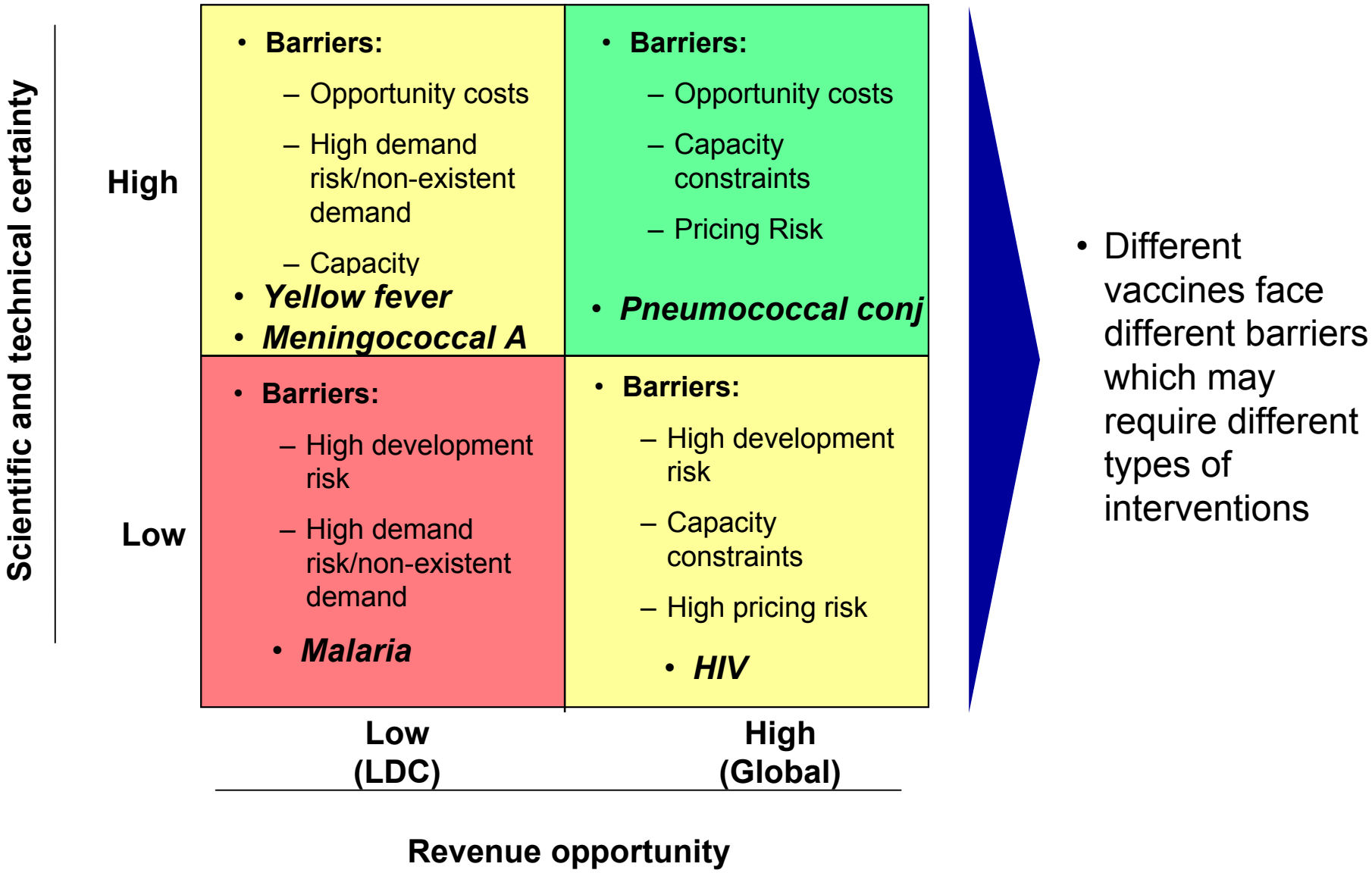
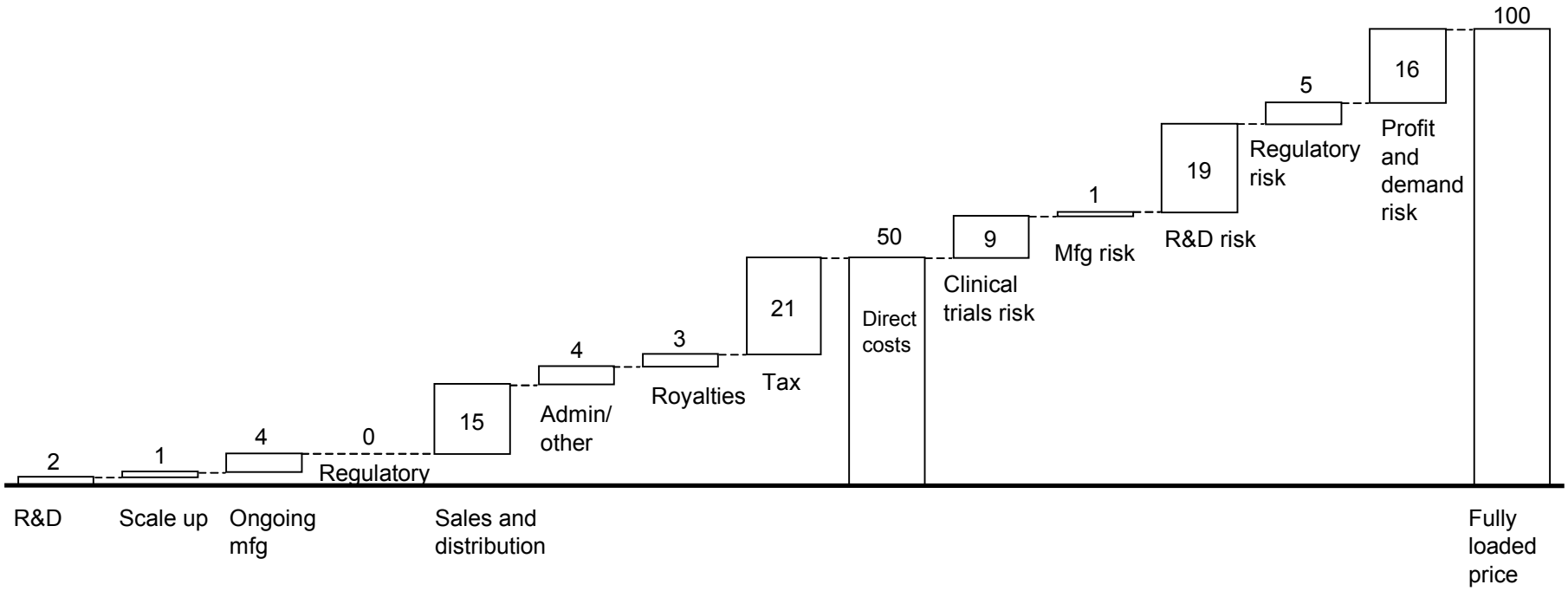


Understanding the relative importance of the the incremental risks and costs is helps target public-private partnerships

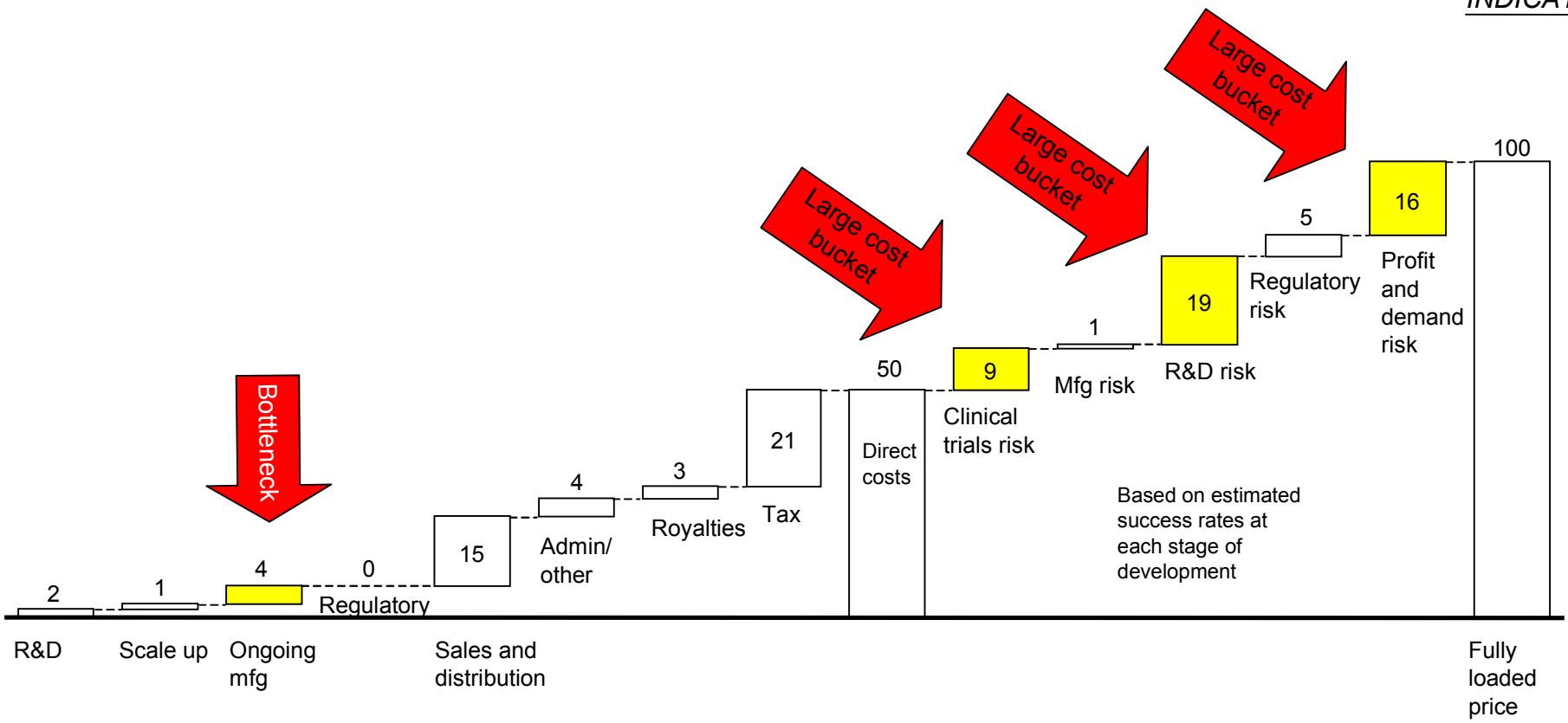
INDICATIVE



Source: Interviews; team analysis * EBIT – Earnings Before Income Tax ** CMO – Contract Management Organizations

The most significant bottlenecks and risks can be identified

INDICATIVE



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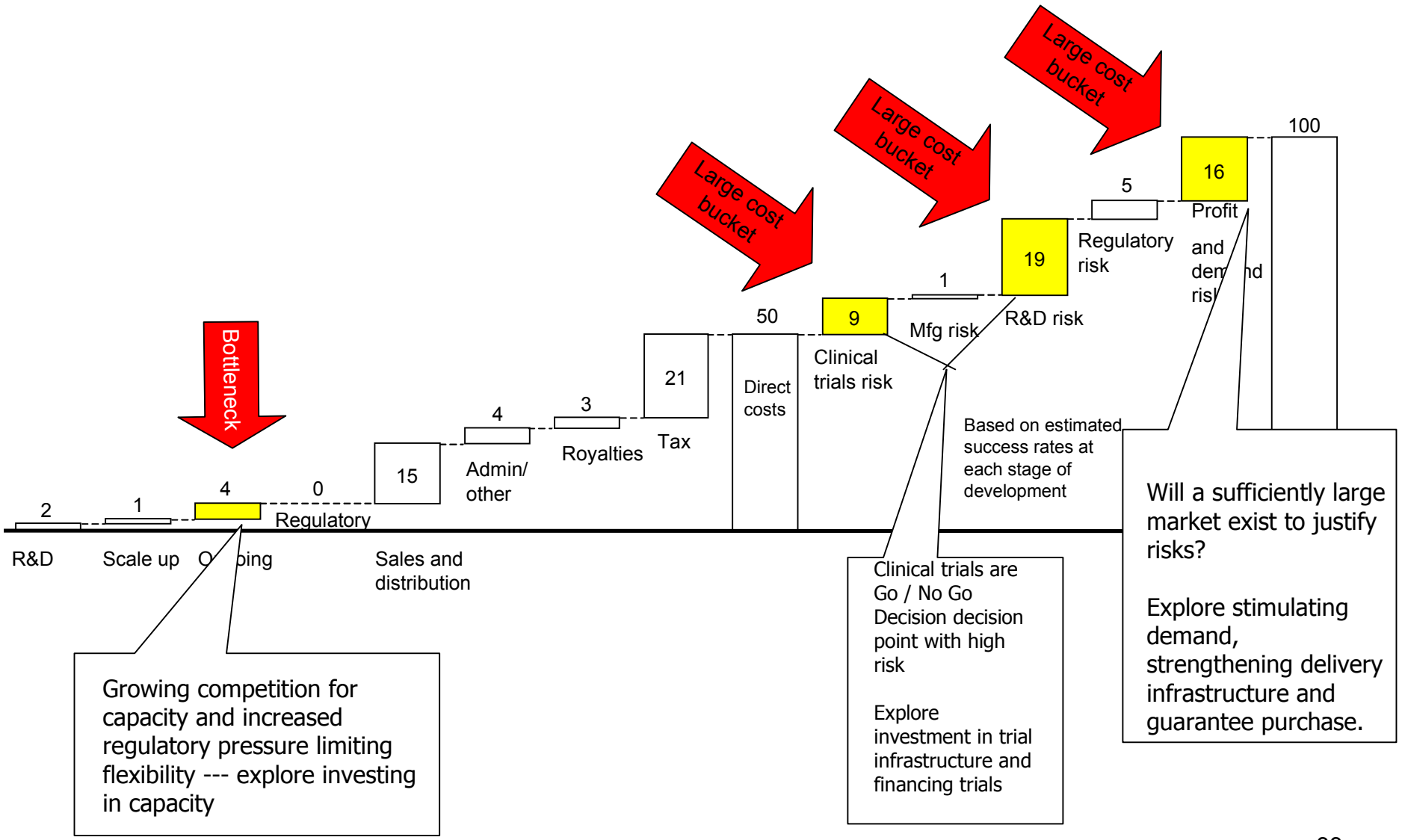
Allowing partners to tailor investments and solutions to share the risks

INDICATIVE



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There is a long list of potential push and pull mechanisms under discussion

PUSH

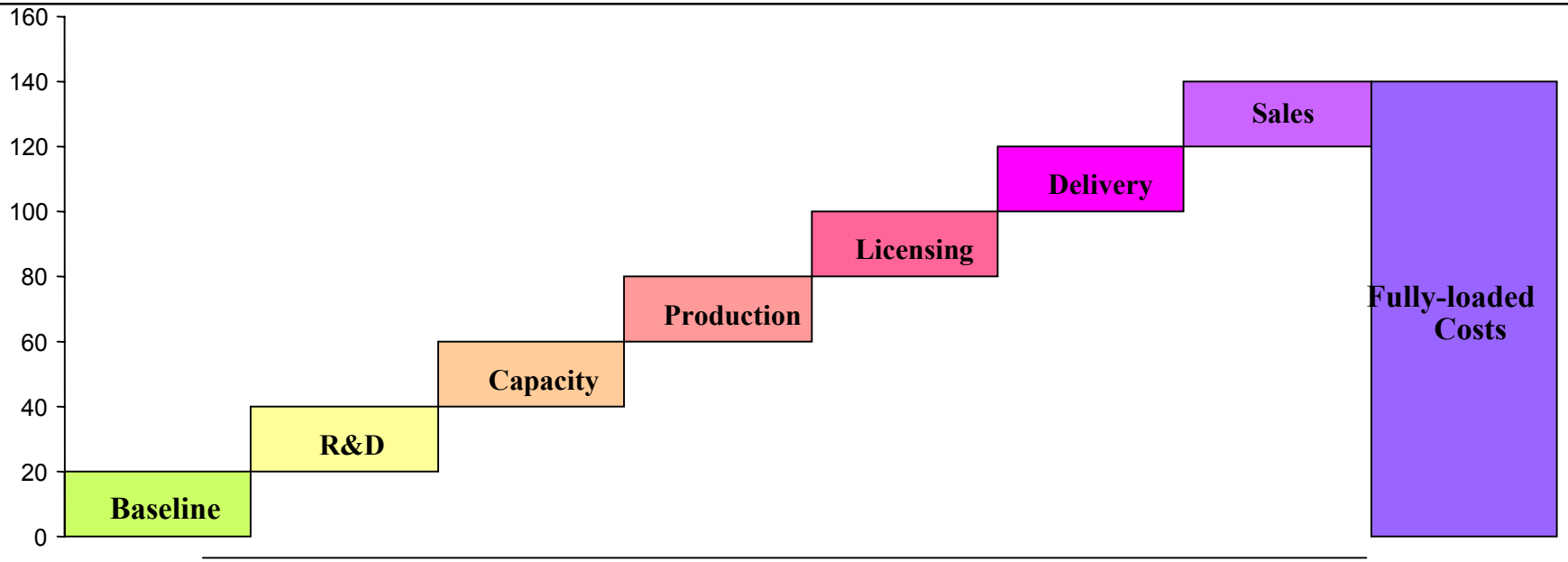
- Direct investment in specific product trials
- Investment in trial infrastructure
- R&D tax credits
- Investment in production capacity
- Harmonize regulatory requirements

PULL

- Increasing the uptake of existing vaccines
- Strengthen/ensure delivery system
- Prizes and tournaments
- Tax credits on vaccine sales
- Tiered pricing to increase total revenues
- Transferable Patents
- Co-payments
- Market guarantees

Mechanisms can be tailored to address the different risks

Illustrative



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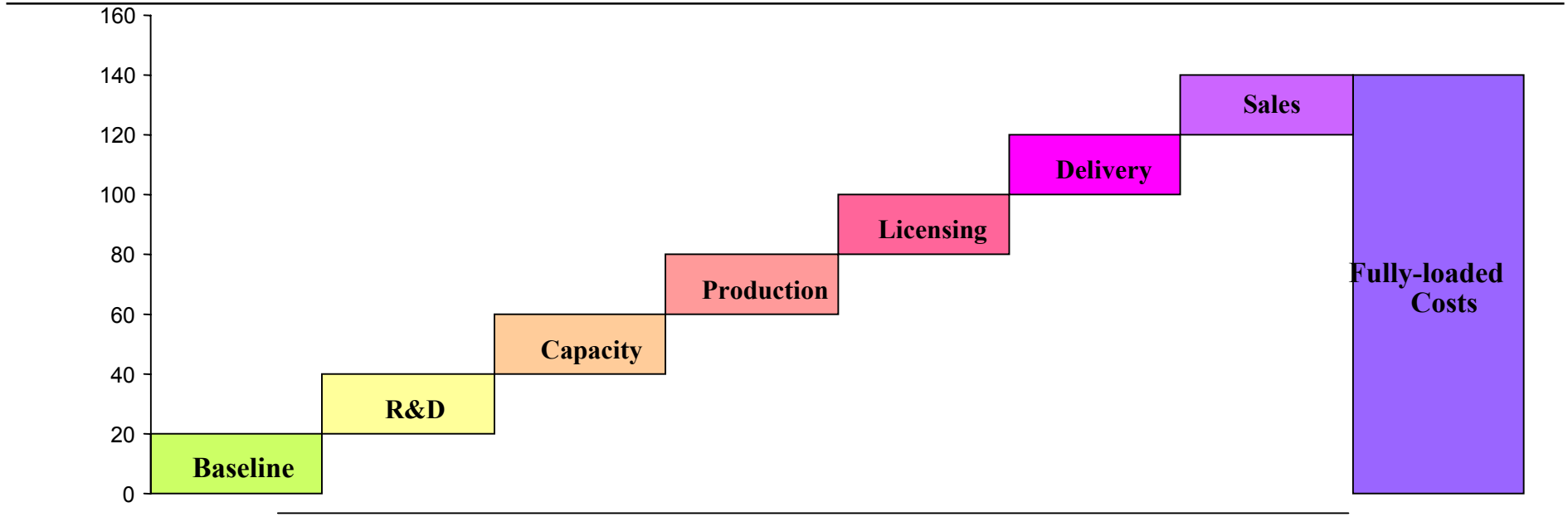

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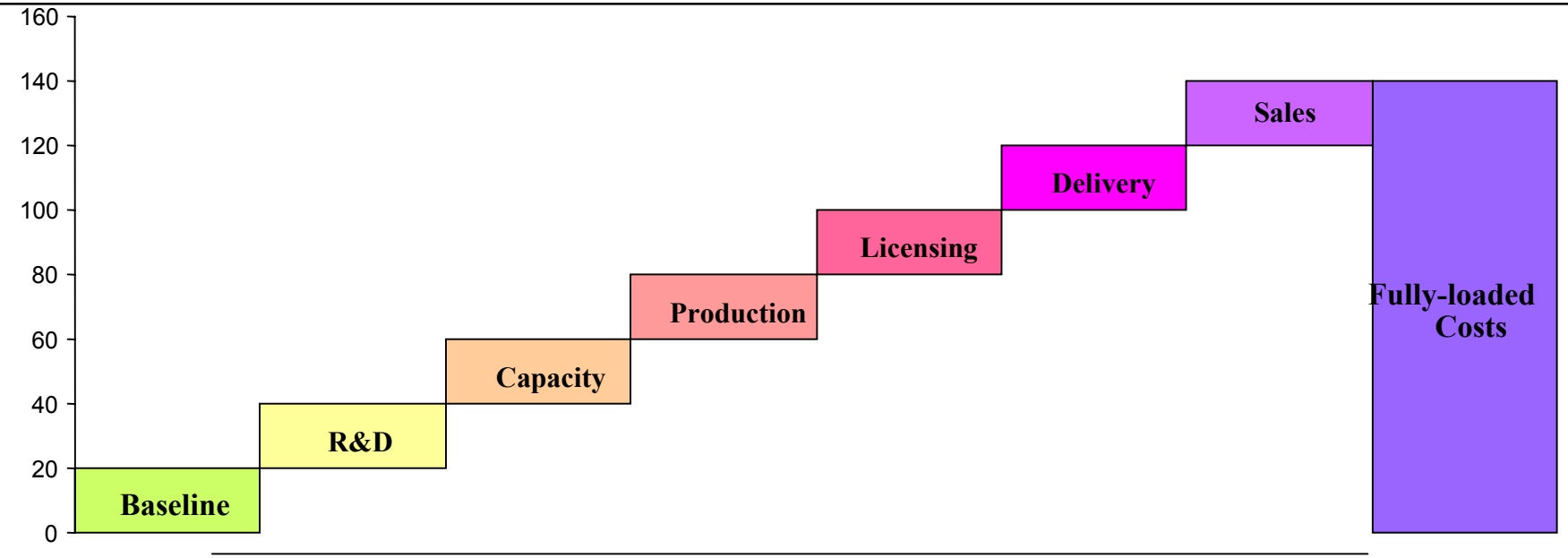

- Direct investment in clinical trials for specific products
- Strengthen trial infrastructure
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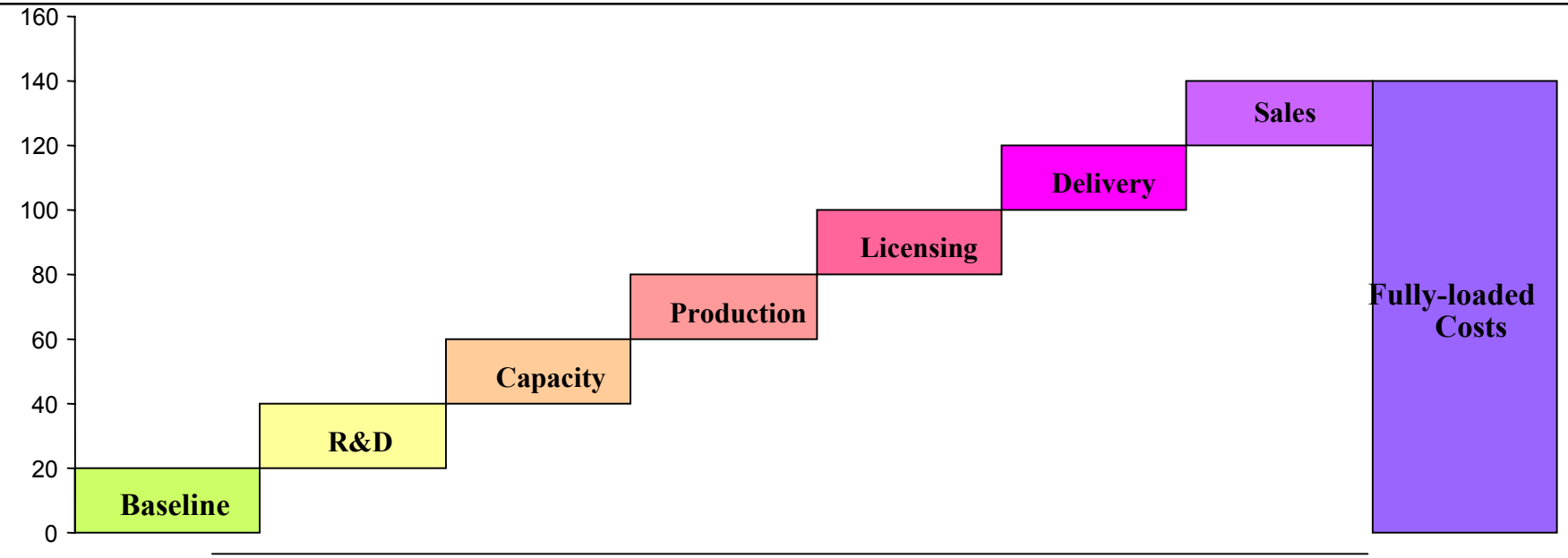

- Direct investment in clinical trials for specific products
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- Investment in capacity

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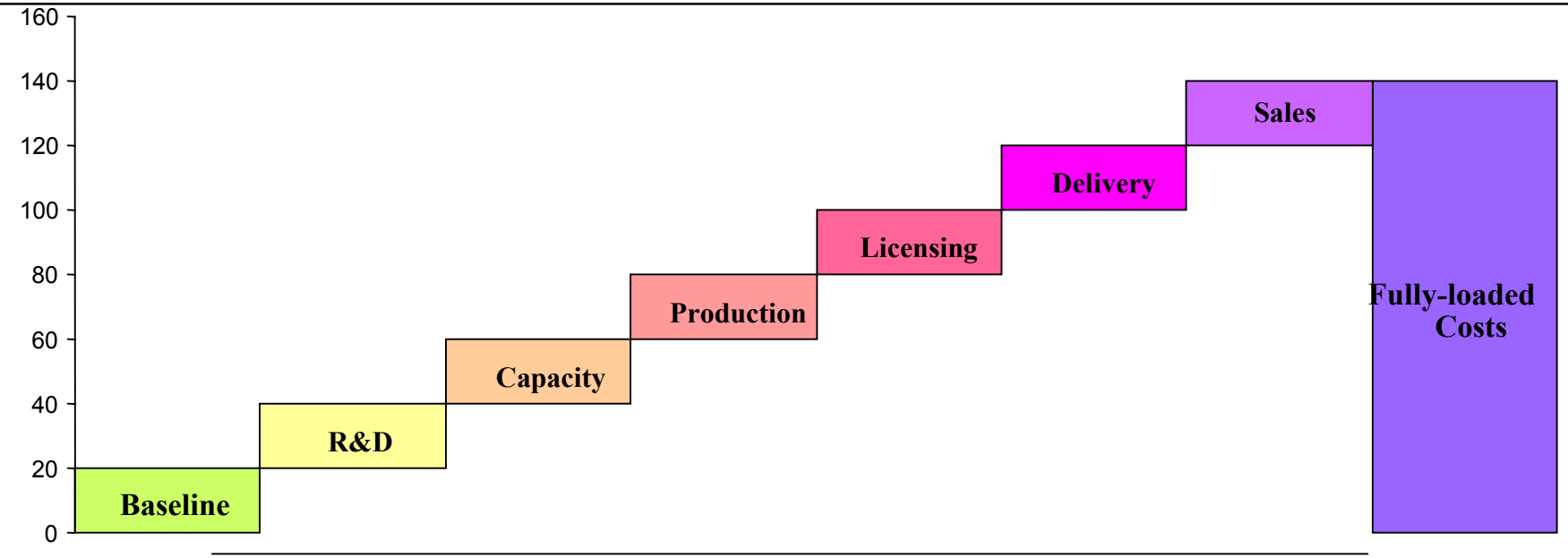

- Direct investment in clinical trials for specific products
- Strengthen trial infrastructure
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- Investment in capacity

- Improve forecasting
- Guarantee offtake

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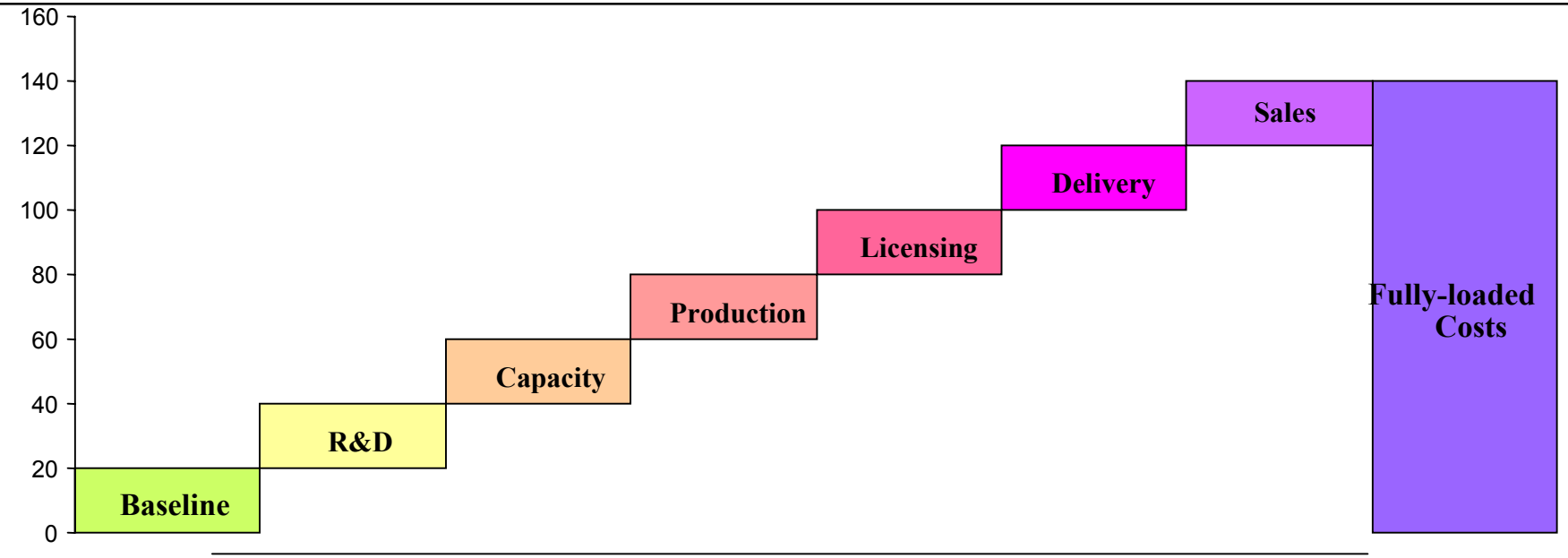

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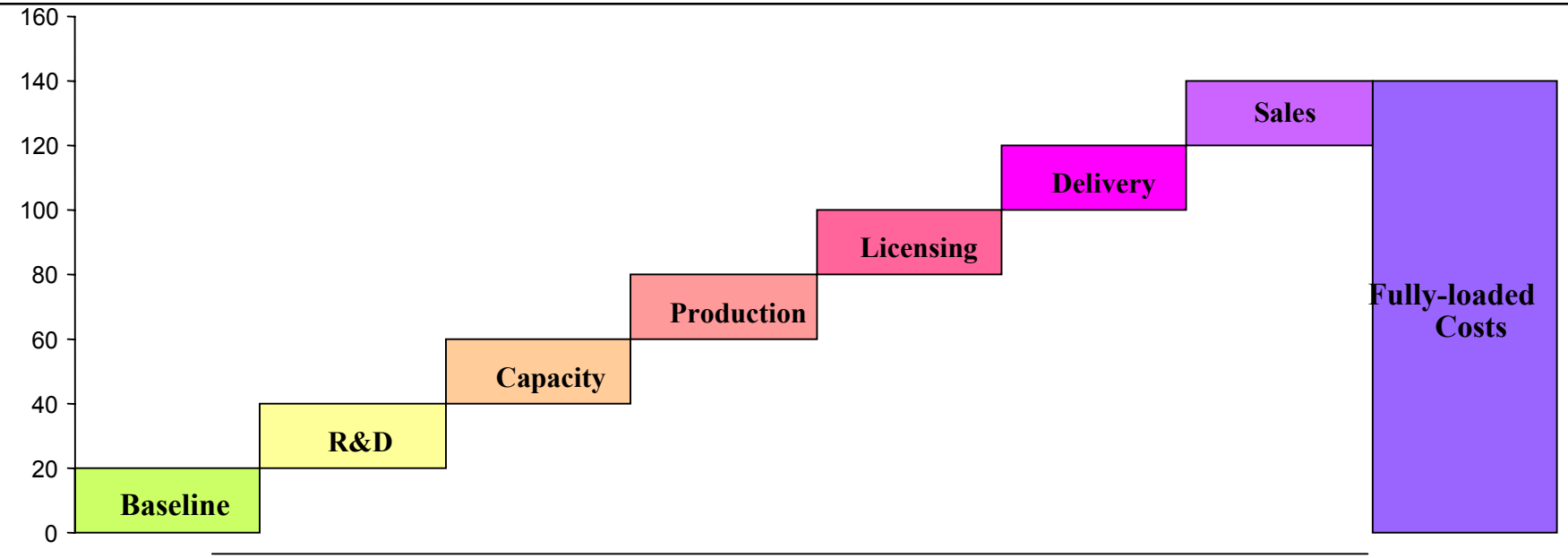

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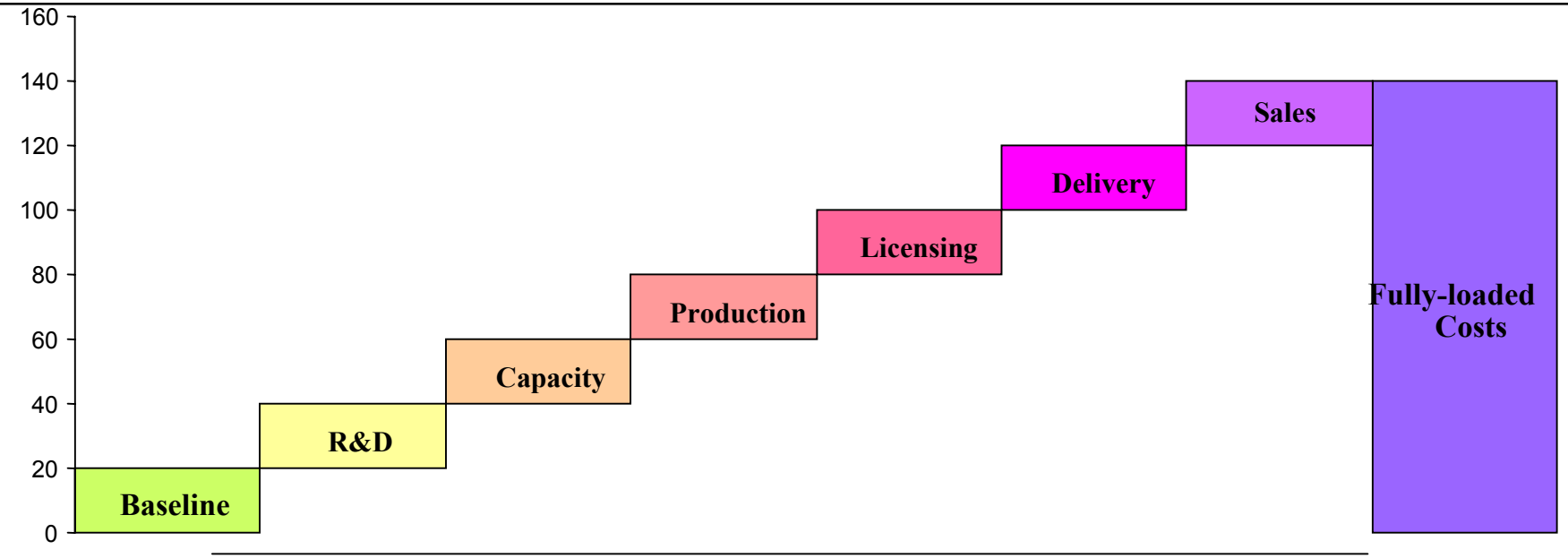

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- Create demand earlier

- Assure today's market's
- Tax credits on sales
- Transferable patents
- Co-payments
- Guaranteed purchase fund

Public Sector Assumes ALL Risk — **Private Sector Assumes ALL Risk**

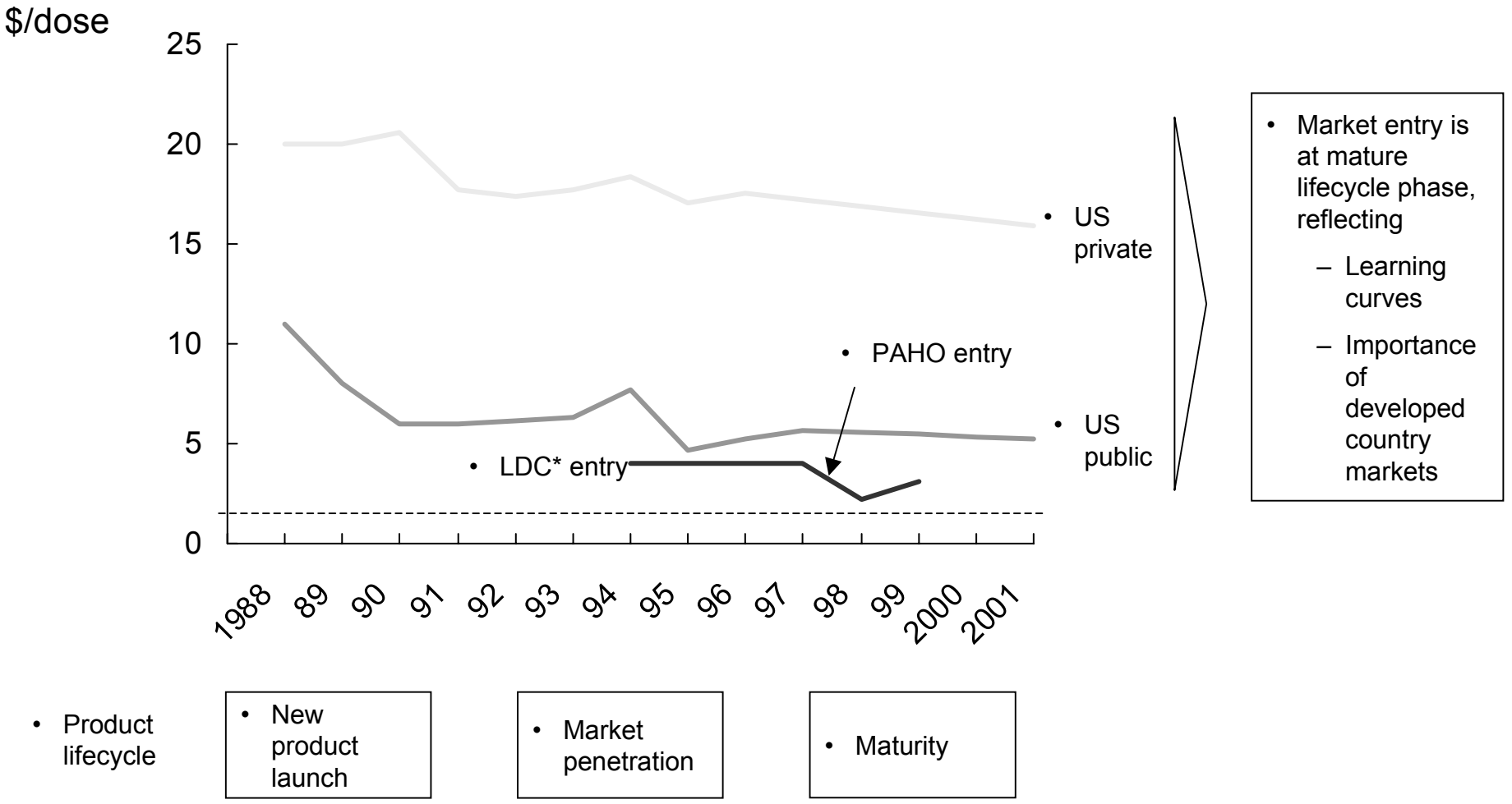
What are our goals?

- Investment to ensure a delivery system capable of reaching infants and other target groups with priority vaccines
- Investment to rapidly develop priority vaccines targeting the diseases of the developing world
- Investment in production capacity to ensure the supply of global vaccines to the developing world
- Pricing which is affordable to the developing world
- Funding to purchase vaccines as soon as they are technically available

- Back Up

Part I: Why Vaccines are Unique: Tiered Pricing

The product lifecycle of Hib vaccine offers a compelling example of successful price tiering.



Partnership:

Ensuring broad LDC access may require new ways to assess and share risk

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	Current model
Introduction:	• LDCs 10 years plus after OECD
Target population:	• OECD
LDC-specific development spend:	• Limited/zero
LDC testing:	• Limited/late
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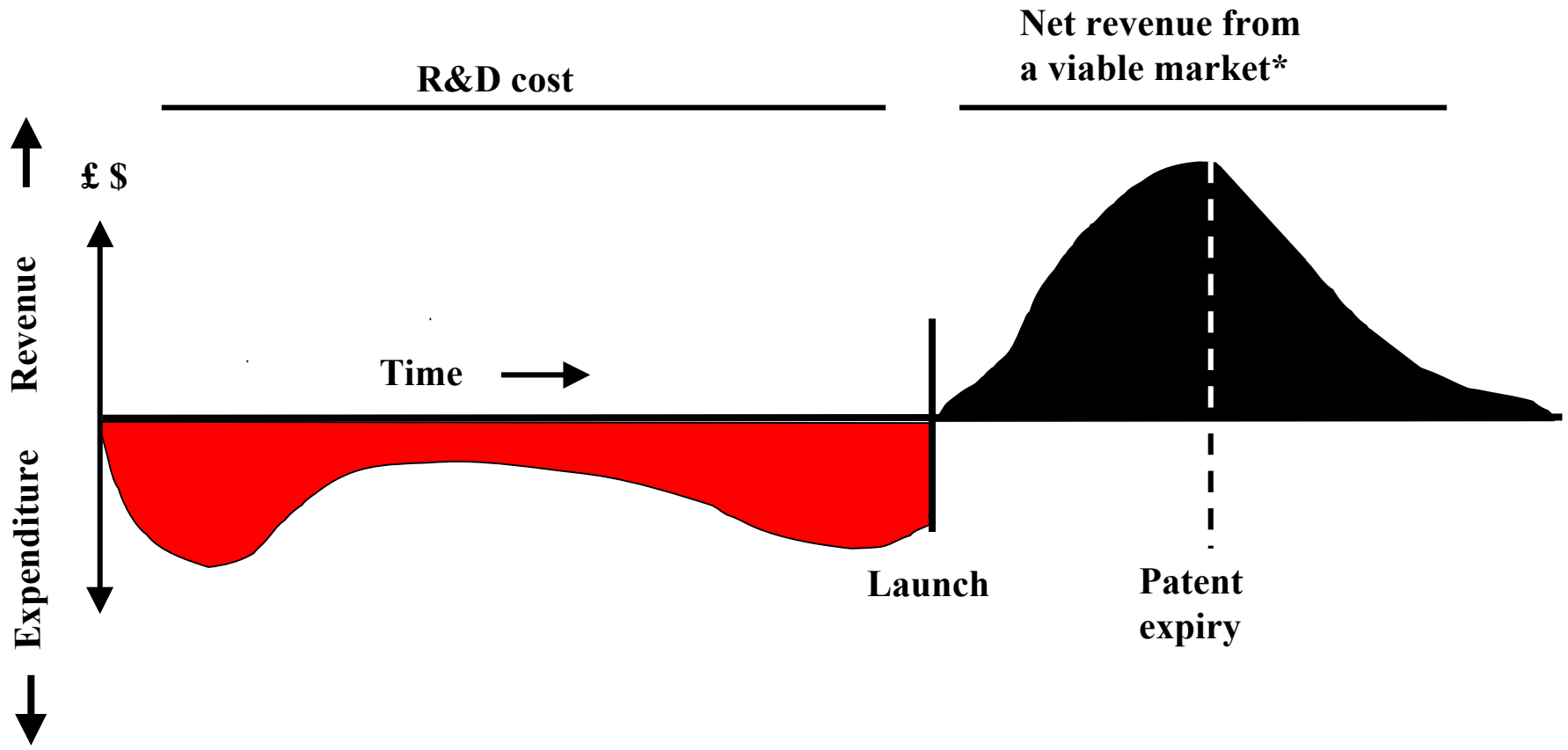
Prices or other incentives must justify full costs of accelerated LDC introduction

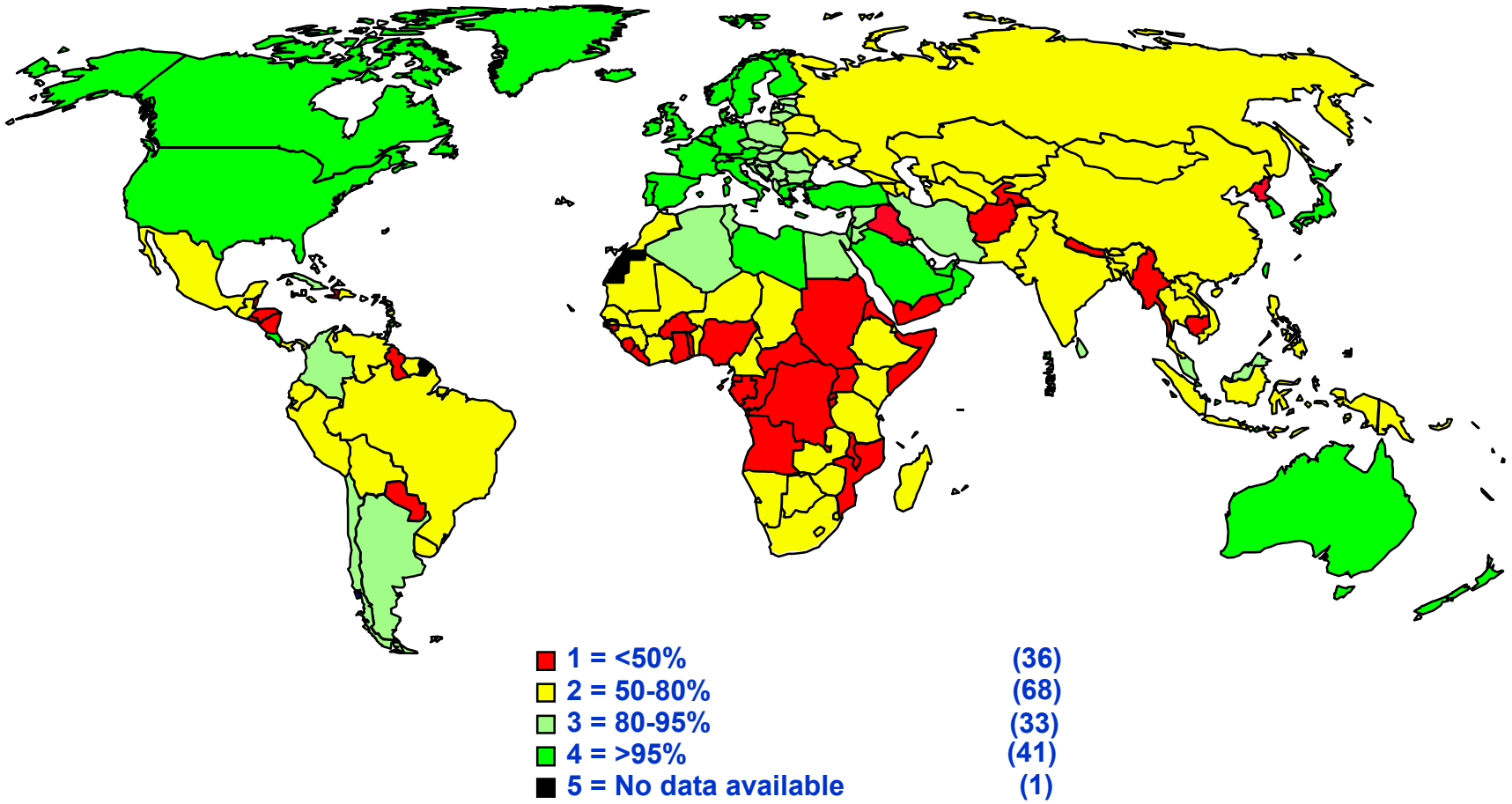
Schematic model of the cash flow of a new medicine



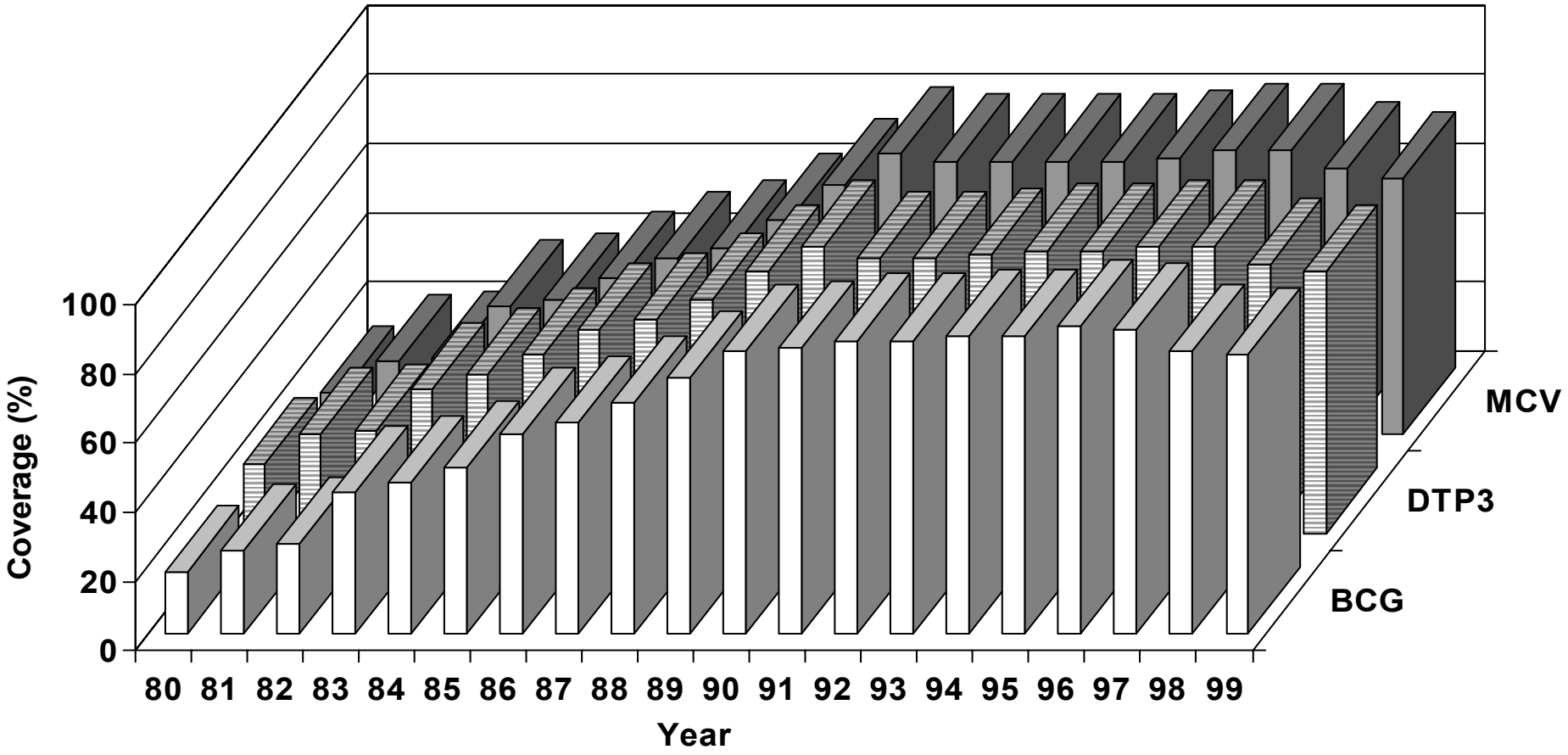
*NB expenditure on clinical studies, manufacturing, marketing etc continues after launch but for simplicity has been netted out.

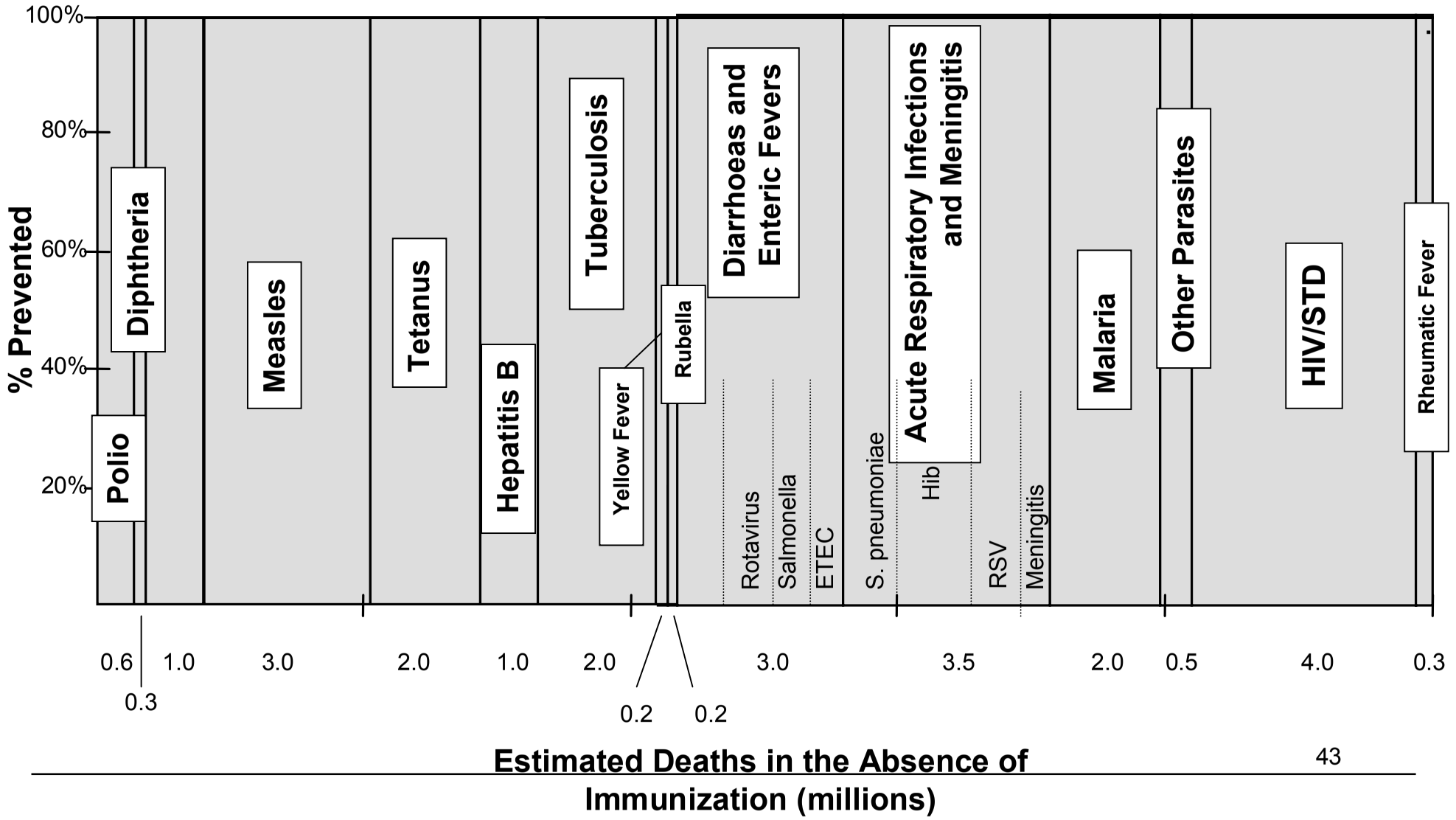
Many people still lack access to essential drugs

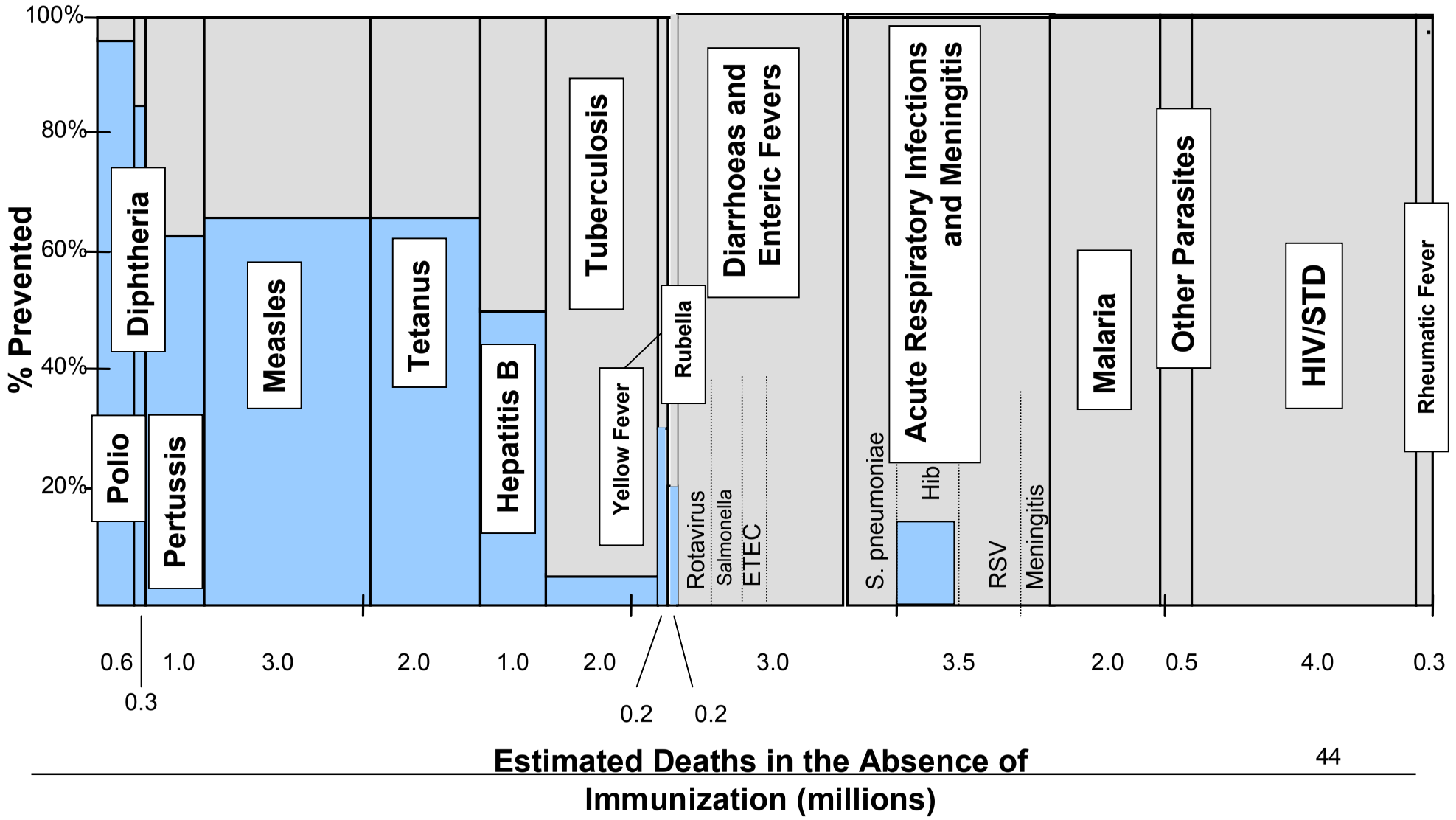
Percentage of population with regular access to essential drugs (1997)



Global immunization coverage of selected vaccines among infants, 1980-1999




100%
80%
60%
40%
20%
% Prevented
Polio
Diphtheria
Measles
Tetanus
Hepatitis B
Yellow Fever
Rubella
Tuberculosis
Diarrhoeas and Enteric Fevers
Rotavirus
Salmonella
ETEC
Acute Respiratory Infections and Meningitis
S. pneumoniae
Hib
RSV
Meningitis
Malaria
Other Parasites
HIV/STD
Rheumatic Fever
0.6
0.3
1.0
3.0
2.0
1.0
2.0
0.2
0.2
3.0
3.5
2.0
0.5
4.0
0.3
Estimated Deaths in the Absence of Immunization (millions)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0.6
0.3
1.0
3.0
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