



Fünf Jahre Cluster Medizintechnologie

Keynote Address: „**Neue Innovationsmodelle
für die Gesundheitsversorgung der Zukunft**“

Professor
Michael Schlender
M.D., Ph.D., M.B.A.

Chairman & Scientific Director
Institute for Innovation & Valuation in Health Care

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Keynote – Fünf Jahre Cluster Medizintechnologie
MedTechDialog (Mannheim, 08. Dezember 2016)

**“Hand clapping for science
is now inextricably linked to
hand wringing
over affordability.”¹**

¹Peter B. Bach

(Memorial Sloan Kettering Cancer Center, New York, NY):

New Math on Drug Cost-Effectiveness.

New England Journal of Medicine 2015 (November 05); 373 (19): 1797-1799.

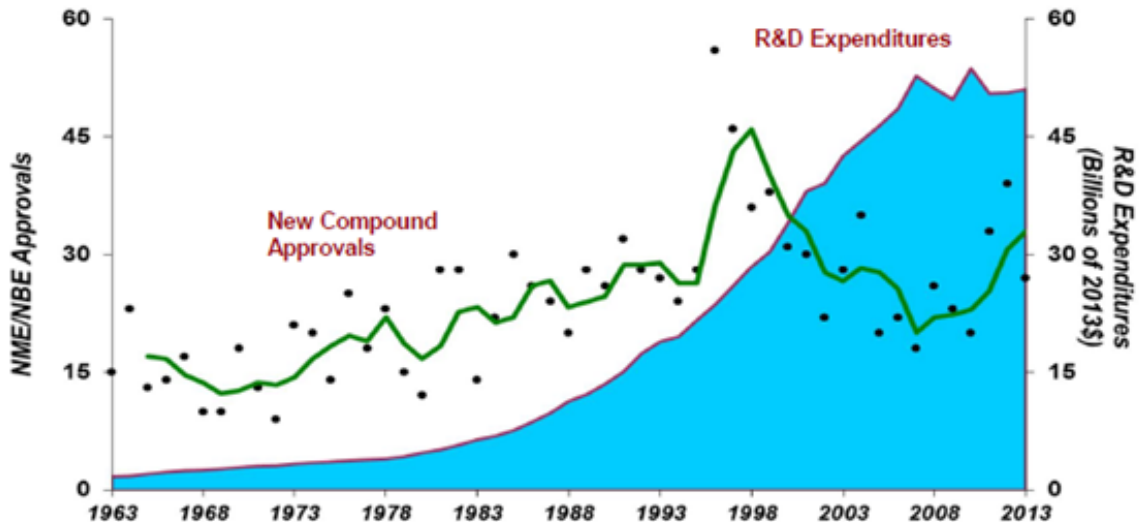


The Burning Platform



Keynote – Fünf Jahre Cluster Medizintechnologie MedTechDialog (Mannheim, 08. Dezember 2016)

New Drug and Biologics Approvals and R&D Spending



R&D expenditures are adjusted for inflation; curve is a 3-year moving average for NME/NBEs
Sources: Tufts CSDD; PhRMA, 2014 Industry Profile

Source: J.A. DiMasi. "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs", Tufts Center for the Study of Drug Development, November (2014). Available: at http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study, s.l.: s.n.



Pharmaceutical R&D: Determinants of Fully Allocated R&D Cost / NME

- ↪ **Out-of-pocket costs**
 - ↪ **Clinical development**
 - ↪ **Preclinical research & development**
 - ↪ **Discovery research**

- ↪ **Clinical success and attrition rates**

- ↪ **Capitalization**
 - ↪ **Development Times (“Time-to-Market”, TTM)**
 - ↪ **Cost of Capital**

NME: New Molecular Entity



Biopharmaceutical R&D: Fully Allocated Cost / NME

Study Reference	Sample of New Molecular Entities	Cost of Capital (real)	Discovery Research (included?)	Geography	Estimated cost of R&D [US\$m, 2011 prices]
Hansen, 1979	First tested in humans between 1963 and 1975	8%	No	USA	199
Wiggins, 1987	1970-1985	8%	No	USA	226
DiMasi et al, 1991	First tested in humans between 1970 and 1982	9%	Yes (estimated)	USA	451
OTA, 1993	-	-	-	-	625
Myers and Howe, 1997	-	-	-	-	664
DiMasi et al, 2003	First tested in humans between 1983 and 1994	11%	Yes (estimated)	USA	1,031
Gilbert, Henske and Singh, 2003	Estimated first tested in humans between 1995 and 2002	-	Yes	Global	(1995–2000) 1,414
					(2000–2002) 2,185
Adams and Branter, 2006	Drugs entering human clinical trials for the first time 1989-2002	11%	Use DiMasi et al 2003	Global	1,116
Adams and Branter, 2010	Drugs entering human clinical trials for the first time 1989-2002	11%	No	Global	1,560
Paul et al, 2010	Estimated 1997-2007	11%	Yes	Global	1,867
Mestre-Ferrandiz et al, 2012					1,506
DiMasi et al., 2015					2,600



Biopharmaceutical R&D: Fully Allocated Cost / NME (2016)

- **most plausible estimate: ~ 1.5 billion US-\$**
- **plausible range from 1.1 to 1.9 billion US-\$**

while the time, risk, and cost profiles of individual projects may substantially deviate from the average ...

... fully allocated economic costs / NME

will invariably include opportunity costs (driven by time to market), cost of failures, and non-allocated costs (e.g., discovery research)

- **Effective R&D management** is a critical success factor, making the most important difference between companies, adding or destroying value.



Burden of Disease and Cost of Cancer¹



- **Burden of Disease** (p.a., EU 2008)
 - 2.45 million people diagnosed with cancer
 - 1.23 million people died because of cancer

- **Cost of Cancer** (p.a., EU 2009)
 - estimated at 126 billion € in total
 - health care accounting for 40%
(i.e., ~51.0 billion €, or 102€ per citizen)
 - productivity loss due to premature deaths ~42.6 billion €
 - productivity loss due to lost working days ~9.43 billion €
 - leading causes of economic cost: lung cancer (18.8 bn €), breast cancer (15.0 bn €), colorectal cancer (13.1 bn €), and prostate cancer (8.4 bn €)

¹R. Luengo-Fernandez, J. Leal, A. Gray, and R. Sullivan: Economic burden of cancer across the European Union: a population-based cost analysis. *Lancet Oncology* 14; 2013: 1165-1174.



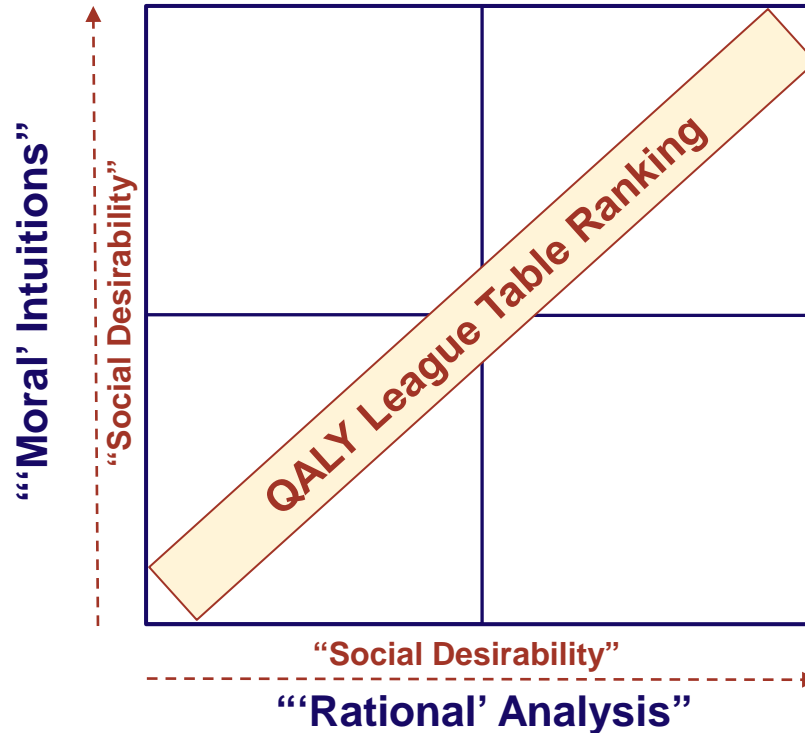
Textbook Example: “QALY League Table”¹

Ranking [original]	Intervention [abbreviated; comparator not stated in original table]	Cost / QALY [£ (1990)]
3	G.p. advice to stop smoking	£ 270
5	Antihypertensive therapy to prevent stroke	£ 940
6	Pacemaker implantation	£ 1,100
7	Valve replacement for aortic stenosis	£ 1,140
8	Hip replacement	£ 1,180
9	Cholesterol testing and treatment	£ 1,480
11	Kidney transplant	£ 4,710
12	Breast cancer screening	£ 5,780
15	Home hemodialysis	£ 17,260
18	Hospital hemodialysis	£ 21,970
20	Neurosurgery for malignant intracranial tumors	£ 107,780
21	Epoetin alfa therapy for anemia in dialysis patients	£ 126,290

¹A. Maynard. *Economic Journal* 1991; 101 (408): 1277-1286

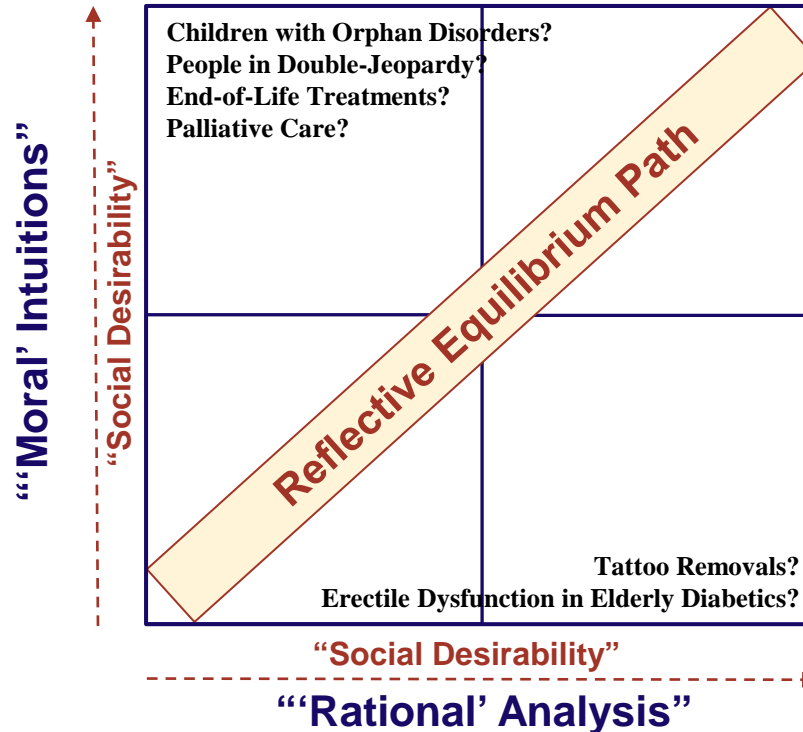


Reflective Equilibrium





Reflective Equilibrium





Revisiting the Fundamental Premise

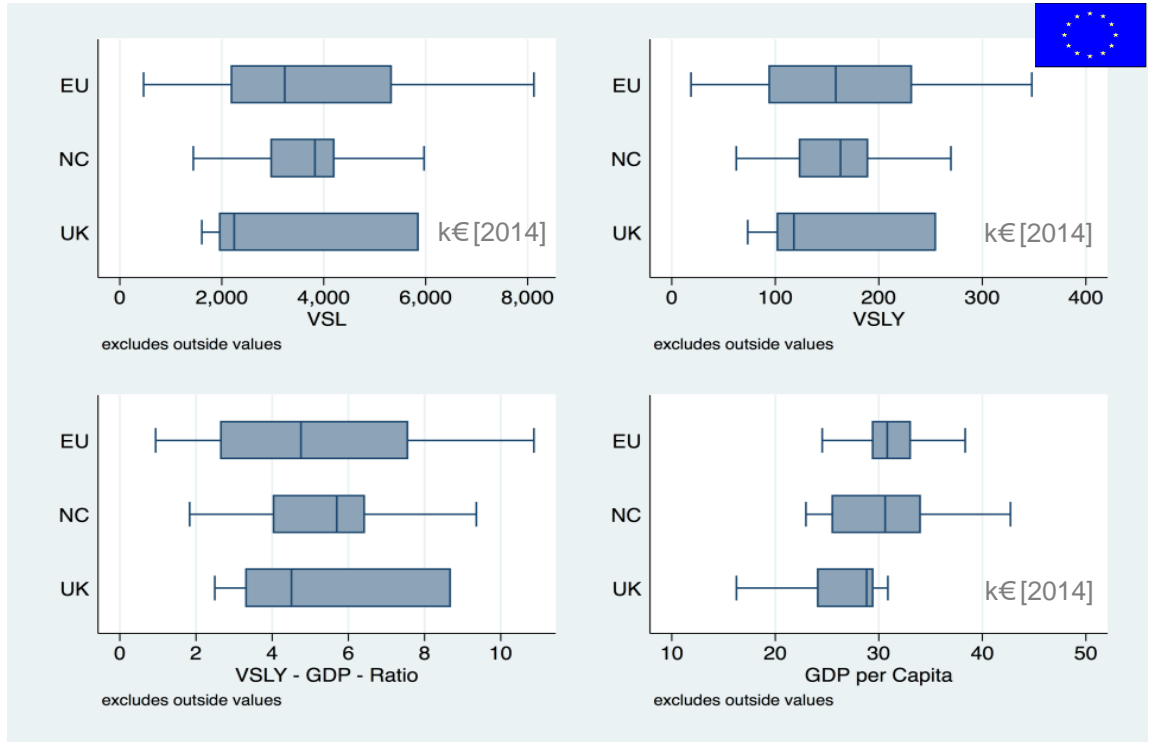
“Social Desirability of an Intervention is Inversely Related to its Incremental Cost per QALY Gained”

**but this assumption may create
Reflective Equilibrium issues:**

- **Sildenafil** for elderly diabetics with erectile dysfunction
- **Removal of Tattoos**
compared to
- **Palliative Care,**
- **Interventions for people with comorbid conditions**
(in “**Double Jeopardy**”, like the chronically disabled)
- **Orphan Medicinal Products (OMPs) for (very) rare disorders**



The Economic Value of a Statistical Life Year¹



¹M. Schlander, R. Schaefer, O. Schwarz (2016)



Definition of Health Technology Assessment (by EUnetHTA)

→ **Health Technology Assessment (HTA)**

is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

- Despite its **policy goals**, HTA must always be firmly rooted in research and the scientific method.



What are Technology Assessments for?

A broad range of expectations (and fears) ...

“restricting use”

“containing costs”

**“issuing guidance to
potential users”**

**“prioritizing for
further evaluation”**

**“alerting users to
future possibilities”**



Health Technology Assessment (HTA)



Martin Luther (1530)

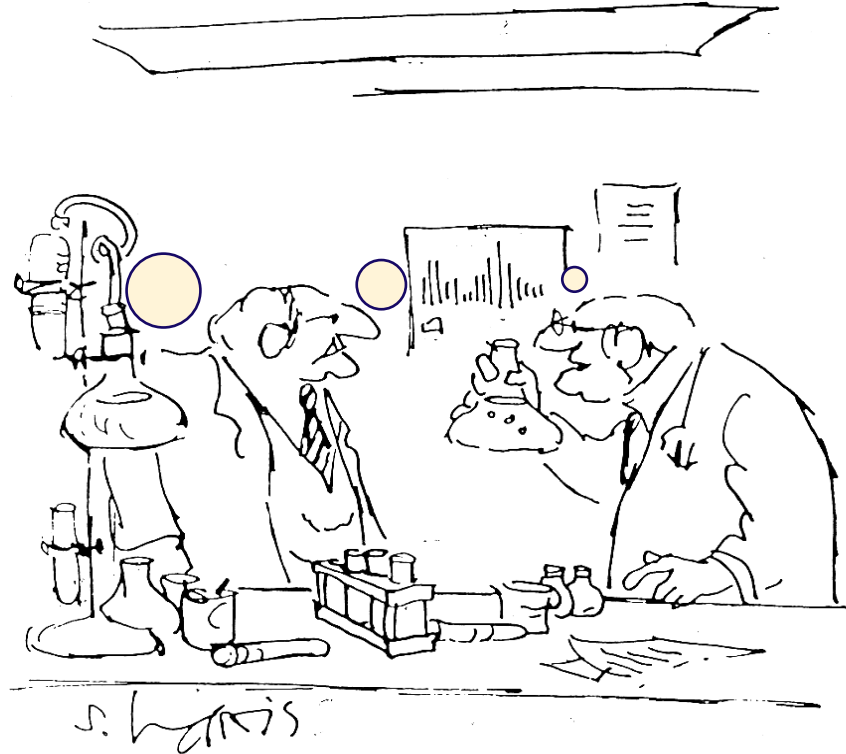
“Wer am Wege baut,
hat viele Meister“

“A house built by
the wayside
is either too high
or too low.”



Health Technology Assessment (HTA)

**“It may well
bring about
immortality
–
but it will
take forever
to test
it.”**





Thank You for Your Attention!

Professor **Michael Schlander**, M.D., Ph.D., M.B.A.

Contact

www.innoval-hc.com

www.michaelschlander.com

michael.schlander@innoval-hc.com

michael.schlander@medma.uni-heidelberg.de

Address

An der Ringkirche 4
D-65197 Wiesbaden / Germany

INNOVAL^{HC}
Institute for Innovation & Valuation
in Health Care