

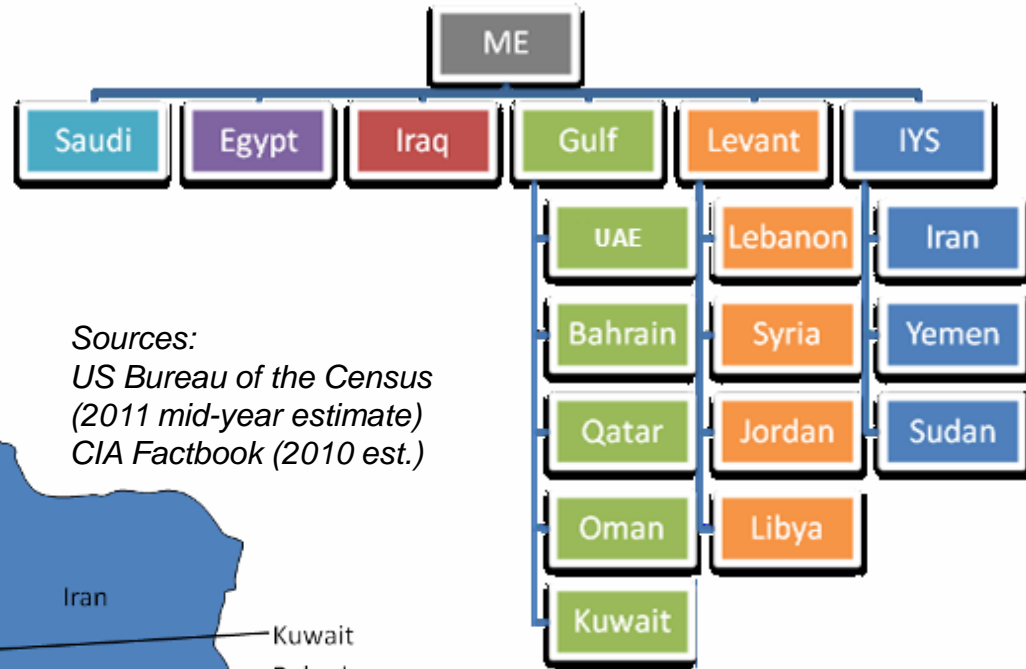
Pharmaco-Economical Overview of Healthcare

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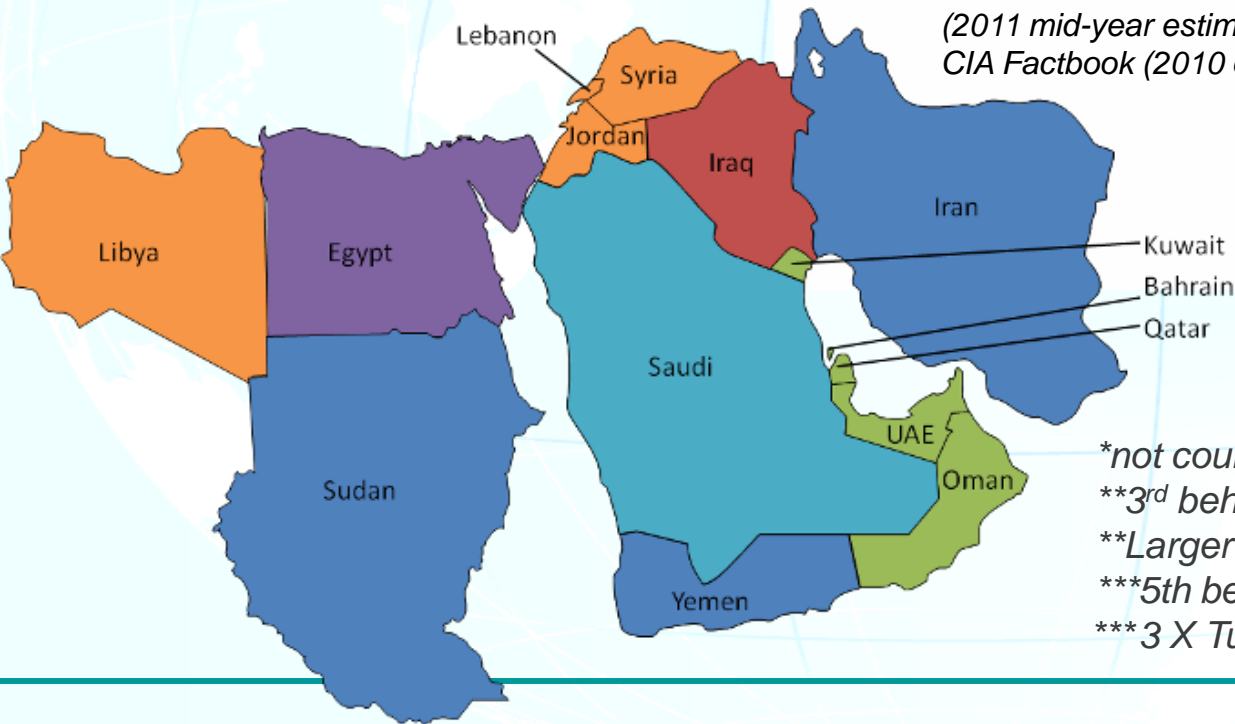
January, 2012

The Middle East

- 15 Countries*, 5 Time Zones
- Population > 333 millions**
- GDP: \$3.13 Trillions***
- 58% of world oil reserves



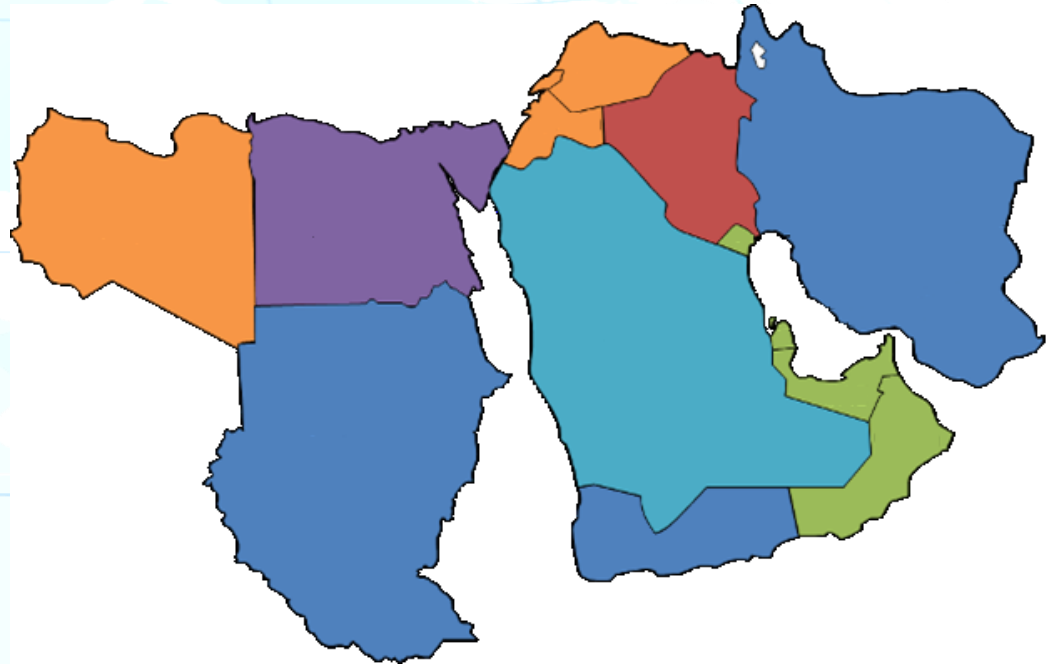
Sources:
 US Bureau of the Census
 (2011 mid-year estimate)
 CIA Factbook (2010 est.)



*not counting south Sudan
 **3rd behind China, India. Ahead of US, Indonesia
 **Larger today than Brazil + Korea in 2020
 ***5th behind US, China, Japan, India
 *** 3 X Turkey, >3/4 India

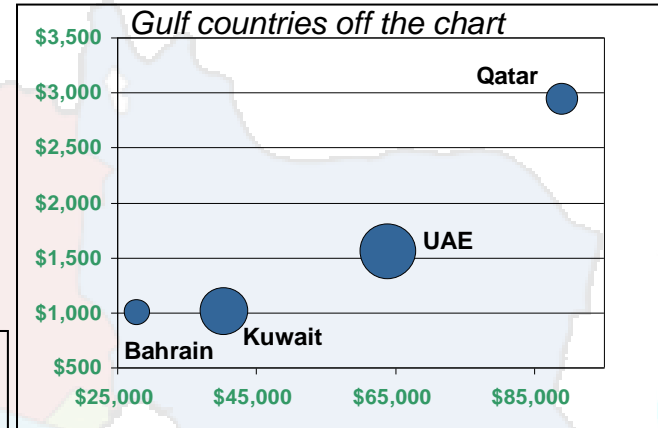
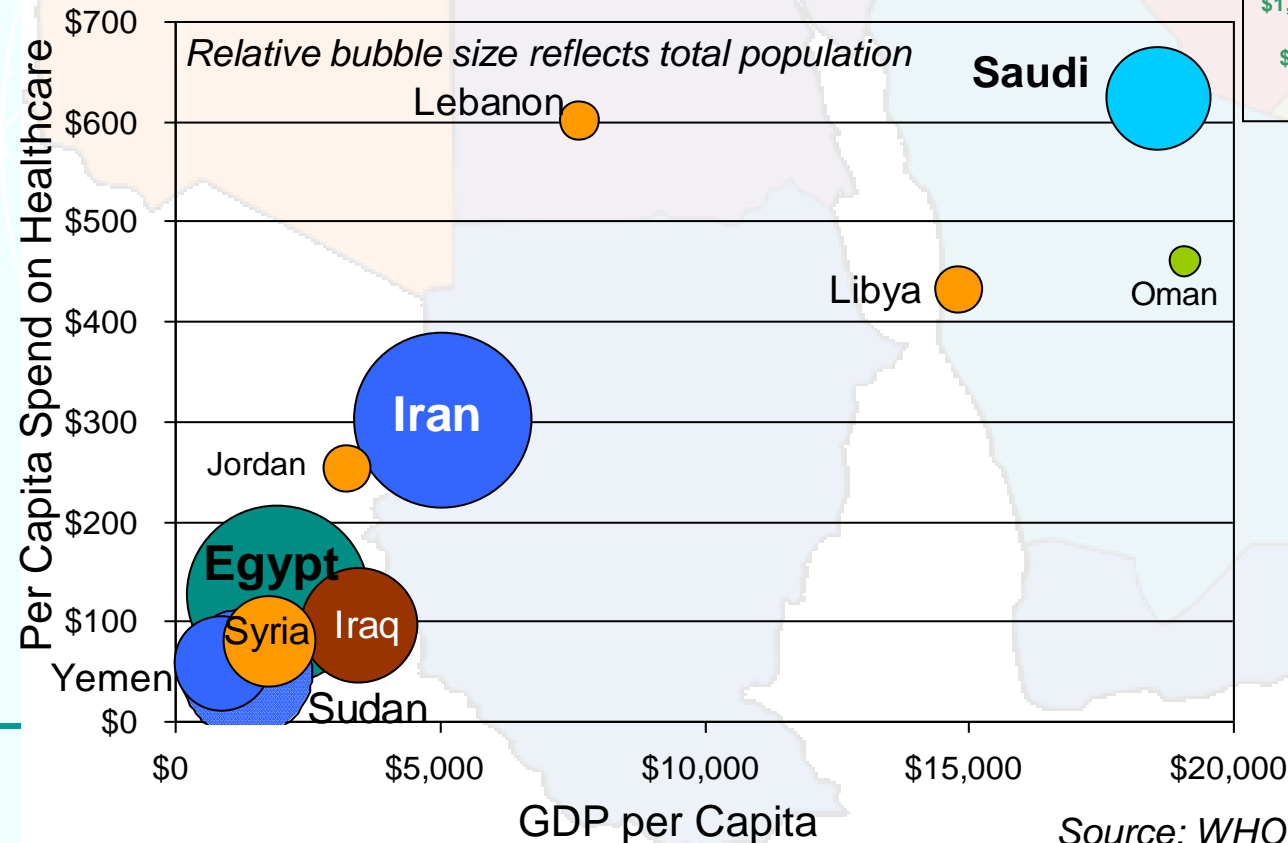
The Middle East: Current Political Environment

- Wave of revolutionary democracy, the extent of which is still unknown
- Anti-government protests likely to continue
- People calling on governments to become more responsive, more open, and more accountable
- Protests focus on legal, political, and economic issues (corruption, low wages, high unemployment)



The Middle East: Countries Overview

- ▶ Two main types of countries economically & demographically:
 - ▶ Large populations, Low income, Low spend on healthcare
 - ▶ Small populations, High income, High spend on healthcare



The Direct Value of Healthcare Investment

- **From 1980 to 2000 each additional dollar spent on healthcare in the U.S. produced tangible health gains valued from \$2.40 to \$3.00**
- **Significant health gains during the same period:**
 - 16% decline in annual mortality rates
 - 25% decline in disability rates for those over 65 yrs of age
 - 4% increase (2.3 yrs) in life expectancy from birth
 - 56% decline in number of days spent in the hospital

Overall Therapy Evaluation

Type of Outcomes	Therapy Name	Therapy A	Therapy B	Therapy A Overall Cost	Therapy B Overall cost
Clinical Outcomes	Efficacy and Safety	Therapies A & B have equivalent E&S			
Economic Outcomes	Treatment Duration	10 Days	10 Days	\$250	\$400
	Drug Cost Per Treatment	\$250	\$400		
Economic Outcomes	Hospital Length of Stay (\$100 per day)	5 Days	3 Days	\$500	\$300
Economic Outcomes	Time off from Work (\$100 per day)	7 Days	4 Days	\$700	\$400
Humanistic Outcomes		Total Cost		\$1,450	\$1,100

Identification of Health Related Outcomes

- Outcomes beyond safety and efficacy which capture the psychological, social, physical, functional, and economic impact of disease and treatment for individual and society
- Identifying Health related outcomes
 - Economic outcomes
 - Hospitalizations avoided
 - Workers productivity
 - Clinical outcomes
 - Clinical efficacy/effectiveness –cure rate
 - Relief, reduction in symptoms
 - Impact on morbidity and mortality
 - Humanistic outcomes
 - Health related quality of life
 - Patients satisfaction and compliance
 - Ability to perform activities
- Challenges
 - Identifying relevant outcomes
 - Valuing outcomes

The Different Steps of Evidence

Efficacy

Effectiveness

Efficiency

The Different Steps of Evidence

- Can it work? = ***Efficacy***
- Does it work in reality? = ***Effectiveness***
- Is it worth doing it, compared to other things we could do with the same money?
= *Cost-effectiveness* = ***Efficiency***

The Different Steps of Evidence

Efficacy



The Different Steps of Evidence

Effectiveness



The Different Steps of Evidence



OR



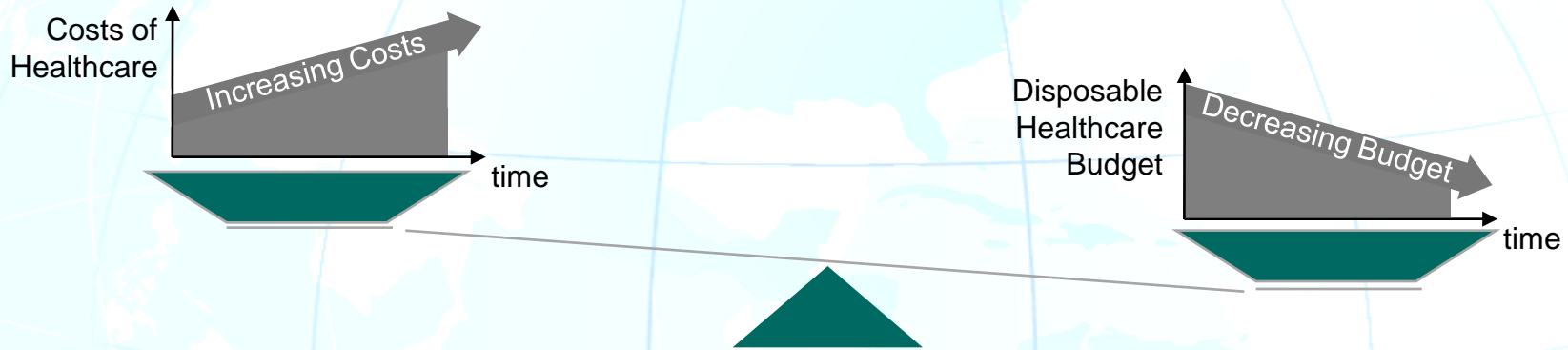
Efficiency

Pharmaco-Economics

- It refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. It is a sub-discipline of Health economics. A pharmacoeconomic study evaluates the cost (expressed in monetary terms) and effects (expressed in terms of monetary value, efficacy or enhanced quality of life)

Factors Impacting the growing imbalance between costs and budget for healthcare stakeholders

The Growing Imbalance Between Healthcare Costs and Budget



Key Drivers:

- An aging population with an increased healthcare demand
- Medical innovation and a more informed consumer claiming 'state of the art' treatment
- Fiscal budget gaps and a refocus of investments from healthcare into other fiscal projects
- Changes in reimbursement methodologies and healthcare funding
- Increasing scrutiny of governments and payers in approving healthcare investments

Value Is Understood Differently



Estimated Value

Seen by the drug manufacturer

Usage Value

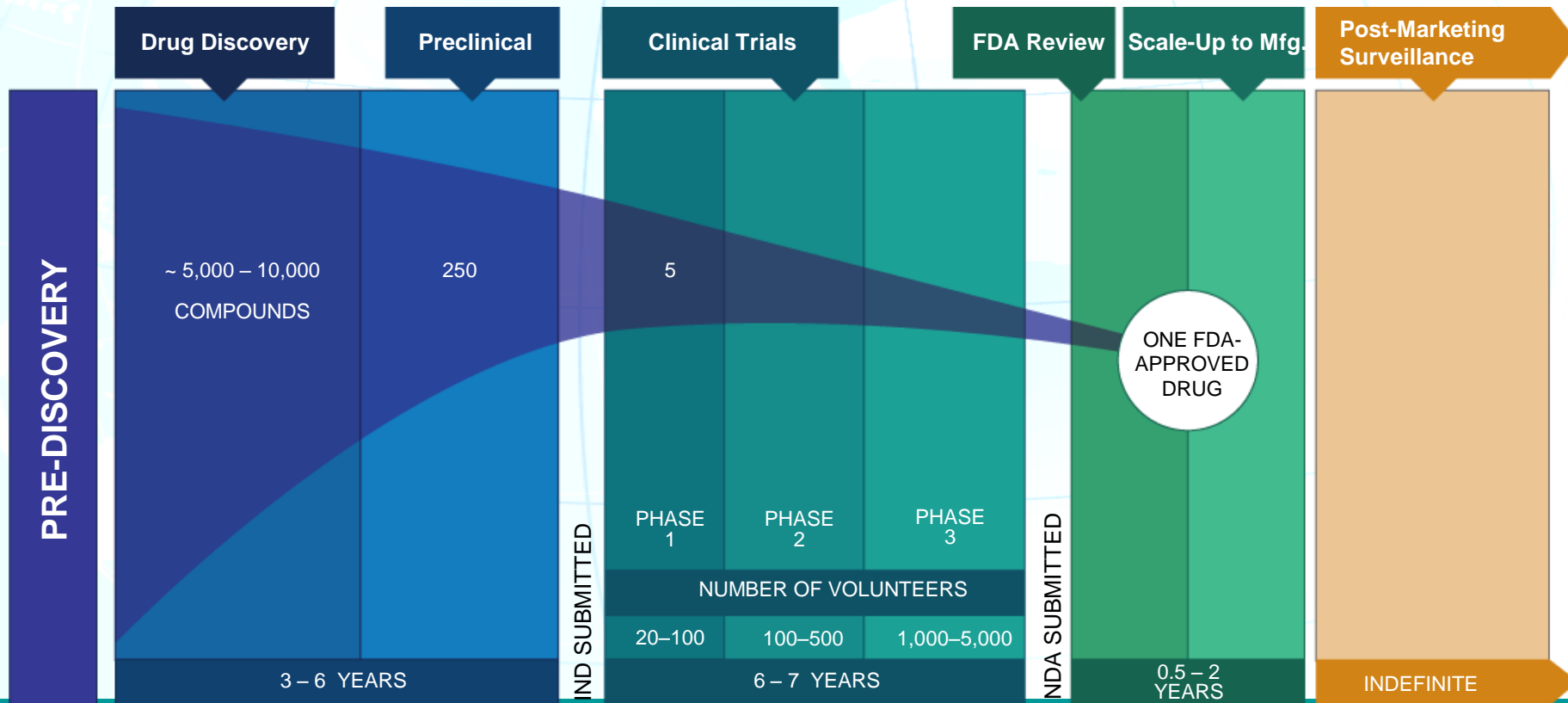
Seen by the prescriber
the patient and the health
authority giving the local
approval

Exchange Value

Seen by the payer

Drug Development Takes Longer Than It Did in the Past

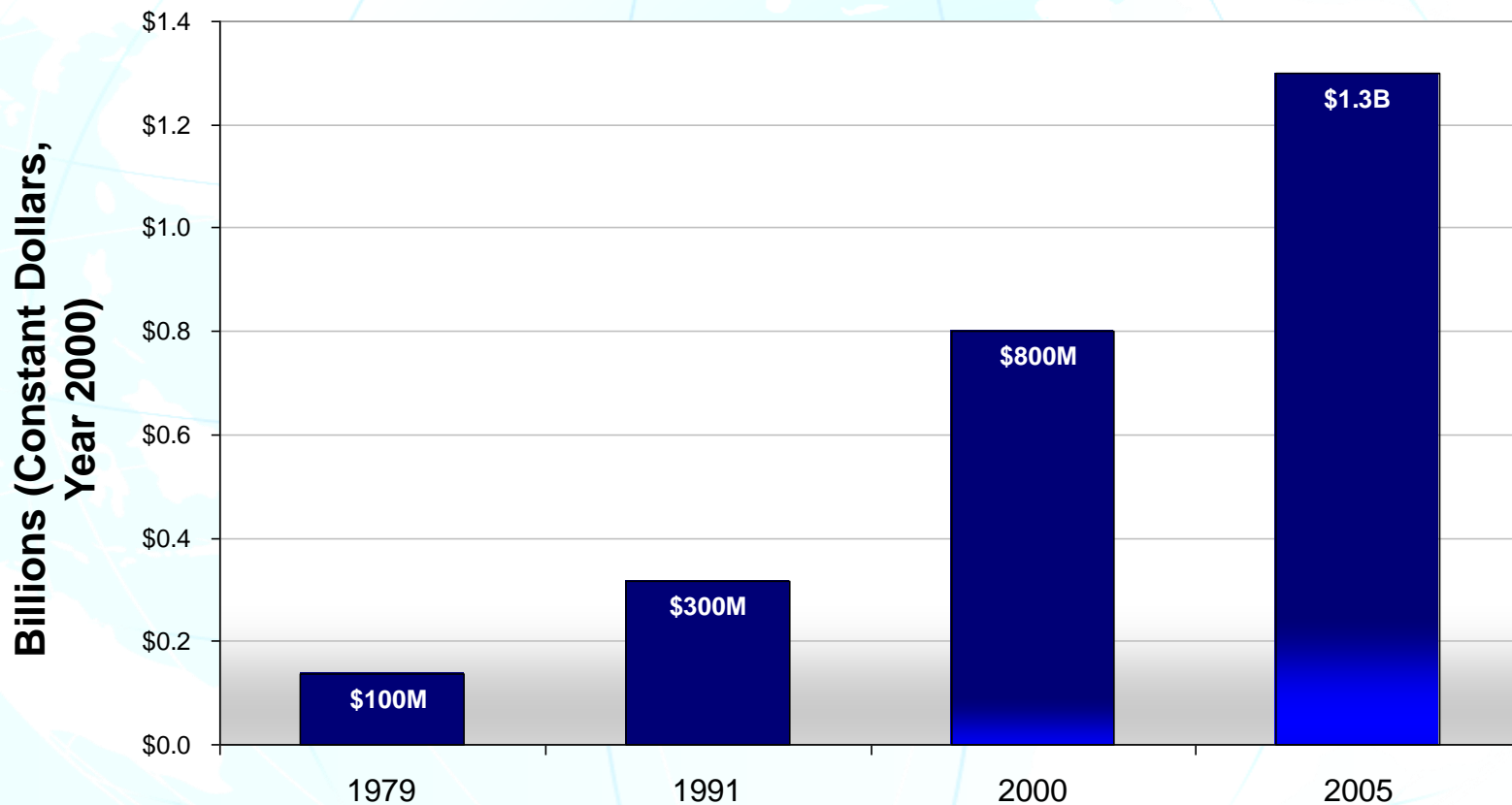
Developing a new medicine takes an average of 10–15 years; the Congressional Budget Office reports that “relatively few drugs survive the clinical trial process”



Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org; CBO, *Research and Development in the Pharmaceutical Industry*, 2006.

The Cost of Developing a New Drug Has Greatly Increased

Cost to Develop One New Drug¹

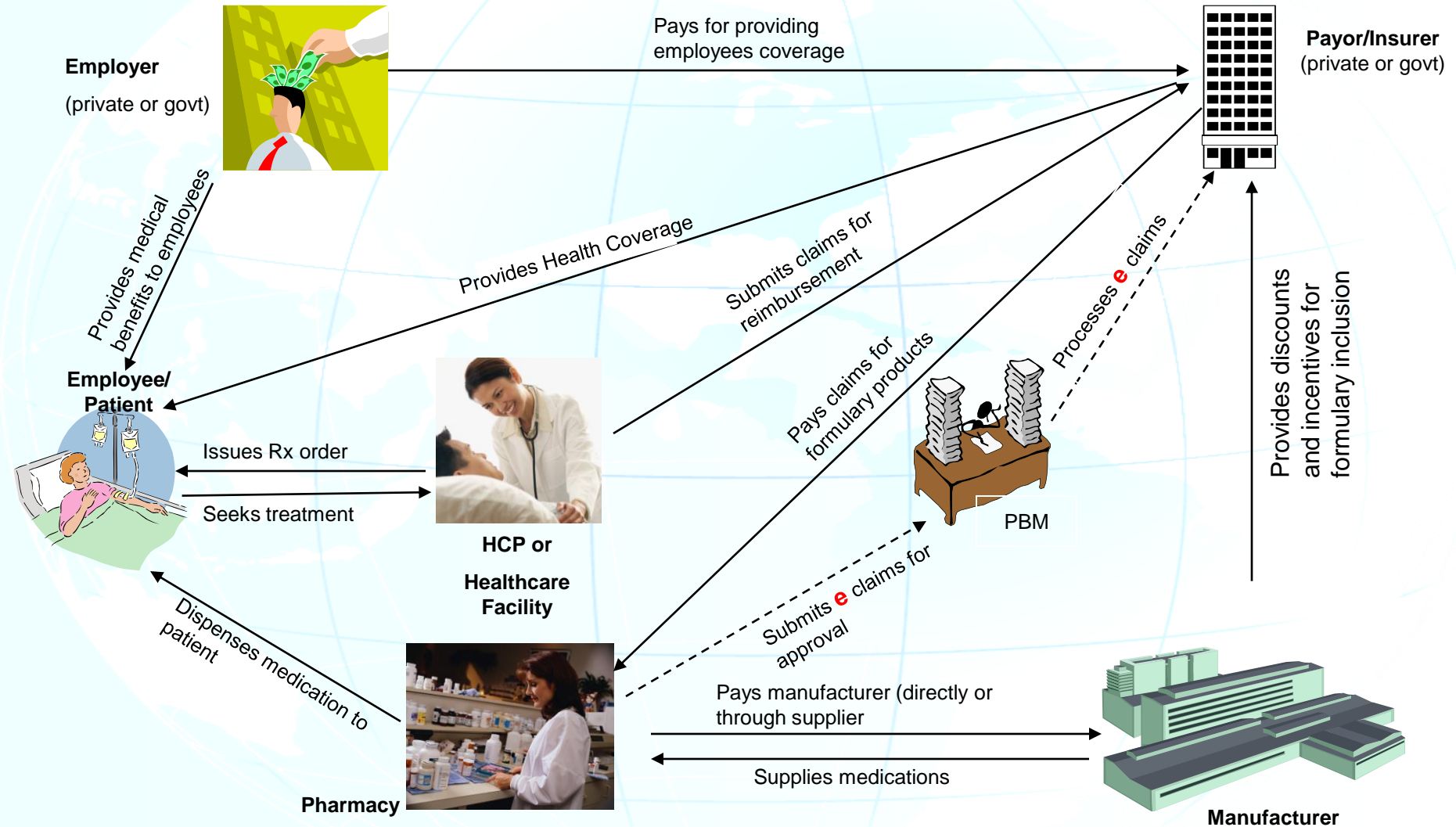


Sources: ¹J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007; J. DiMasi et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 2003.

Current Payor Landscape in the Middle East Region

- Ministries of Health across multiple countries provide drug coverage to specific segments of the population as well as for specific disease entities
- Government health institutions providing coverage to their own employees, mainly government/military sectors.
- Governmental health authorities who provide services to the residence of specific regions
- Private Health insurance companies who provide coverage to beneficiaries through employers contracting.
 - **This is the fastest growing segment in the payor area across most countries.**
- Out of pocket business

Stakeholders Involved (Money Flow)



Management Spending Tools

Formulary

- A defined list of medications, by therapeutic category, that determines the level of member benefit
 - Determined by P&T , MD and Pharm D
 - Cost effective therapies
 - Generic preferred
 - Rebate-driven brands
- Structured Tiered Approach
- Co-pay/co-insurance driven tiering system prioritizing availability of drugs based on the above criteria

Example on Tier Structure

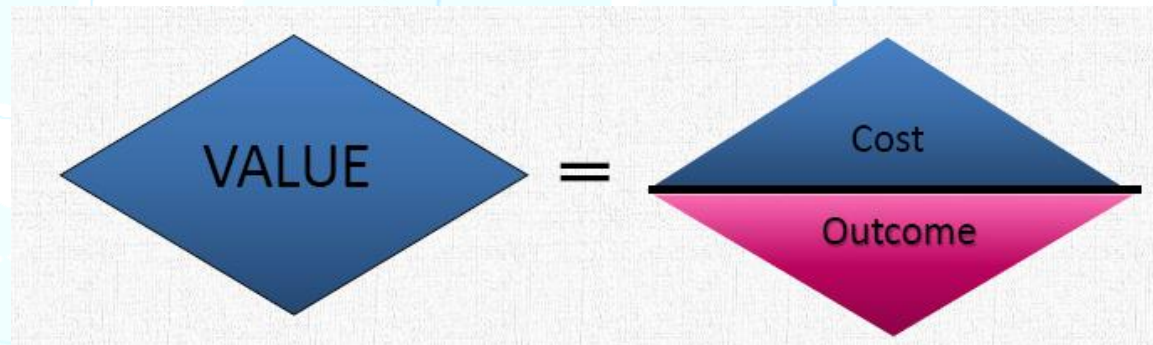
Tier Level	Tier 1	Tier 2	Tier 3	Tier 4	NDC Locked
Products	Generics	Preferred brands	Non-preferred brands	Biologics	Products not to be covered under any circumstances
Approximate patient co-pay or co-insurance	\$10	\$25 - \$35	\$50 - \$70	% of total cost	Full cost
Motive for Placement	Least expensive	Generic not available. Therapeutically necessary. Rebate negotiated with manufacturer	Generic not available. Therapeutically necessary. Rebate not provided by manufacturer	Expensive therapy. Generally over \$500 per Tx	Not therapeutically valuable

Rebate and Incentive Agreements with Manufacturers

- Manufacturers contract with PBMs on specific products to provide them rebates on quarterly basis based on utilization trends within specific market baskets.
- Examples on those agreements are as follows
 - Flat discount rebate
 - Market share rebate
 - Index to nation rebate
 - Volume based discounting rebate
 - Risk sharing agreement
 - Value Based Insurance Design

Key Issues for Health Decision Makers

- Healthcare is getting too expensive
- We need to prioritize
 - Step 1: Do not pay for treatments that do not deliver value
 - Step 2: Define Value: How much do we pay for what we get?



Additional Terminology

- “Cost-effective”
 - The investment is “good value for money”
 - It is *not* equivalent to cost-saving

- “Cost-saving”
 - The return on investment saves more in terms of prevented morbidity/mortality than the investment itself
 - An intervention may be “not cost-effective”, “cost-effective” or “cost-saving” depending on different modeling assumptions and perspectives

Quality-Adjusted Life Years (QALY)



- A standard health outcome measure in cost-effectiveness analysis
- Accounts for quality and quantity of life
- Cost/QALY quantifies economic (cost) and health benefits (QALY) of a medical intervention

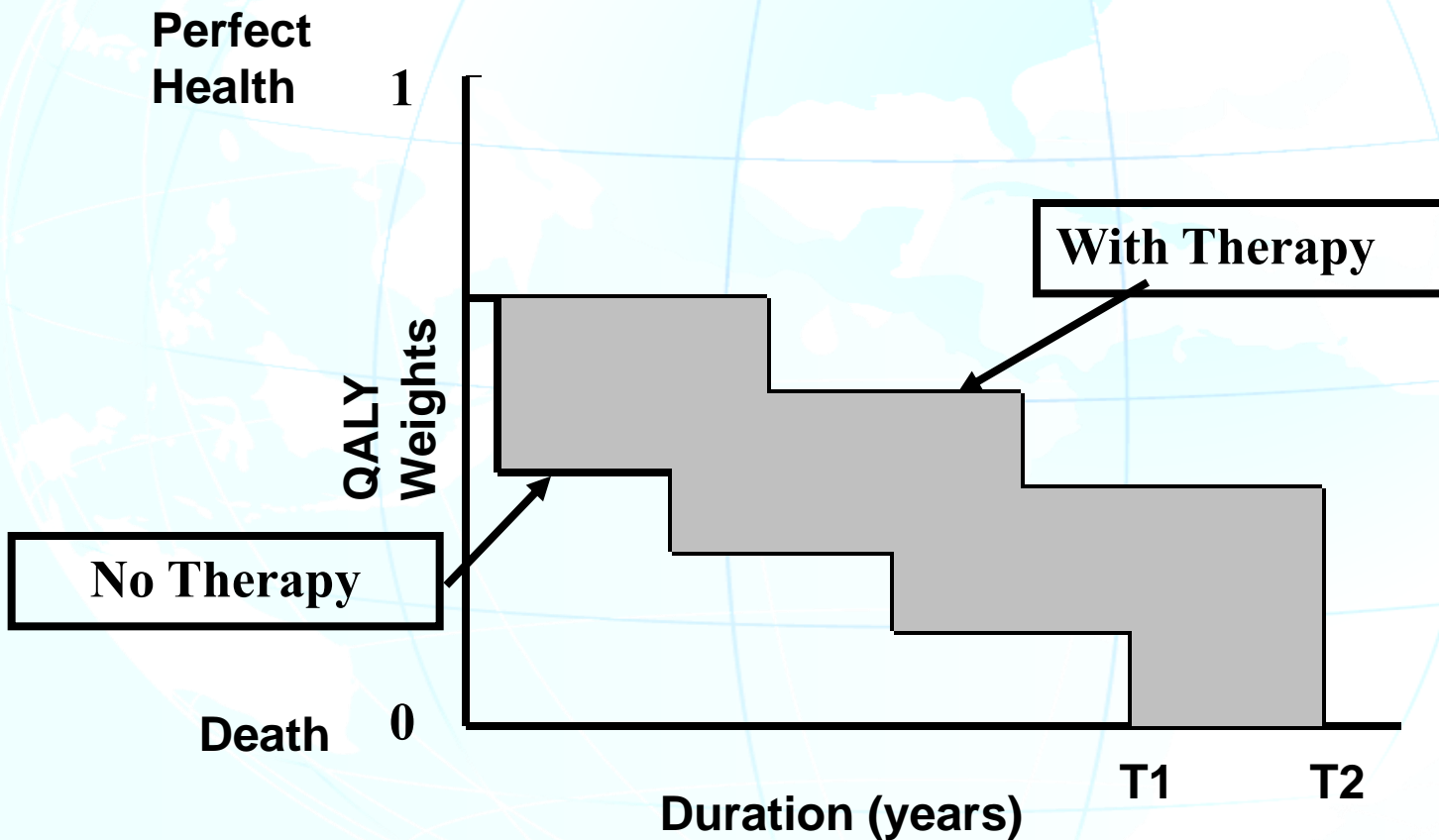
Quality-Adjusted Life Years

- Two components of calculation of QALYs
 - Quality weight (utility or preference) of each health state which individual may experience
 - Quality weight may range between 0 and 1



- Length of time of each health state (Quantity)
- One QALY is the mathematical equivalent to one person living one year in perfect health

QALY Gained



Source: Torrance G.W. (1996). Designing and conducting cost-utility analyses. In: Quality of life and Pharmacoeconomics in clinical trials. Second edition, pp. 1105-11.

Incremental Cost-Effectiveness Ratio (ICER)

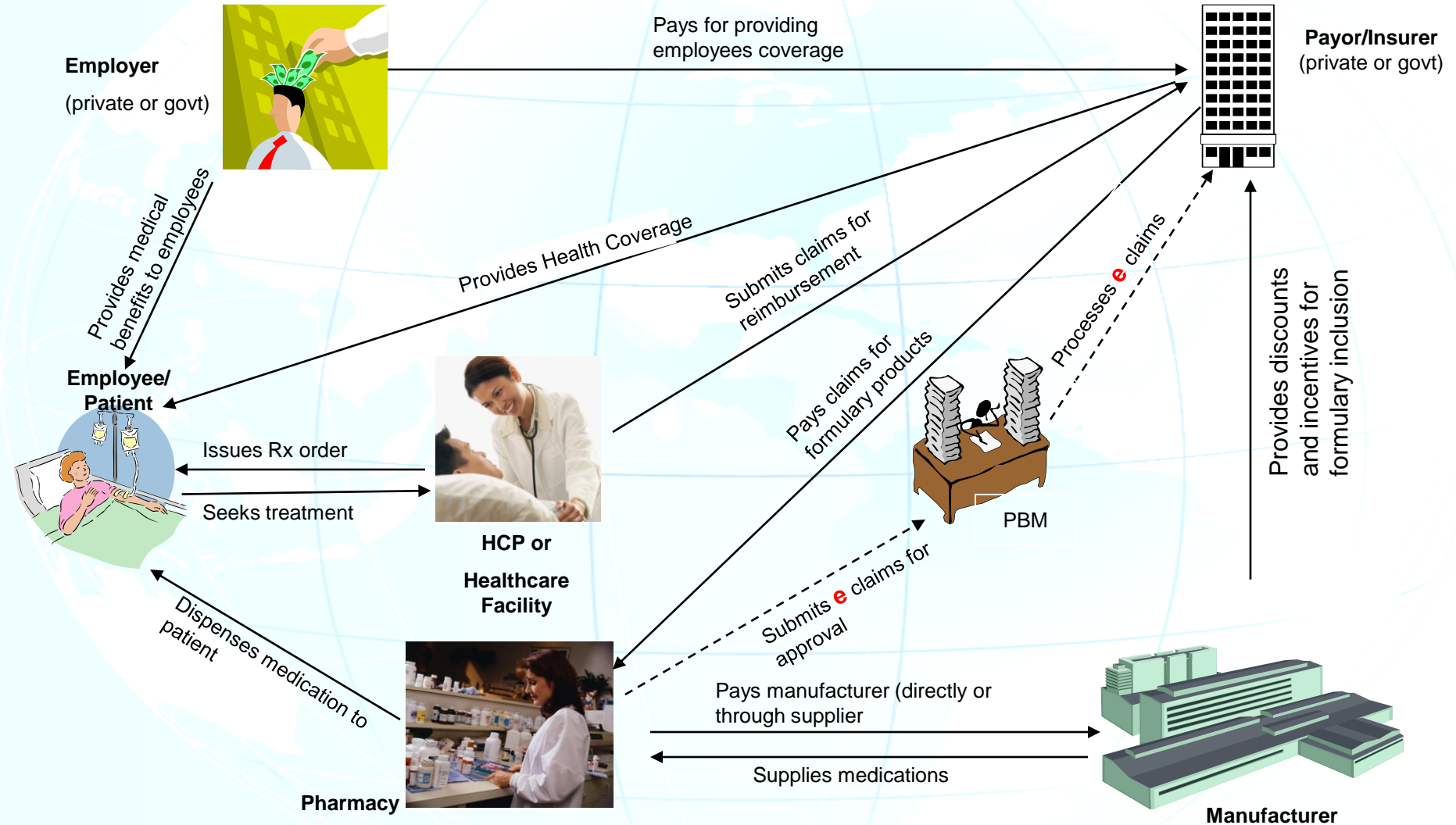
$$\frac{\text{Cost}_{\text{Vaccination}} - \text{Cost}_{\text{No vaccination}}}{\text{Outcome}_{\text{Vaccination}} - \text{Outcome}_{\text{No vaccination}}}$$

- Hypothetical Example

Strategy	Cost (\$)	QALY	ICER
No Vaccination	50,000	10	-
Vaccination	130,000	15	-
Difference	80,000	5	16,000

- ICER threshold may vary by decision-maker:
< \$50,000 - \$100,000 per QALY often considered cost-effective.

Stakeholders Involved (Money Flow)





Pricing Excellence, Principles and Beyond

Exponential Volume Increase in Relation to Unit Price Reduction

		if your present margin is						
		50%	45%	40%	35%	30%	25%	20%
		to produce the same profit sales volume must increase by						
And you reduce your price by	2%	4%	5%	5%	6%	7%	9%	11%
	4%	9%	10%	11%	13%	15%	19%	25%
	6%	14%	15%	18%	21%	25%	32%	43%
	8%	19%	22%	25%	30%	36%	47%	67%
	10%	25%	29%	33%	40%	50%	67%	100%

Source HMH

PRICING PRINCIPLES Advantages and Disadvantages

- ❖ Value-Based Pricing
- ❖ Cost-Plus Pricing
- ❖ Customer-Driven Pricing
- ❖ Competition-driven Pricing



Calculating Profitability

TERM	CALCULATION
Net Selling Price	Gross List Price - Discounts
Total Net Sales	Net Selling Price X Volume
Cost Per Unit	Variable Cost per Unit + Fixed Cost Per Unit
Total Cost of Goods Sold (COGS)	Cost per Unit X Volume
Total Profit Gross Margin (PGM) in \$	Total Net Sales - Total Cost
Total Profit Gross Margin (PGM) as %	(Total Net Sales - Total Cost) / Total Net Sales
Operating Income	Total PGM in \$ - Promotional and Selling Expenses

A		Gross List Price per dose (GLP)		\$95.00
B		Discount	40%	\$38.00
C	(A - B)	Net Ex-MSD Selling Price (LNSP) per dose		\$57.00
D		Volume in number of doses		10,000
E	(C * D)	Total Net Sales		\$570,000
F		Manufacturing Cost (COGS) per dose		\$6.00
G	(21% * C)	Royalty Cost per Dose	21%	\$11.97
H	(F + G)	Total Cost per Dose		\$17.97
I		Volume in number of doses		10,000
J	(H * I)	Total COGS in \$		\$179,700
K	(E - J)	Total Profit Gross Margin (PGM)		\$390,300
L		Promotional Expense		\$70,000
M		Direct Selling Expense		\$120,000
N	(L + M)	Total Promotional and Selling Expense		\$190,000
O	(K - N)	Net Operating Income		\$200,300

Competition-driven Pricing Which Market Share is the Best?

Which Market share do you want to have in your market?



10%

50%

75%

100%

Competition-driven Pricing Higher Volume Looks Very Appealing

<u>Share</u>	<u>Volume</u>
10%	2,000
50%	10,000
75%	15,000
100%	20,000



Which market share do you want to have in your Market?

Competition-driven Pricing Competition Is Selling 10,000 Packs at \$10 Each



<u>Share</u>	<u>Volume</u>	<u>Price</u>
10%	2,000	@ \$ 12.00
50%	10,000	@ \$ 10.00
75%	15,000	@ \$ 8.00
100%	20,000	@ \$ 7.00



Which market share do you want to have in your Market?

Driving the Top Line

Market Share	Volume	Price	Net Sales
10%	2,000	\$12.00	\$24,000
50%	10,000	\$10.00	\$100,000
75%	15,000	\$8.00	\$120,000
100%	20,000	\$7.00	\$140,000



We are Gaining Market Share, Why Do We Lose Profits?

<u>Share</u>	<u>Volume</u>	<u>Price</u>	<u>Profit</u> <u>(\$5 cost)</u>	
10%	2,000	@\$12.00	\$14,000	
 50%	10,000	@\$10.00	\$50,000	
75%	15,000	@\$ 8.00	\$45,000	
100%	20,000	@\$ 7.00	\$40,000	