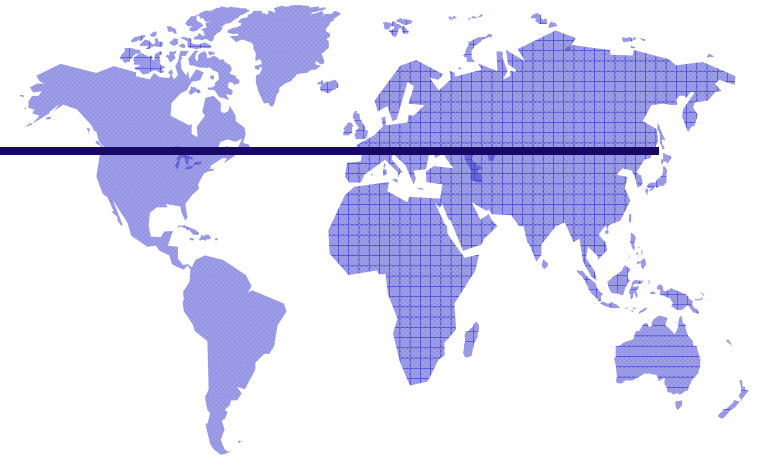


# Europe: Problem Child or Rising Star?

---



Outlook and Opportunities for Growth

Professor

**Michael Schlander**

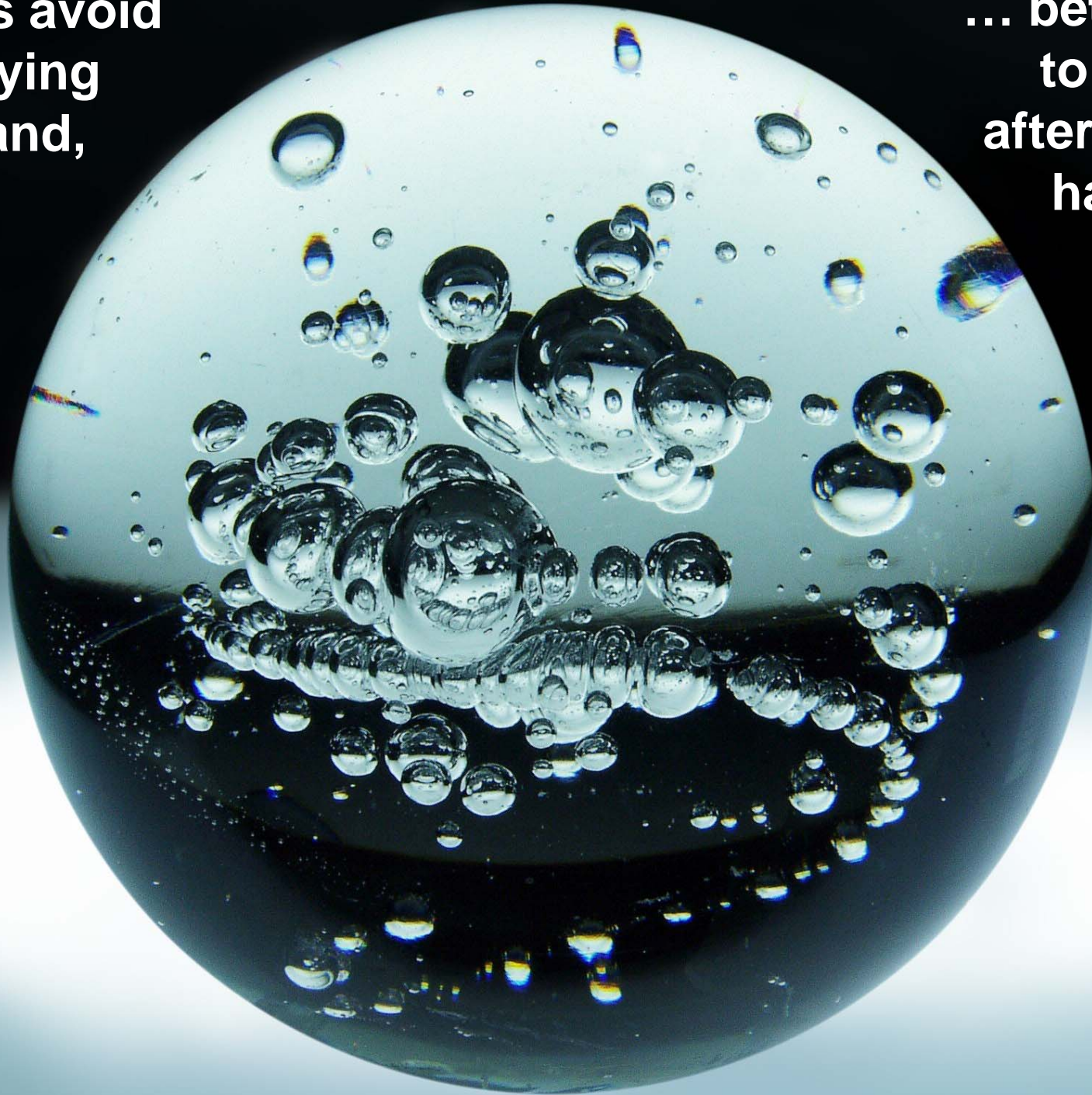
M.D., Ph.D., M.B.A.

**Institute for Innovation & Valuation in Health Care (INNOVAL<sup>HC</sup>)**

University of Heidelberg & University of Applied Economic Sciences Ludwigshafen



**“I always avoid  
prophesying  
beforehand,  
because  
it is  
much ...**



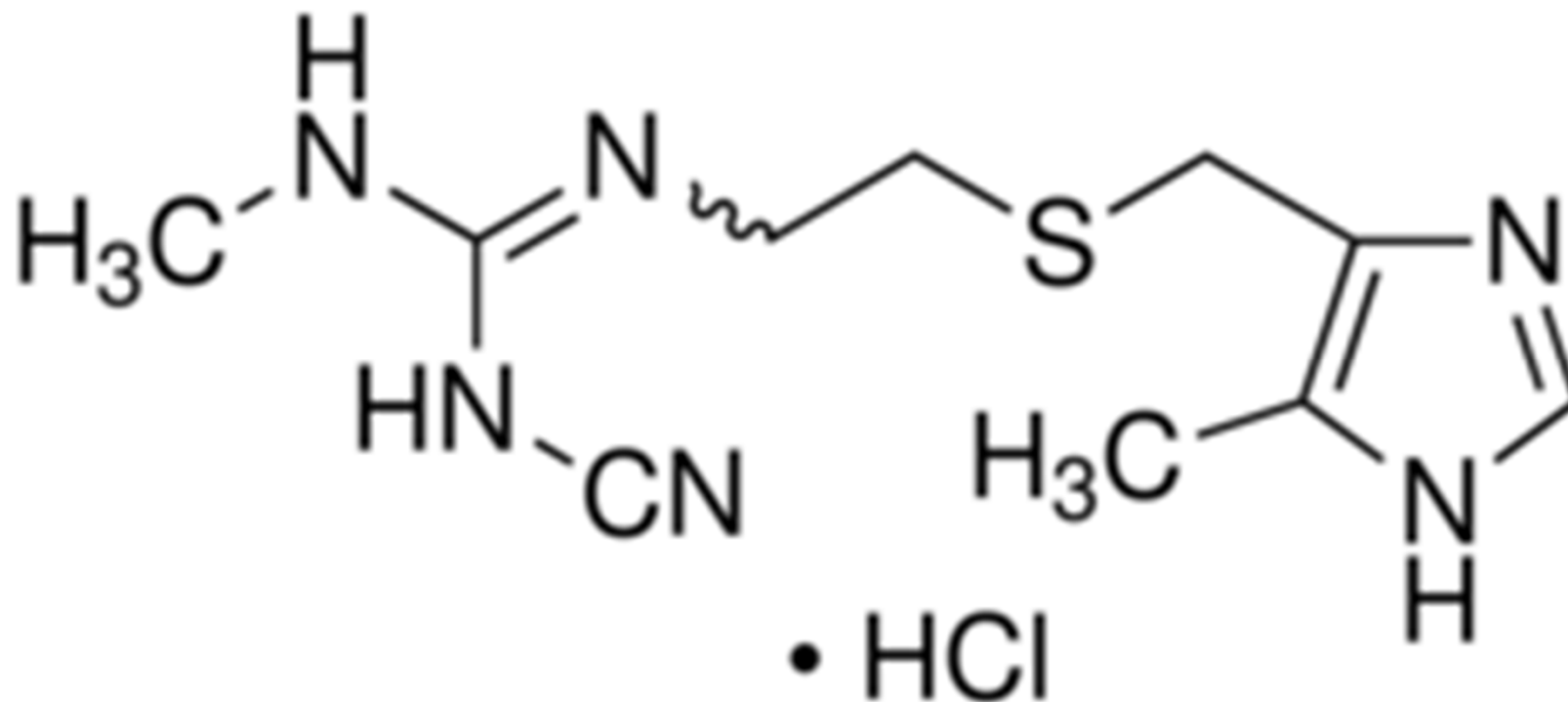
**... better policy  
to prophesy  
after the event  
has already  
taken  
place.”**

**Winston Churchill**



# THE GOOD OLD DAYS

Time Gone By...



### Acid-Related Ulcer Disease<sup>1</sup>

#### Reflux Esophagitis

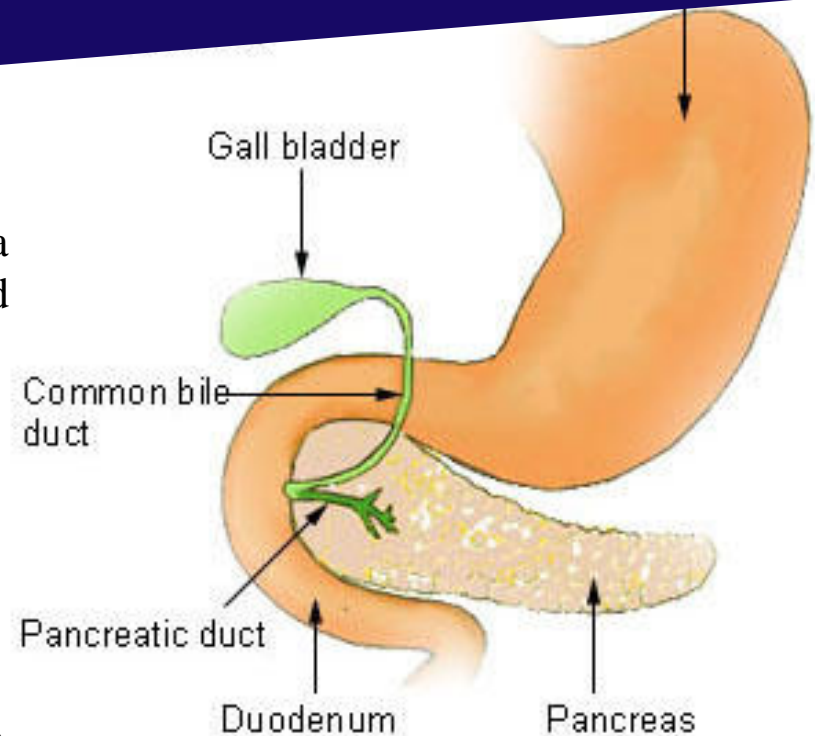
Inflammation and ulcer formation can occur at the lower end of the esophagus as a result of „leakage“ or backward flow of acid gastric juice from the stomach.

#### Gastric Ulcer

The ulcers occurring at the lower end of the stomach are called **gastric ulcers**. They are often the result of a modified and hence more vulnerable gastric wall (mucus membrane).

#### Duodenal Ulcer

In such cases the stomach produces an excessive amount of acid gastric juice, which irritates and erodes the mucuous membrane.



<sup>1</sup>in the 1980s and 1990s, the “pre-H.pylori” era

### The Management of Ulcers Before Cimetidine (Tagamet)

#### Medical Therapy

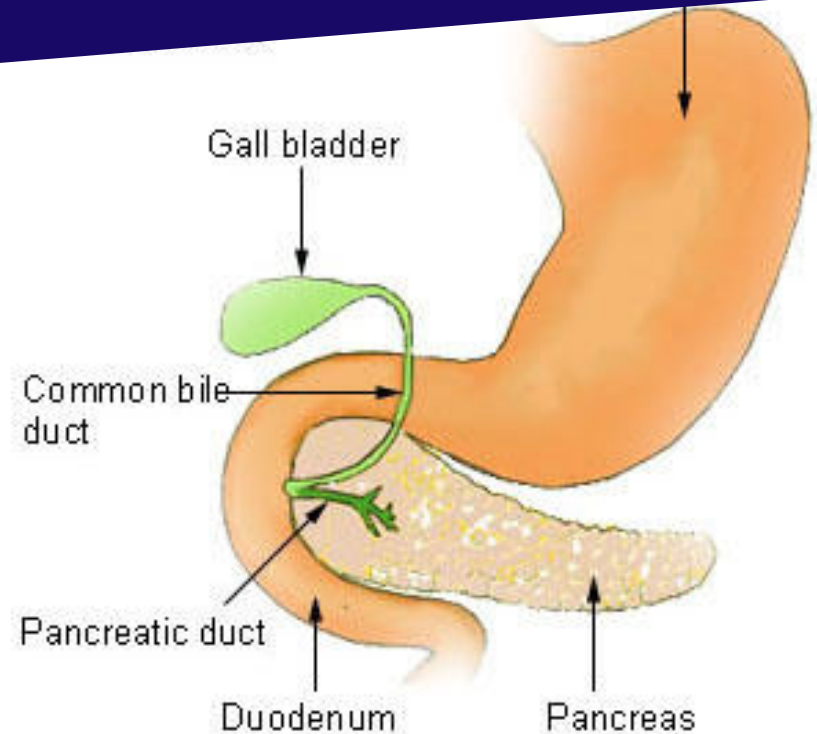
- Antacids to neutralize acid for 4 to 8 weeks
- Cost approximately \$0.20 per day

#### Surgery

- Vagotomy

=> **H<sub>2</sub>RAs reduce acid production and heal 70% of duodenal ulcers.**

=> **A pharmacological breakthrough!**





# THE GOOD OLD DAYS

## Time Gone By...

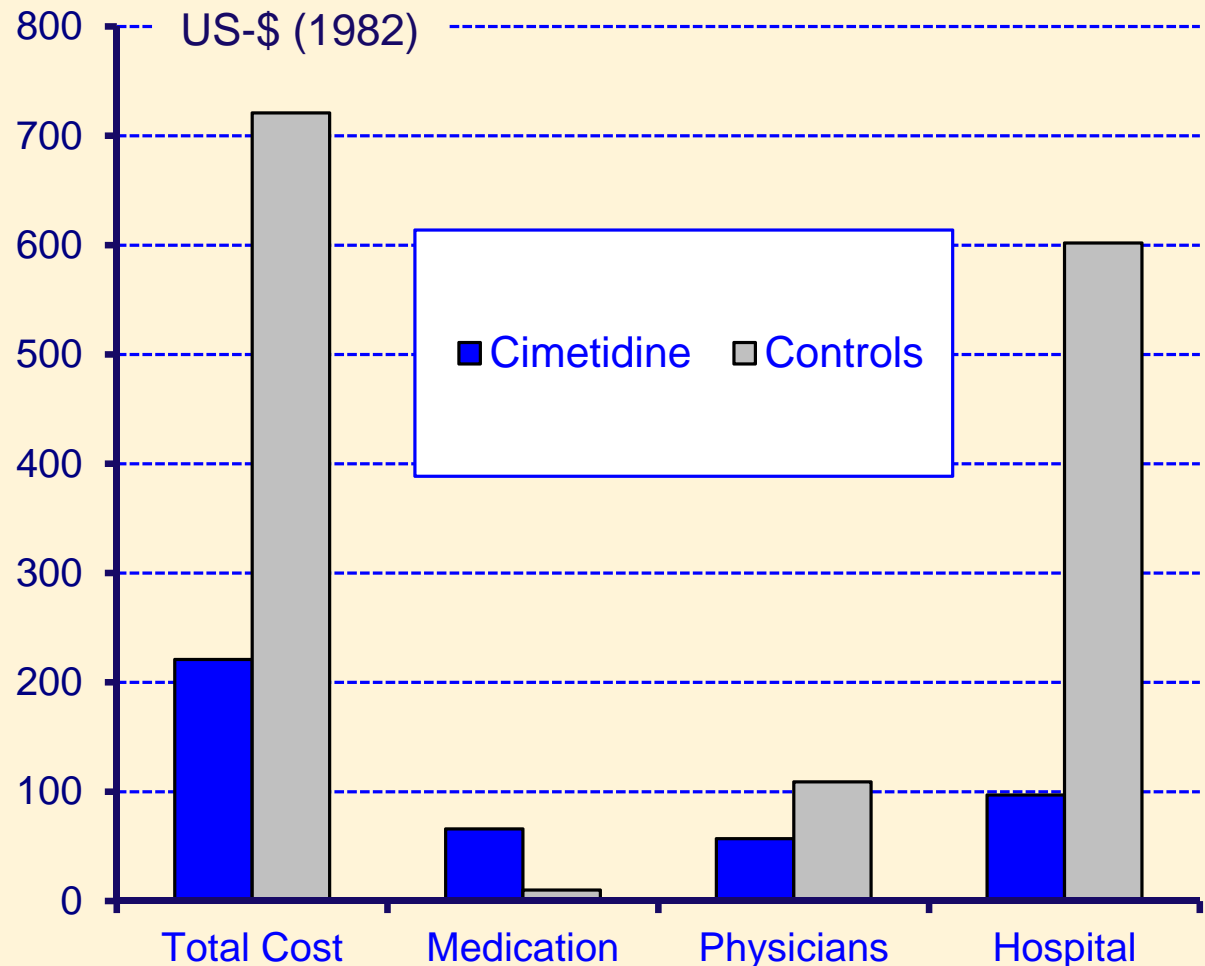
### Value Differentiation: Tagamet versus Antacids (1976-78)

		Antacids	Tagamet
<b>Efficacy</b>	Healing	XXX	XXX
	Pain Relief	XX	XXX
<b>Safety</b>	Side Effects	XXX	?
	Interactions	XXX	X
<b>Administration</b>	Frequency	X	X
	Form / Taste	-	XXX
<b>Price</b>	(Daily Cost)	\$ 0.20	\$ 0.80

### The Birth Hour of “Pharmacoeconomics”

#### Tagamet Health Economics:

- Some H.E. data based on clinical studies (loss of workdays)
- Experimental studies showing reduced need of surgery
- Burden of disease studies creating awareness of magnitude and the drivers of cost (direct and indirect)



<sup>1</sup>J. Geweke and B.A. Weisbrod (1982)

# THE GOOD OLD DAYS

## Time Gone By...

### The Anti-Ulcer Market Situation in 1982

		Tagamet	Zantac
<b>Efficacy</b>	Healing	XXX	XXX
	Pain Relief	XXX	XXX
<b>Safety</b>	Side Effects	XX	?
	Interactions	X	XXX
<b>Administration</b>	Frequency	XX(X)	XXX
<b>HE Support</b>	Cost/Benefit	Yes	No
<b>Price</b>	(Daily Cost)	\$ 0.80	\$ 1.10

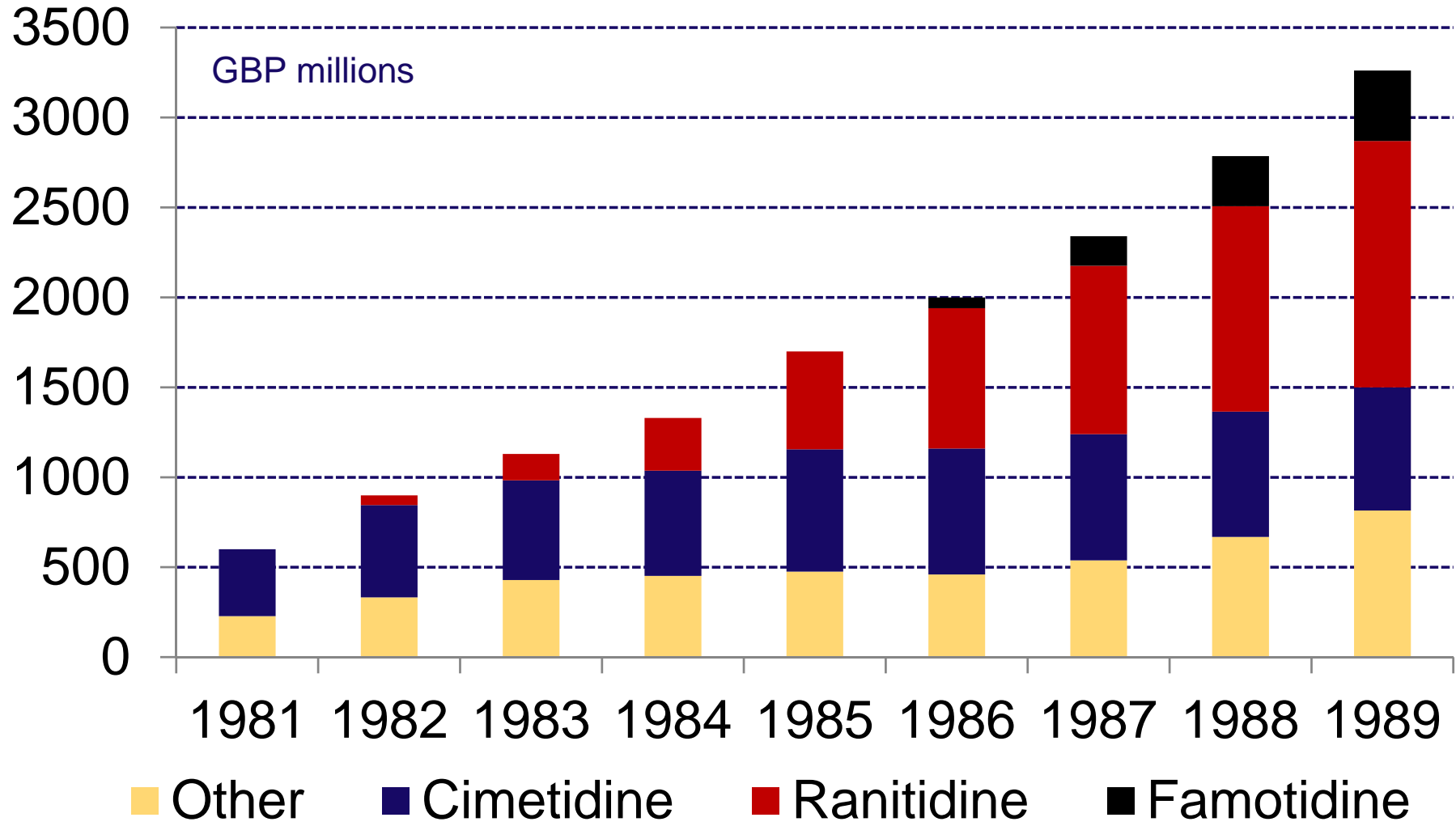
- Tagamet – No. 1 in the world, the first 1 billion \$ drug.
- SK&F dominates gastroenterology .
- Attitude to Tagamet: excellent but expensive.
- **Zantac promoted to be “fast, simple, and specific”.**



# THE GOOD OLD DAYS

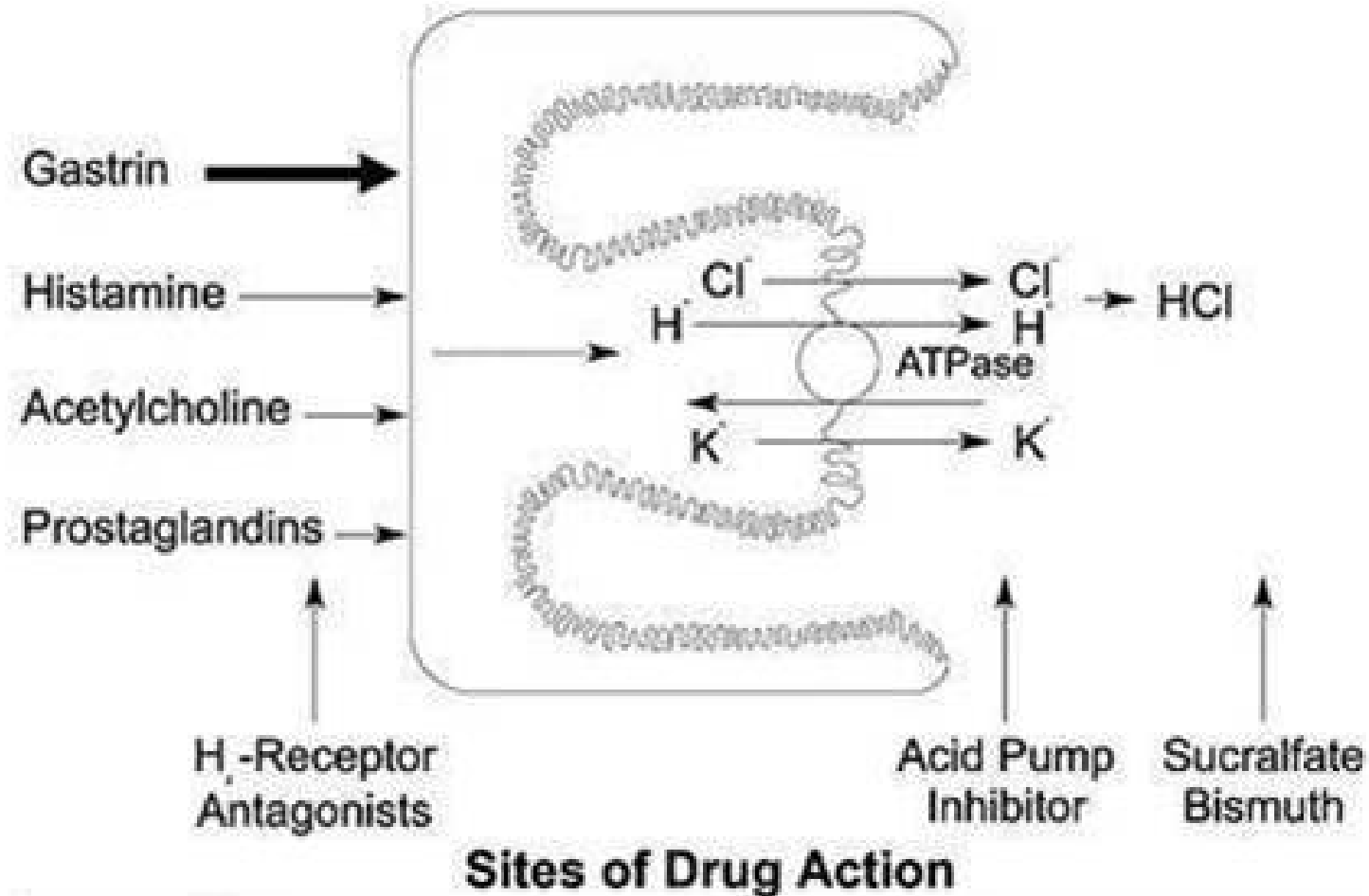
## Time Gone By...

### The Worldwide Anti-Ulcerant Market in the 1990s<sup>1</sup>



<sup>1</sup>Data source: Glaxo, INSEAD, Fontainebleau (1991)

### Omeprazole – Another Pharmacological Breakthrough

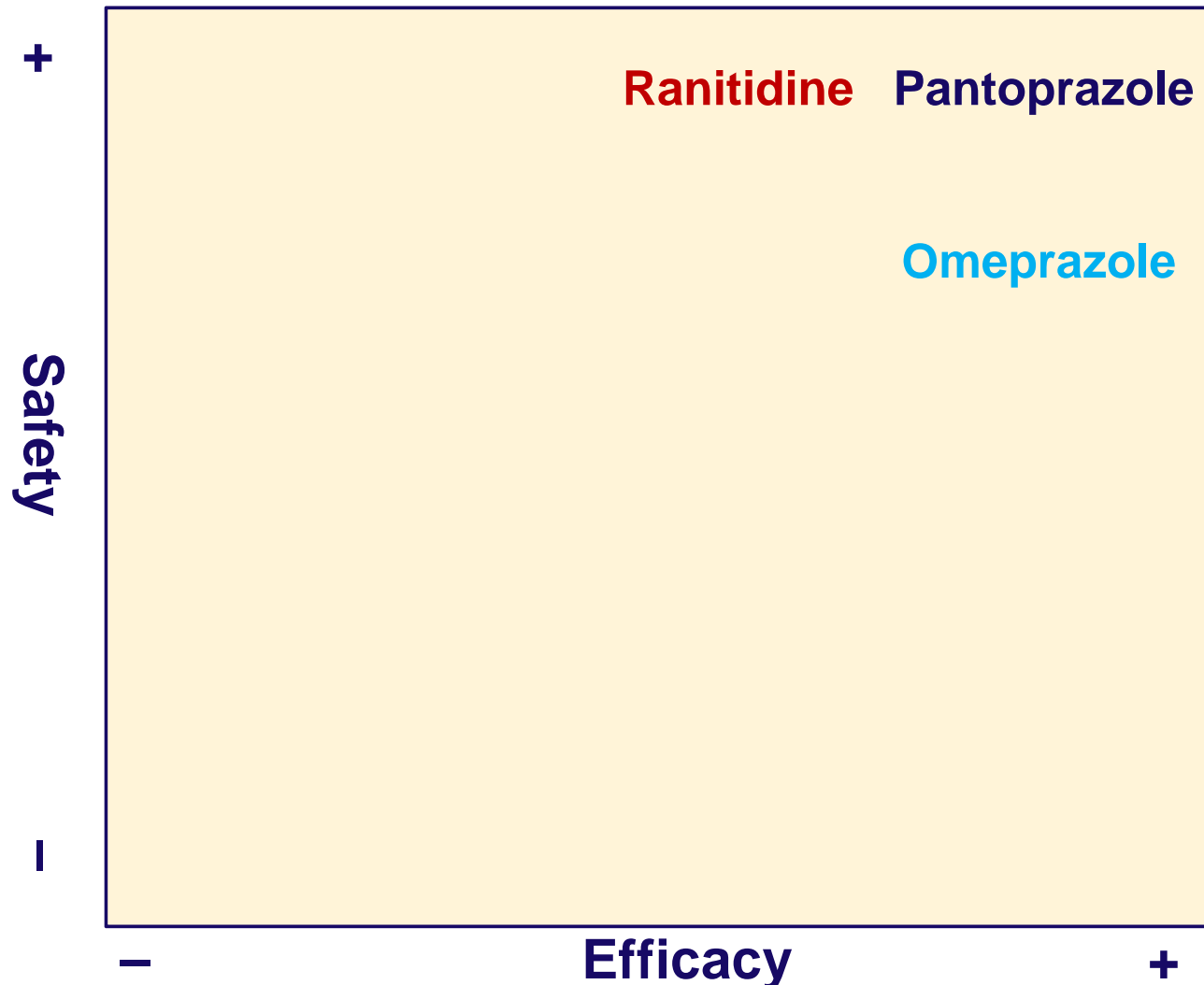


# THE GOOD OLD DAYS

## Time Gone By...

The Launch of Losec (1988)			
		Zantac	Losec
<b>Efficacy</b>	Healing	XX	XXX
	Pain Relief	XX(X)	XXX
<b>Safety</b>	Side Effects	XXX	?
	Interactions	XXX	XX
<b>HE Support</b>	Cost / Benefit	(X)	Yes
Changing Concept:	daily cost to cost of treatment course		
<b>Price</b>	(Daily Cost)	\$ 1.10	\$ 1.80

### The Third PPI: Pantoprazole Positioning (1994)

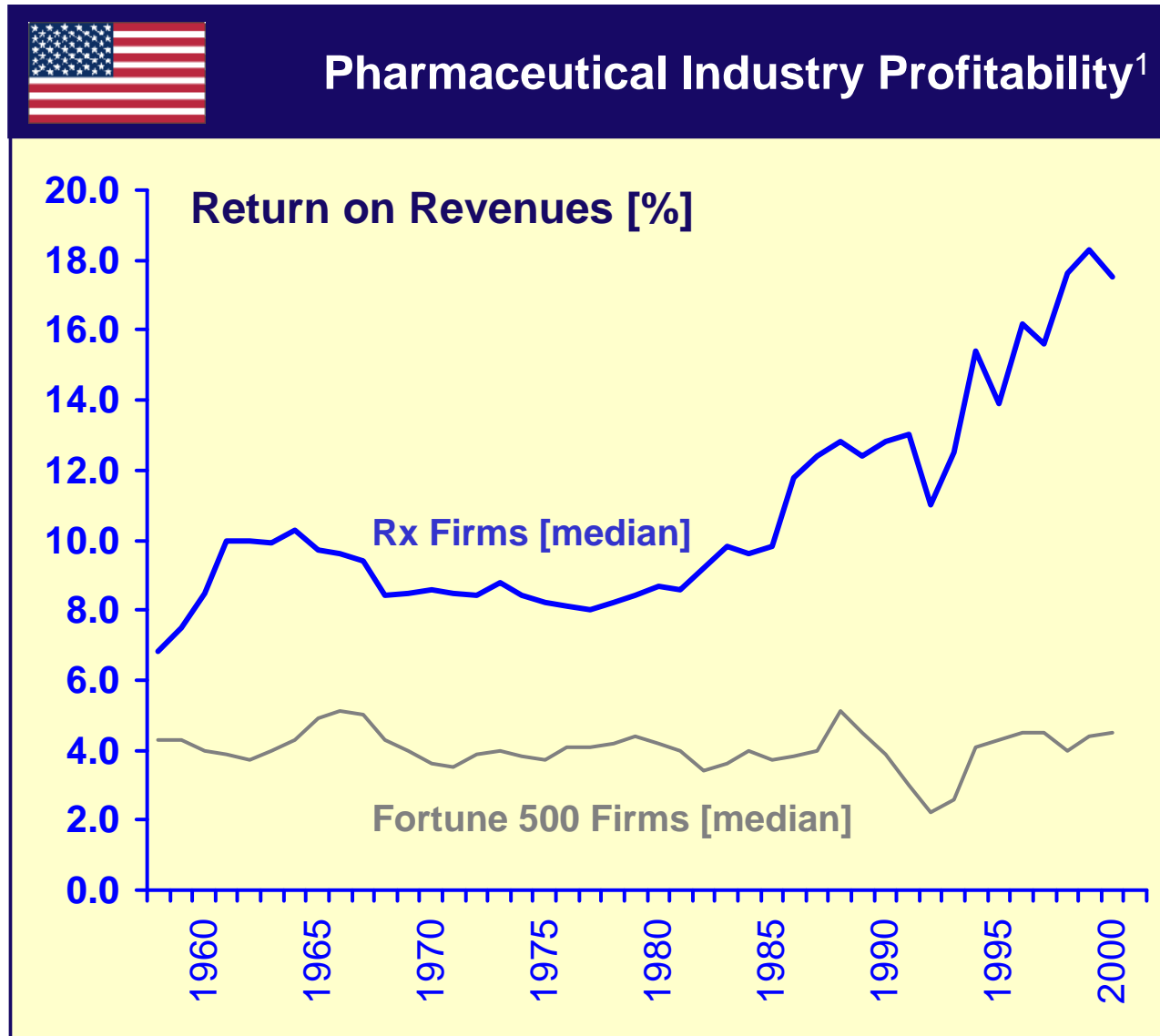


“Precision” Claim

... but launched at 15% discount compared to Losec (Omeprazole)

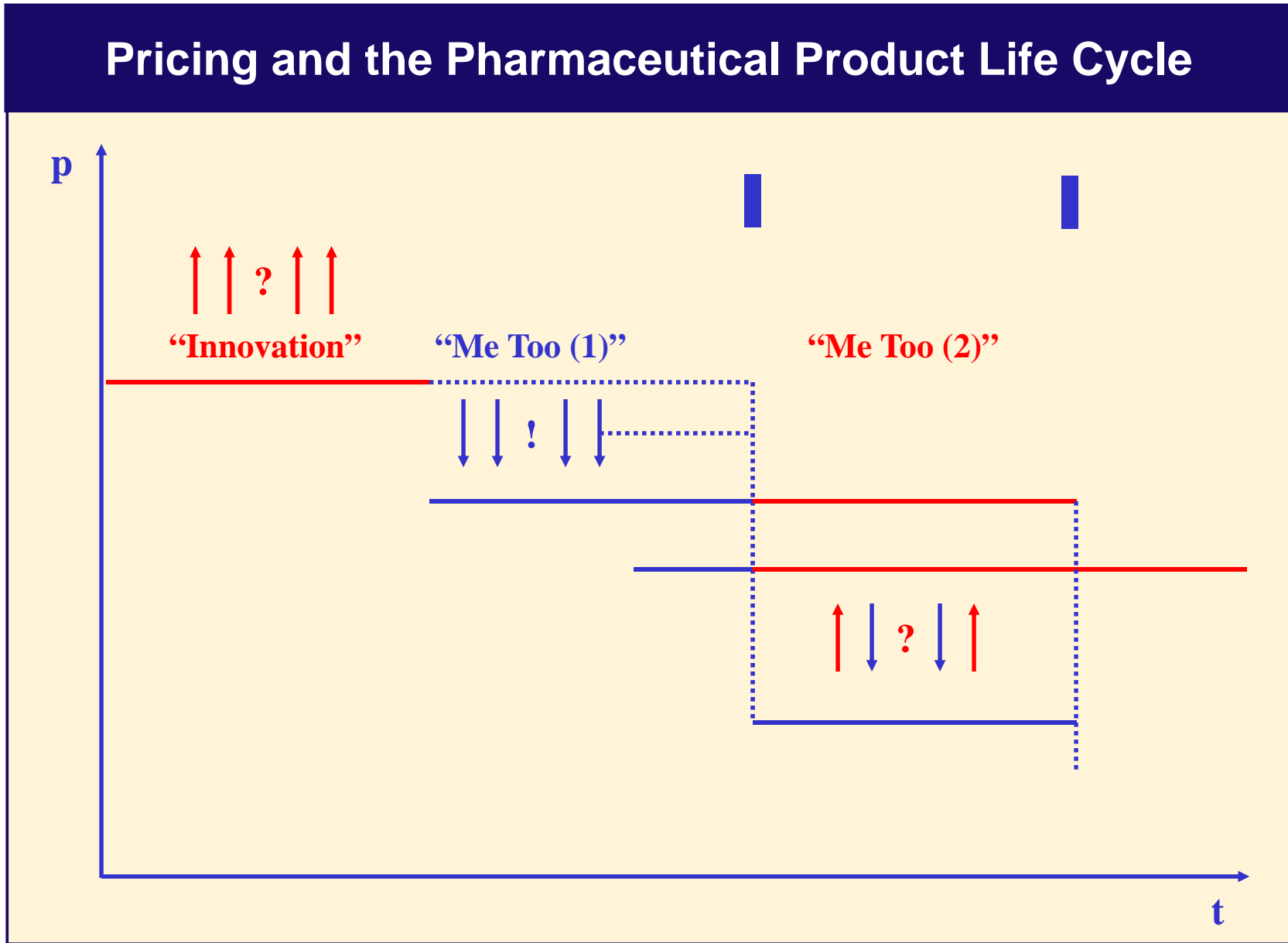
# THE GOOD OLD DAYS

## Time Gone By...



<sup>1</sup>Data source: Fortune Magazine 1958-2002; S. Schondelmeyer 1995, 1999

Product life cycle phases heavily influence the economic impact of “me-too” products

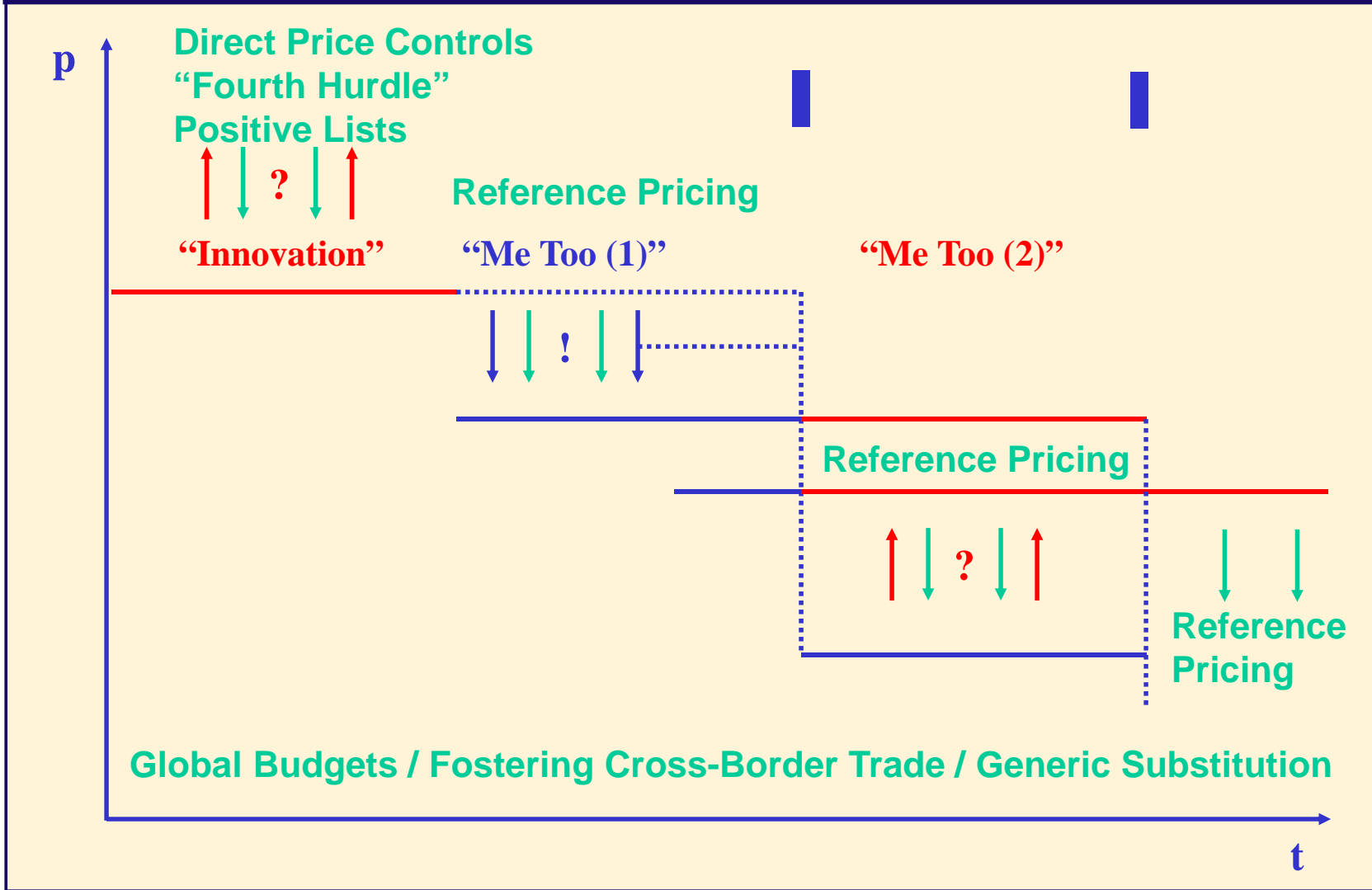


© INNOVAL<sup>HC</sup>, Prof. Dr. Michael Schlander, Wiesbaden / Germany, June 2013





### Regulation and the Pharmaceutical Product Life Cycle



© INNOVAL<sup>HC</sup>, Prof. Dr. Michael Schlander, Wiesbaden / Germany, June 2013



### Conventional Wisdom

#### Value-Driven New Product Development

- Time to Market (...)
- **Marketing Authorization: Regulatory Approval**
  - Profiling
  - Target Summary of Product Characteristics
- **Strategic Marketing: Commercialization**
  - Product Life Cycle Management
  - Positioning
- **Market Access**
  - Value Identification, Value Demonstration, Value Communication
  - Reimbursement and Pricing

# “VALUE FOR MONEY”

## Commonly Held Beliefs

### Conventional Wisdom

- The Marketing Mix:
  - Product
  - Promotion
  - Place
  - Price
- “Pricing is **the moment of truth**
  - all of marketing comes into focus in the pricing decision.”<sup>1</sup>
- Pricing is the mechanism of **capturing value** from customers. Then – what is the [added] **value** of a health technology? Perceived value, preference-based individual value, [comparative] clinical effectiveness, clinical efficacy, safety, tolerability, ... convenience ..., social value, objective value, monetary value ... ?

<sup>1</sup>Raymond Corey (Harvard Business School)

# “VALUE FOR MONEY”

## “Values Talk”: A Canadian Policy Analysis<sup>1</sup>

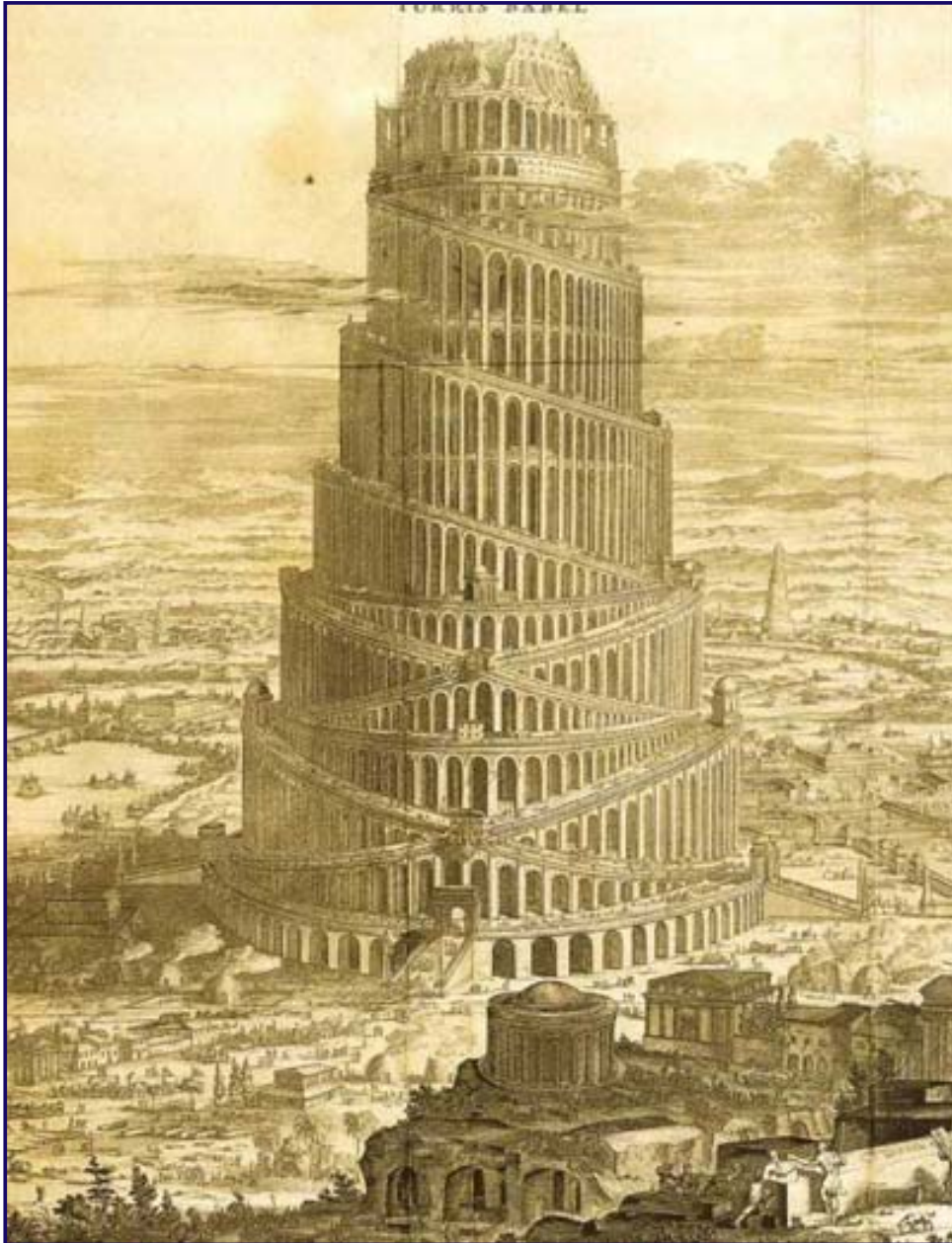


Illustration by Athanasius Kircher

### A Tower of Babel ...

- Referral to many different and often incommensurate things...
- **A key paradox:**  
The discourse about values is both very important and very ambiguous...
- Stakeholders may be tempted to react to this problem with either  
**reductionism**  
(focusing on one particular definition of values to the neglect of other relevant types)  
or  
**nihilism...**  
(either rejecting all values analyses as equally unreliable, or accepting all as equally credible)

# NICE PERSPECTIVES?

## A High Profile

### “What Could Be Nicer Than NICE?”<sup>1</sup>



#### → **Pearson and Rawlins (2005)<sup>2</sup>:**

“The conditions seem ripe for a NICE in the United States ...”

#### → **Smith (2004)<sup>3</sup>:**

*“The triumph of NICE”:*

“NICE is conquering the world ... and may prove to be one of Britain’s greatest cultural exports along with Shakespeare, Newtonian physics, The Beatles, Harry Potter, and the Teletubbies ...”

#### → **WHO (2003)<sup>4</sup>:**

“Published technology appraisals are already being used as international benchmarks ...”

<sup>1</sup>A. Williams (2004)

### NICE Technology Appraisal Process

- Three (to four) phases
  - Scoping
  - Assessment
  - Appraisal
  - Appeal (if lodged by one or more consultees)
- Frequently acclaimed features
  - NICE objective of appraising the evidence in a way that is **“objective, unbiased, and methodologically sound”**<sup>1</sup>
  - An appraisal process that can be described as being **“inclusive, consultative, transparent”**<sup>1</sup>

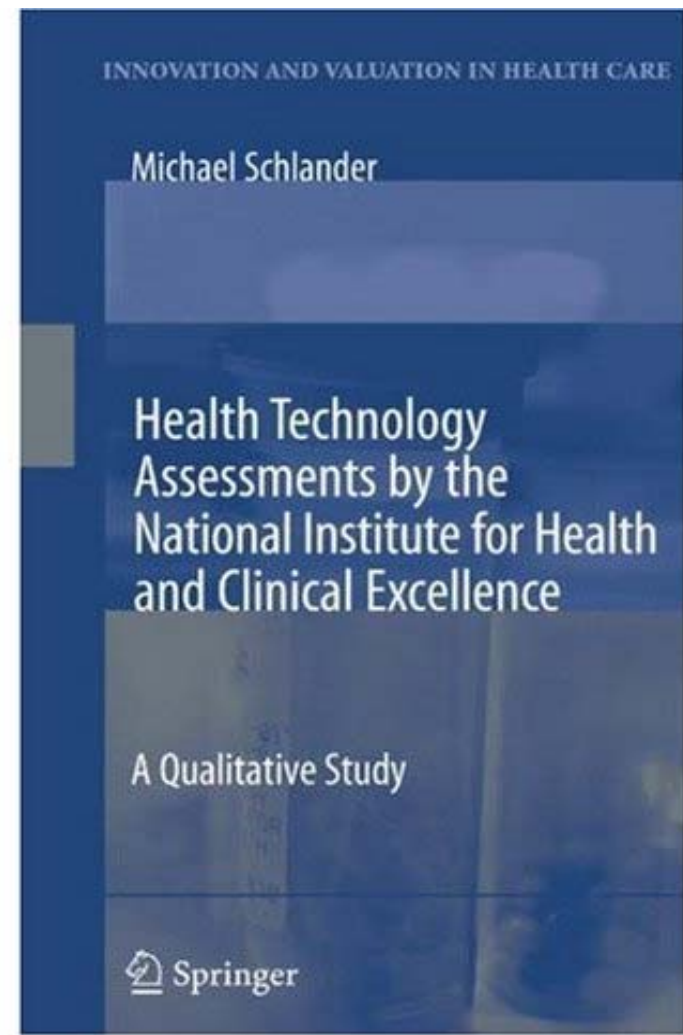
<sup>1</sup>C. Longson, ISPOR Annual Meeting, Arlington, VA, May 20, 2001



### How Robust Are NICE Technology Appraisals?

#### Some Issues

- ▭ Timing of Technology Appraisals?
- ▭ Approach to Uncertainty?
- ▭ Integration of Clinical and Economic Expertise?
- ▭ Availability of Sufficient Resources?
- ▭ Efficiency-First Approach?
- ▭ (Almost) Exclusive Reliance on QALYs?
- ▭ Enforcement:  
Internal Quality Assurance?  
Implementation of Guidance?



# HAS NICE GOT IT RIGHT?

“What More Could Anyone Ask For?”

NICE is “the closest anyone has yet come to fulfilling the economist’s dream of how priority-setting in health care should be conducted.”



... “[NICE] is transparent, evidence-based, seeks to balance efficiency with equity, and uses a cost-per-QALY benchmark as the focus for its decision-making. *What more could anyone ask for?*”

**Alan Williams (1927 – 2005)**

# HAS NICE GOT IT RIGHT?

“What More Could Anyone Ask For?”

NICE is “the closest anyone has yet come to fulfilling the economist’s dream of how priority-setting in health care should be conducted.”

However:  
“Experience has taught me that it is not uncommon for an economist’s-dream-come-true to be seen as a nightmare by everyone else.”



Alan Williams (1927 – 2005)

**“Economic Evaluation  
in Health Care:  
Is It Really Useful  
or  
Are We Just Kidding Ourselves?”<sup>1</sup>**

“Let’s face it: most health economists have an  
**interest**

in the continued growth of the subdiscipline.”

**Obstacles** may be “(i) the short-term nature of the decision making process; (ii) problems in interpreting studies; (iii) lack of timeliness in study results; and (iv) importance of **other factors** in decision making.”<sup>1</sup>

<sup>1</sup>**Michael Drummond (2004)**

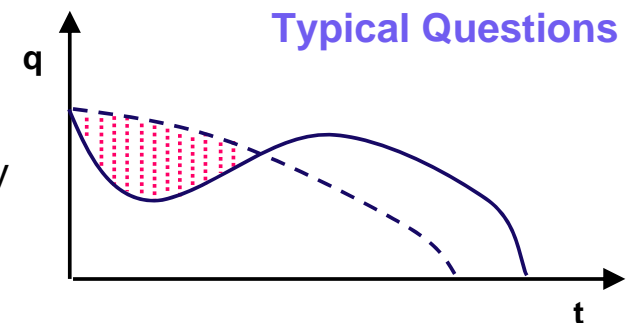
# THE LOGIC OF COST-EFFECTIVENESS

Quality-Adjusted Life Years (QALYs)  
as a measure of (health-related) outcomes<sup>1</sup>

## Three Distinct Ways How to Use QALYs

Same intervention  
for  
Same indication  
(same patient group)

“Does the Utility Gain  
Outweigh the Disutility  
of Treatment?”  
e.g., cancer chemotherapy



Different interventions  
for  
Same indication  
(same patient groups)

“How Can We Integrate a  
Variety of Clinical Outcomes  
in one Summary Measure?”

Alternative: disaggregated (cost consequence) analysis

Different interventions  
for  
Different indications  
(different patient groups)

“How Can We Determine the Most Efficient Allocation  
of Scarce Health Care Resources  
across a Wide Range of Competing Interventions?”  
“Efficiency” usually defined in terms of QALY maximization

**QALYs as a utility measure of health-related consequences**

<sup>1</sup>This is *not* a comprehensive list. For example, QALYs may also be used in descriptive (non-comparative) economic analyses.

### Does “Context” Matter?

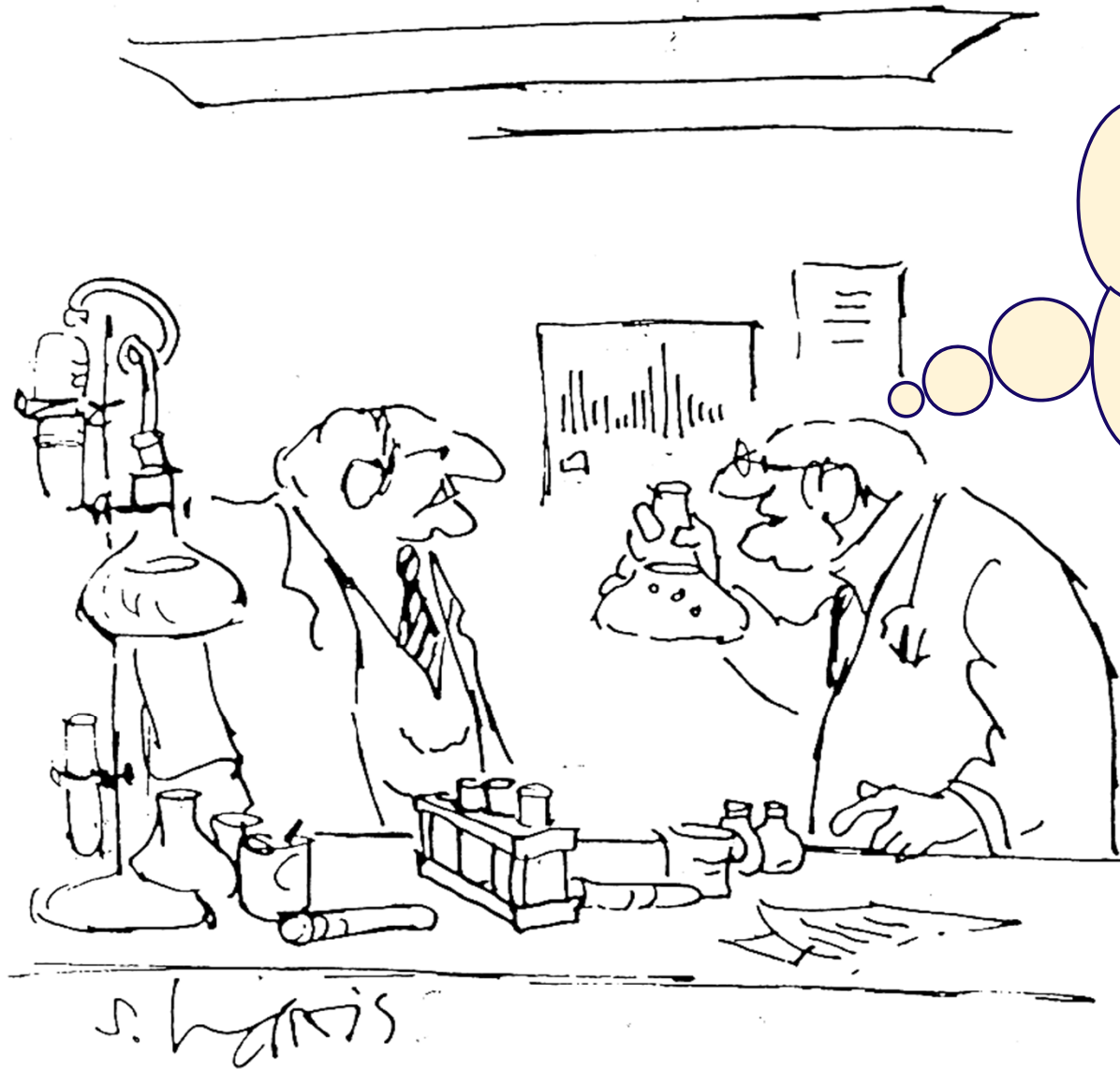
- **Empirical evidence** supports a role of the following<sup>1</sup>:
  - **Severity** of initial health state
    - Level of impairment  
in addition to improvement (difference)?
  - **Rule of rescue**
    - Identifiable individuals  
(but is being “visible” morally relevant?)
  - **Potential** for health improvement
    - e.g., the permanently disabled and chronically ill?  
(who have less QALYs to gain)
  - Patients with **high-cost illnesses**

<sup>1</sup>cf. recent reviews by P. Dolan et al. (2005), J. Richardson and J. McKie (2005), M. Schlander (2005); further considerations include (but are not limited to) age, responsibility for dependants, and number of patients or program size.



# MODELING, UNCERTAINTY AND JUDGMENT

## Economic evaluation of new medical technologies



**“It may well  
bring about  
immortality**

**–**

**but it will  
take forever  
to test it.”**

# HELPING THE REGULATORS GETTING IT RIGHT

Working with stakeholders  
Shaping the environment in a cooperative spirit

**The Need for a New Paradigm**

## Vision

**Pricing  
Reimbursement**  
(Shaping the regulatory environment)

Determination  
Relationship Building

## Societal Values & Economic Analysis

**What is "Value"?**  
*Normative Health Economics*  
(Shaping the scientific environment)

Objectives of Health Care  
Dynamic versus Static Efficiency

## Corporate & Business Level Strategy

*Reconciling Concepts of "Value" & Change Management*  
(Broad Interaction with Management: R&D, Commercial Functions)

## A New Leadership Role

Persuasiveness  
Credibility & Integrity

## Identification of Value Drivers (& Valuation)

*"State-of-the-Art": In-Depth Methodological Competence*  
(In-Line Products / LCM, R&D Projects, In- and Out-Licensing Opportunities)

## Operational Excellence

Impeccable Execution  
Team Management

### The Enhanced Strategic Role of HE&P

#### → **International Pharmaceutical Industry:**

1950s – 1970s      The Research-Driven Paradigm

1980s                The Market-Driven Paradigm

1990s                The Value-Driven Paradigm

Now:                 New Definitions of Value &  
New International Heterogeneity

} ever increasing complexity

#### → **The New Challenge:**

Redefining the business model

Reconciling different perspectives of value

→ Health Economics, Pricing & Market Access capabilities as critical success factors

***THANK YOU FOR YOUR ATTENTION!***

**Contact**

[www.innoval-hc.com](http://www.innoval-hc.com)

[www.michaelschlander.com](http://www.michaelschlander.com)

[michael.schlander@innoval-hc.com](mailto:michael.schlander@innoval-hc.com)

[michael.schlander@medma.uni-heidelberg.de](mailto:michael.schlander@medma.uni-heidelberg.de)

**INNOVAL<sup>HC</sup>**

---

**Institute for Innovation & Valuation  
in Health Care**