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"There is no point designing world-class products if you cannot commercialize them"

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Market Access

"Not the prolonged arm of Marketing"

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Peter Stegmaier, Editor-in Chief "Market Access & Health Policy"

You open the door

Limits of Marketing & Sales Force			
Exubera [®] : First inhalative Insulin High price			
Investment	2 800 Mio \$		
Revenue I-III/2007	12 Mio \$		
Pfizer withdraws the product from the market in 2008. Official reason: Insufficient acceptance			
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HEOR				
Input	⇔	Outcome		
Costs of drug or service				
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Target Group

National policy makers, reimbursement authorities, agencies and budget holders involved in decisions regarding

- market access
- reimbursement
- listing, coverage

You have to know how they think and speak

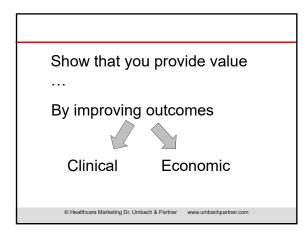
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Basis for Data

Scientific evidence, usually from clinical trials

Not all good clinical investigators have the same power to influence reimbursement decisions

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HEOR: Main Types			
Cost-Minimization Analysis	СМА		
Cost-Benefit Analysis	CBA		
Cost-Effectiveness Analysis	CEA		
Cost-Utility Analysis	CUA		
Case studies			
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Cost Minimization Analysis			
	Captopril		
Original	1.00 Euro		
Generic version	0.50 Euro		
Theoretical savings			
	0.50 5		
	0.50 Euro		
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Cost Benefit Analysis		
ACE Inhibitors in heart failure Hospital admissions per year Costs per admission Reduction of admissions	0.1 Mio 5000 £ 10%	
Theoretical savings		
0.1 Mio x 5000 £ x 10% = 50 © Healthcare Marketing Dr. Umbach & Partner www.umbachp.		

Cost Benefit Analysis

Costs and benefits are both valued in cash terms.

Criteria to Measure the Benefit

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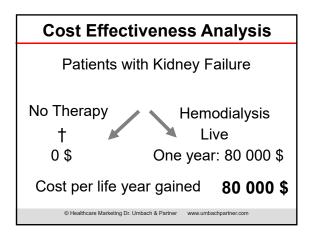
Demonstrate potential savings:

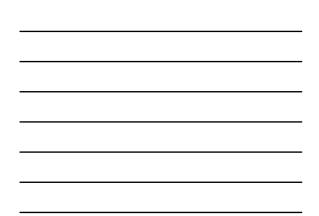
The new product can reduce or shorten

- hospital admissions
- duration of hospital stay
- duration of ICU (Intensive Care Unit) stay
- number of diagnostic procedures
- concomitant medication
- time nurses spent on preparing the product

...

- number of follow-up visits





"Good Value"

More than half of the US oncologists:

Patients should have access to effective cancer treatments only if those treatments are a "good value," or less than \$100,000 per life-year gained.

Fiercepharma 21 January 2010 Cancer docs judge cost-effectiveness of drugs





Cancer Center Says "No"

The Memorial Sloan-Kettering Cancer Center announced that it will not offer patients the cancer drug Zaltrap. Top executives do not believe the drug is worth the price tag: Zaltrap has proved to be no better than a similar medicine we already have for advanced colorectal cancer while its price - at \$11,063 for a month of treatment is more than twice as high.

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Cost Effectiveness Analysis

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Measures outcomes in 'natural units',

Examples:

- mmHg
- symptom free days
- life years gained

Cost Utility Analysis					
Subjective quality of life is estimated to calculate <i>well-years</i> instead of <i>years</i>					
Pro- duct	Life years gained		Quality of life factor	Quality of life adjusted life years (QALYs)	
A B	0.9 1.0	x x	100% 80%	= 0.9 = 0.8	
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Cost Utility Analysis

Measures outcomes in a composite metric of both length and quality of life

Note: There is some international variation in the precise definitions of each type of analysis.

Josef Hecken, head of the German G-BA plans to consider "Quality of Life" as one of their criteria.

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Market Access Strategy

Packaging data in the right way, for the right stakeholders and payers* at the right time

* national and local decision-makers, policy makers and budget-holders

Basis: RCT = Randomized Clinical Trials

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Bayer's Nexavar Cancer Drug Fails to Win Recommendation of U.K. Agency

NICE: The price is simply too high to justify using NHS money. The cost of Nexavar couldn't be justified by its marginal benefit.

Cost-benefit info: Nexavar extended the lives of liver cancer patients by an average of 2.8 months at a cost of $\pounds 27,000$ (\$38,850).

To sweeten the deal, Bayer had offered a buythree-get-one-free deal, but that wasn't enough to sway the agency.

NICE = National Institute for Health and Clinical Excellence in the UK
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Special Cases: Orphan Drugs

Examples in the EU:

Alglucosidase (Myozyme®) from Genzyme Morbus Pompe Bosentan (Tracleer®) from Actelion

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Pulmonary Hypertension

Market Access Country-specific Approach National Differences You have to know how they think

Germany

IQWiG = Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

 \rightarrow G-BA

Gemeinsamer Bundes-Ausschuss

Sektorübergreifendes, oberstes Beschlussgremium der gemeinsamen Selbstverwaltung: Kassenärztliche Bundes-vereinigung, Kassenzahnärztliche Bundesvereinigung, Deutsche Krankenhaus-Gesellschaft, Spitzenverband Bund der gesetzlichen Krankenkassen, Patientenorganisationen, unparteiischer Vorsitzender

France: La Haute Autorité de Santé

Drugs: Commission de la Transparence *measures* Amélioration du Service Médical Rendue

Price Negotiations with Comité Economique des Produits de Santé

<u>Medical Devices:</u> CNEDiMTS La Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé

http://www.has-sante.fr/portalil/jorns/c_5267/actes-medicaments-dispositifs-medicaux?cid=c_5267 © Healthcare Marketing Dr. Umbach & Partner www.umbachpartner.com

Italy

Agenzia Italiana del Farmaco (AIFA)

- Technical-Scientific Committee (CTS)

- Pricing- and Reimbursement Committee (CPR)

Pharmind 74, Nr, 5, 2012

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UK

NICE National Institute for Health and Clinical Excellence

PRPS

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Pharmaceutical Price Regulation Scheme



Market Access Strategy

(Repetition)

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* national and local decision-makers, policy makers and budget-holders

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Where you could save money

More prevention: Change in life style Less administrative procedures Less diagnostic procedure (cardiology ...) Less surgical procedures (hips, knees) Less hospitalizations Less prescriptions