

# *Intellectual Property and Pharmaceuticals*

## *Access to Medicines and Bioethics*

*WIPO Seminar, 2-3 May 2007*

*SAFS, Dr. Soňa Strachotová, MBA*

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# *Agenda*

- *SAFS*
  - *Pharmaceuticals & Biotechnologies*
    - *Pharmaceutical Industry*
  - *Access to Advanced Therapies*
    - *Slovak Republic „Case“*
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## *Slovak Association of Research Based Pharmaceutical Companies*

- Established in 1997
  - Exclusively R&D companies “Big Pharma“
  - Max 30 % of local generic turnover in value is allowed
  - 22 members, 55 % of total SK market value (14 bill. SKK )
  - 2 professionals: ED, PR
  - Board: 5 members elected every 2 years
  - EFPIA of member since 2004 ( EU federation of Pharmaceutical Industry and Associations)
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**What you can't see with your naked eye**

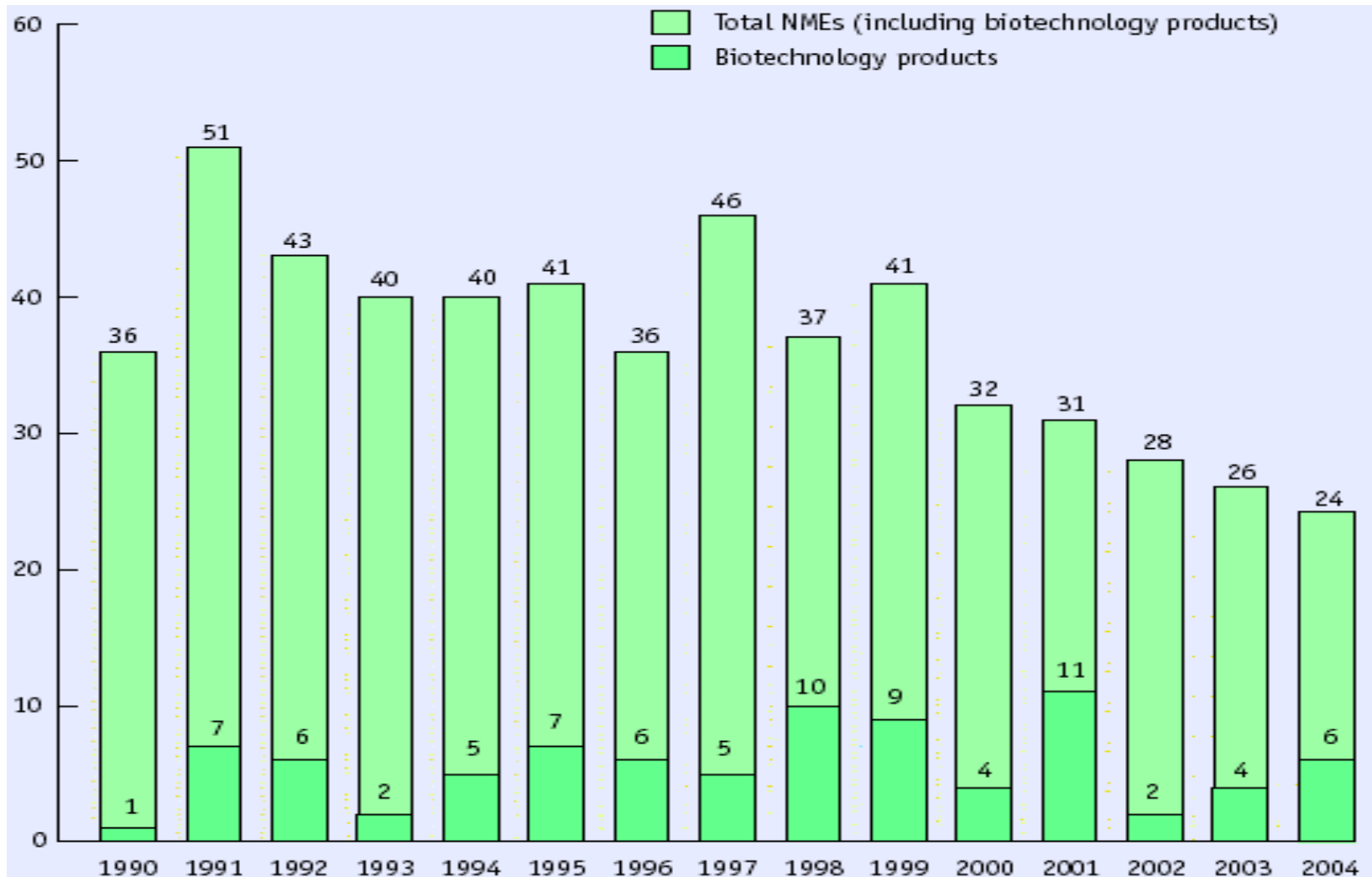


**May be even more hidden than you thought...**

*Pharmaceuticals*  
&  
*Biopharmaceuticals*

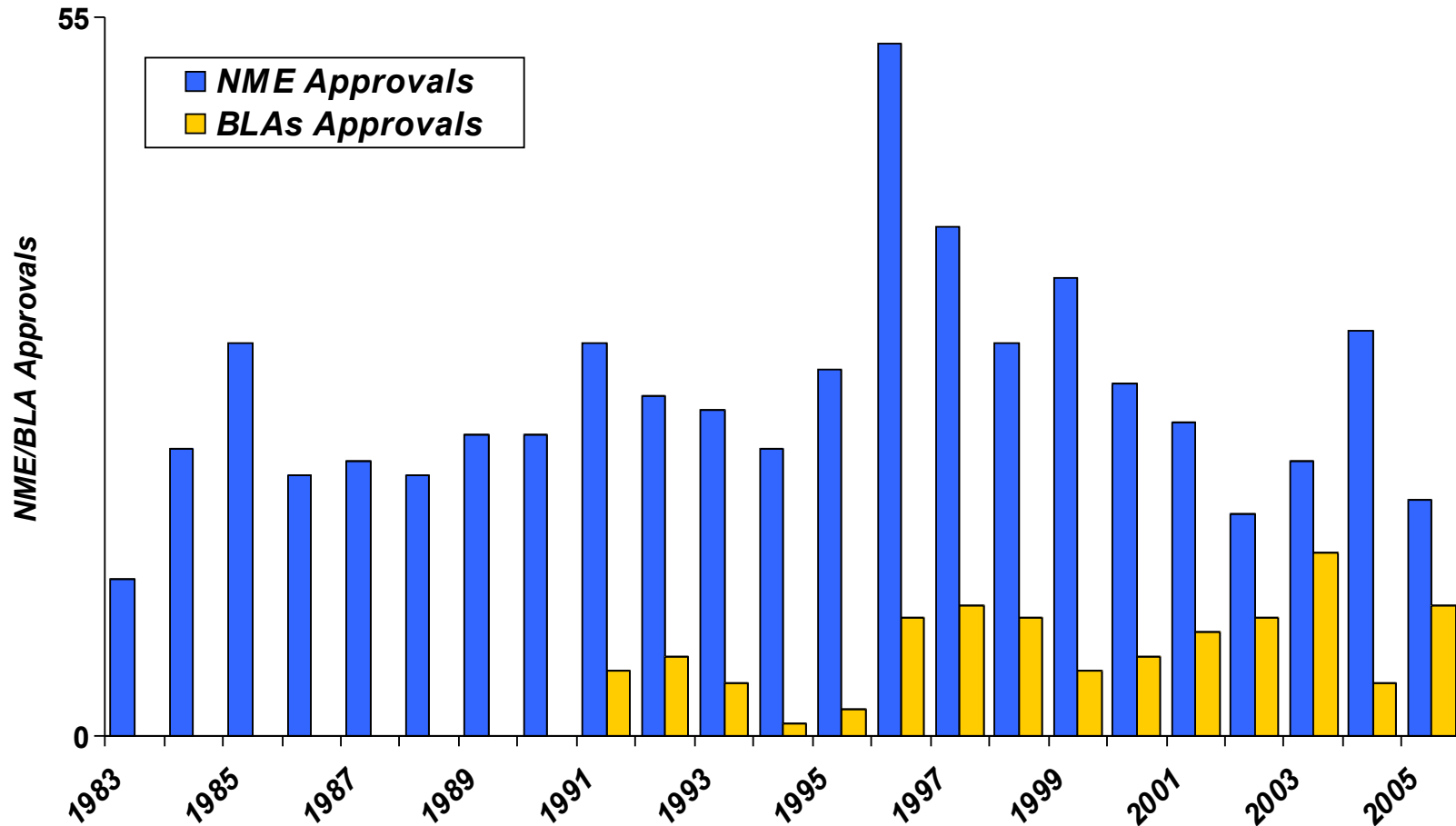
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# *No. of New Molecules and Biotech Product Worldwide 1990-2004*



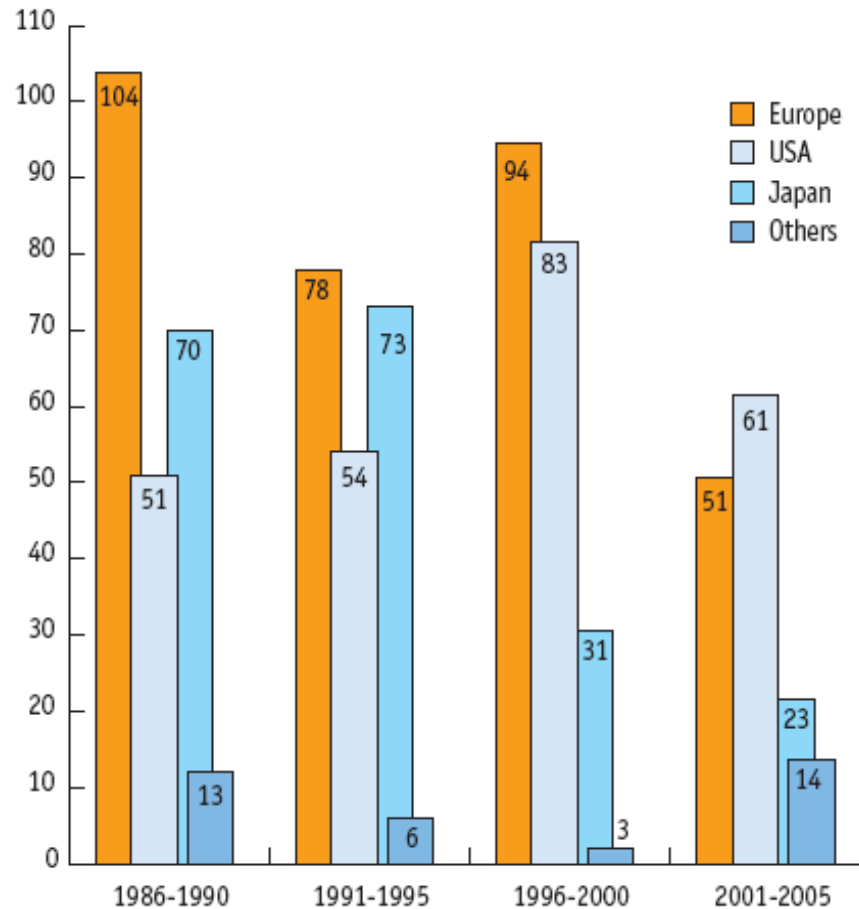
Source: CMR  
International

# *NME Approvals are Declining – Biologics are Filling the Void*



Source: FDA, K. Kaitin – Tufts Center for the Study of the Drug Development

# *Origin of New Chemical or Biological Entities (1986-2005)*

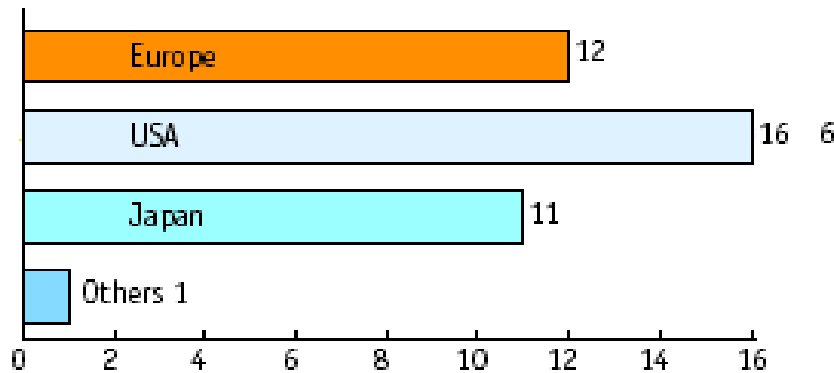


Source: SCRIIP – EFPIA calculations (according to nationality of mother company)



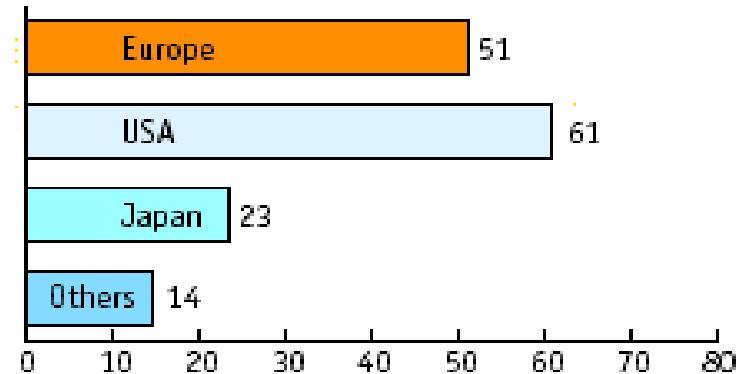
*Of the top 10 worldwide products in 2005, 7 originate from the US against 3 from Europe.*

ORIGIN OF THE TOP 40 COMPANIES  
BY R&D INVESTMENT, 2004-2005



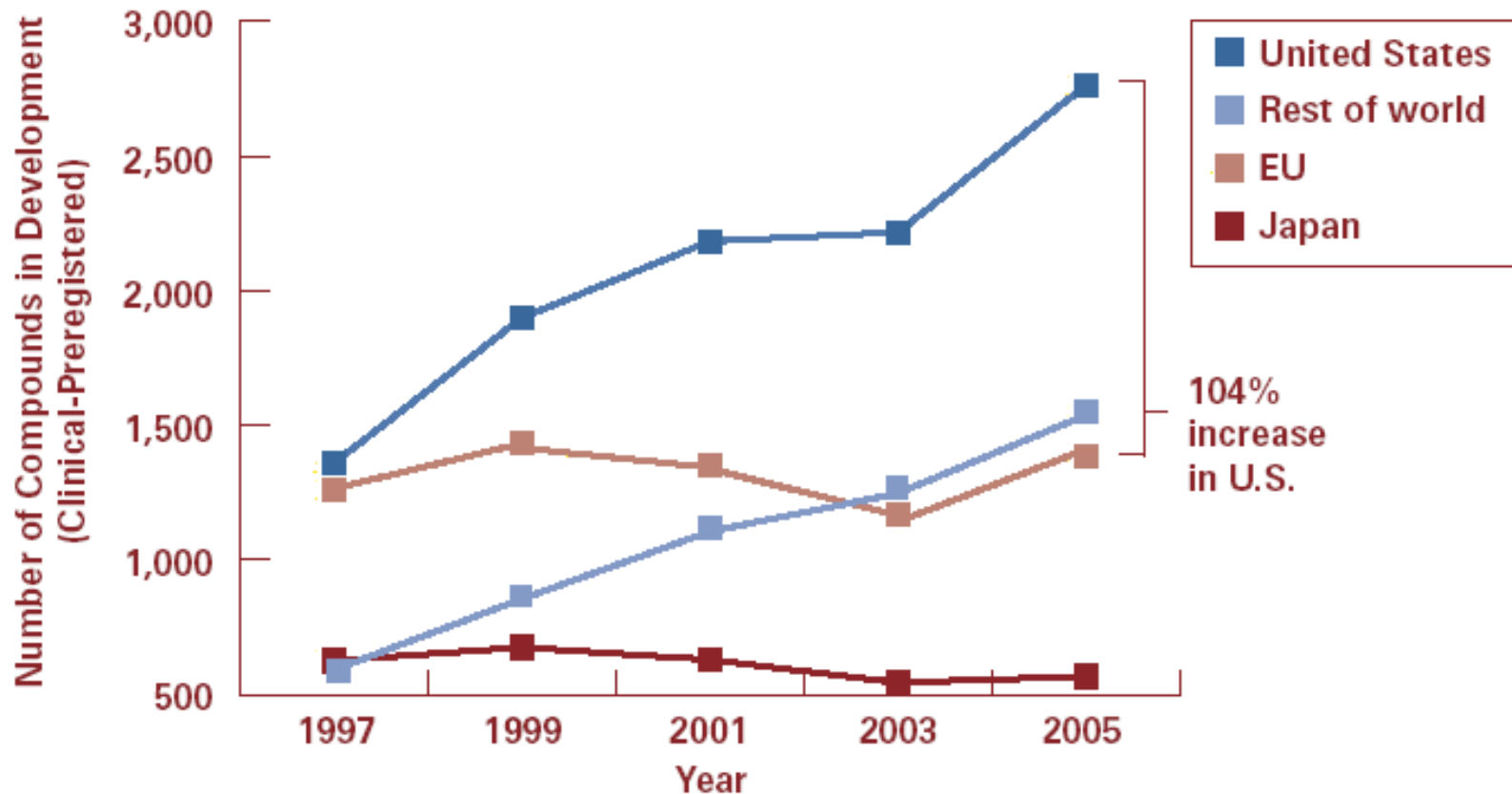
Source: UK Department of Trade and Industry,  
The 2005 R&D Scoreboard - EFPIA  
calculations

NEW CHEMICAL AND BIOLOGICAL  
ENTITIES LAUNCHED IN THE PAST  
FIVE YEARS, 2001-2005



Source: SCRIP, 2005 - EFPIA calculations

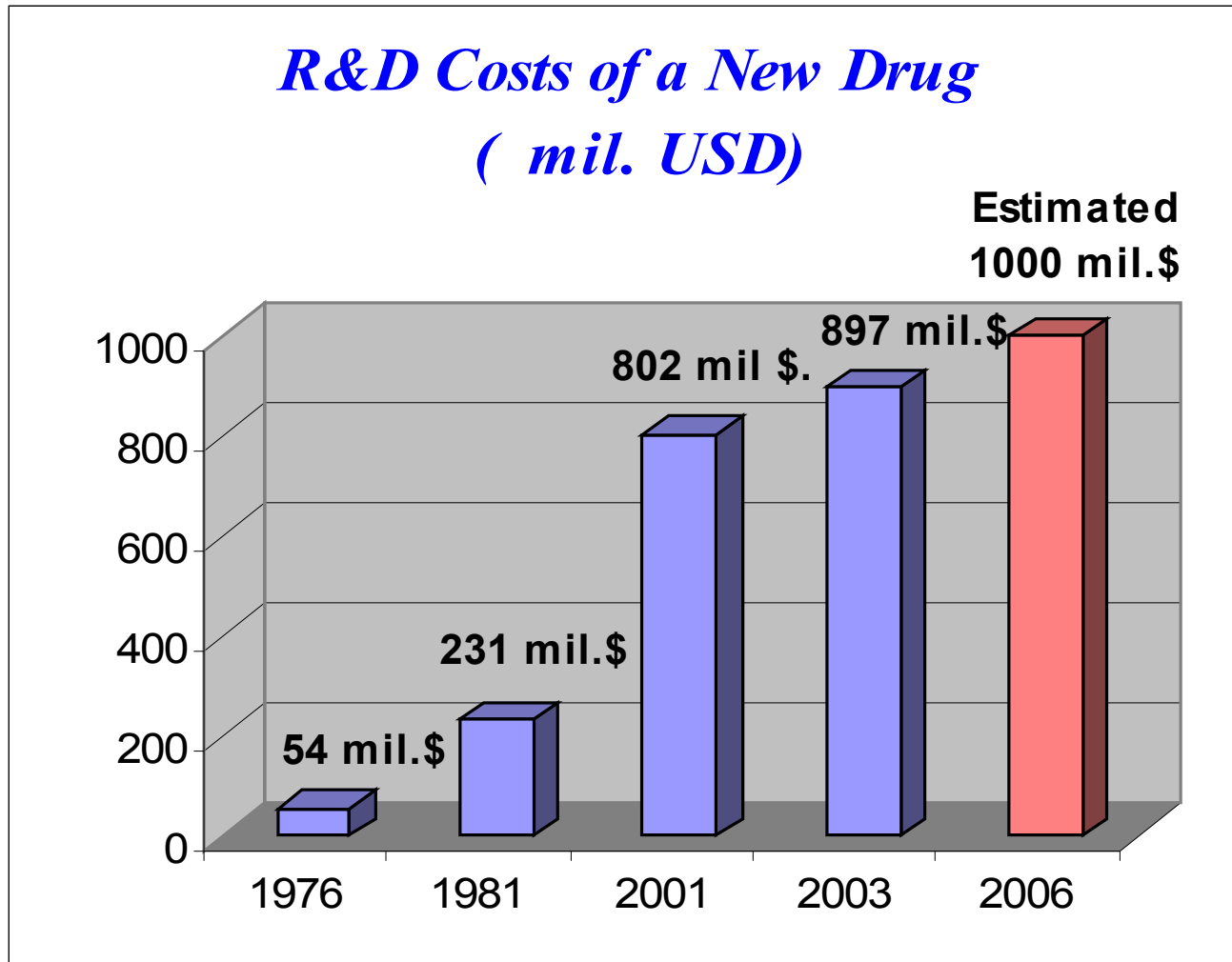
# *United States Leads the World in Biopharmaceutical Development*



Note: Comparisons were completed in June of each year. Some compounds will be at different phases for different indications.

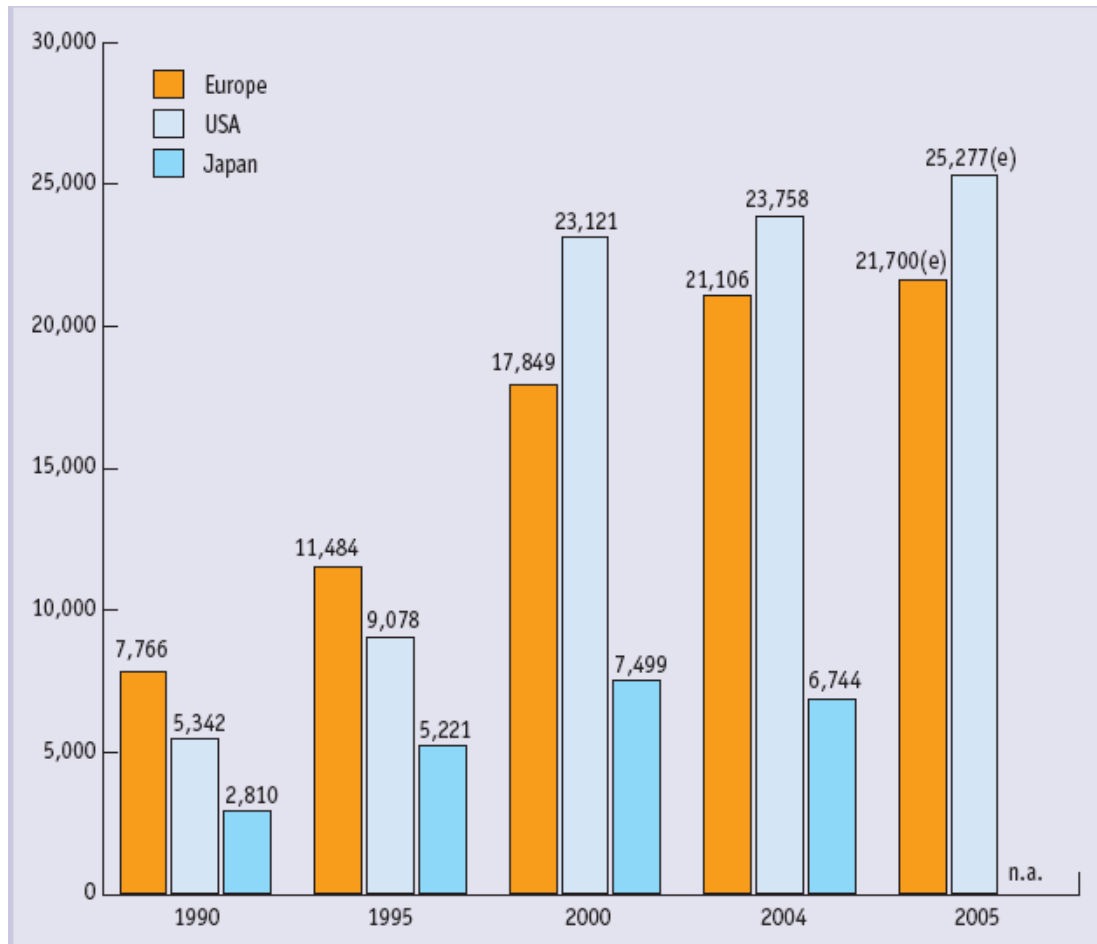
Source: Adis R&D Insight Database, customized run (December 2005).

# What are the reasons ?



# Pharma R & D investments by regions

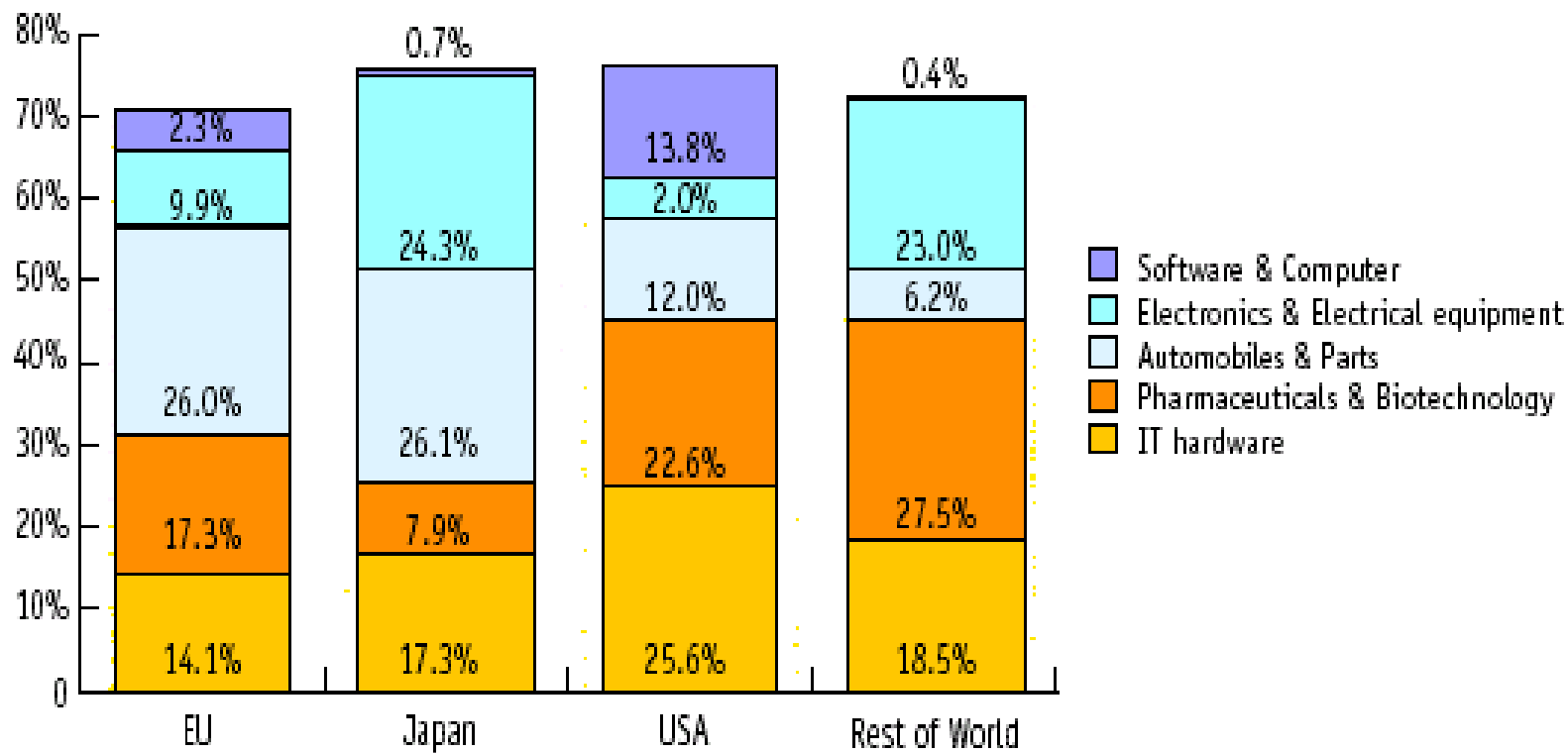
Pharmaceutical R&D Expenditure in Europe, USA and Japan  
(€ Million, Current Exchange Rates), 1990-2005



Source: EFPIA member associations, PhRMA, JPMA

# Shares of Top 5 Sectors in Total R&D Investment

(Top 942 Companies by Main World Region in 2004)



Source: The 2005 EU industrial R&D investment scoreboard, European Commission

# *Biopharmaceuticals*

## *Europe vs. USA (2005)*

	Europe	USA
Revenues (€ million)	7,862	38,413
R&D expenditure (€ million)	2,630	12,844
Net loss (€ million)	1,562	1,711
Number of public companies (units)	122	329
Number of employees (units)	33,340	137,400*

Although Europe's biopharmaceutical sector is growing Europe practically missed out on the first wave of biotech start-ups in the 1980s, most European biotech companies are significantly smaller than their US counterparts.

\*2004 data; Source: Ernst & Young, 'Beyond Borders, The Global Biotechnology Report 2006' (data relate only to publicly traded companies)

# *What is critical for success ?*

## Investments



Supportive environment for  
innovation

- » Drug Legislation
  - » IPR
  - » Economic considerations/ Health and HC as  
priority – motivating rewards for innovators
  - » Solved Ethical Considerations  
( or at least open public discussion..)
-

# *European Union*

## Drug legislation

- **Directive 2001/83/EC** on the Community Code relating to medicinal products for human use
- **Regulation (proposal) on advanced therapy medicinal products** amending Dir. 2001/83/EC and Reg. (EC) No. 726/2004  
Passed EP in first reading [on 25 April, 2007](#)

## IPR

- **Directive 98/44/EC** on the legal protection of biotechnological inventions
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## *EU – Ethical Considerations*

Advanced Therapy Regulation passed thanks to adoption of “Compromise package of amendments“. **With the compromise package, the subsidiarity and Member States’ national legislations on ethics will be fully respected.**

Indeed, the **European assessment and decision will not deprive a Member State of its right to reject a product based on their ethical values.**

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## *„Case“ Slovak Republic and Access to Advanced Therapies*

- EU Drug Legislation - transposed
  - IPR – transposed
  - Investments to health and HC ?
  - Ethical considerations ?
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## *SK – strict ethical regulations on bioresearch*

- **Act on Healthcare 576/2004 coll.**

### **§ 26, bod 10)**

Research without health indication cannot be provided on  
living human foetus or zygota

- **Criminal Act 300/2005 coll.**

**§ 161** - more detailed provisions, up to 15 yrs jail

- **Stem cell research, tissue engineering, gene and cell  
therapy ?**
-

## *What about Slovak patients ?*

- Strong need of public education and discussion based on scientific facts not emotions only....
- This could lead to less conservative approaches and more friendly environment for research and production investments

### *Otherwise*

- Some of “ Advanced Products“ should be accessible just thanks to free movements of goods or patients across EU....
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*Thank You for Attention*

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