



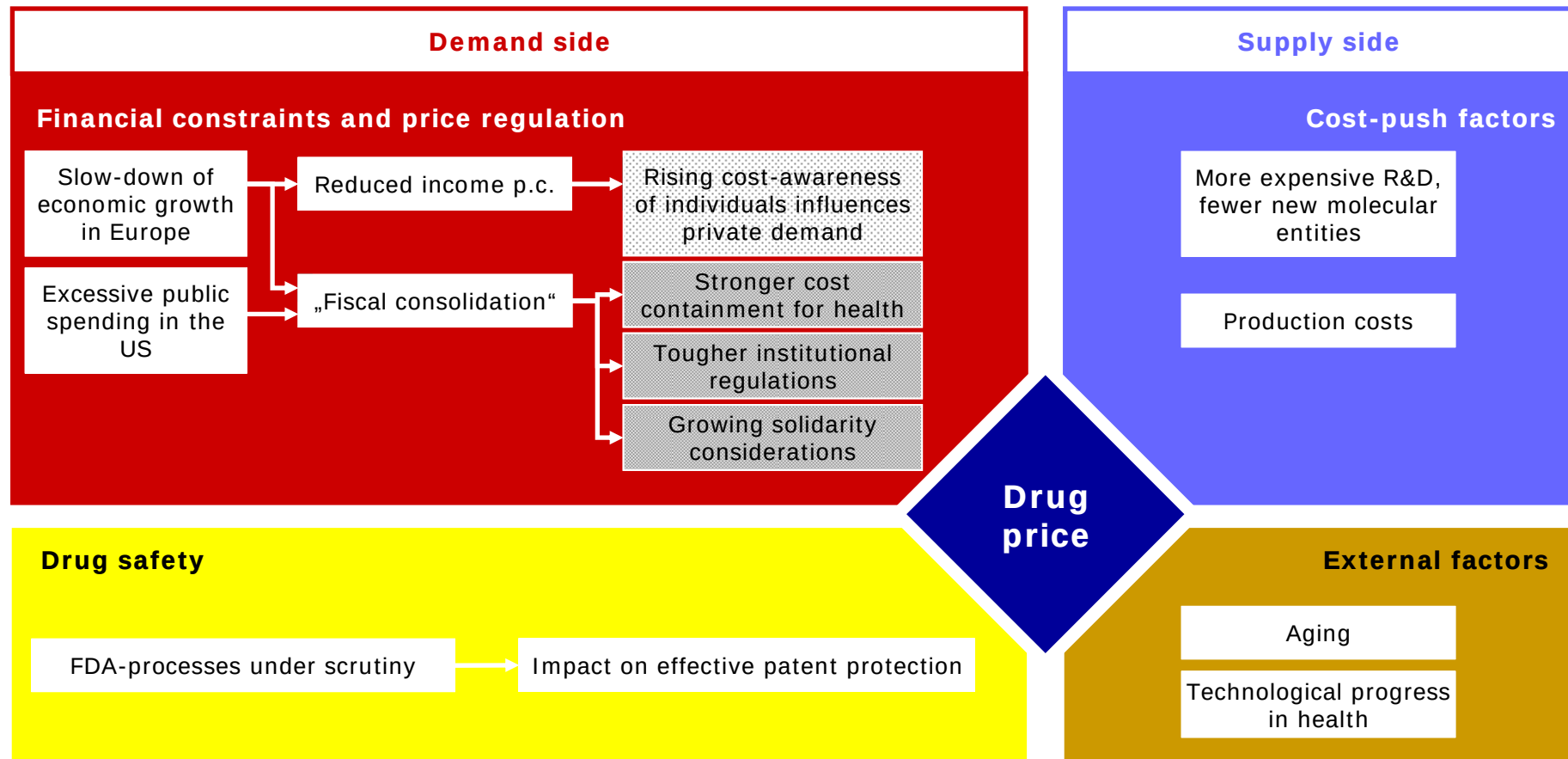
GIRP-Autumn-Meeting

The Pharmaceutical Industry: Structural Trends and Pricing-Policies

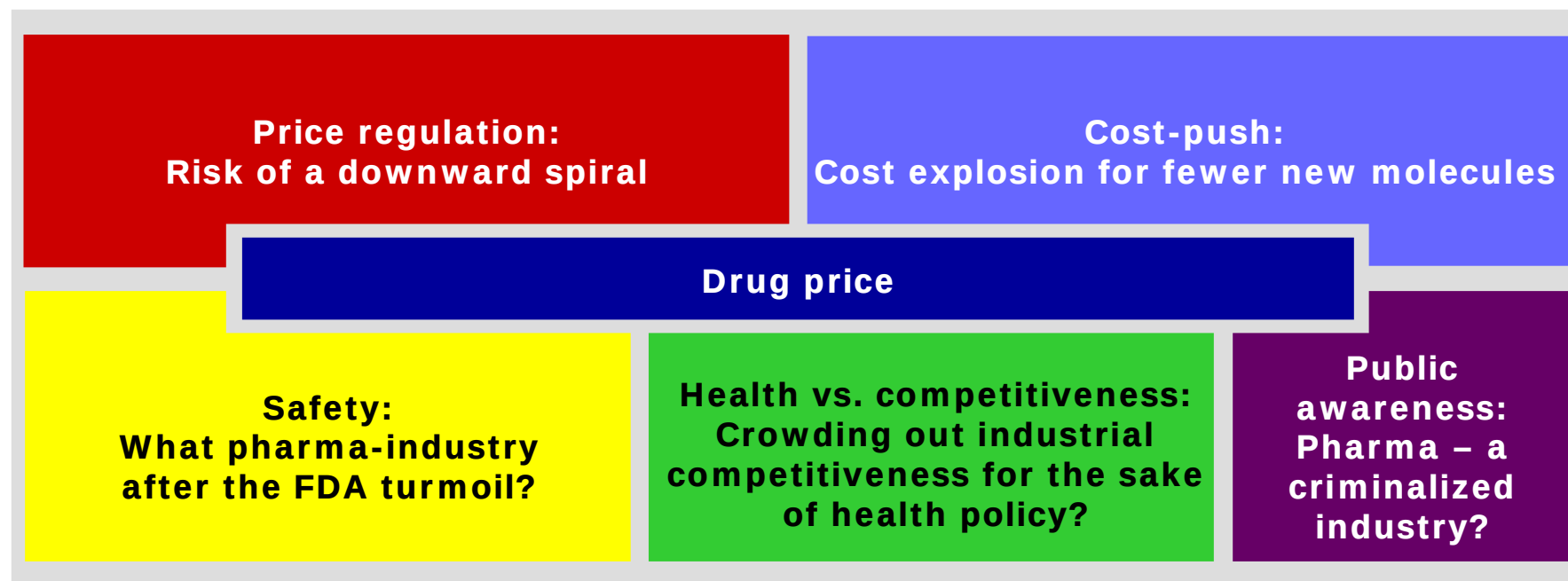
W. Clement
www.ipf-ac.at
Brussels, 30-11-2004

▶ I	Salient Factors influencing Drug Prices	03
▶ II	Price Regulation	05
▶ III	Safety	16
▶ IV	Cost-push	19
▶ V	Health vs. Competitiveness	21
▶ VI	Public Awareness	23

I. Salient Factors influencing Drug Prices – the general Picture



I. Salient Factors influencing Drug Prices – the general Picture



II. Price Regulation – Risk of a downward Spiral

Tougher price regulation ahead due to:

- ▶ Economic stagnation in Europe
- ▶ Public over-spending in the US
- ⇒ Risk of a downward spiral



II. Price Regulation – Risk of a downward Spiral

Public demand for reimbursed drugs is subject to:

Tougher cost containment
through budget finance for
drugs

More stringent institutional
regulations

Regulatory tools

Public price repression via

Social considerations
(„solidarity“)

- » Social prices may lead to moral hazard
- » Market segmentation, Ramsey pricing

Price comparisons

- » Time series
- » Average, individual and reference pricing

II. Price Regulation – Risk of a downward Spiral

Public Demand – „Social pricing“ and Uniform (single) pricing

- ▶ Solidarity considerations are frequently brought forward by the payers - Social security, Sickness funds (and the LSE) – to justify lowering drug prices
- ▶ P. Kanavos (LSE): „Authorities have an incentive to ensure that patients are not charged more than what they are prepared to pay, on grounds of public health, social solidarity and economic efficiency“ (Overview on pharmaceutical pricing and reimbursement in Europe, Paper for DG Enterprise February 2001, p.9)
- ▶ Pharma companies sometimes react by advocating uniform prices of the product after EMEA approval despite different markets (segmented by regions, by population groups – both characterized by differing purchasing power)

II. Price Regulation – Risk of a downward Spiral

Public Demand – „Social pricing“ and Single pricing

⇒ **Both considerations seem to be misleading:**

- ▶ Mixing social policy with pricing may distort any signal on the markets (markets for social goods **and** competitive markets for drugs), Social objectives should be achieved with social policy not with pricing.
- ▶ Forwarding different prices for drugs on different markets („price discrimination) is a necessary precondition to recoup the high fixed-costs of R&D. This is rational and should even lead to overall maximization of social welfare. Hence, efficiency and equity considerations can be achieved together.
- ▶ This argument is backed by the theory of Ramsey-Pricing: Differential pricing on segmented markets follows the inverted demand-elasticity: $(p-c)/p=1/e$; Price-sensitive (low income) drug consumers will be charged a smaller mark-up, because otherwise they would reduce their consumption.

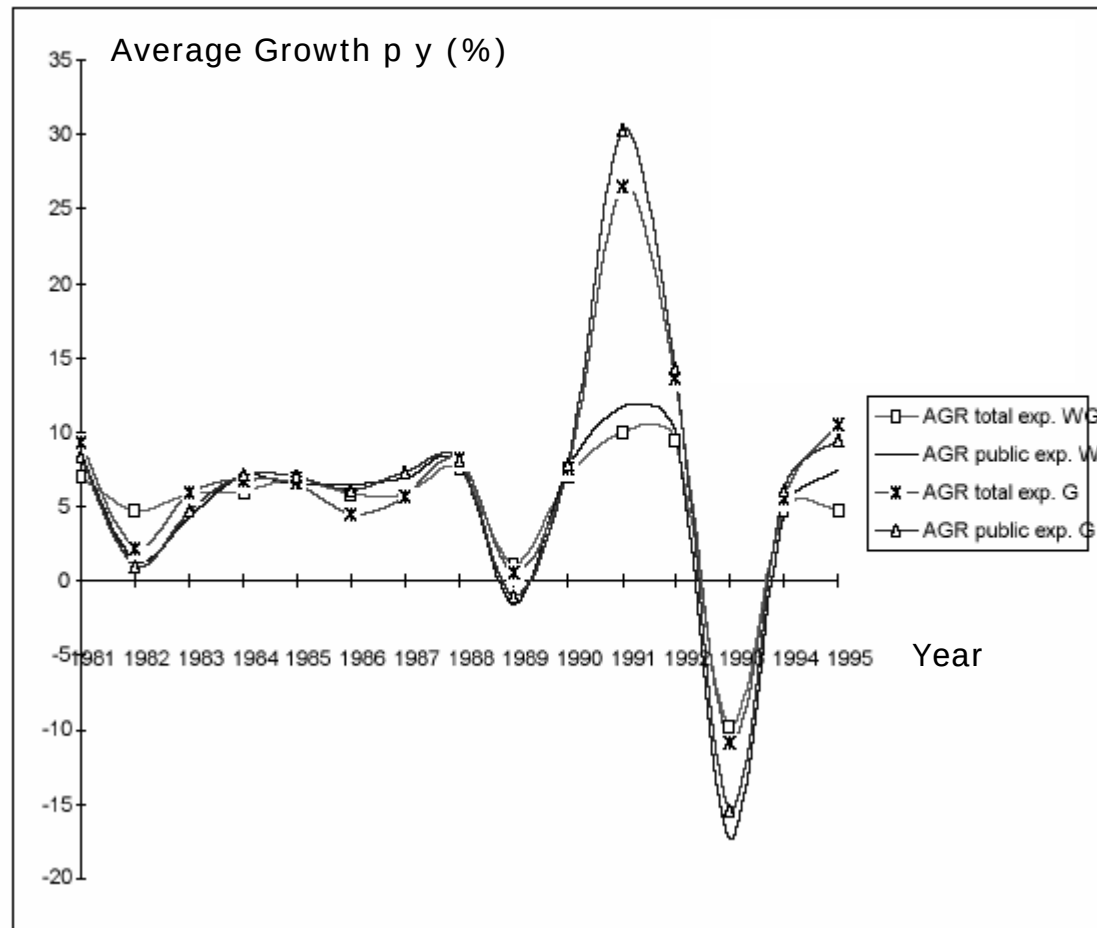
II. Price Regulation – Risk of a downward Spiral

- ▶ Despite the rationale of differential pricing, high income countries tend to overrule the concept. Parallel trading and reference priced regulation counteract differential pricing. Ultimately, this can lead both to suboptimal provision of new drugs and shifting of production- location.
- ▶ The topic is particularly acute (and little understood) with reference to developing countries or underdeveloped regions.
- ▶ Beyond price-discrimination on segmented markets specific price-volume contracts could be considered and can also lead to an overall optimum.

II. Price Regulation – Risk of a downward Spiral

Public Demand - Price comparisons (Time series)

Germany and the German Federal Republic

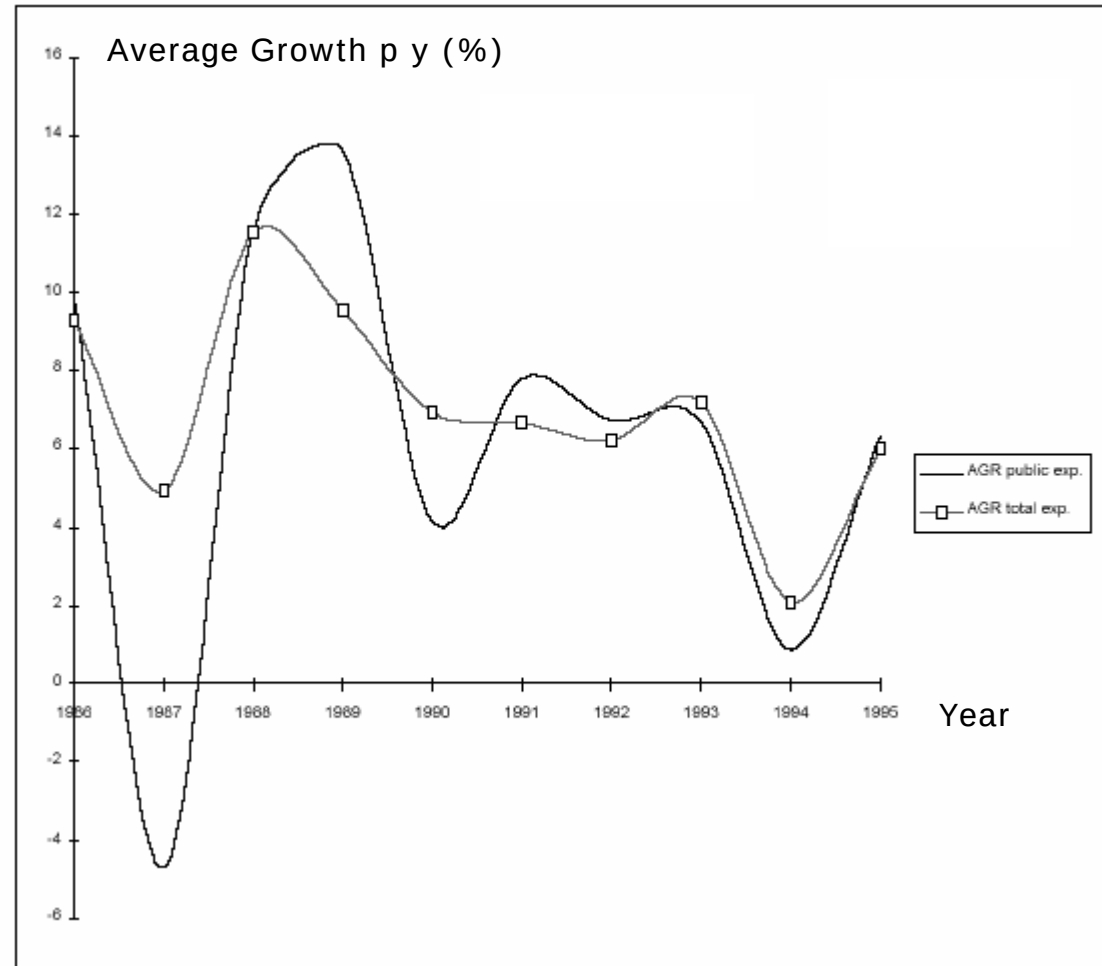


II. Price Regulation – Risk of a downward Spiral

Public Demand - Price comparisons (Time series)

France

⇒ Can price-controls achieve more than what the long-term trend does anyway?



II. Price Regulation – Risk of a downward Spiral

Public Demand - Price comparisons

- ▶ Cross-national comparisons of drug prices are frequently used as a reference for positioning domestic prices (at a lower level), mostly during reimbursement.
- ▶ While average price-comparisons (whole pharmacy market) are also applied for certain purposes the most stringent impact is triggered by **price comparisons for individual products**. Here, the term “AEP – Average European Price - is much in fashion (Italy, Spain, Austria..?) but extremely fuzzy.
- ▶ Despite (malevolent) neglect by price authorities one has to repeat over and over the major flaws of such comparisons:
 - ⇒ **Data availability**
 - ⇒ **Correct definition of identical pharmaceuticals**
 - ⇒ **What pharmaceuticals selected for comparison (basket?)**
 - ⇒ **Weighted or non-weighted averages**
 - ⇒ **Price level (ex factory or retail prices?)**
 - ⇒ **Comparisons of prices only or together with volumes/sales**
 - ⇒ **Conversion with exchange rates versus purchasing power parities (PPPs)**

II. Price Regulation – Risk of a downward Spiral

Public Demand - Price comparisons

Reference Pricing

Citation from one article:

“..systematic reviews...suggest that RBP has been successful at temporarily capping drug prices. However, other factors...make it difficult to isolate specific effects of RBP....Where the reference price is based on the lowest priced drug(s) in the group, RBP appears to be one of the few strategies likely to be effective at encouraging doctors to use the least expensive agents as first-line therapy...”*)

*) Ioannides-Demos et al., Pharmacoeconomics Sept 2002

II. Price Regulation – Risk of a downward Spiral

► And where is the wholesaler in all that?:

⇒ Panos Kanavos (LSE):

„...wholesalers have very limited influence on the choice or volume of drugs prescribed, and none on their price.“

(Overview on pharmaceutical pricing and reimbursement in Europe, Paper for DG Enterprise February 2001, p.47)

⇒ Distribution accounts for almost half of the retail price!?

⇒ What are the implications of vertical integration of distribution upstream and downstream?

⇒ Literature on pharma-pricing does not distinguish between ex-factory prices and retail prices. Apparently distribution is reduced to a percentage margin!?

► Conclusion:

⇒ The common market for pharmaceuticals seems to be way ahead both on theoretical and practical grounds; national regulators and industry prefer the present system, despite some efforts of „harmonization“, together with EMEA

⇒ Even if any single regulatory measure seems to be adequate to the regulating bureaucrat – taken together, the spiral moves downward. It is another striking example of what the Austrian Nobel Prize Laureate F.A. von Hayek termed „The road to serfdom“. Plain economists would call it a Prisoner's dilemma.

II. Price Regulation – Risk of a downward Spiral

Private demand for drugs subject to:

- ▶ Lower income per head will lead to slowing of demand in the longer run
- ▶ Private demand may shift towards more Generics and OTC
- ▶ Reduced demand likely because of higher co-payment
(overall a 10% increase in prescription charge reduces demand by 1 to 3%)
- ▶ How is one to limit moral hazard behavior (waste and over consumption) by the individuals since a third party is paying anyway?
- ▶ Ultimately: Private price repression due to economic factors, but control for the impact of external factors: Aging! which works in the opposite direction

- ▶ Turmoil in the industry after David Grahams (Associate director for drug safety at FDA) testimony before the Senate Finance Committee:
 - ⇒ ***Not only VIOXX is a case but similar questions arise with: Bextra (Pfizer), Crestor (Astra Z.), Merida (Abbot), Accutane (Roche), Serevent (Glaxo)***
- ▶ FDA's acting Director Galson has taken steps to alert consumers
- ▶ Graham's comment: "Senior management at the FDA did everything in their power to intimidate me prior to my testimony"
- ▶ **Thus:**
 - ⇒ More rigorous scrutiny by FDA is to be expected (hitherto FDA „too cosy“ with drug companies)
 - ⇒ EMEA may act similarly due to the Confidentiality Arrangement between EU/EMA and FDA which implies exchange of information and documents and sharing of product-related information as well as quarterly routine exchange of information on applications, pharmacovigilance inspections etc.

► **Consequences:**

- ⇒ Longer and more expensive approval process
- ⇒ More clinical trials requested
- ⇒ Later market entry
- ⇒ Risks of litigation
- ⇒ Withdrawal of some drugs likely
- ⇒ Shorter effective patent protection
- ⇒ Legal procedures against generics in order to lengthen patent protection
- ⇒ Monitoring after release, pharmacovigilance

Impact of reducing the effective patent protection:

- Drug prices are frequently calculated on the basis of compensating the high R&D-costs for the drug:
 - ⇒ The minimum earnings required should at least be equal to the R&D cost plus production and overhead costs.
 - ⇒ Reducing the time of patent protection leads to an *exponential* increase of earnings needed : $dE/dt = Ct/(T-t)^2$
- Hence, the earnings curve is steeper, which would have to be achieved by higher volume and/or higher prices

Consequences for pricing

- ▶ Fewer medicines approved
- ▶ Later acceptance and reimbursement
- ▶ Induced steep price increases
- ▶ All efforts to be made to lengthen patent protection
otherwise R&D in new molecules becomes an unattractive investment
- ▶ Consider the introduction of a provisional license

- ▶ The „big pharma’s golden era“ (Reuters health summit, Nov 17th) could be over for other reasons:
 - ⇒ Are Blockbusters still the main strategic objective of companies?
 - ⇒ (According the criterion: sales more than \$ 1 billion per year; e.g. *Pfizer’s Lipitor* generates \$ 10 billions/year, *Astra’s Crestor* should have brought \$ 4,1 bn by 2008 equal to 22% of earnings)
 - ⇒ If blockbusters become fewer and fewer, hence, drugs have to be targeted at smaller groups of people
 - ⇒ First: The stock exchange reaction after doubts about Astra Zeneca’s Crestor (because of panic: -10% of the value in one day)
 - ⇒ For the smaller segments of the drug market, pharma companies would have to charge high prices to compensate for the R&D costs. How then can big companies reap the cost advantages of economies of scale? New company–size distribution may lie ahead (esp. for genetically engineered drugs)

► Perspectives for pricing

- ⇒ Slow down of productivity from research laboratories
- ⇒ Soaring costs of R&D (\$ 1bn for a new drug according to WHO)
- ⇒ More selection on potential new molecular entities
- ⇒ How is one to compensate for huge sales losses
- ⇒ Provide for compensation payments for patients (\$ 10 bn for Vioxx?)
- ⇒ Add risk-premium on new drugs („Vioxx lifts the general price level“)
- ⇒ Shift rising costs on to new ex-factory prices!?

V. Health vs. competitiveness

- ▶ The present discussion in the field of pharmaceuticals is dominated by issues of securing high standards in the health system, their public funding and concerns over safety of drugs.
 - ⇒ Does this lead to crowding out the industrial competitiveness for the sake of health industry?
 - ⇒ Who cares of trading-off savings in health and tough regulation versus loss of competitiveness of companies, of value added and of jobs?
 - ⇒ Does anyone in your country know how many skilled jobs are being secured (directly and indirectly) by the pharma sector?
 - ⇒ Could the Industry Minister withhold against his Counterparts from the Health Department?
 - ⇒ Has some expert, Prime Minister influence on the fact that a truly holistic perception of the health system (covering hospitals, physicians and drugs) including the intransparent financial flows could bring about hefty savings?

V. Health vs. competitiveness

- ▶ A study (Bain, Addressing the Innovation divide, 2004) demonstrates the macroeconomic costs in Europe of saving on drugs:
 - ⇒ It is common knowledge that Europe occupies a „Free ride position“ since prices of prescription drugs in Europe are much lower than in the US and spending per head is 60% less.
 - ⇒ On the other hand there is a transatlantic shift in R&D. High-value jobs and profits are being created in America. The US is spending 30 bn annually, Europe only 20 bn. Between 1998–2002 Europe launched 44, the US 85 new molecules. In 2002 industry profits were 121 bn, 60% generated in America.
 - ⇒ Fast access to profitable markets gives a clear advantage to the US.
 - ⇒ Example Germany (1/5th of Europe's market): Germany saved 19 bn because of less spending on drugs. Trading that off against losses from R&D, patents and loss of skilled jobs and headquarter shifted elsewhere, it seems that this saving is in fact a 3 bn loss.
 - ⇒ From this perspective, free-riding is rather expensive!

VI. Public awareness: Pharma – a criminalized industry?

- ▶ What pharmaceutical industry after Vioxx (Graham's testimony: “..Vioxx related injuries equivalent of 2 – 4 aircraft dropping out of the sky every week for 5 years”, cited in Wall street Journal)?
- ▶ Senator Grassley (Finance Committee chairman): „The FDA must protect the public safety, not the profits of drug companies“
- ▶ Extremely negative media coverage of the industry („Putting profits before patients“)

Un ex-haut fonctionnaire du médicament

“ Les pratiques du secteur sont parfois inavouables. Elles peuvent aller jusqu'à la filature et aux menaces de mort. ”

Pierre Costes, n° 1 de MG France, syndicat de généralistes

“ La formation continue des médecins est malheureusement sous-traitée aux laboratoires, via les congrès. ”

Stanislas Degail, secrétaire général adjoint de l'ordre national des médecins

“ La pléthore d'études de l'industrie pharmaceutique noie le poisson et... le médecin. ”

médecins Le marketing forcené des labos

Pour les groupes pharmaceutiques, vendre vite le produit qu'ils développent depuis des années est vital. Alors, tous coups sont permis et la pression sur les praticiens est énorme.