

**ECONOMICS OF
THE VACCINE
MARKET:
SIZE, GROWTH
AND REVENUES**

Relationship between research funding and burden of disease

Condition	Global BoD (Million DALYs)	% of Total Global BoD	R&D Funding US\$ Millions	R&D Funding US\$ per DALY
All BoD ¹	1,470	100	105,900	72
HIV/AIDS + TB + Malaria ¹	167	11.4	1,400	8.4
CVD ²	148.19	9.9	9,402	63.45
Diabetes ²	16.19	1.1	1,653	102.07
HIV/AIDS ²	84.46	5.7	2,049	24.26
Malaria ²	46.49	3.1	288	6.2
TB ²	34.74	2.3	378	10.88

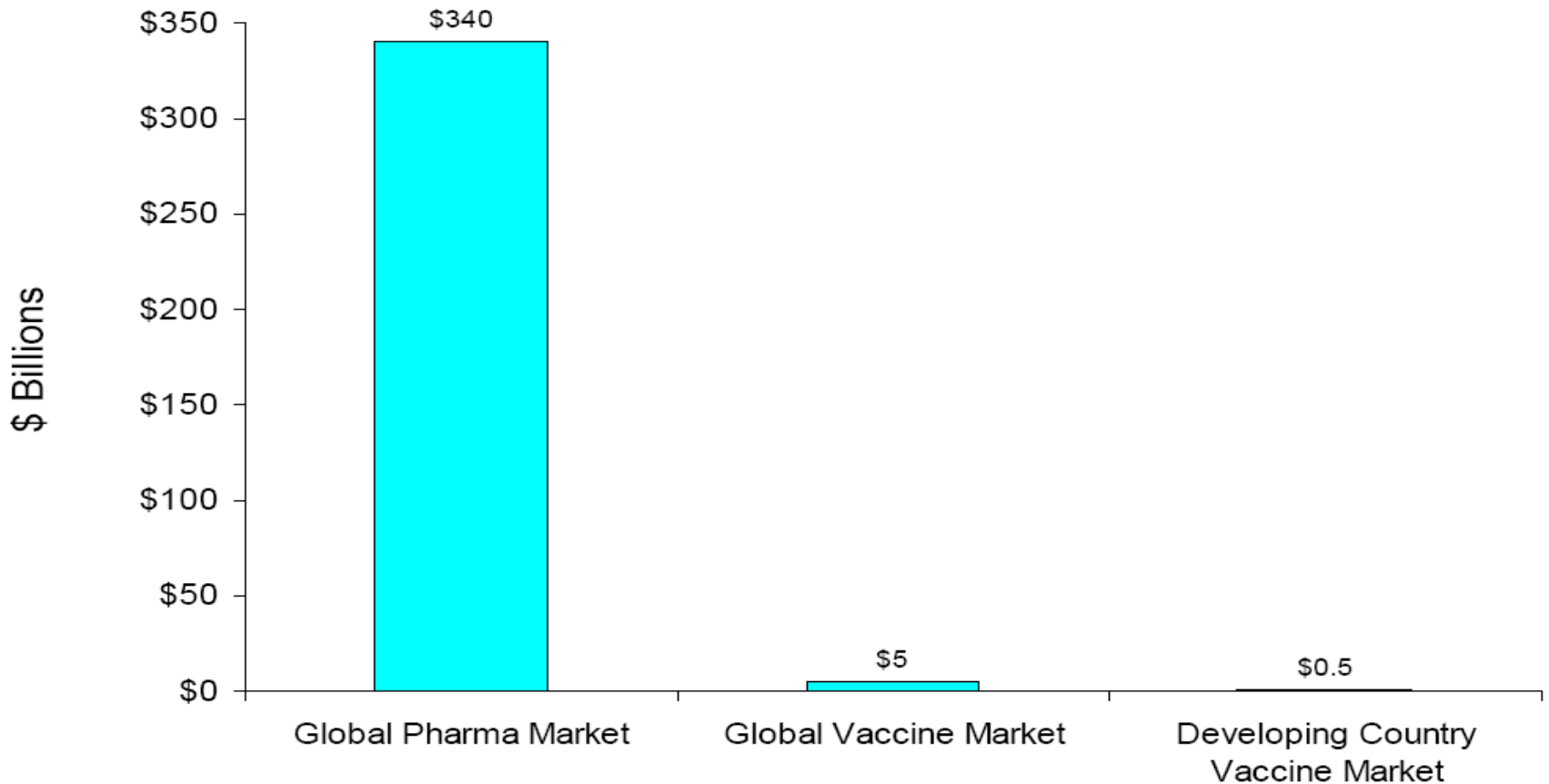
¹ Financial data for 2001 from *Monitoring Financial Flows for Health Research, Volume 2*, Global Forum for Health Research, 2004; BoD data from WHO Global Burden of Disease, World Health Organization, 2002.

² Based on bibliometric assessment of R&D spending presented by G Lewinson et al. (Forum 8, Mexico City, November 2004) and work by the Malaria R&D Alliance.⁹

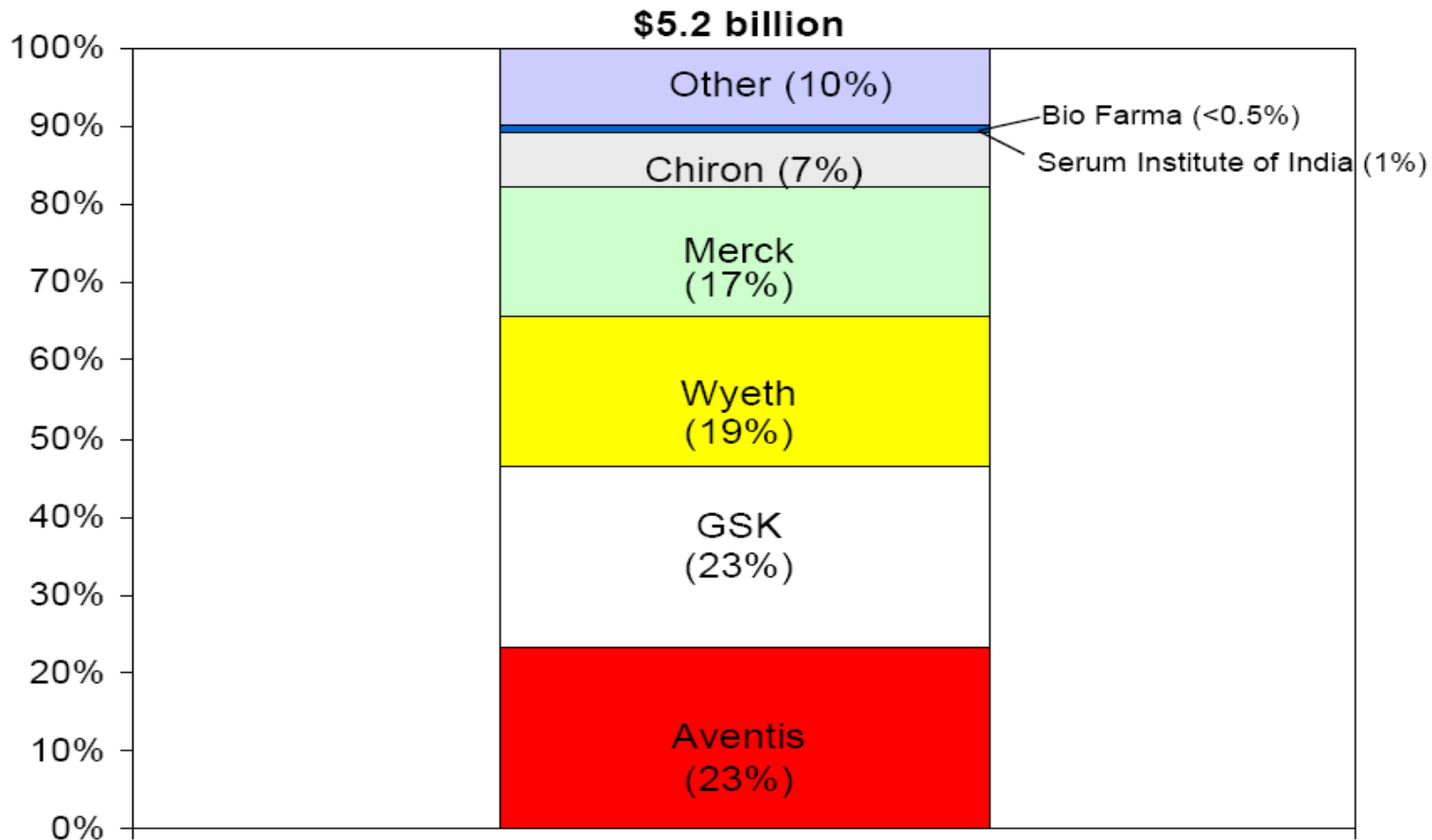
Source: Global Forum for Health Research “Monitoring Financial Flows for Health Research” (2006)

http://www.globalforumhealth.org/filesupld/monitoring_financial_flows_06/Resourcing%20research%20for%20health.pdf

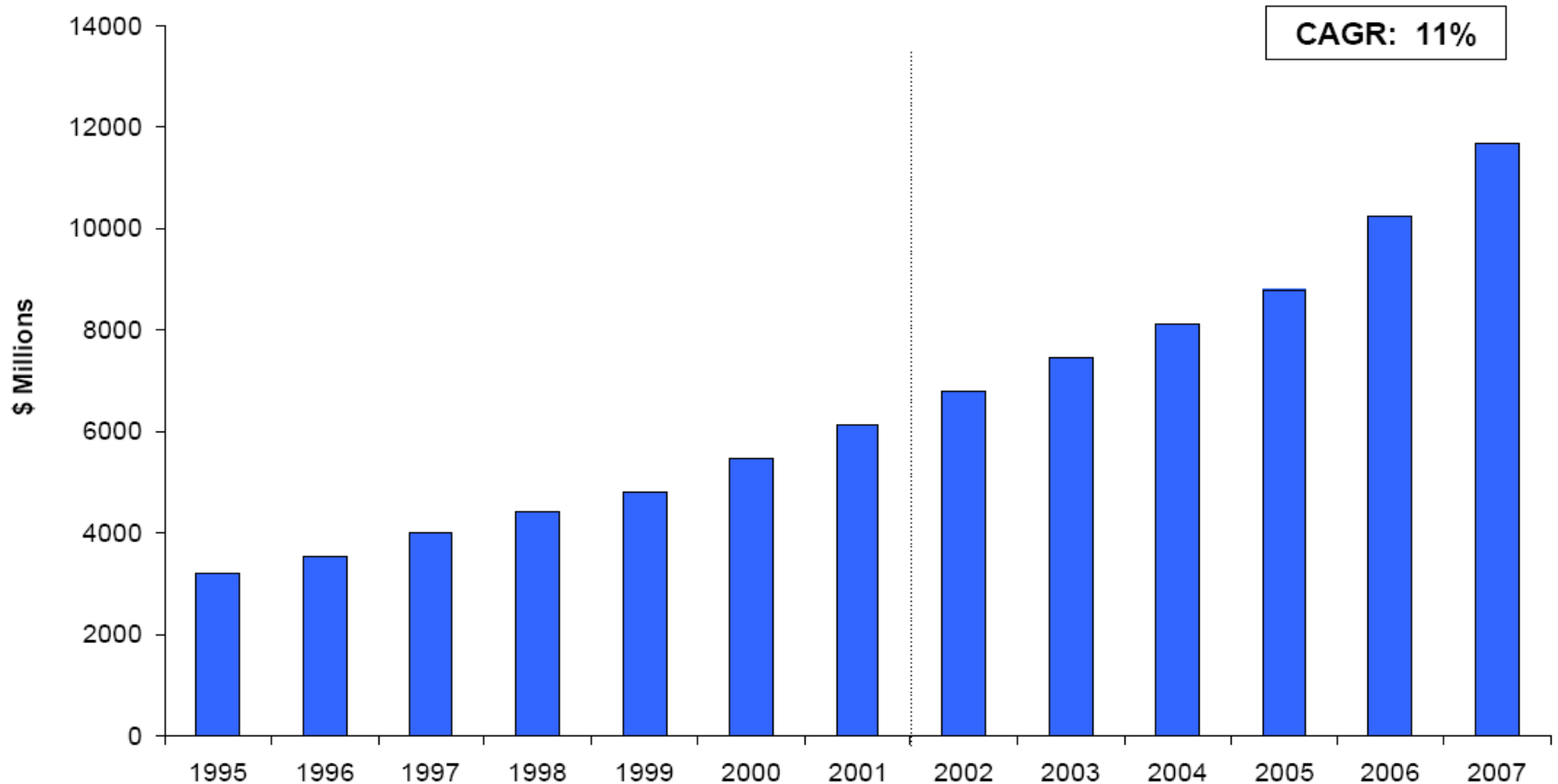
Vaccine market tiny as percent of global pharma market (2000, see below for recent surge)



‘Big pharma’ still dominated (2000 figures). But lots of tech transfer development in recent years has started to change this (and is not picked up on this diagram)



Recent strong growth of global vaccine market

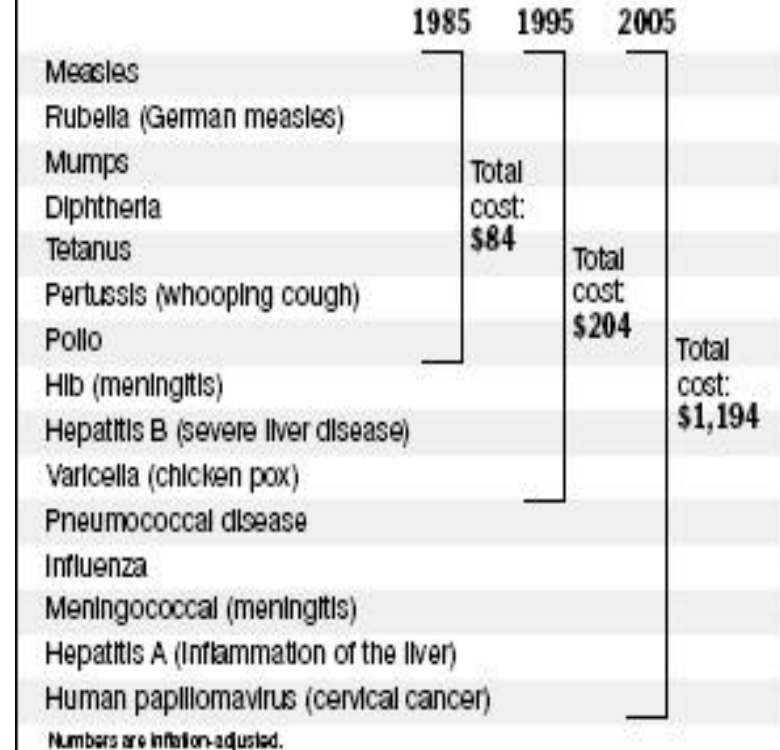


Combination products very profitable in richer markets

- Prices on older vaccines are lower than the latest new vaccines, but rising:
 - Usually reformulated versions that get around federal price cap
 - E.g. GlaxoSmithKline in 2004 combined its vaccines for diphtheria, tetanus, pertussis and hepatitis B into Pediarix
 - More convenient but costlier
 - \$42 for separate shots
 - \$70 for Pediarix

Vaccines Get a Shot in the Arm

The number of recommended childhood and adolescent immunizations has grown.

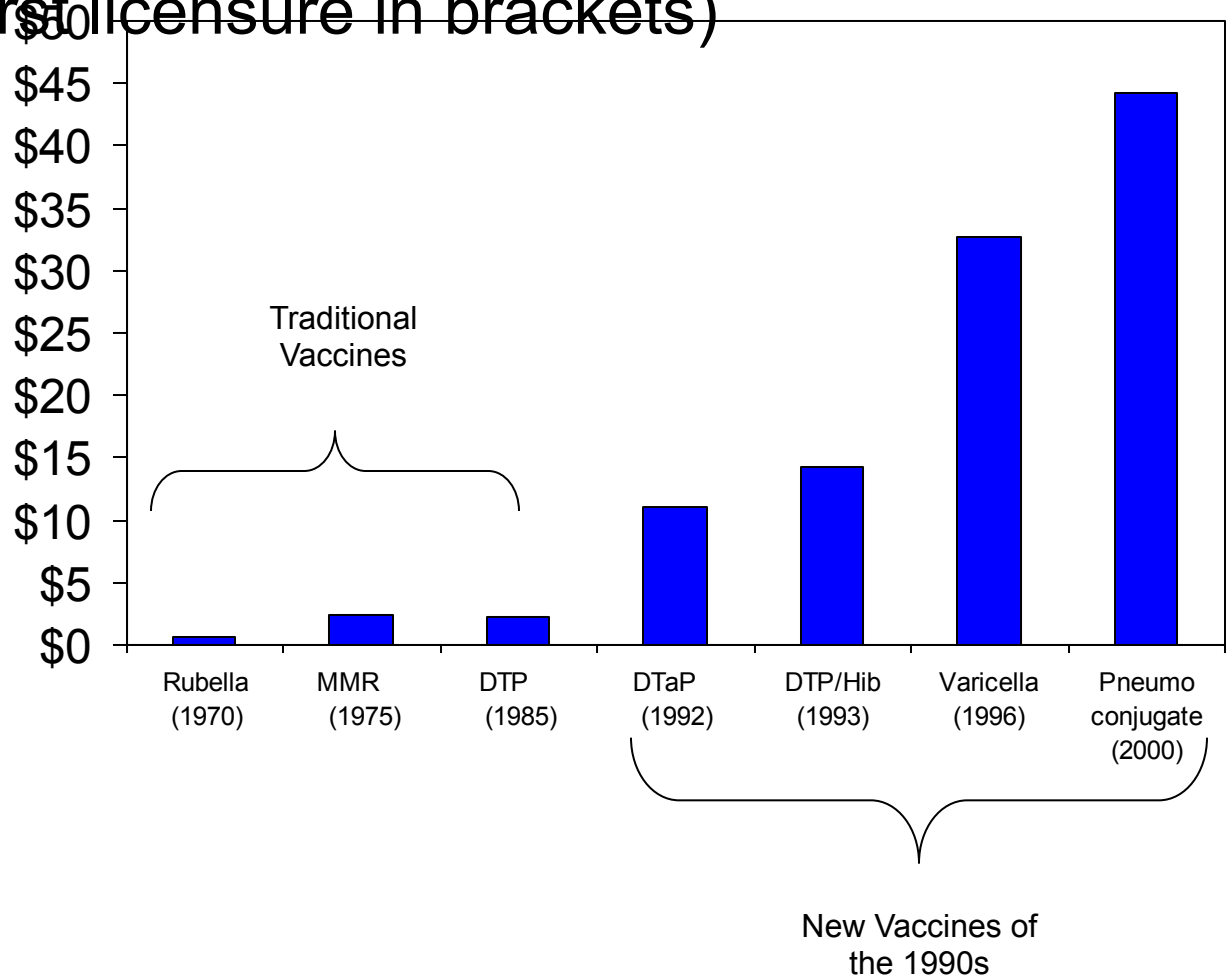


SOURCE: Centers for Disease Control and Prevention

The Philadelphia Inquirer

Pricing: Traditional vs. 'New' Vaccines

Prices for newer vaccines are orders of magnitude larger than prices for the traditional vaccines (year of first licensure in brackets)

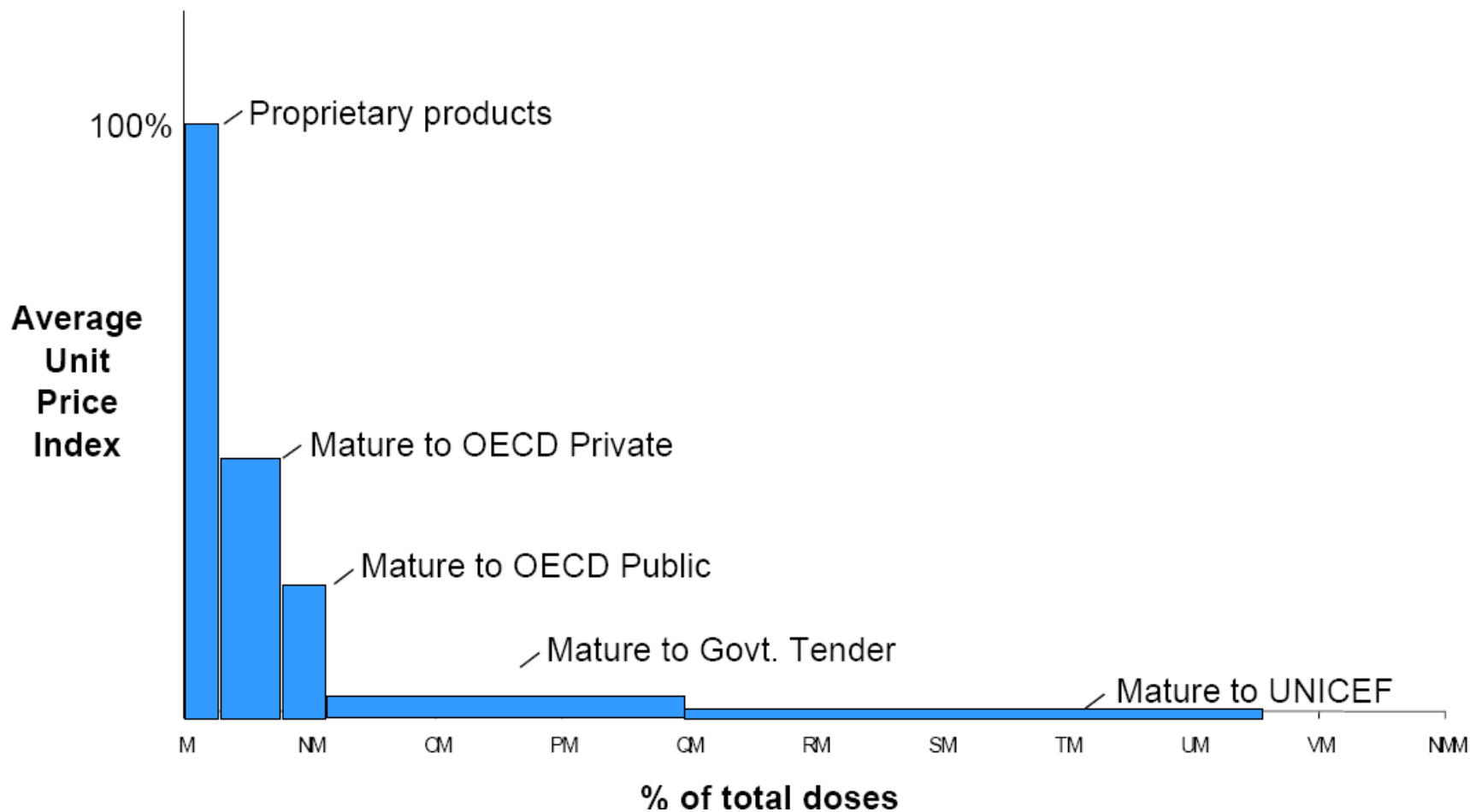


Update: Revenues from vaccines

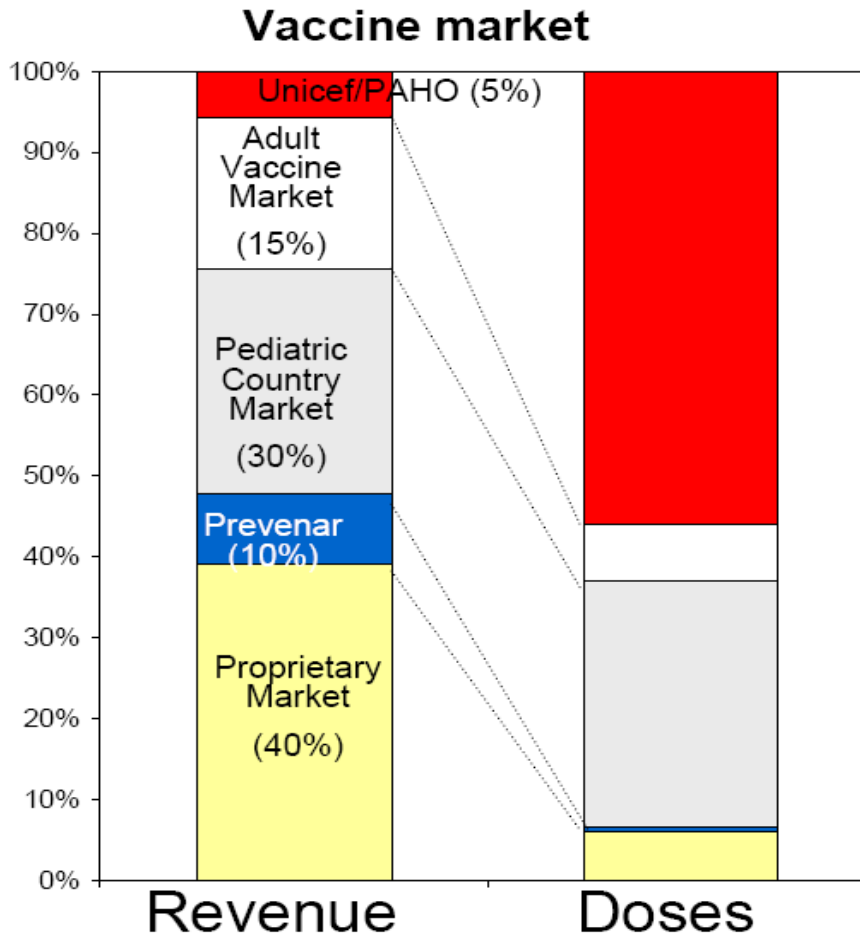
- Since 1985, the number of illnesses preventable by vaccines has DOUBLED due to scientific breakthroughs
 - Traditional scourges like diphtheria through to newer targets like cancer
- Average rate of growth of global vaccine market has been about 11% per year since 1995
- Vaccine revenues growing 50 percent faster than drug revenues
- ‘Traditional’ notion that a vaccine is a one-off and hence will not be profitable and hence that developers will not invest... does not so necessarily hold water

* Mercer, Fogarty

Typical vaccine market profile for a supplier



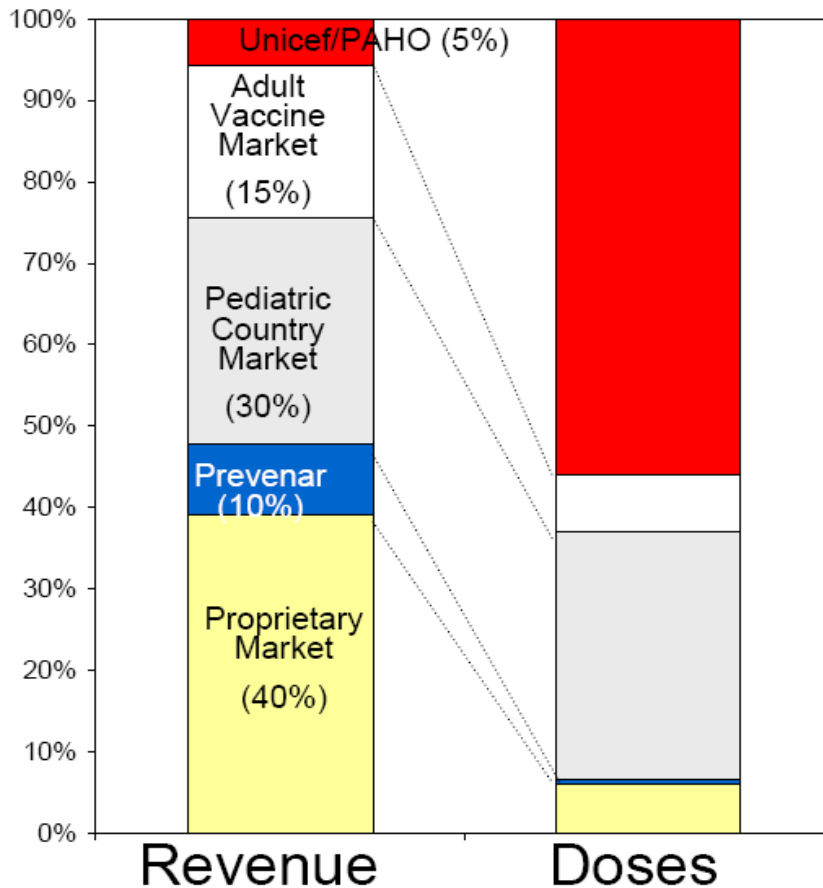
Product and customer groups



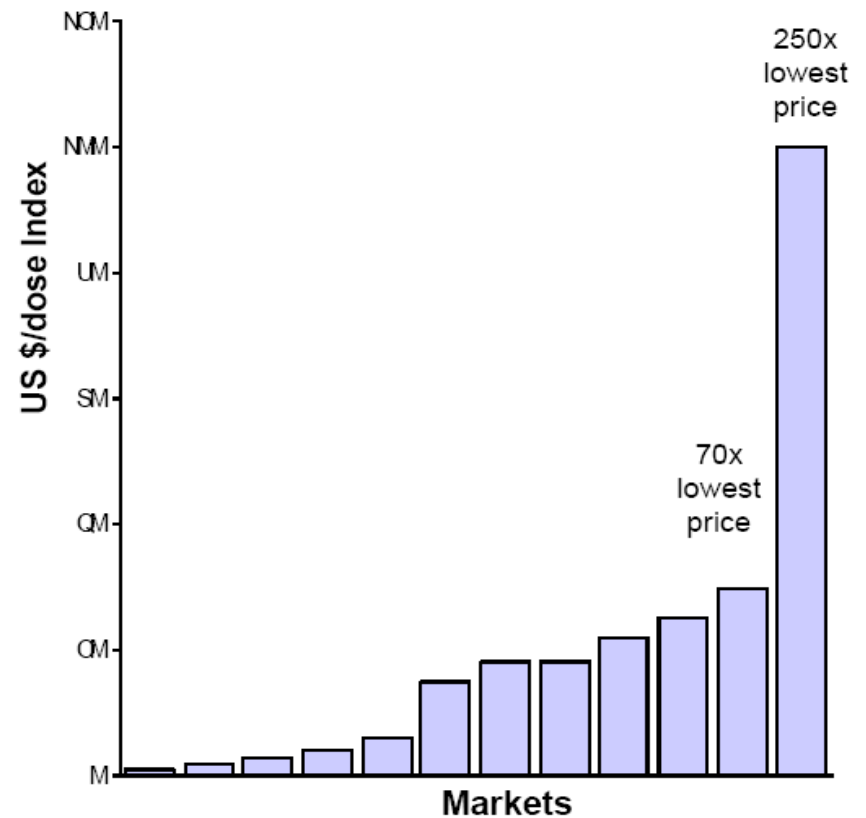
UNICEF and PAHO account for 5% of the revenues and roughly 50% of the volume

Differential pricing makes it possible to reach the poor

Vaccine market



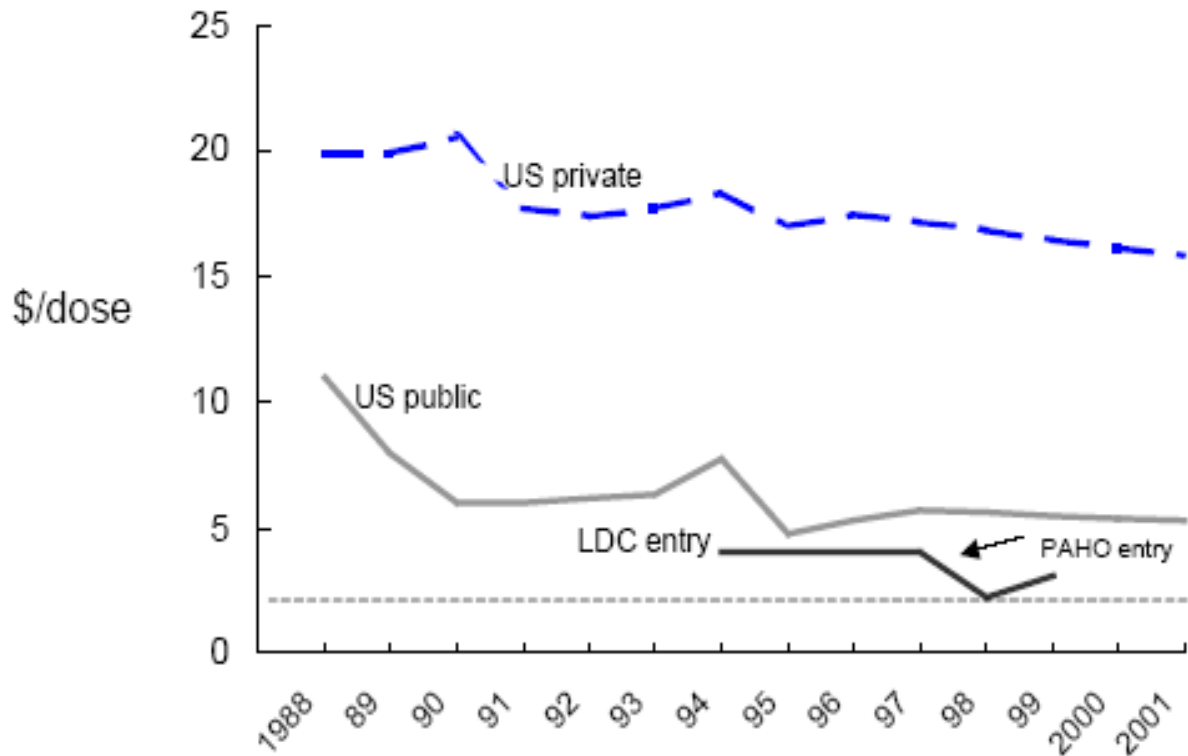
Differential pricing: OPV



Typical vaccine product lifecycle

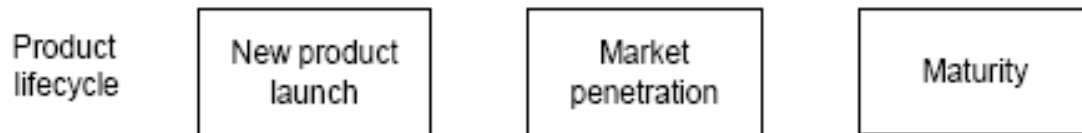
Factor	New Product Launch	Market Penetration	Product Maturity
Number of producers	Low	Multiple, industrial	High: Mixed industrial/developing
Pricing	High, Uniform	Tiered within and across markets (industrial/private): high average	Tiered within and across markets (global): low average
Cost	High	Medium	Low
Profitability	High	High	Moderate
Available Capacity	Low	High	Potential surplus
Availability	Poor	Good in industrial	Good globally
Market demand	Low	High, industrial and private	High, global

Tiered pricing of Hib vaccines



Market entry is at mature lifecycle phase, reflecting

- Learning curves
- Importance of developed country markets



**SOME
PRODUCT
DIVERGENCE
OVER TIME**

Vaccine manufacturers changing product lines: Rise of tailored products serving different markets



Tailored to the Developing Market	Disease	Tailored to the Industrial Market
Measles	Measles	MMR
DTwP	Pertussis	DTaP
OPV	Polio	IPV
Monovalent, DTwP-Hep B	Hepatitis B	Monovalent, DTaP-Hep B, DTaP-Hep B-IPV-Hib, Hep B-Hib, Hep A-Hep B
Monovalent, DTwP-Hib, DTwP-Hep B-Hib	Hemophilus Influenzae type b	Monovalent, DTaP-HepB-IPV-Hib, Hep B-Hib
Mening A/C polysaccharide	Meningitis	Meningitis C conjugate, (Meningitis BC conjugate)

Country Spotlights: Japan, UK, US, Canada

Industrialized countries have changed their vaccine demands. The changes may reflect epidemiology or fear of adverse reactions.

Japan		UK		USA		Canada	
1985-1990	1995-2000	1985-1990	1995-2000	1985-1990	1995-2000	1985-1990	1998-2000
Diphtheria, Pertussis	DTaP	DTwP	DTwP-Hib	DTwP	DTaP + Hib	DTwP or DTwP-IPV	DTwP-IPV+Hib ↓ DTwP-IPV//Hib ↓ DTaP-IPV//Hib
OPV	OPV	OPV	OPV	OPV	IPV	OPV or IPV	IPV
MMR	Measles, Rubella	Measles	MMR	MMR	MMR	MMR	MMR
BCG	BCG	BCG	BCG high risk	-	-	-	-
JE Emergency use	JE	-	Meningitis C conj.	-	Varicella, Hep B, Hep A in selected areas	-	Hep B (infants or adolescents)

Product Targeting

 Planned product
 Current product

	Tailored to the DC Market			Tailored to the Industrial Market				New		Future	
	Measles	DTwP	OPV	MMR	DTaP	IPV	Mening C conjugate	DTwP-Hep B or Hib	Pneumo	Rotavirus	Multivalent meningitis conjugates
DC Mfgs											
BioFarma											
Vacsera											
Razi/Pasteur											
Butantan/Biomanguinhos											
India Private Sector											
Cuba											
China											
Industrialized Mfgs											
Aventis											
Chiron											
CSL											
GSK											
Merck											
Wyeth-Lederle											

DC manufacturers traditionally have concentrated on the developing country market. In the future, they plan to focus on the newer and future vaccines which may have global applicability

Some industrialized country manufacturers are continuing to supply all types of vaccines

Summary points

Vaccine products are diverging. This is unlikely to change in the near term.

On the demand side

- UN agencies often demanded large but unpredictable volumes of traditional vaccines
- UN agencies are demanding new combination products tailored for the developing market
- Industrialized countries are changing their vaccine usage reflecting epidemiology and fear of adverse reactions

On the supply side

- Some industrialized manufacturers are tailoring new vaccines to industrial markets in lieu of traditional vaccines
- Developing country manufacturers are increasing capacity for supply of traditional vaccines and future products are tailored to developing markets

Implications for availability, pricing, regulation

Sudden changes in demand or supply (e.g manufacturing failures of any supplier) may threaten public sector immunization programmes

Investment in capacity will be necessary to meet demand for new vaccines

Although traditional vaccines have had very steady and low prices, new vaccines are orders of magnitude more expensive

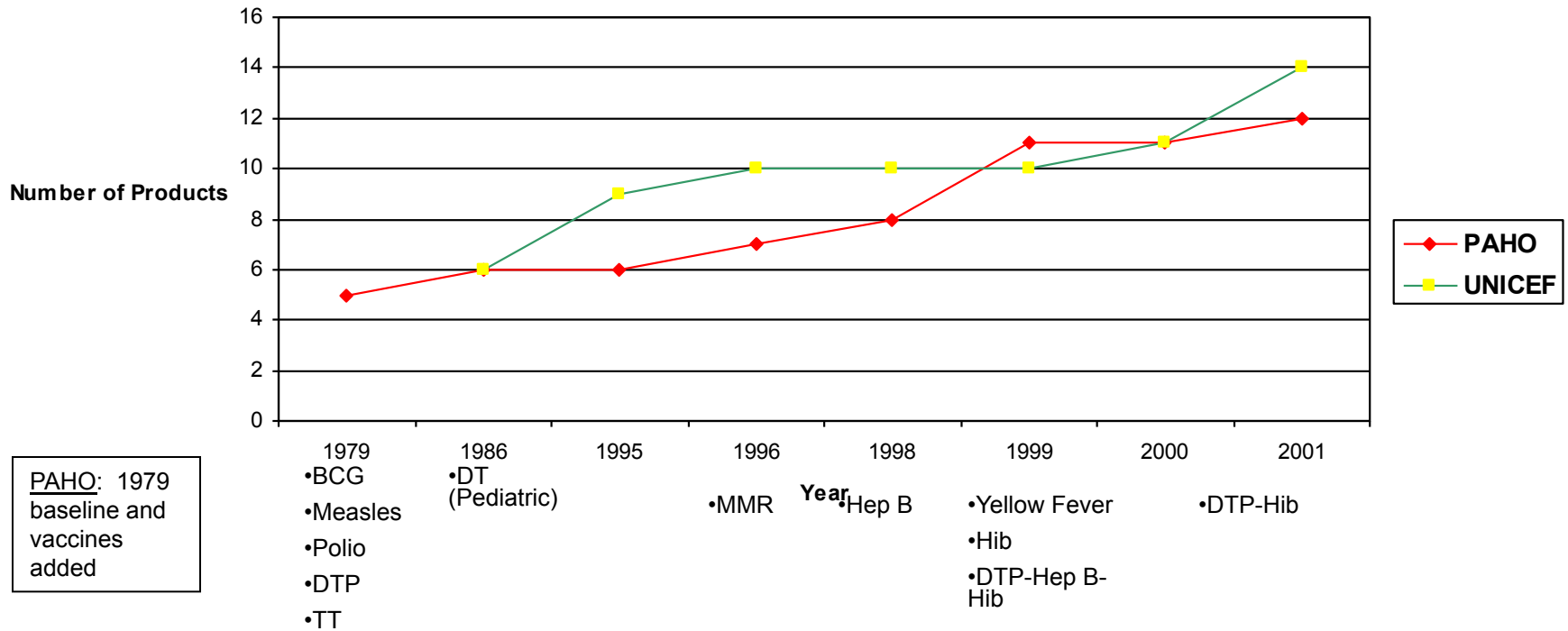
The supplier base of UN agencies increasingly includes developing country manufacturers

Regulatory requirements are impacting prices and capacity

CHANGING PATTERNS OF UNICEF/PAHO DEMAND FOR & SUPPLY OF VACCINES

UN agency demand: PAHO and UNICEF changed their vaccine demands

(three decades of data, needs recent update)



PAHO: 1979 baseline and vaccines added

- BCG
- Measles
- Polio
- DTP
- TT

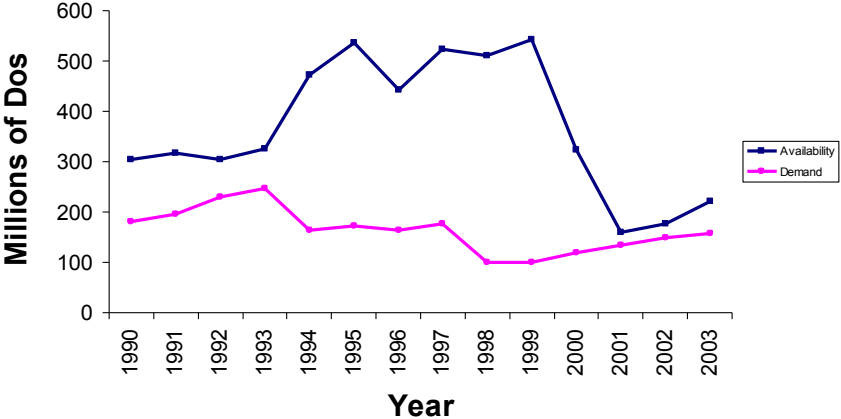
UNICEF: 1986 baseline and vaccines added

- BCG
- TT
- DT
- DTP
- Measles
- OPV
- Yellow Fever
- Hep B
- Td
- -Men AC
- MMR
- Hib
- DTP-Hep B
- DTP-Hep B-Hib

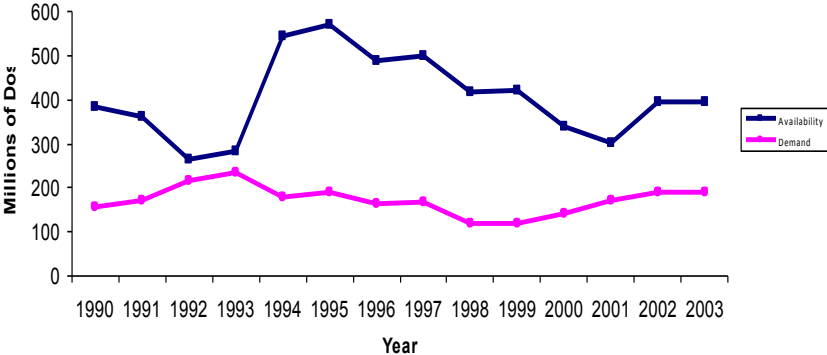
UNICEF demand and availability 1990-2003

Demand and availability are converging for UNICEF-supplied traditional vaccines. This demand is largely being met by DC/EE manufacturers as the market diverges. Thus divergence makes supply more tenuous.

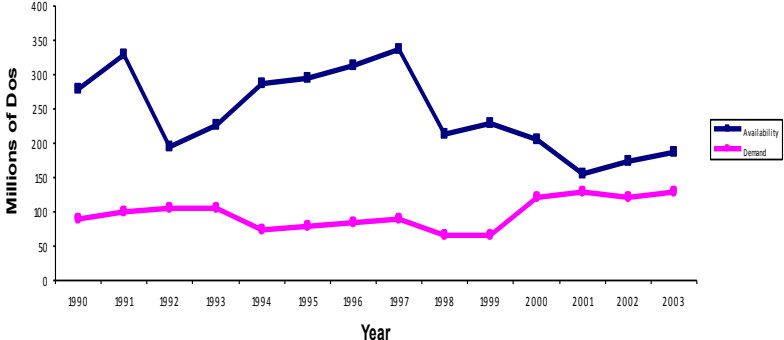
DTwP



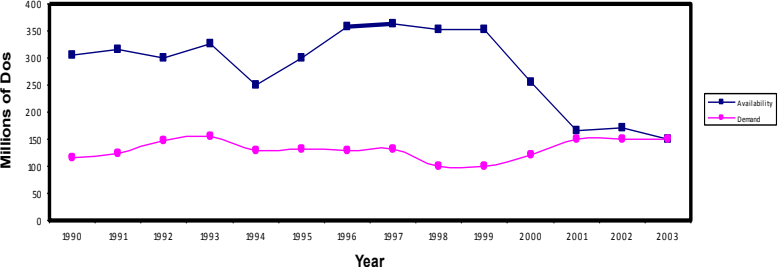
TT



Measles

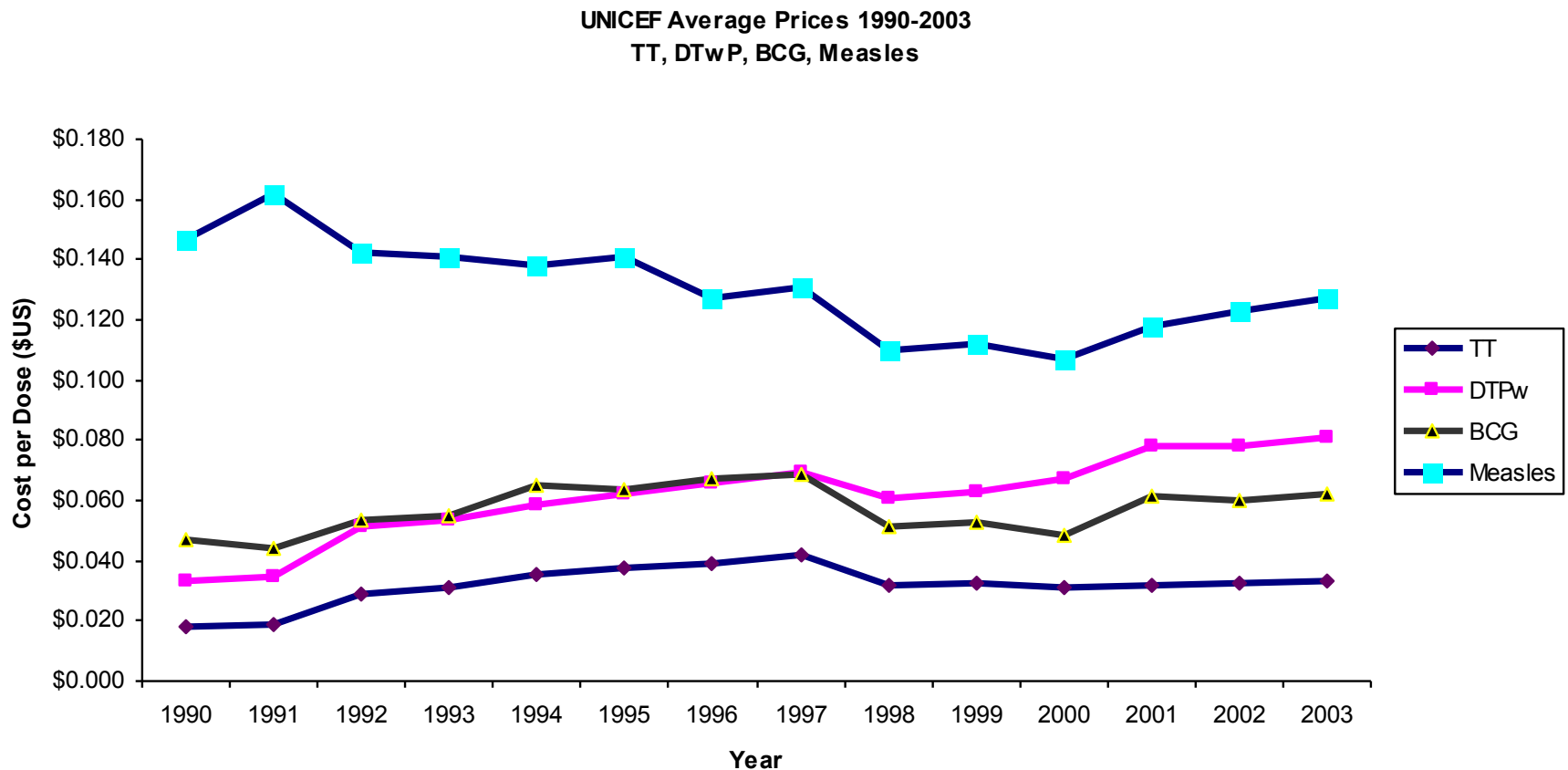


BCG



Pricing: UNICEF average prices

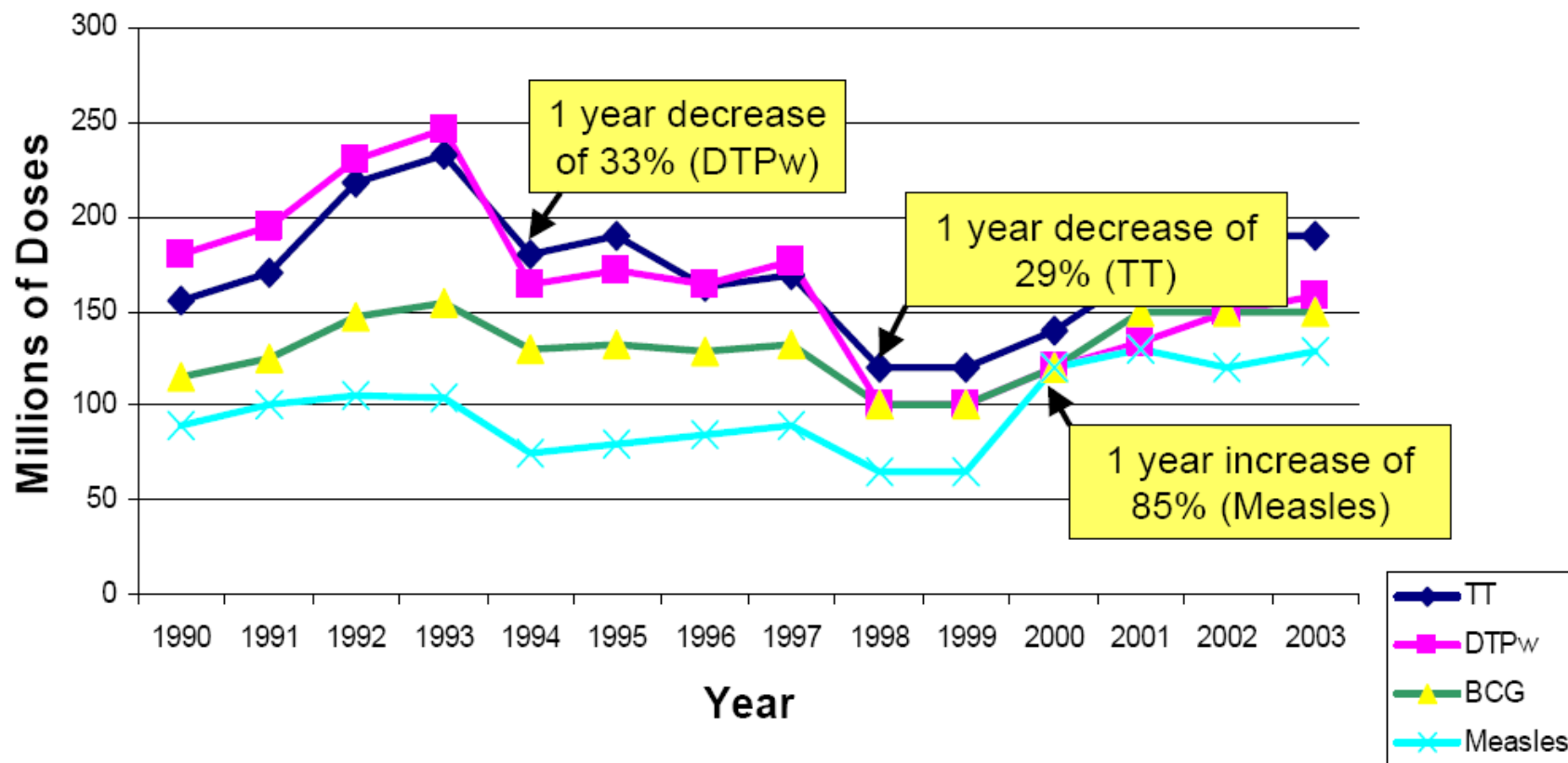
Prices have remained static for traditional vaccines



UN agency demand: volume

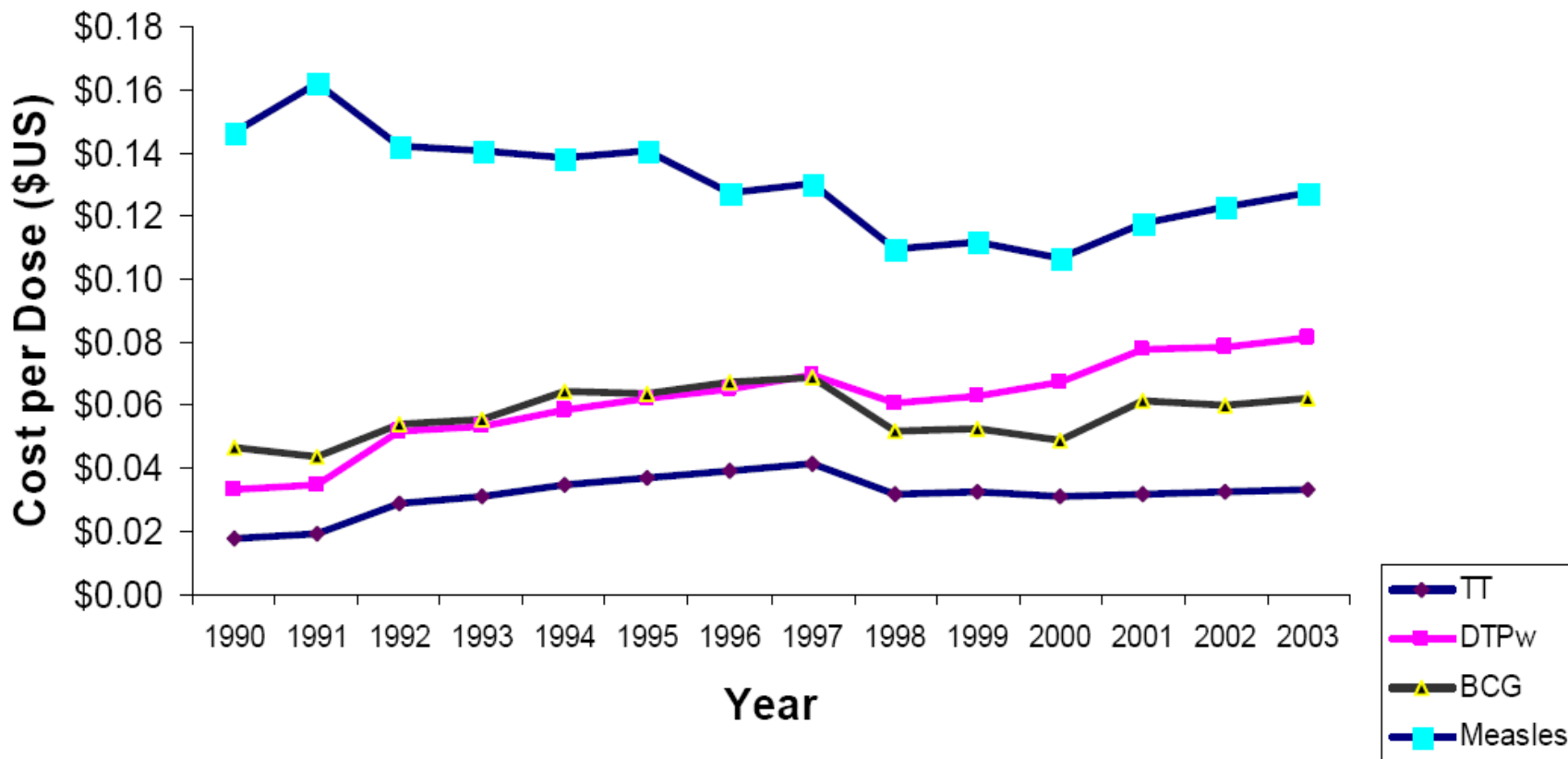
UNICEF demands large volumes of traditional vaccines. However, the demand has fluctuated and at times been unpredictable. This needed to and has now improved

UNICEF Demand 1990-2003



Prices have stayed stable in the face of fluctuating demand

UNICEF Average Prices 1990-2003



UN agency mix of suppliers

Over the past 20 years, PAHO and UNICEF have changed supplier base to a mix of industrialized and developing country/
emerging economy (DC/EE)¹ manufacturers

DC/EE manufacturers

Vaccine	1986	1996	2001
Measles	Institut Merieux SKB Sclavo Evans Connaught	PMC Biocine Il Zagreb SKB Biken Evans Serum India	Aventis Biken Serum India
Polio	Inst Merieux SKB Sclavo Connaught	PMC Biocine SKB Chiron Behring	Aventis Chiron Vaccines GSK Biofarma
DTP	Inst Merieux Connaught Swiss Serum Behring	PMC Serum India Swiss Serum CSL Biocine Chiron Behring	Aventis Biofarma CSL Serum India
TT	Inst Merieux Connaught Swiss Serum Behring	PMC Human Serum India Swiss Serum CSL Biocine	Serum India Biofarma CSL Human
Hep B	--	SKB Cheil LG Green Cross	LG Green Cross Cheil (recomb)* Bharat* Shantha*
Hib combos	--	--	Aventis Chiron GSK

Note: 1 DC = Developing country, EE = Emerging economy. * = not yet WHO-prequalified

Source: PAHO, WHO (note the data here is not fully up to date)

NEW VACCINES AND TECHNOLOGIES

Current and future vaccines and Technologies

Current vaccines

- BCG ^a
- Cholera (inactivated and live) ^b
- DTP and DTP-based combinations ^a
- *Haemophilus influenzae* type b ^a
- Hepatitis A ^a
- Hepatitis B ^a
- Influenza ^a
- Japanese encephalitis (inactivated and live) ^b
- Measles ^a
- Meningococcus (polysaccharide and conjugate) ^a
- Mumps ^a
- Pneumococcus (polysaccharide and conjugate) ^a
- Polio (OPV and IPV) ^a
- Pseudomonas ^b
- Rabies ^b
- Rift Valley fever ^b
- Rubella ^a
- Tetanus toxoid ^a
- Tick-borne encephalitis ^b
- Typhoid ^b
- Varicella ^a
- Yellow fever ^a

Available but underused immunization supportive technologies

- Pre-filled injection devices
- Vaccine vial monitors on all vaccines

New or improved vaccines anticipated by 2015

- Dengue ^d
- DTaP (with two P antigens) ^d
- Enterotoxigenic *Escherichia coli* (ETEC) ^d
- Group A streptococcus ^d
- Human papilloma virus ^c
- Influenza for pandemic response
- Japanese encephalitis (improved) ^c
- Malaria ^d
- Measles (aerosol) ^c
- Meningococcus A (multi-serotype conjugate) ^c
- New combinations of existing vaccines ^d
- Pneumococcus (improved conjugate or protein-based) ^c
- Polio (inactivated vaccines based on Sabin strains) ^c
- Polio (monovalent OPV type 1) ^d
- Respiratory syncytial virus ^d
- Rotavirus ^c
- Severe acute respiratory syndrome (SARS) ^d
- Shigella ^d
- Typhoid (conjugate) ^d
- West Nile fever ^d

New immunization supportive technologies anticipated by 2015

- Jet injectors
- Thermostable vaccines
- Vaccine aerosols
- Vaccine nasal sprays
- Vaccine patches

^a Available for immediate use in routine immunization.

^b Available for specific regions or circumstances.

^c In a late stage of development.

^d Licensing expected in 2010–2015.