

1st INTERNATIONAL FORUM ON BUSINESS DEVELOPMENT IN API & GMP FINE CHEMICALS

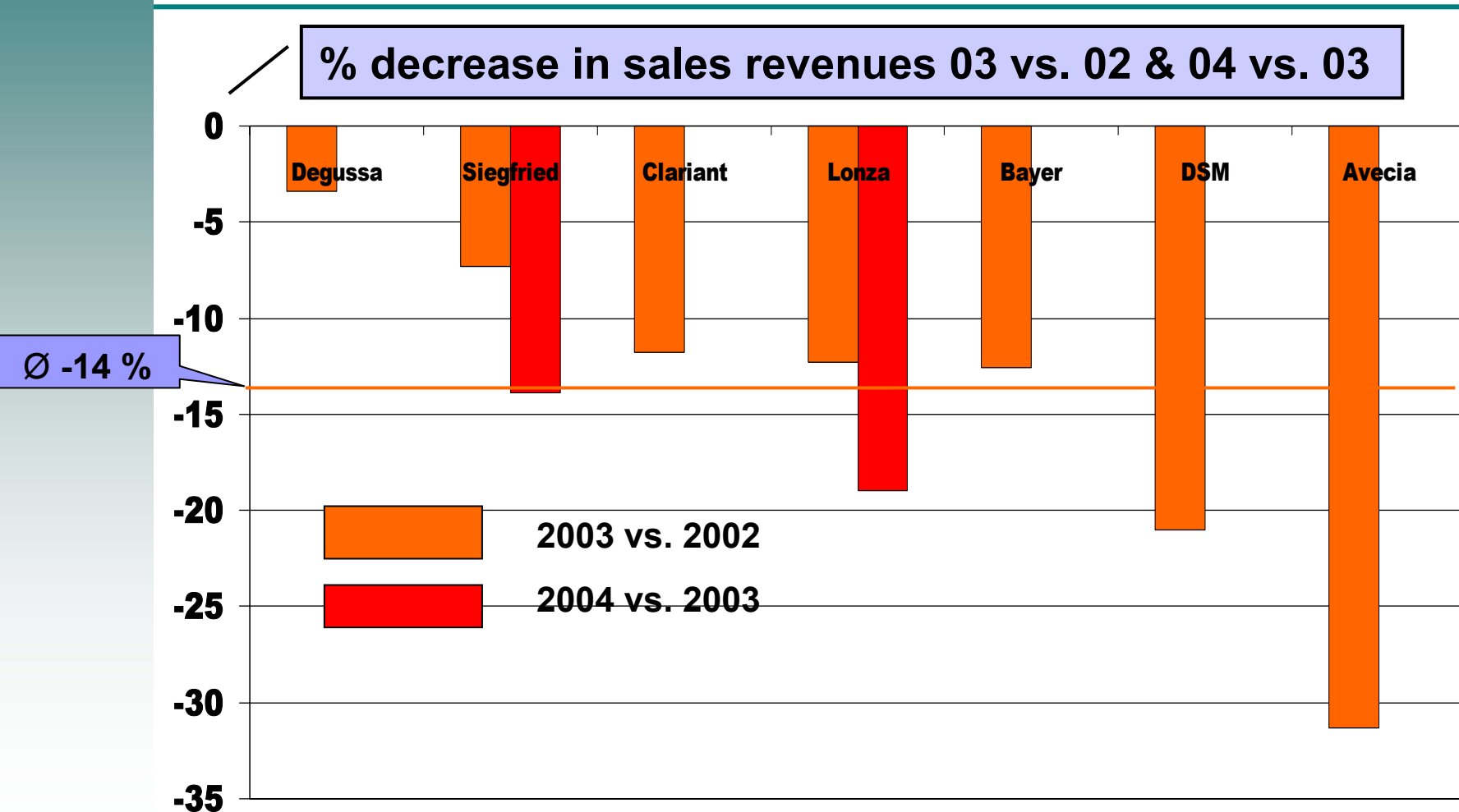
21-22 February 2005

Sheraton Roma, Rome

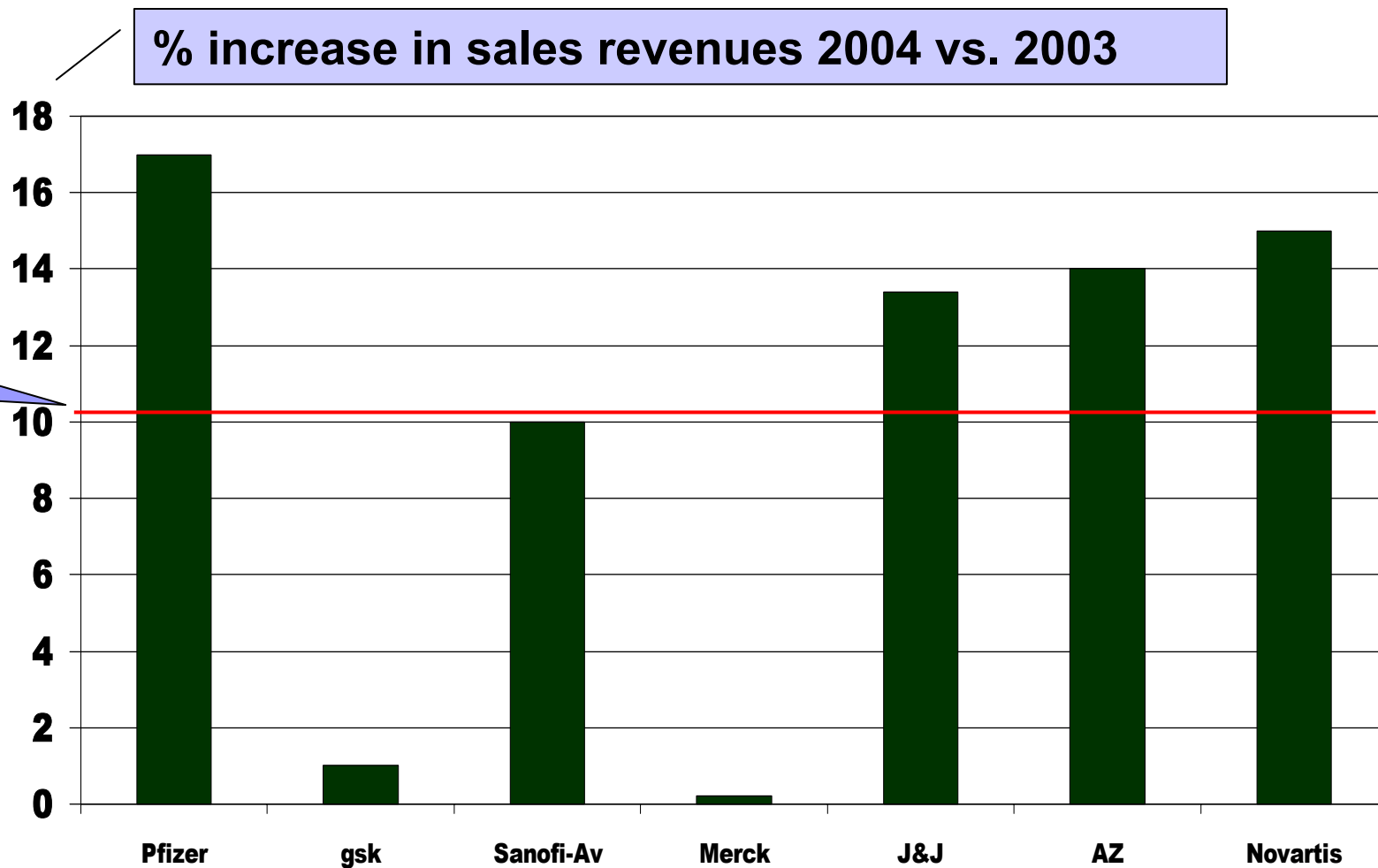
Why Fine Chemical Business Development has Failed

Peter Pollak

Sales Development of Major European Fine Chemical Comp. 03 / 02 & 04 / 03



Sales Development of Major Pharma Companies 2004 / 2003



Big Pharma's Outsourcing Policy

about Strategic vs. Opportunistic Outsourcing ...

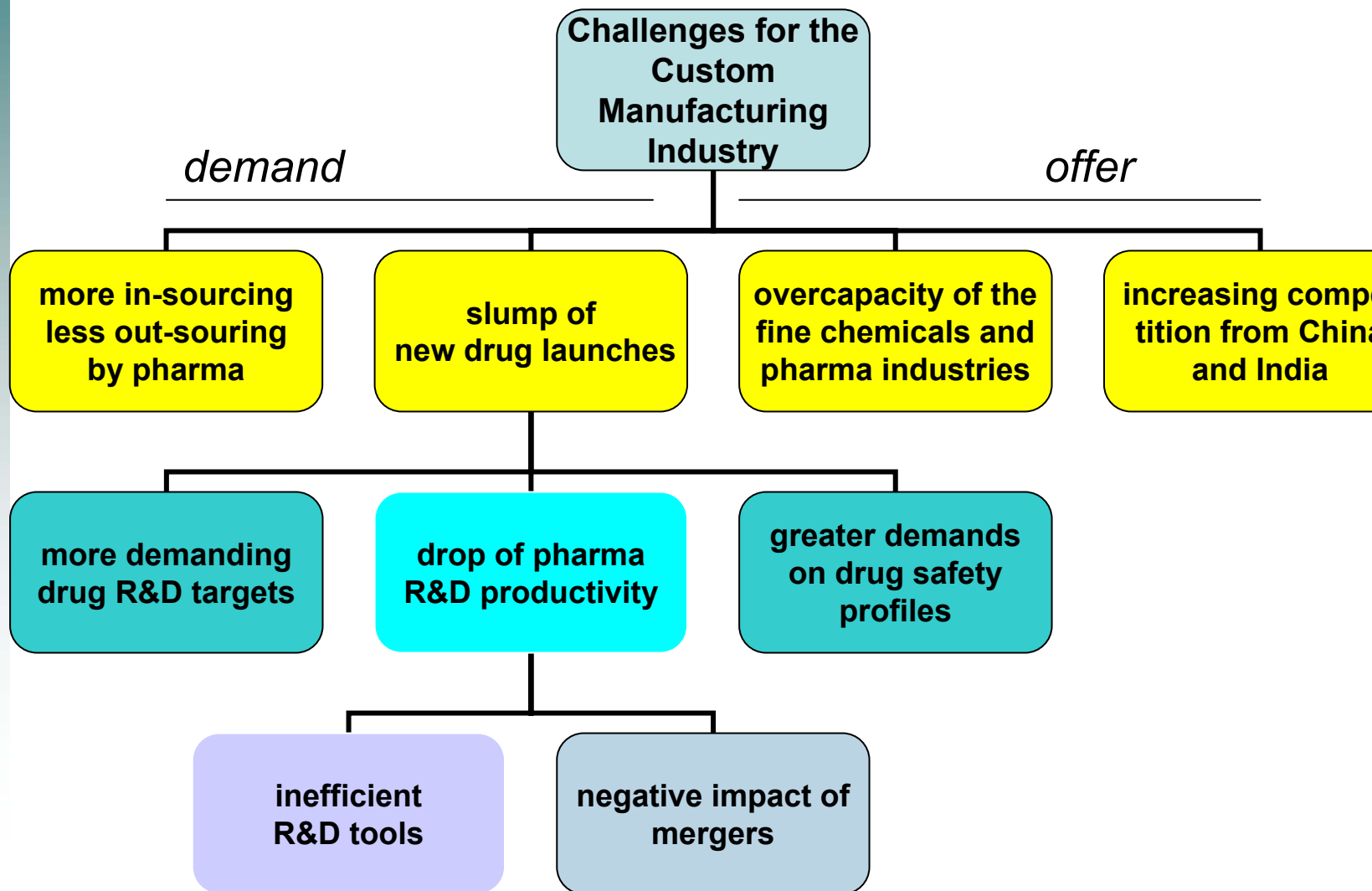
**„We are seeing more vividly that
truly strategic outsourcing
never really took hold in the industry“**

Martin H. (Jay) Joyce,
President of the the Pharmaceutical Outsourcing Management Association (POMA)
CMR, 14 April 2003, Focus Report

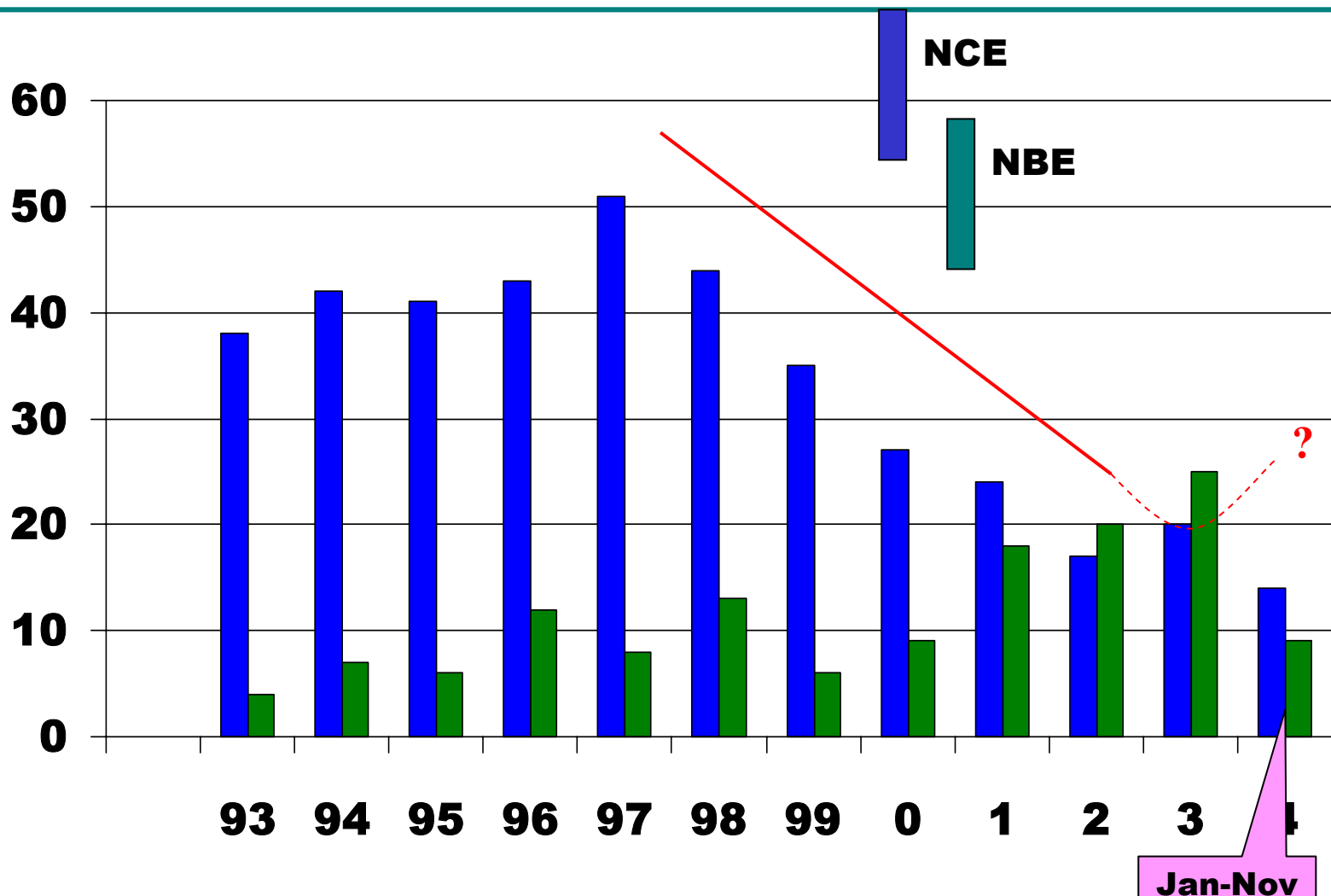
Misconceptions

- Growth of demand is outpacing growth of offering
- „Big Pharma will outsource all chemical manufacturing
- Custom Manuf. is a Seller's Market
- Big is beautiful
- We just lack a good organization
- We are the best


Custom Manufacturing: The Offer / Demand Hierarchy



FDA Approvals for New Drugs



Pharma Investment Projects

| Company | Product | Location | Investment |
|--|-----------------------------|-----------------------------------|-------------------|
| Biogen | Pipeline Products | Hillerod, Denmark | \$ 340 mio |
| Boehringer-Ingelheim | Enbrel | Biberach, Germany | \$ 250 mio |
| Genentech + Wyeth | Herceptin | Vacaville, CA USA | \$ 600 mio |
| Hoffmann-La Roche | Avastatin, Herceptin | Basel, Switz. Penzburg, De | \$ 350 mio |
| Novartis  | Diovan | Basel, Switz. Grimsby, UK | \$ 330 mio |

source: CMR, Dec. 2004, PP

Baruch Lev

**New York University
Stern School of Business
New York**

www.baruch-lev.com

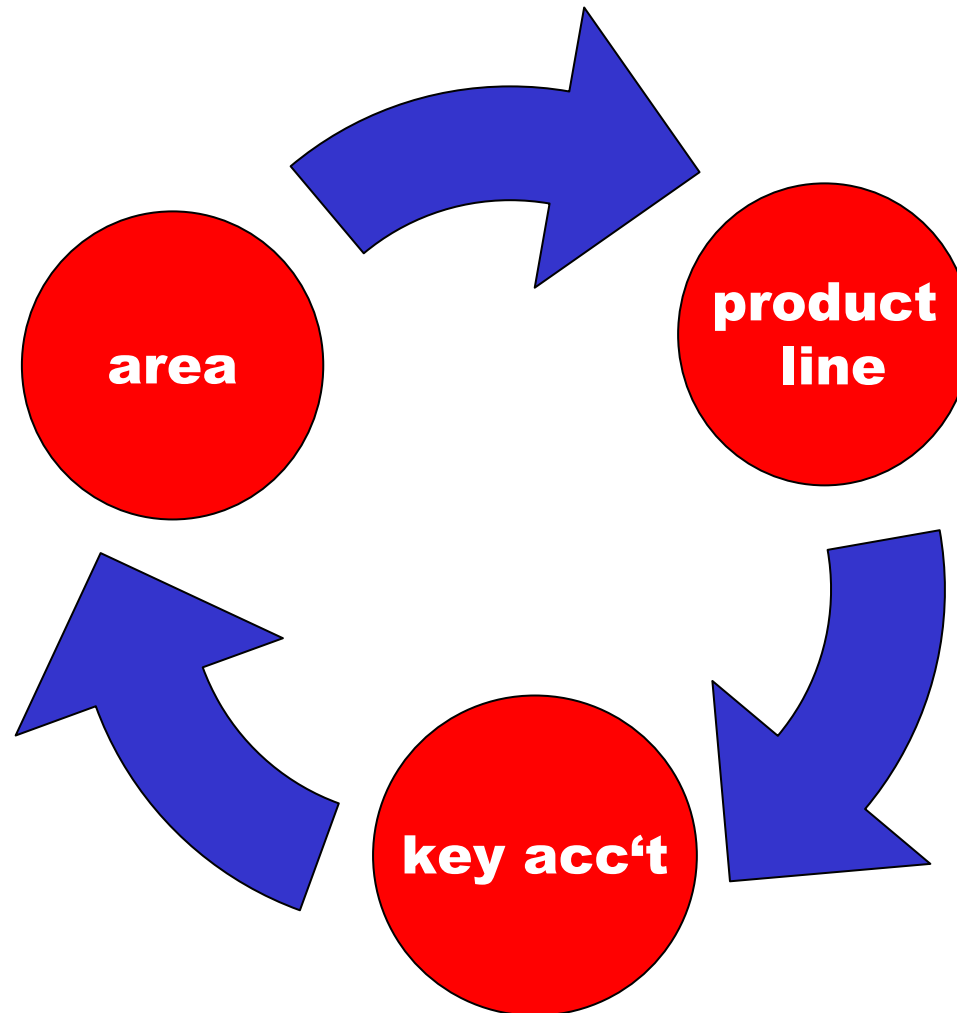
R&D and Capital Markets

Journal of Applied Corporate Finance, Winter 1999, *pp* 21-35

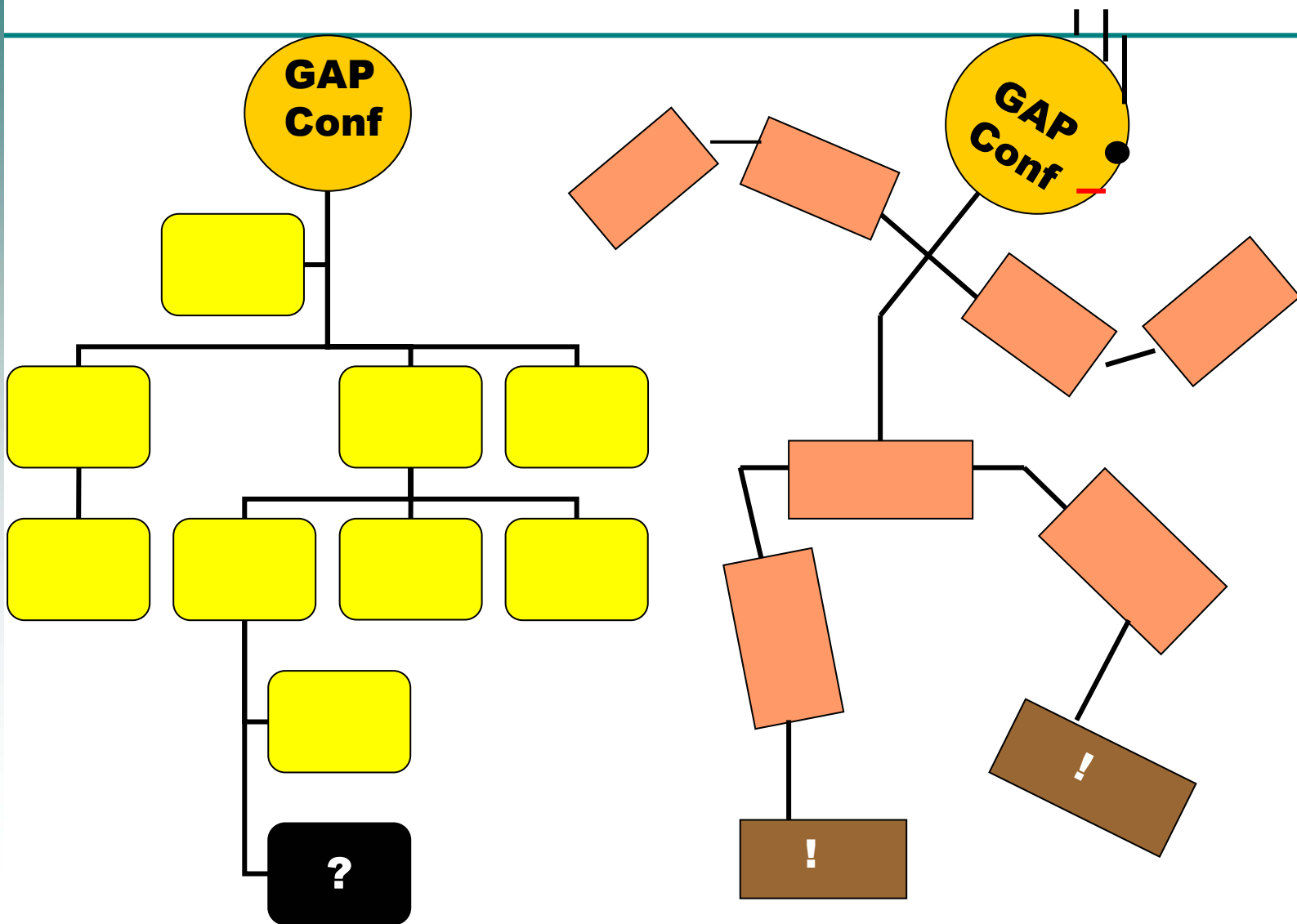
Supply Contracts: From a Seller's to a Buyer's Market

| | prior to 2000 | after 2000 |
|--------------------------------------|---------------------------|-----------------------|
| contract duration | 5 years | 1 year |
| capital guarantee | yes | no |
| take or pay clause | yes | what is this ? |
| number of suppliers | sole | lowest offer |
| volume forecasts | binding | spot orders |
| price adaptation | ↗ price index, etc | ↘ x % per year |
| process improv. benefits | to supplier | to customer |
| penalties for off-take delays | to supplier | to customer |
| customer inventions | to supplier | to customer |
| R&D expenditures | to supplier | to customer |

The Organization Carousel



Organization Development



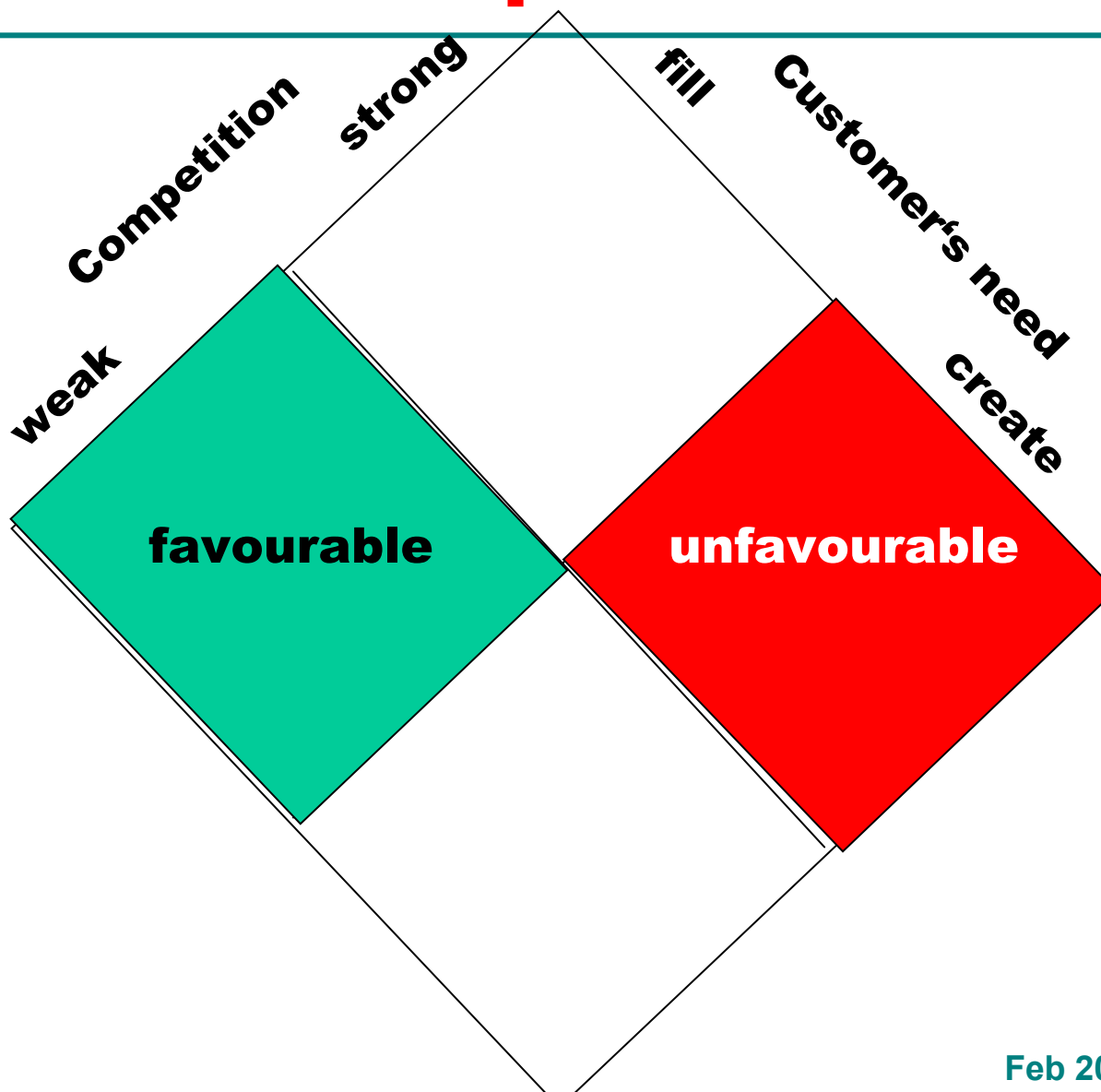
We are the Best – are we?

- **Value:** Cost Leadership, Quality, Reliability
- **Flexibility:** change aversion
- **Speed:** How many days for an offer?
- Risks? Bureaucracy?
- Handling of customer complaints?

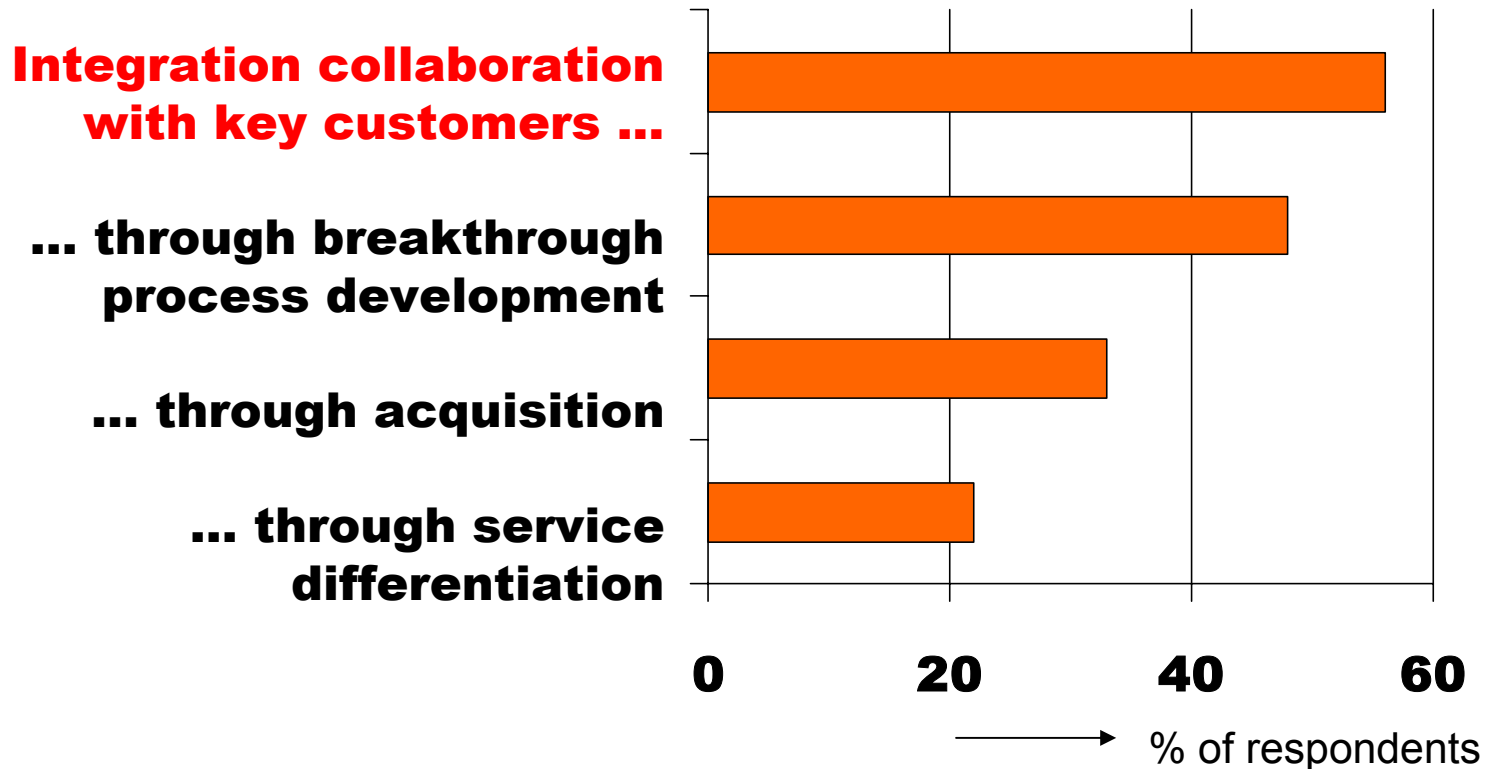
Yardsticks

- on time
- on budget
- first time right
- change control

The challenge for Fine Chemicals Business Development



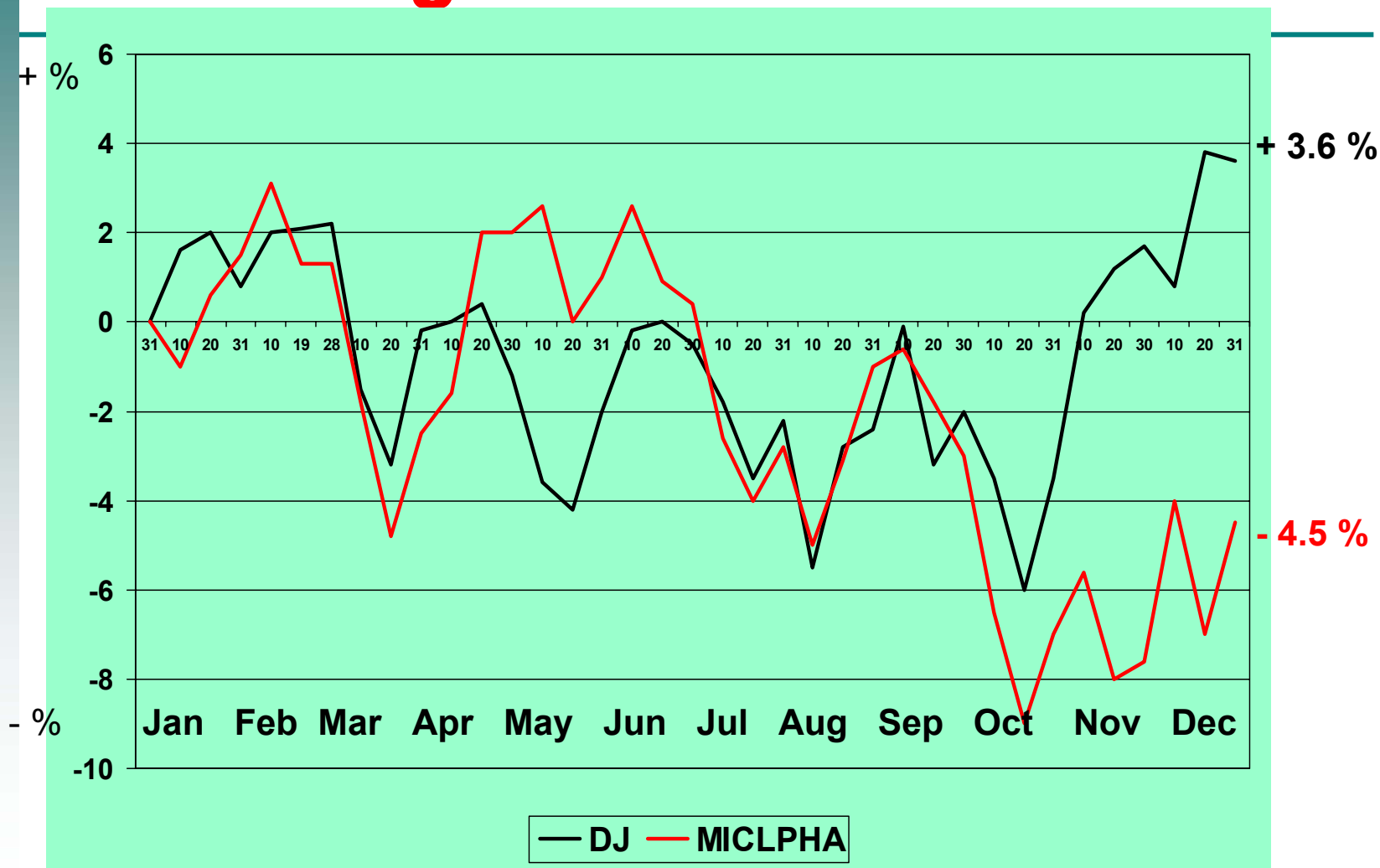
Marketing Excellence



source: accenture, 2003

Dow Jones Industrial vs. Bloomberg Pharma Index

2004



source: Bloomberg (adapted)

Two Bright Spots on the Demand Side

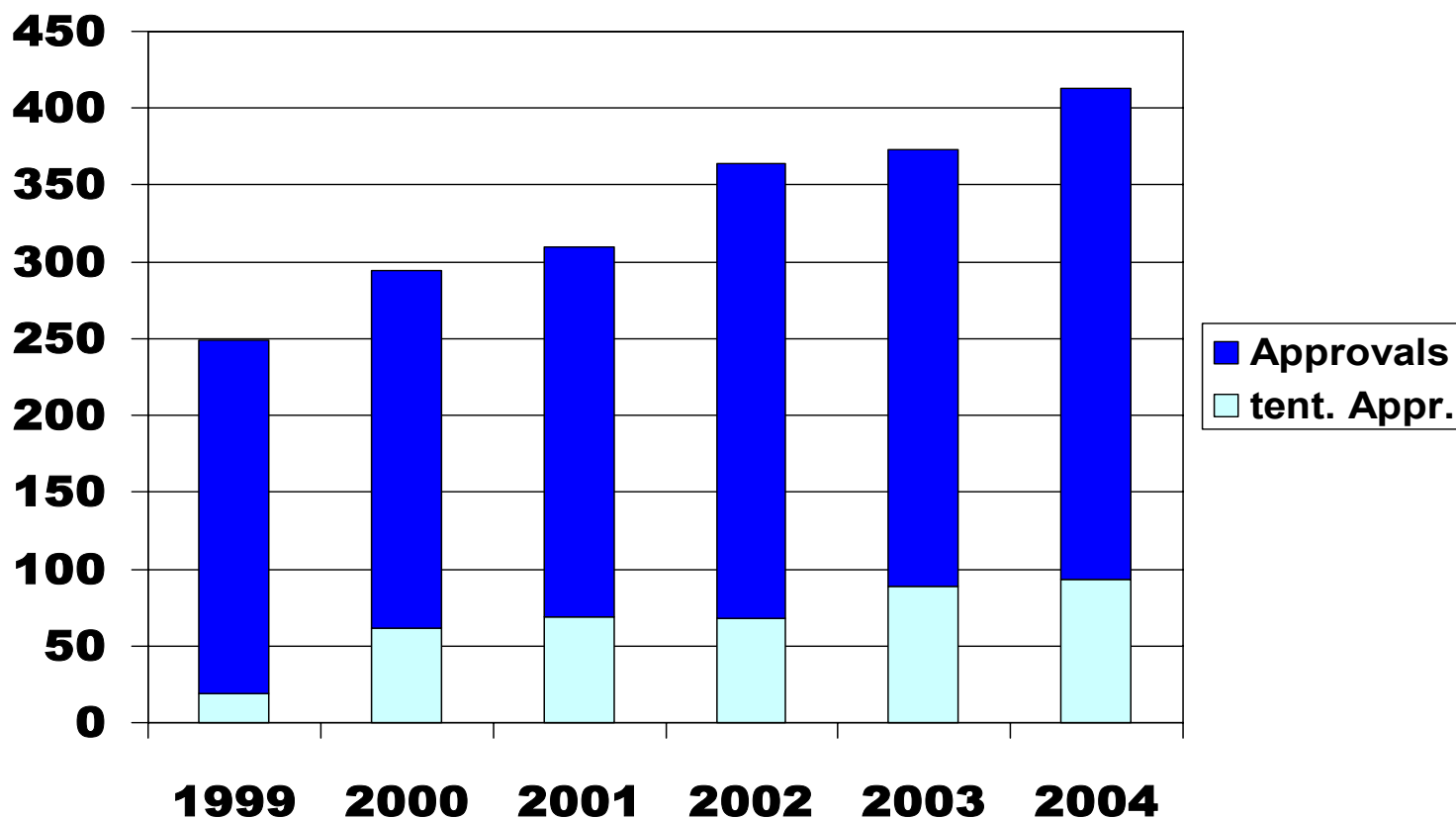
Custom Manufacturing

- Higher R&D productivity & new R&D tools coming to fruition
- Resolving Big Pharma's „Two Cultures Splits“
 - ❶ intellect intensive research à la Hollywood
 - ❷ capital intensive development, production and marketing à la Detroit

API-for-Generics

- Continued double digit growth of demand

Generic Drug Approvals



source: FDA / Center for Drug Evaluation & Research