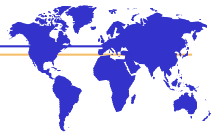
Socio-economic aspects of new drugs



"What does society want?"

Prof. Dr. Michael Schlander

AGAH – Annual Meeting
Bonn, February 24, 2003

Arbeitsgemeinschaft für angewandte Humanpharmakologie (AGAH)

universität Witten/Herdecke

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AGENDA

Topics to be covered[1]

- **New drugs as a cost driver**
  health care market dynamics
- **Societal preferences**
  recent population surveys
- **Economic impact of new drugs**
  relating costs to effectiveness
- **The "fourth hurdle"**
  international experience and issues
- **Implications**

[1]Important related but separate areas are beyond the scope of this presentation, including the regulatory environment of German statutory sick funds and its implications for their financial status; the economic, ethical, medical and legal dimensions of "rationing" health care; the distinction of necessary vs. beneficial health care

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Executive Summary

- New products are the driving force behind increasing prescription drug expenditures worldwide.
- Past cost containment efforts have, to a large extent, neglected the benefits of pharmaceutical products.
- The peculiarities of health care delivery create multiple market failures. Hence, public health systems require substitutes to determine cost-effectiveness or "value for money", to allocate resources efficiently, and to balance incentives for innovation with fair access to health care.
- Societal preferences (such as fairness, appropriateness, and access to innovation) need to be taken into account.
- The introduction of a "fourth hurdle" as an effective market entry barrier does not meet these objectives.

NEW DRUGS AS A COST DRIVER

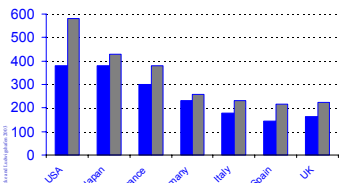
- Health Care Market Dynamics

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

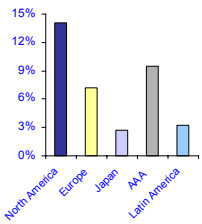
The pharmaceutical world market

Pharmaceutical Growth Rates by Region

Pharmaceutical Sales per Capita (US-$, 1998)
for 2002, projected data [gray columns][1]



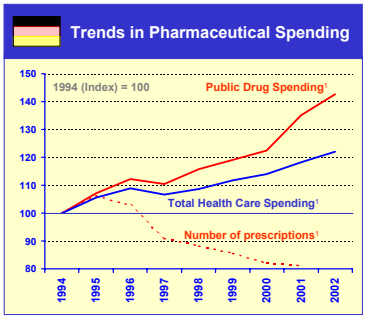
Global pharmaceutical market
CAGR 1997-2001; constant US-$ Growth[2]



[1]Data source: Pharma Prognosis 1998-2002;
[2]data source: IMS MIDAS MAT December 2001. IMS Health 2002

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

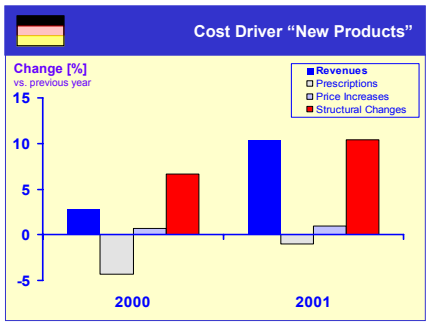
Since 1995, the prescription drugs bill has risen faster than total health care spending. Pharmaceuticals are perceived to contribute to the financial crisis of health care systems.



¹Sources: BMG, Arbeits- und Sozialstatistik; Schwabe und Paffrath 1995 – 2002; all data ("public") refer to statutory sick funds (GKV)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

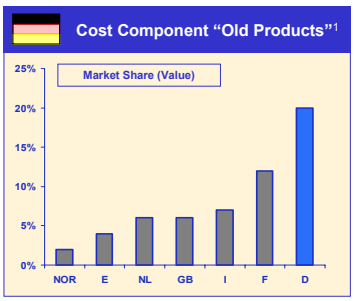
In line with the dynamics of other European pharmaceutical markets, new products have been the dominant growth driver in Germany.



¹Public sector (statutory sick funds, GKV) retail prescription drug spending; data source: Schwabe and Paffrath 2001, 2002

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

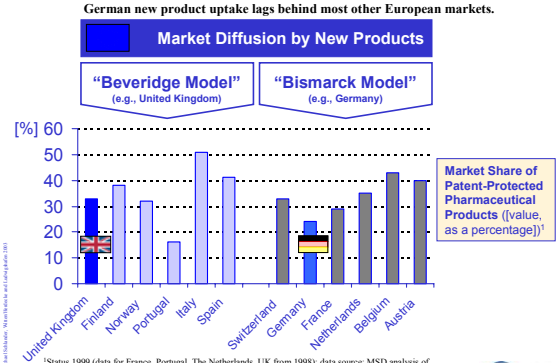
Different from other European health care systems, old products[1] command a significant market share in Germany.



¹Data source: MSD analysis of IMS Health data (1998-2001); S.J. Oschmann (2001)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

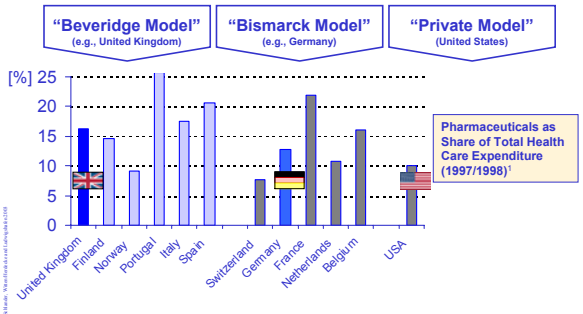
Prescription drug spending analyses indicate that German new product uptake lags behind most other European markets.



[1]Status 1999 (data for France, Portugal, The Netherlands, UK from 1998); data source: MSD analysis of IMS Health data, 1999, 2000: S.J. Oschmann (2001)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

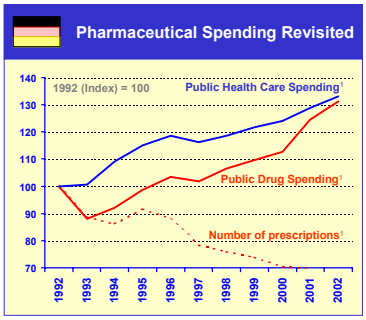
Pharmaceutical spending in perspective: drugs as a part of the health care system



[1]Source: OECD (2001)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

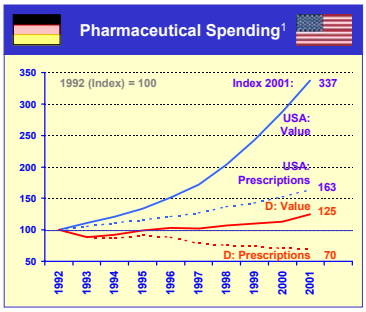
Pharmaceutical spending in perspective: drugs as a part of the health care system



[1]Sources: BMG, Arbeits- und Sozialstatistik; Schwabe und Paffrath 1993 – 2002; preliminary data for 2002; all data on "public" spending refer to statutory sick funds (GKV)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

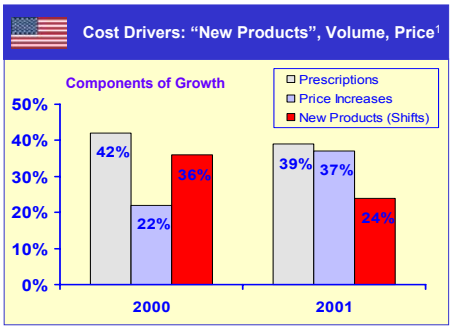
Escalating prescription drug expenditure in the United States is an indicator of pharmaceutical market dynamics in the absence of regulation.



[1]Data sources: Germany (drug expenditure by GKV), WIdO; Schwabe und Paffrath 1993 – 2002; USA (retail spending on prescription drugs), American Institutes for Research (AIR) analysis of Scott-Levin data

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

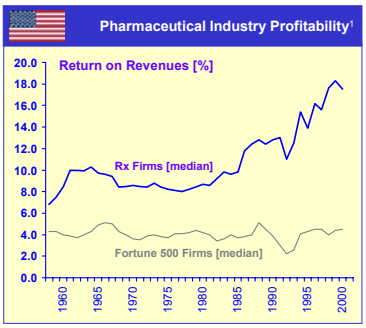
Components of growth in U.S. prescription drug spending as an indicator of pharmaceutical market dynamics in the absence of regulation



[1]Data source: American Institutes for Research (AIR) analyses of Scott-Levin data, reported by National Institute for Health Care Management (NIHCM) 2001, 2002

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

In the United States, the gap in profitability between prescription drug firms and Fortune 500 firms has widened substantially during the 1990s.



[1]Data source: Fortune Magazine 1958-2002; S. Schondelmeyer 1995, 1999

SOCIETAL PREFERENCES

- Recent Population Surveys

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Recent population surveys in Germany

Issues with Public Surveys

- **Validity**
  - Lack of in-depth understanding (asymmetric **information**, intrinsic complexity of problems) may limit the **validity** and **robustness** of population survey results.
- **Objectivity**
  - Health care in Germany is a >250 billion € business. Some published surveys may have been designed to support certain positions of interested parties instead of gathering reliable information; hence, biased questionnaires may have been applied, and some interpretations may be interest-driven.
- **Publication bias**
  - For similar reasons, the likelihood of substantial publication bias has to be taken into account.

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Principal data sources

Recent Population Surveys

- **Janssen-Cilag Population Study 1998**[1]
  - Representative population sample: 2,200 persons age >18; computer-assisted face-to-face interviews
- **Janssen-Cilag Population Study 2002**[2]
  - 1,000 members of statutory sick funds (GKV), 500 each, age 25 – 34 and age 60 – 69
  - Interviews (face-to-face); field phase first half of 2001; interactive simulation of choice of insurance coverage
- **GKV-Monitor 1998 – 2002**[3]
  - 3,000 members of statutory sick funds (GKV), age 16 – 65
  - Interviews by phone; field phase typically during 2nd quarter

[1] Jürgen Wasem: "Das Gesundheitswesen in Deutschland: Einstellungen und Erwartungen der Bevölkerung." Janssen-Cilag, Neuss (1998)
[2] Janssen-Cilag: "Der Patient vor der Wahl – Durch mehr Wissen zu mehr Verantwortung - Ergebnisse der Bevölkerungsbefragung 2002" (2002)
[3] Klaus Zok: "Was erwarten die Versicherten von der Gesundheitsreform?" WIdO (2002); WIdO: "Anforderungen an die GKV: Einschätzungen und Erwartungen aus Sicht der Versicherten" (2000)

Health Care System: Public Perceptions

- **Satisfaction with health system** — **74%[1]** (1998)
  - High quality of health care provision — 52%[4] / 86%[1] (2002/1998)
  - Overall situation has deteriorated — 68%[2] (2001)
  - Overall situation will deteriorate — 59%[4] (2002)
  - Perception of unequal access ("*fairness*") — 58%[1] / 61%[4] (1998/2002)
  - Awareness of inefficiency / waste of resources — 61%[4] / 76%[1] (2002/1998)
- **Health insurance**
  - Awareness of moral hazard / "free rider behavior" — 76%[1] (1998)
  - Health insurance premiums will rise — 76%[2] – 91%[4] (2001/2002)
  - Health care coverage by (statutory) sick funds has not been reduced — 65%[3] / 39%[4] (1998/2002)
  - Health insurance coverage will be reduced — 71%[4] (2002)

[1]Janssen-Cilag Population Study 1998; [2]Janssen-Cilag Population Study 2002; [3]WIdO: GKV-Monitor 1998/99; [4]WIdO: GKV Monitor 2002

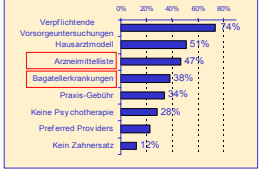
Financing Health Care: Public Preferences

- **Solidarity as guiding principle** — **80%[2] – 84%[5]** (>47%[3])
  - Families should be the insured unit — 77%[1] / 79%[3]
  - Premiums should be independent of health state — 75%[3] / 80%[1]
- **Attempts to reduce public deficits**
  - …should not focus on the health care system — 89%[1]
- **Higher insurance premiums**
  - …are preferred if alternative is reduced coverage — (41%[2]) – 71%[4] (2001/02)
- **Insurance coverage**
  - Individual options re. extent of coverage — 59%[3] – 72%[4] (up to 94%[2])
  - In a simulation model[2], of those (93.5% of participants) who selected one or more options, 54% achieved a net reduction of their premiums, 13% no net change, and 33% realized an increase (by +16% on average).

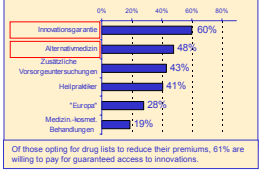
[1]Janssen-Cilag Population Study 1998; [2]Janssen-Cilag Population Study 2002; [3]WIdO: GKV-Monitor 1998/99; [4]WIdO: GKV Monitor 2002; [5]WIdO 2000 (n=1,128)

Individual Insurance Coverage: Options Accepted in Simulation[1]

Reducing Premiums



Increasing Premiums[2]



Of those opting for drug lists to reduce their premiums, 61% are willing to pay for guaranteed access to innovations.

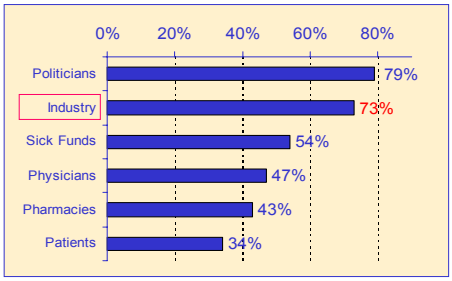
[1]Source: quoted from Janssen-Cilag Population Study 2002 [© Janssen-Cilag, Neuss 2002], interactive simulation model;
[2]"increasing premiums" implies willingness-to-pay

Pharmaceuticals: Public Perceptions

- **Drug prices are too high** — **89%[1]**
  - Patient co-payments should not be increased — 87%[2] – 88%[4]
  - Sick funds should control drug prices — 88%[3]
  - Sick funds should provide information about benefits of new treatments and of new drugs — 76%[3] / 73%[3]
  - Industry profitability should be reduced — 55%[1]
  - Opting for drug lists (if premiums reduced) — 47%[2] – 56%[3*] (65%[3**])
  - Supporting a positive list for drugs — 29-43%[1]
- **Willingness to pay for guaranteed access to innovations** — **60%[2]**

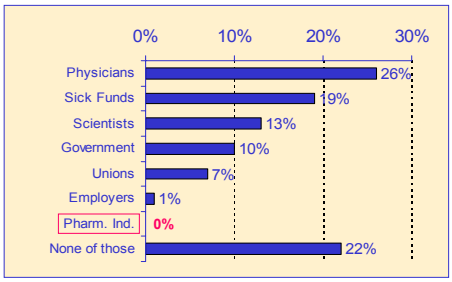
*irrespective of reduced premiums; **"Drugs should be paid for by sick funds only if and when their use is efficacious and appropriate."
[1]Janssen-Cilag Population Study 1998; [2]Janssen-Cilag Population Study 2002;
[3]WIdO: GKV-Monitor 1998/99; [4]WIdO: GKV Monitor 2002

Responsibility for Financial Crisis[1]



[1]Janssen-Cilag Population Study 1998

Trust in Patients' Agents[1]



[1]Janssen-Cilag Population Study 2002; according the same survey, 78% of respondents wish institutionalized public participation such as a "Citizen Council"

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Recent population surveys in Germany

Selected Public Perceptions

- **Cost containment**
  - Very limited public support for the political focus on cost-containment ("Beitragssatzstabilität").
- **Pharmaceutical products**
  - "Drug prices should be controlled."
  - The public rejects increased cost-sharing on drugs.
  - There is a strong public preference (and willingness-to-pay) for access to innovations.
- **Pharmaceutical industry**
  - The pharmaceutical industry is believed to contribute to the financial crisis of the health care system. "Drugs are part of health care – the pharmaceutical industry is not."[1]

[1]Heinz Redwood

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Health care resource allocation:
"balancing cost-effectiveness and fairness"[1]

Societal Preferences[1]

- **Fair distribution of health care services**
  - People think the efficiency with which society distributes health care resources must be balanced with the perceived fairness, or equity, of this distribution.
- **Give priority to severely ill patients**
  - even when their care is less cost-effective
- **Avoid discrimination against people with chronic illness or disability**
  - even when their treatments are not cost-effective

[1]Taken from: P.A. Ubel: "Pricing Life" (2001), pp. 69ff.

ECONOMIC IMPACT OF NEW DRUGS

- Relating Costs to Effectiveness

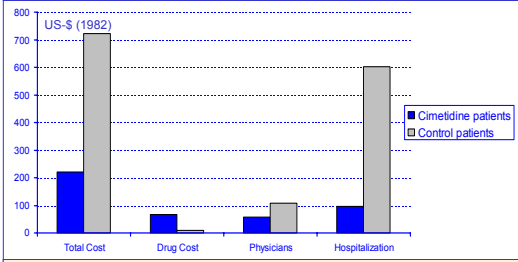
International trends

Economic Evaluation of New Medical Technology

- New medical technologies provide new opportunities for prevention and treatment; they can reduce or increase health care costs.
- Economic evaluation is appropriate in situations of **market failure**, for instance, when the ultimate consumer does not pay for the commodity:
- Medical (/health) technology assessment (MTA/HTA) as a new tool for health care policy:
- New technologies have to prove to be good "value for money" (**cost-effectiveness**).

Component management approaches frequently result in misleading conclusions

The Early Days of Economic Evaluation of New Drugs



Cimetidine provides the historic example for cost savings achieved within the health care system by an innovative new drug. Data from Medicaid Michigan[1].

[1]J. Geweke, B.A. Weisbrod (1982)

Substantial benefits may accrue outside the realm of third-party payers

A Case for a Broad Perspective in Economic Evaluations

- **Cholinesterase inhibitors** (e.g., donezepil, rivastigmine, and galantamine) have been shown to improve cognition in patients with **mild to moderate Alzheimer's disease**. Benefits include prolonged time that patients have without severe disease, and decreased burden of caring for patients.
- International modeling studies have indicated cost-savings compared to no treatment, resulting from the delay in time until full-time care in patients will be required[1].
- Cost-savings have been found to be sensitive to the cost of institutional care. Extent and type of formal care available in different health care settings varies substantially[2].

Drug treatment of Alzheimer's Disease may provide substantial savings on formal and informal care, even though conclusive German evidence is lacking.

[1]K.A. Lyseng-Williamson, G.L. Plosker (2002); [2]B. Jönsson et al. (2000)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Routine clinical practice does determine actual cost-effectiveness of interventions

Changes in Cost-Effectiveness over Time

- Original evaluation (1988 data)[1]: cost of **erythropoietin** vs. blood transfusions in **chronic renal failure**: **£ 107,145 / QALY gained**
- Since 1988, significant changes occurred in the way EPO is used:
  - Dose reduction (role of timing and iron supplementation)
  - Change in relative prices (e.g. EPO vs. blood)
  - New information on transfusion need and survival
- A replicate (2000 data)[2]: **£ 171,810 per QALY gained**
- Re-evaluation based upon actual utilization data (2000 data)[2]: **£ 17,067 per QALY gained**

Erythropoietin for treatment of chronic renal failure provides an example for significantly different cost-effectiveness results if based on actual utilization[1,2].

[1]B. Leese, J. Hutton, A. Maynard (1992); [2]E. Remák et al. (2002)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Economic evaluation of new medical technologies

Key Questions Addressed

1. **Safety**
   - Does it harm? (controlled conditions)
2. **Efficacy**
   - Can it work? (controlled conditions)
3. **Effectiveness**
   - Does it work and is it safe? (normal practice)
4. **Efficiency**
   - Is it cost-effective?

THE CONCEPT OF THE "FOURTH HURDLE"

- International Experience and Issues

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Two concepts of the "fourth hurdle"

Use	Abuse
Rational Resource Allocation	**Cost-Containment**
¬ Parallel existence of pharmaceutical "overuse", "underuse" and "misuse"[1] ¬ Funding required to eliminate underuse of innovative drugs estimated at 8.6 bn DM[1] ¬ Potential savings by eliminating "controversial drugs" estimated at 1.2 bn €[2] ¬ Tool to identify and to provide guidance to correct "market failures": ¬ On a rational basis, re-direct resources to ensure their most cost-effective use	¬ Focus (exclusively?) on new products ¬ Direct price regulation ¬ Effective market entry barrier ¬ With or without Health Technology Assessments (HTAs) ¬ With HTAs: Australia, Canada, … ¬ Without HTAs: Italy, France, … ¬ Frequently a part of component management or budgeting approaches

Both: providing a (last resort) defence of public health care systems against "frivolous pharmaceutical pricing practices" in the face of "market failures"[3]**?**

[1]Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen; Addendum zum Gutachten 2000/2001 (December 2001);
[2]U. Schwabe u. D. Paffrath (2002); *'for instance'*: B. Müller-Oerlinghausen (Arzneimittelkommission der deutschen Ärzteschaft, 1999): "Pharmaindustrie: Wucherpreise auf dem Rücken der Solidargemeinschaft"; N. Bloom, J. Van Reenen (Institute for Fiscal Studies, London, and University of California at Berkeley, 2001): "In publicly funded healthcare systems pharmaceutical price regulation is necessitated … because of over-prescription and the monopoly power of firms with on patent drugs."; Sozialdemokratische Partei (SP Schweiz, Bern 2001): "Die Preisspirale durchbrechen!", and many others…

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

The "fourth hurdle" as a market entry barrier

Fourth hurdle requirements prior to reimbursement

- ¬ Australia ("PBAC"; guidelines first published in 1992)
- ¬ Canada ("CCOHTA"; Ontario: guidelines since 1994)
- ¬ More recently followed:
  - ¬ Finland, Portugal, The Netherlands (in pilot phase; scheduled for full implementation by 2005), …
- ¬ Traditionally (without HTA) restricted access:
  - ¬ Italy, France, Greece, …
- ¬ A different approach in England and Wales: National Institute of Clinical Excellence ("NICE") since 1999
  - ¬ NICE guidance to the National Health Service (NHS) has been mandatory since December 2001

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

The NICE concept of the "fourth hurdle"

National Institute of Clinical Excellence

- ¬ Stated objective: "faster access to modern treatments…"
- ¬ **Fourth hurdle in a system of free pricing**
  - ¬ with statutory profit control ["PPBS"]
  - ¬ with automatic reimbursement of licensed products
- ¬ **Production of clinical guidelines**
  - ¬ clinical efficacy no longer sufficient; **criteria:**
    - ¬ clinical effectiveness (evidence-based medicine)
    - ¬ cost-effectiveness
    - ¬ NHS impact (the "fifth hurdle")
- ¬ **High level of transparency …**
  - ¬ … but: selection of technologies for assessment?
  - ¬ … but: commercial-in-confidence data?

The NICE concept of the "fourth hurdle"

The International Impact of NICE

- High international attention to NICE appraisals and spill-over effects to price and reimbursement negotiations
- Promoting a tendency towards the requirement of more stringent evidence of clinical benefits, such as:
  - data to substantiate product claims
  - data on patient subgroups who benefit most
  - choice of most appropriate comparator
- No "EURO-NICE" (G10 recommendation, 2002)
- Informal relationships with other international HTA agencies (e.g., DIMDI in Germany)
- Other countries considering to adopt the NICE model (e.g., "*Deutsches Zentrum für Qualität in der Medizin*"?)

The concept of the "fifth hurdle"

Budgetary Impact ("Affordability")

- **Rationale:** Without the overall budgetary impact, cost-effectiveness analysis cannot identify the **opportunity cost** of adopting a new technology.
- **In practice: Can the new intervention, within the constraints of a given budget, be funded?**[1]
  - Perspective of the third-party payer
  - Part of the appraisals performed by NICE
  - Mandatory in Australia and Finland
- **Potentially restricted view:**

  Might foster a tendency to neglect the benefits of interventions and fall behind "cost-effectiveness"[2]

[1]Budgetary impact considerations implicitly played a role when reimbursement of so called "life style" products such as Viagra® was denied in Germany and elsewhere.
[2]Australian and Finnish guidelines do not request data on societal benefit within budgetary impact analyses.

The fourth hurdle: international experience

Feasibility of Implementation

- **Within the logic of cost-effectiveness,** international experience[1] demonstrates:
  - "Fourth hurdle" requirements are "workable".
  - Pricing decisions may or may not be linked with reimbursement decisions.
- Empirically, some of the problems include:
  - Access to innovations may be delayed.
  - Cost-effectiveness may change over time and decisions may have to be reviewed.
  - Cost-effectiveness thresholds need to be defined.
  - Other criteria than cost-effectiveness ratios may be incorporated (e.g., seriousness of the health condition, availability of alternative interventions, budgetary impact; affordability to patients if not reimbursed).

[1]cf. M. Drummond (2002)

The fourth hurdle as a barrier to market entry: experience and issues

Access to Innovation

- **Empirical evidence** shows that "fourth hurdle" requirements, including direct price regulation, at or prior to market entry or reimbursement does lead to delayed access to new medical technology:
  - Early examples from Australia[1] included finasteride (for BPH), sumatriptan (for migraine), beta-interferons (for multiple sclerosis), dornase-alpha (for cystic fibrosis).
  - More often than total refusal, however, restrictions in use have been placed on new products (e.g., proton pump inhibitors as second line therapy [Australia] or gemcitabine for pancreatic cancer in patients with Karnofsky status ≥50 and acetylcholinesterase inhibitors for Alzheimer's disease in patients with an MMSE score >12 [United Kingdom]).
- In contrast to these effects, **public preference** has been identified for free **access to innovation**.

[1]Source: M. Schlander (1998)

The fourth hurdle as a barrier to market entry: experience and issues

The Paradox of the Fourth Hurdle

- **Health economic appraisals at the time of or before market entry are prone to error:**
- "Internal" versus "external" validity of data: The experimental context of clinical trials does not represent actual practice (utilization).
  - Highly selected patient populations
  - Fixed dosing regimens
  - Multiple protocol-induced biases in treatment
  - High prevalence of specialized investigators
  - Over-reporting of non-clinically relevant events
  - Focus on intermediary instead of long-term outcomes
- Valid health economic assessments need to be based upon actual practice.

The fourth hurdle: experience and issues

Cost-Effectiveness Thresholds

- To make incremental cost-effectiveness ratios relevant, a criterion – threshold(s) – need(s) to be defined above which medical interventions are deemed less efficient.
- Empirically, such thresholds vary considerably:
  - In New Zealand, PHARMAC uses NZ-$ 20,000 / QALY gained[1]
  - In Australia, the PBAC has used thresholds in a range between A-$ 42,000 / LYG and A-$ 76,000 / LYG[2]
  - In the United Kingdom, NICE uses a threshold of approximately £ 30,000 / QALY gained
  - In the United States, US-$ 100,000 / QALY has been suggested[3]
- Some of the issues include the justification of thresholds, their flexible use (according to which additional criteria?), consistency with other sectors of public spending, and the consideration of societal values and preferences.

[1]C. Pritchard (2002); QALY: "quality-adjusted life year"; [2]George et al. (2001); LYG: "life year gained"
[3]D.M. Cutler, M. McClellan (2001)

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

The fourth hurdle: experience and issues

Ethical Aspects

- While an ethical imperative can be postulated to eliminate waste and inefficient use of (scarce) resources:
- **The "cost-effectiveness logic" is based upon (act) utilitarian thought**, i.e. to maximize social utility. It is "normative" only within the boundaries of this approach (cf. "utility theory")[1].
- By definition, it does not incorporate other **values** – neither distributional aspects ("**fairness**" of access to health care) nor concepts of need (e.g., re. minor health problems – "**appropriateness**"[2]).
- This explains[3] why **attempts to allocate health care resources purely on grounds of cost-effectiveness have failed without exception.**

[1]the "cost-effectiveness logic" reflects an even more restricted view ("medical utilitarianism" has been differentiated from "general utilitarianism" – a "cost-benefit logic") owing to its focus on measurable health outcomes; cf. Gramlich (1990), P. A Ubel (2001); [2]the term "appropriateness" usually relates to the distinction between necessary and purely beneficial medical services; [3]not excluding other factors; cf. A. Maynard, K. Bloor (1995)

IMPLICATIONS

SOCIO-ECONOMIC ASPECTS OF NEW DRUGS

Some implications for rational resource allocation

Conclusions and Recommendations

- Evaluating the cost-effectiveness ("value for money") of medical interventions represents a powerful tool to substitute for market failures.
- Evidence of clinical effectiveness should serve as a pragmatic starting point, as there is no cost-effectiveness without it.
- There is no rationale to use different criteria for new vs. established products (nor for drug treatment vs. non-pharmaceutical medical) interventions.
- Interventions may be prioritized for appraisal according to their relevance, i.e. their opportunity cost (or "budgetary impact").
- Appraisal processes should be independent from third-party payers.
- Cost-effectiveness thresholds should be consistent across public sectors, considering societal preferences.
- The inherent limitations of the "cost-effectiveness logic" demand consideration of societal values and preferences beyond the maximization of total utility.