

The Current Environment for Pharmaceutical Innovation:

Global Trends in Drug Development

Kenneth I Kaitin, Ph.D.
Director, Tufts Center for the Study of
Drug Development, Tufts University

MSD-Stockholm Network IP Academy
Tel-Aviv, Israel, February 16, 2006

30th
anniversary
1976–2006

Tufts Center for the Study of Drug Development

Agenda

- ◆ **The current environment**
- ◆ **Major challenges for developers**
- ◆ **Drug development metrics**
- ◆ **The generic drug industry**
- ◆ **The Israeli environment for innovation**
- ◆ **Conclusions**

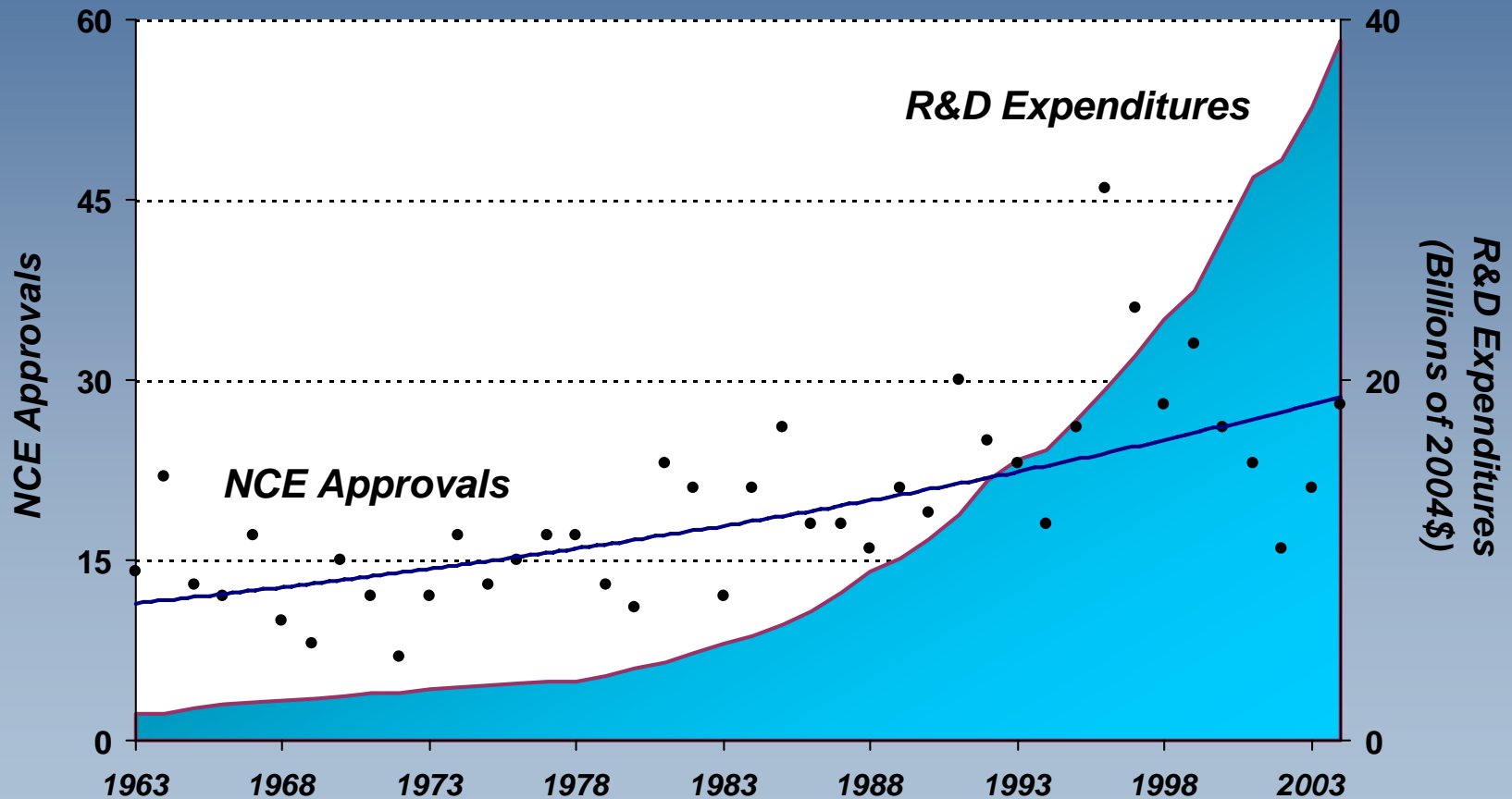
The Current Environment

Major Threats to Pharmaceutical Innovation

- ◆ **Industry productivity and output**
 - Rapidly rising R&D costs
 - Increasing size of clinical trials
 - Increasing regulatory pressure
- ◆ **Political threat of price controls in US**
 - Rising global healthcare costs
 - Global price disparities
- ◆ **Public discontent**
 - Safety of prescription drugs
 - Regulatory agency accountability
 - Industry Rx marketing practices

*Industry Productivity Concerns:
A Call to Action within the
Research-Based Industry*

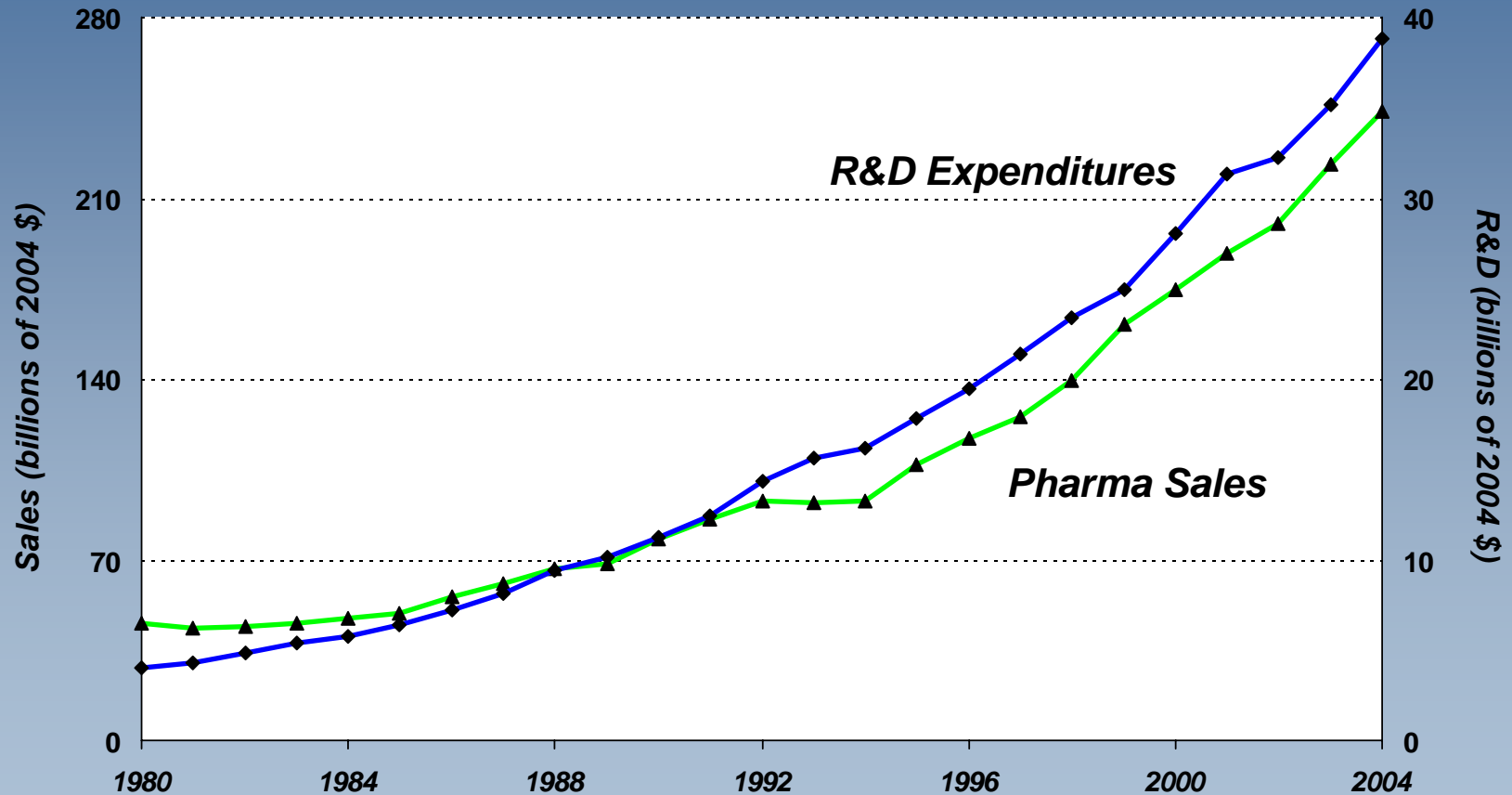
New Drug Approvals Are Not Keeping Pace with Rising R&D Spending



R&D expenditures are adjusted for inflation

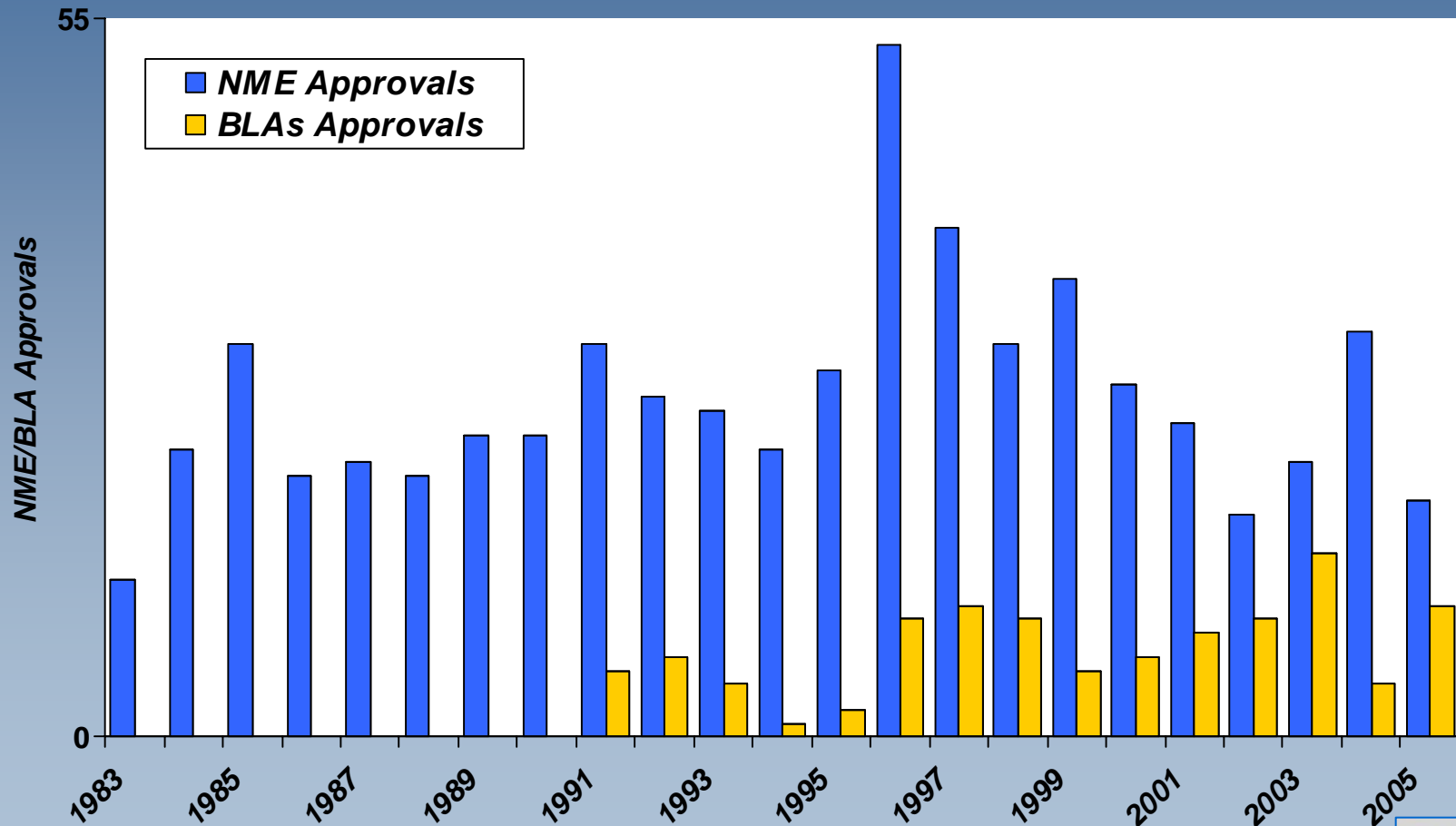
Source: Tufts CSDD Approved NCE Database, PhRMA, 2005

Pharma Industry Sales are Generally Keeping Pace with R&D Spending



Source: PhRMA, Tufts CSDD Analysis, 2005

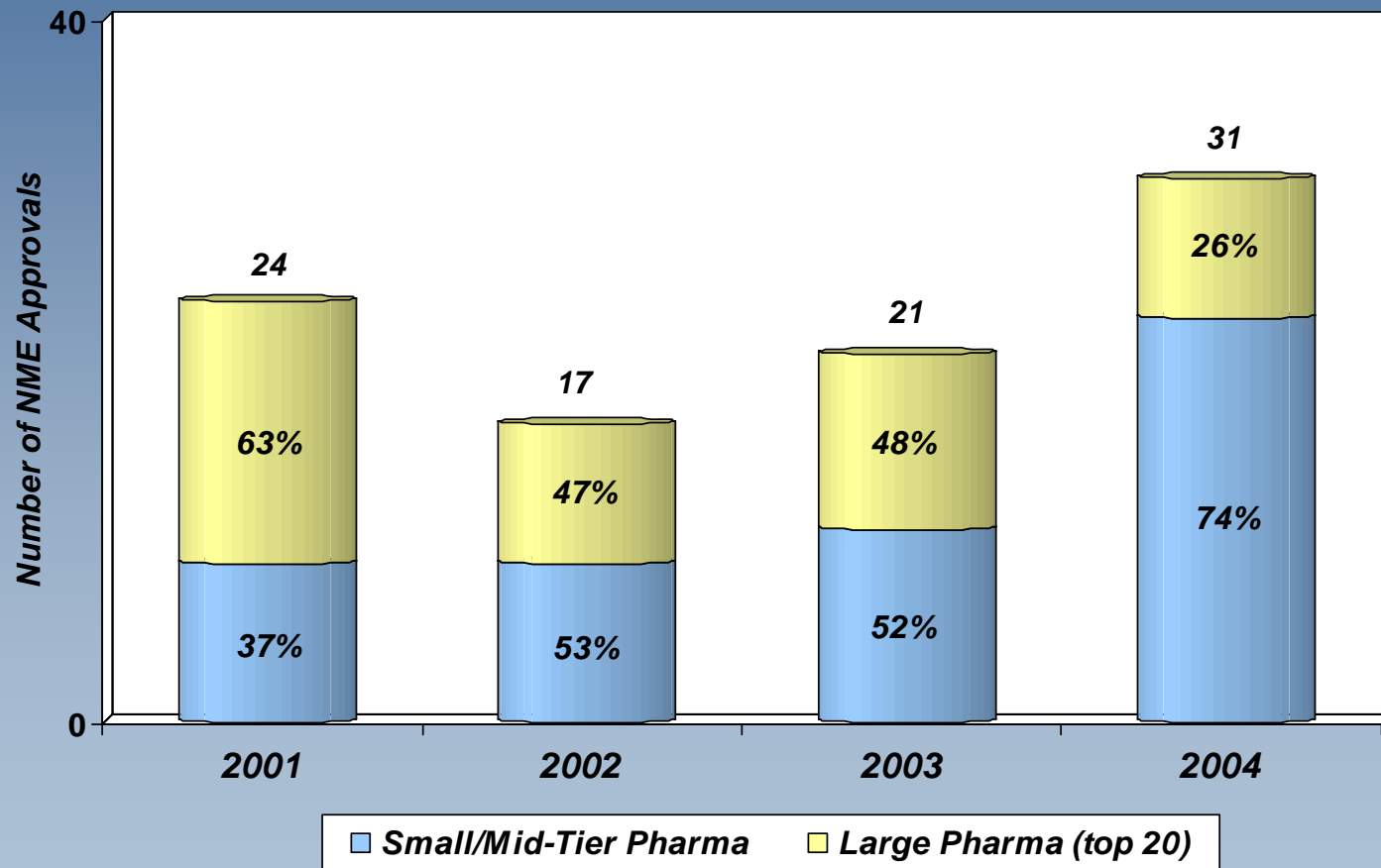
NME Approvals are Declining – Biologics are Filling the Void



Source: FDA

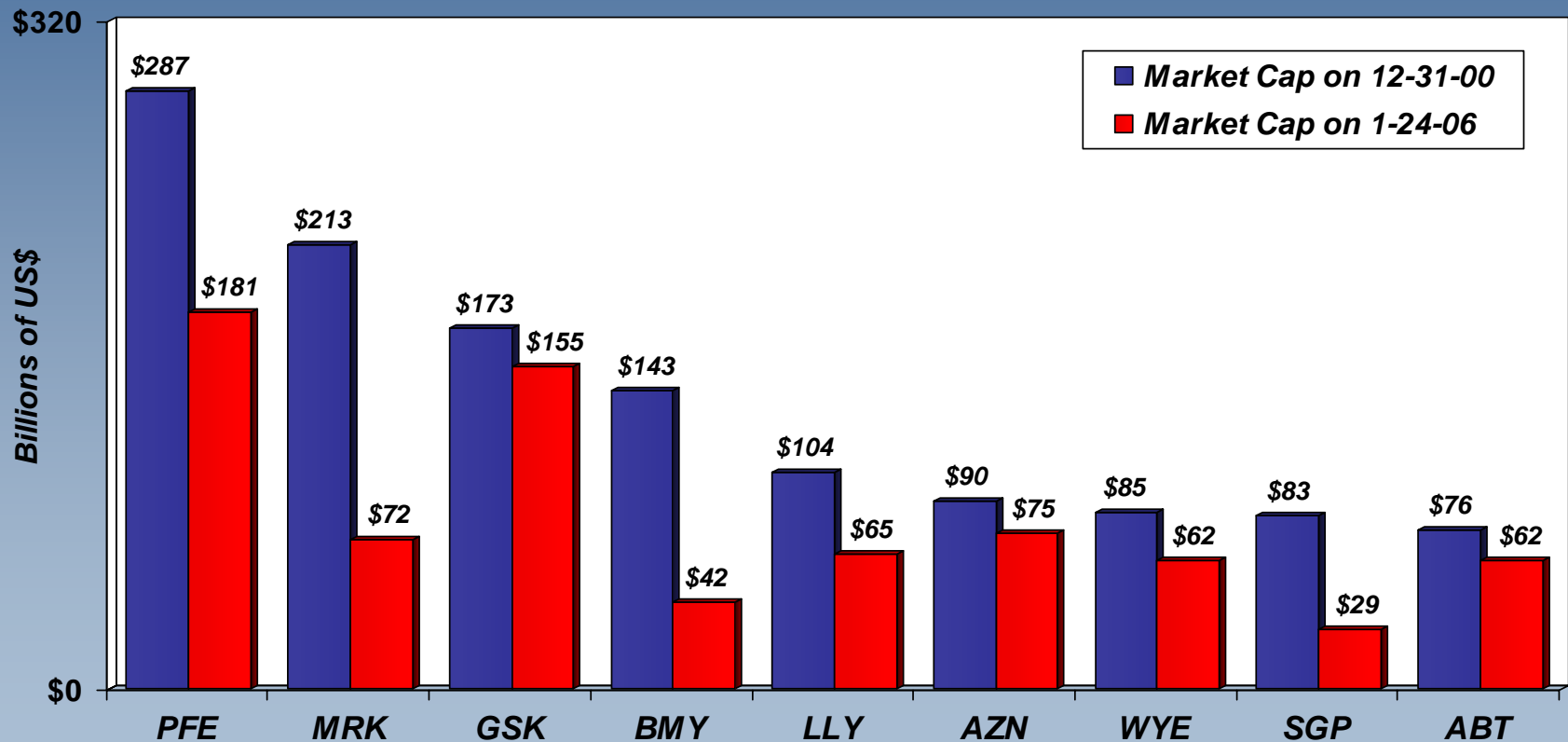


Growing Percentage of NME Approvals are from Small/Mid-Tier Pharma Firms



Source: Ventiv Health, 2005

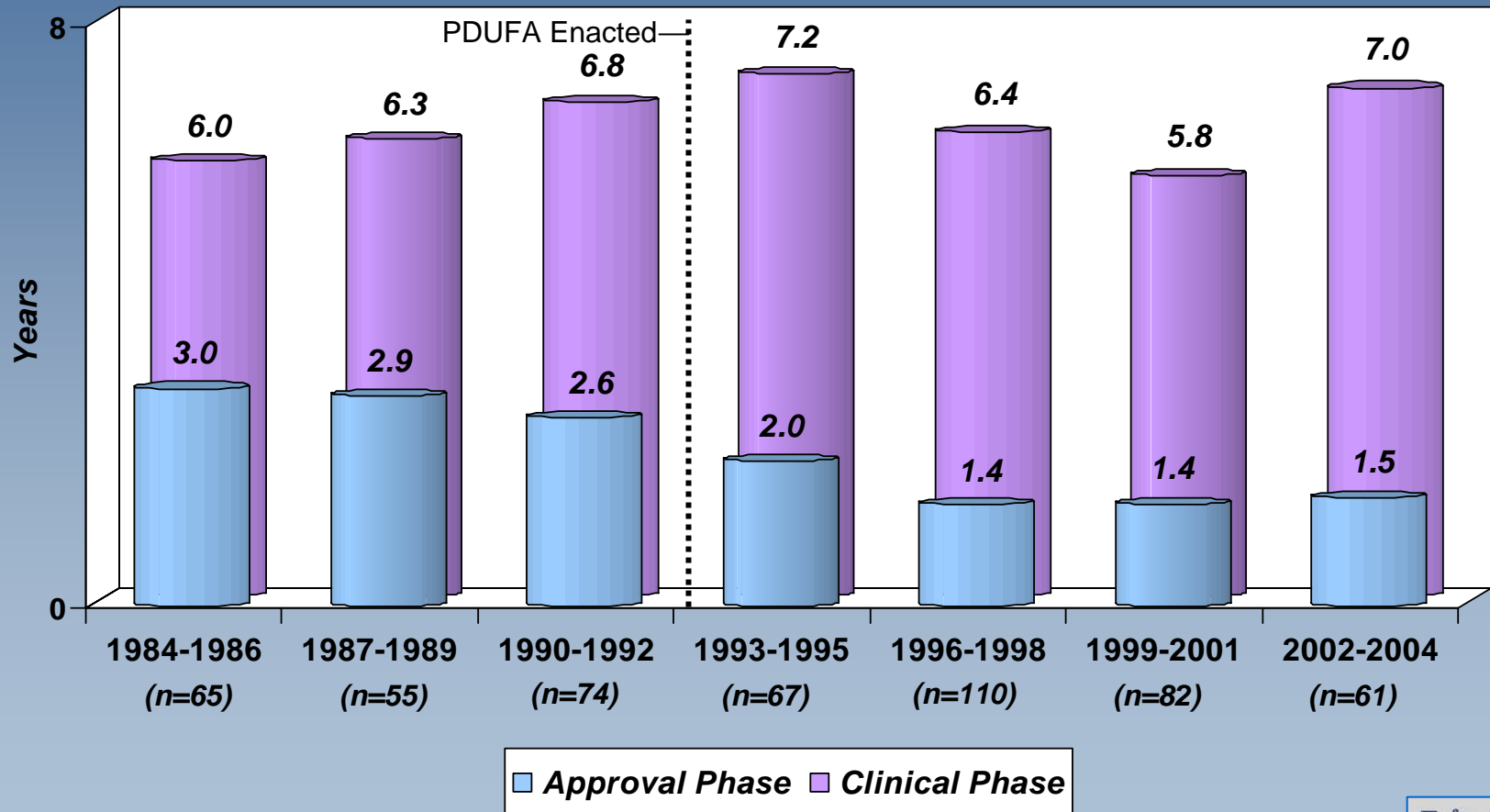
Market Cap has Declined for Many Major Pharmaceutical Firms



Source: www.valueline.com, Tufts CSDD analysis, 2006

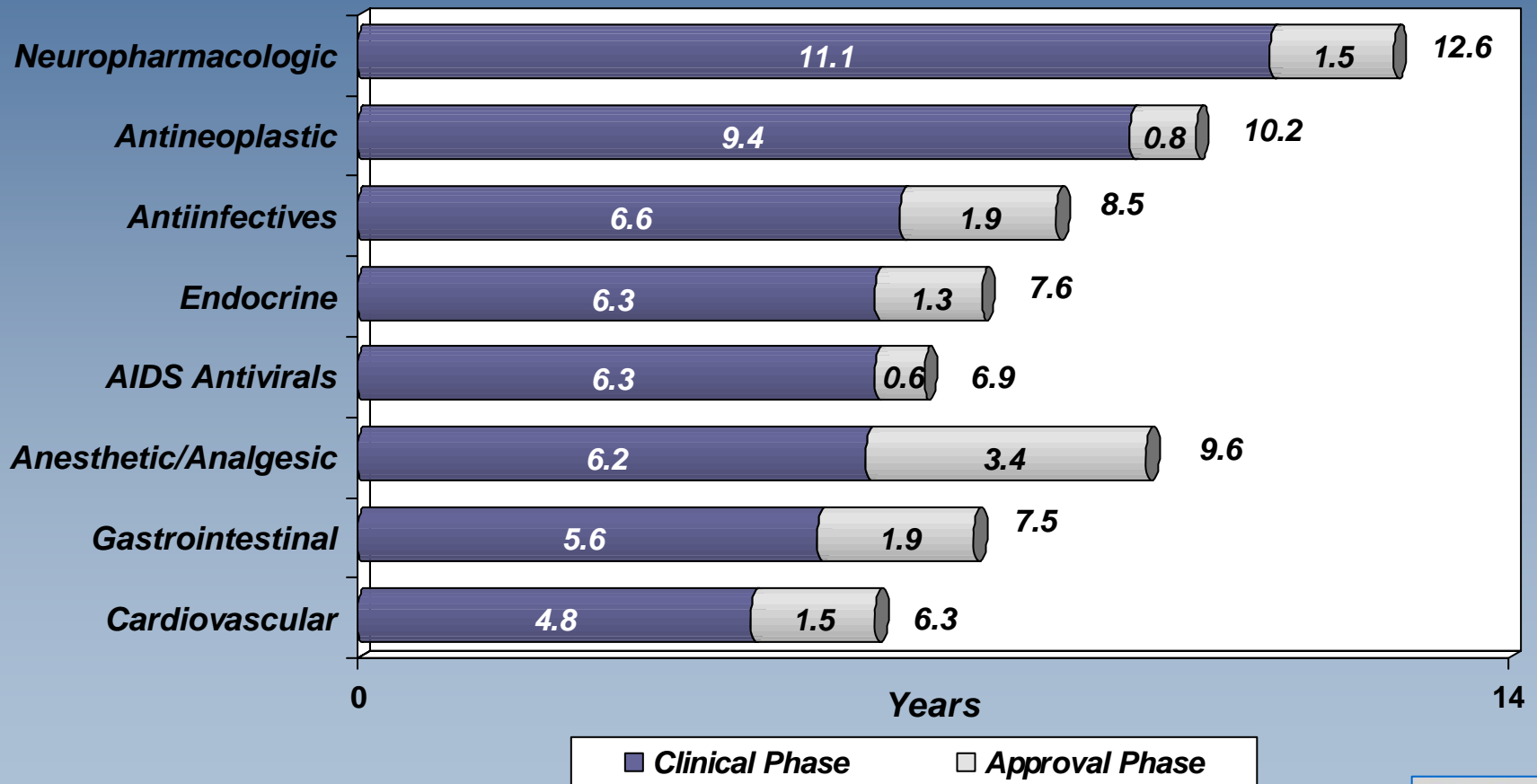
*Current Drug Development
Metrics*

Clinical and Approval Times over Two Decades



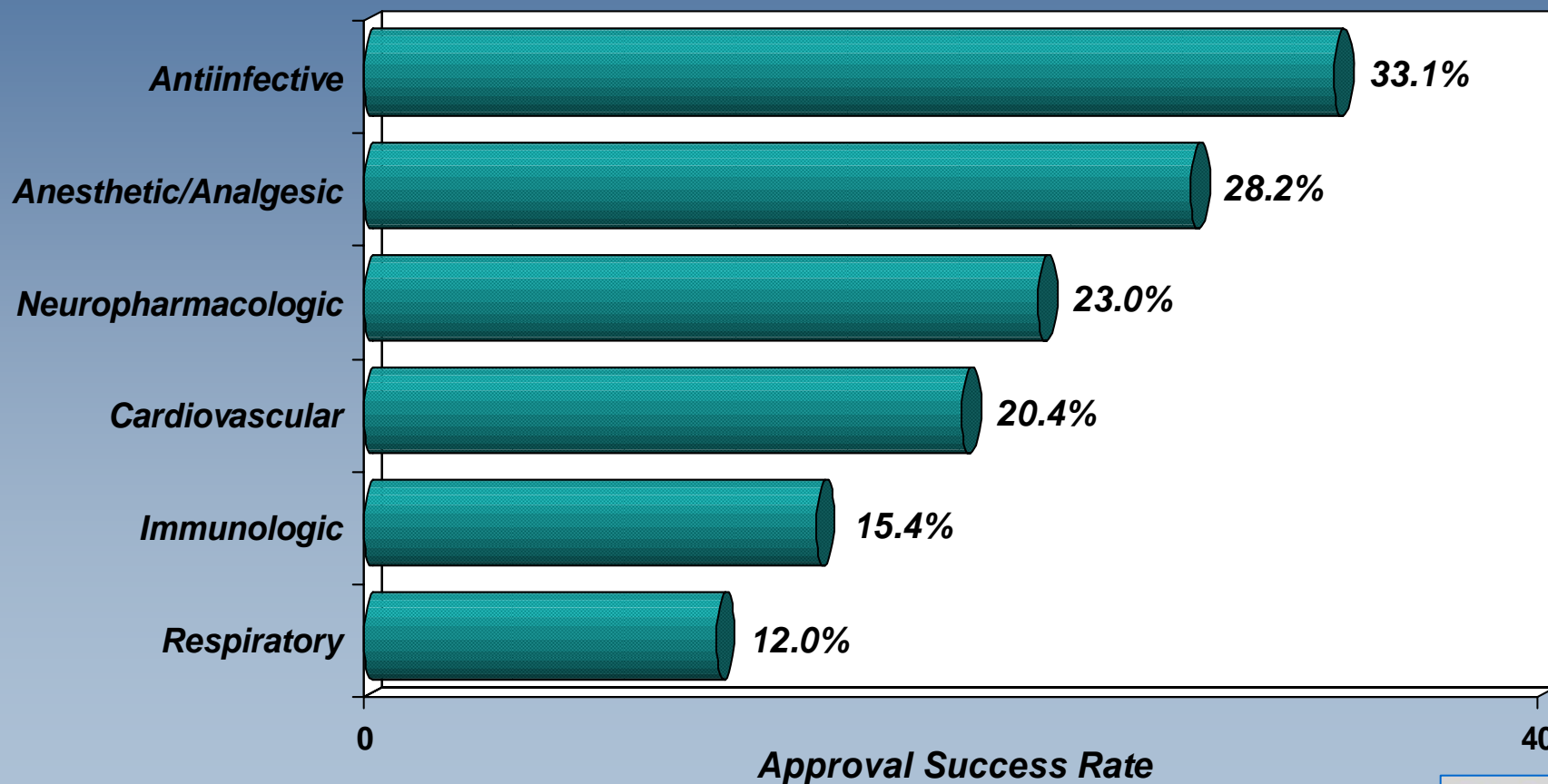
Source: Tufts CSDD Approved NCE Database, 2005

Clinical and Approval Times Vary Across Therapeutic Classes, 2002-04



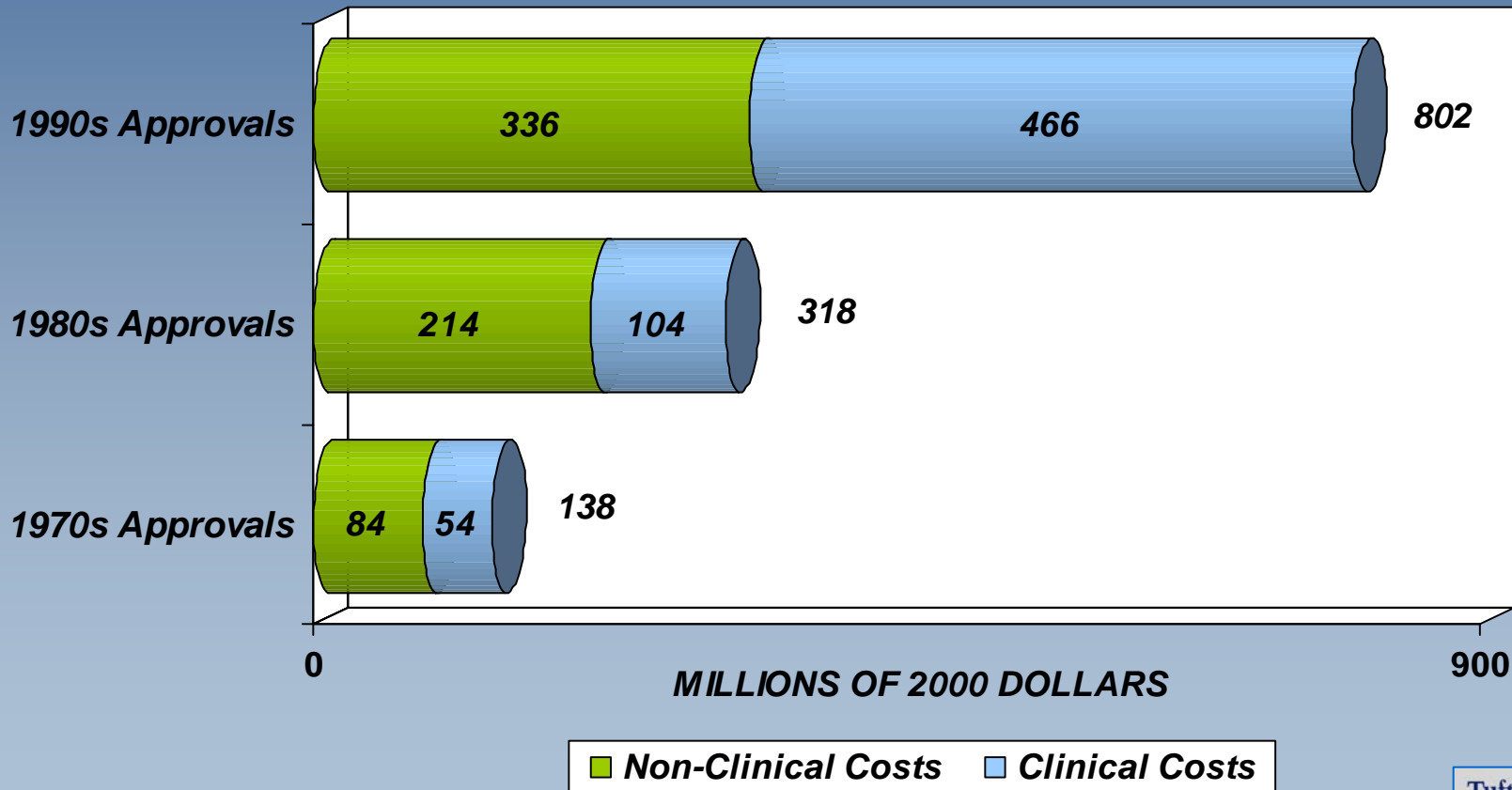
Source: Tufts CSDD, 2005

Approval Success Rates for NCEs Also Vary by Therapeutic Class



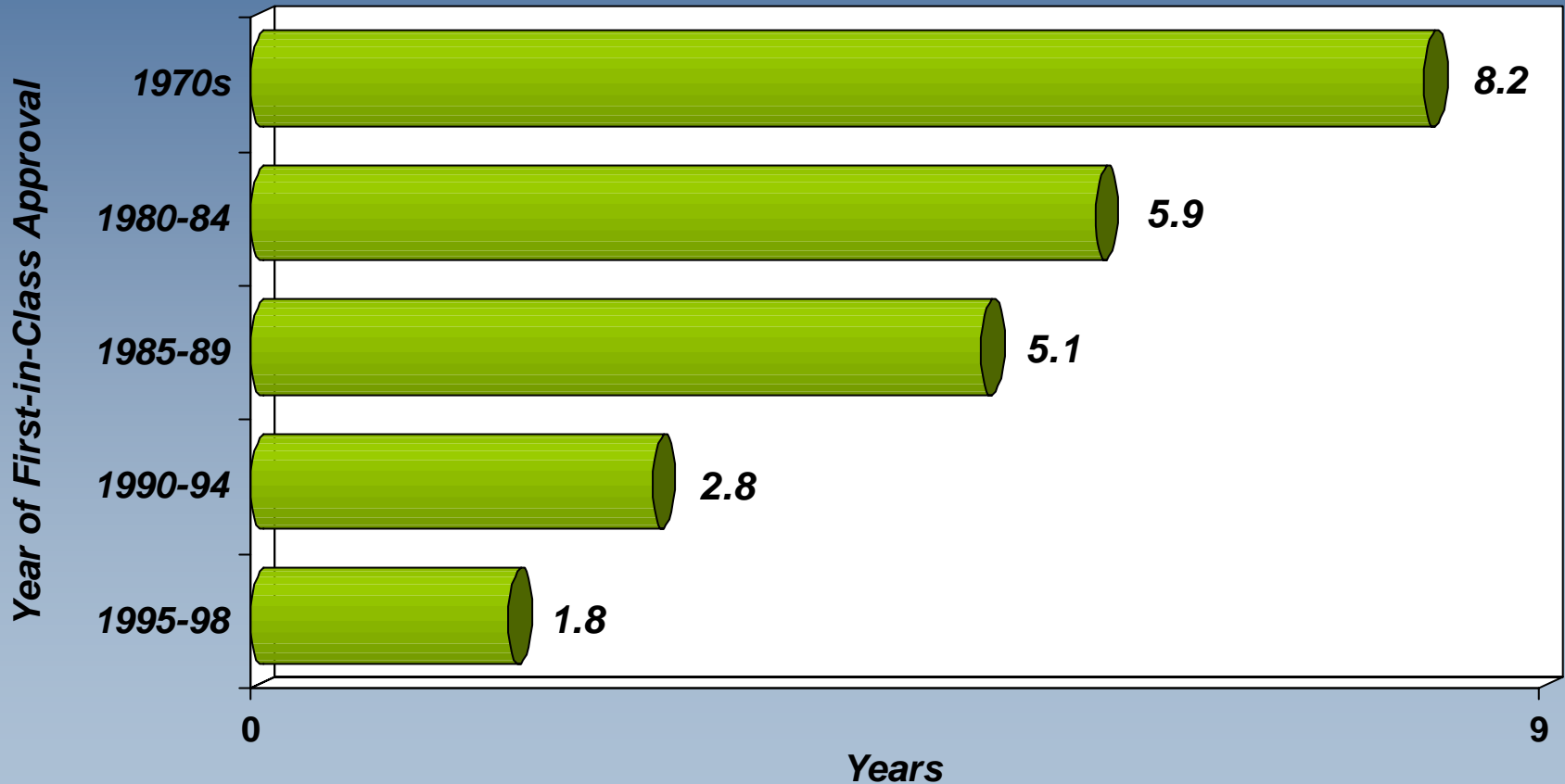
Source: DiMasi, Clin Pharm Ther, 2001;69:297-307

Capitalized Costs have Increased 481% from the 1970s to the 1990s



Source: DiMasi et al., *J Health Econ*, 2003;22:151-185

Market Exclusivity for First-in-Class has Declined: Mean Time to First Follow-on Approval



Source: DiMasi, Paquette, *Pharmacoeconomics* 2004;22(Suppl 2):1-14

Opportunities and Challenges for Research Based Pharma Industry

Opportunities

- ◆ Positive regulatory climate in US and EU
- ◆ Rapid expansion of scientific knowledge
- ◆ Move to smaller niche markets
- ◆ Collaborative relationships with small tier pharma and biotech firms

Challenges

- ◆ Rapidly rising R&D costs
- ◆ Declining market exclusivity periods
- ◆ M&As and industry consolidation
- ◆ Public/political pressure to stem healthcare costs

Industry Must . . .

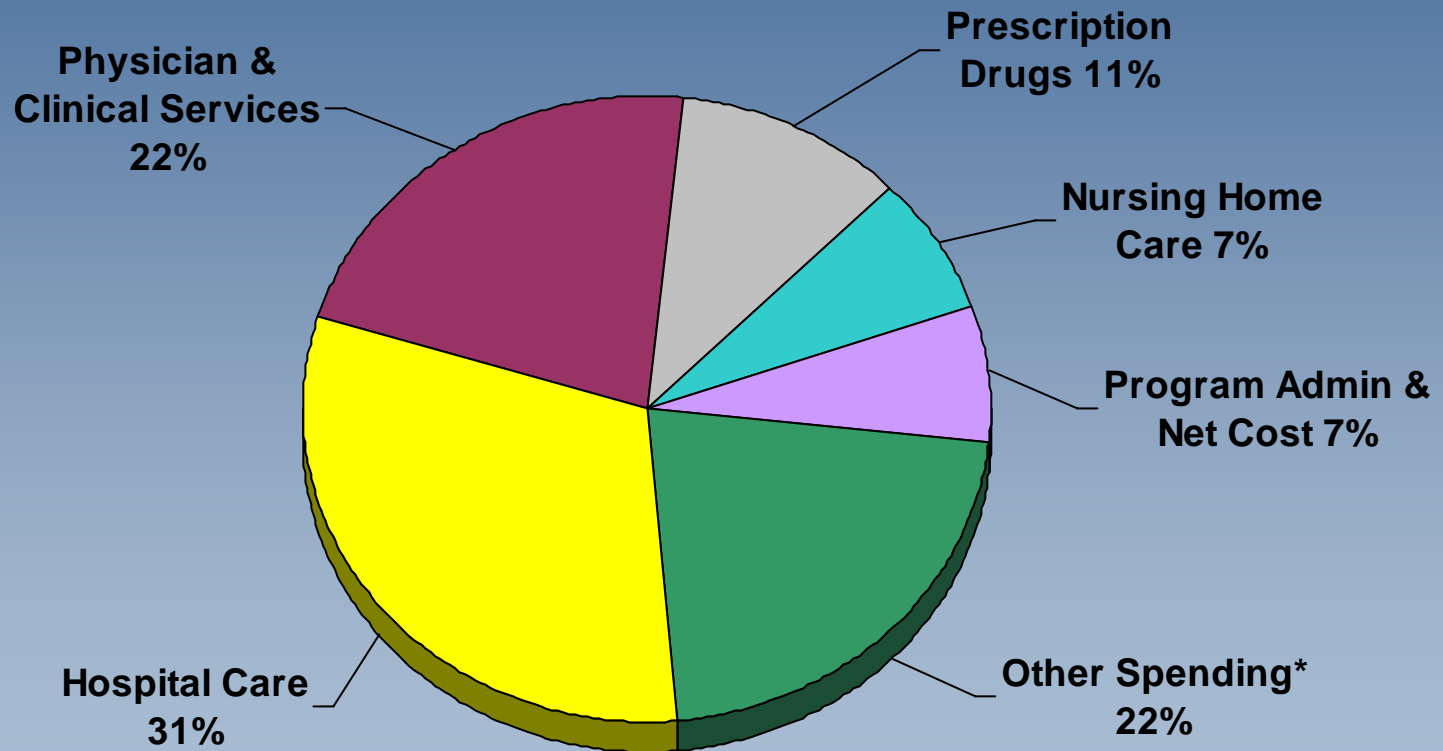
- ◆ Improve R&D efficiency
- ◆ Focus on core scientific strengths
- ◆ Develop global R&D capabilities
- ◆ Optimize strategic partnerships and collaborations
- ◆ Work closely with regulatory agencies

Government Must . . .

- ◆ Foster an environment that encourages innovation
- ◆ Be transparent
- ◆ Control health care costs without diminishing patient care or inhibiting R&D
- ◆ Create and maintain public trust

The Generic Drug Industry

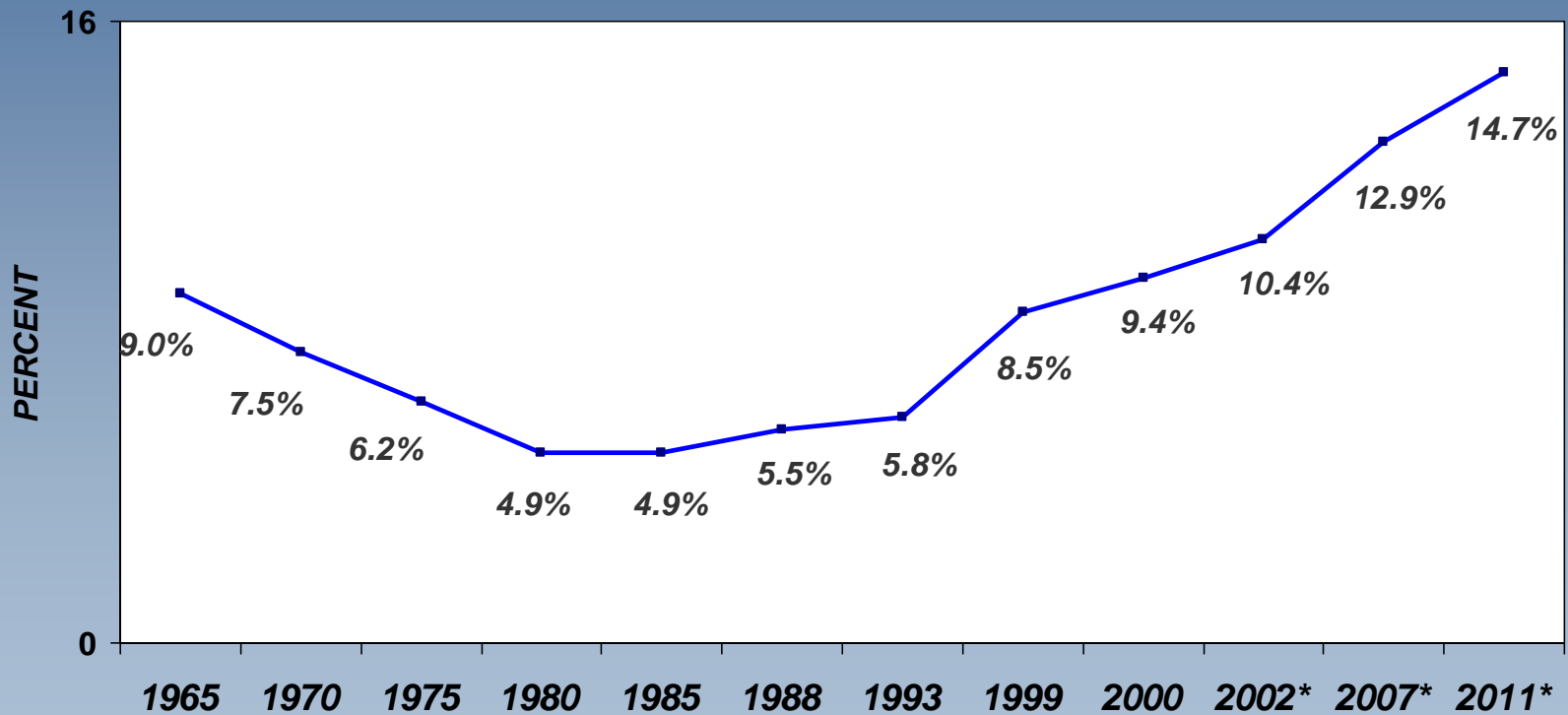
Total U.S. Health Care Expenditures by Category



**Other spending: dental services, other prof services, home health care, durable med products, OTC medicines, sundries, public health, research and construction*

Source: www.cms.hhs.gov/statistics, 1/08/04

Outpatient Prescription Drugs as a Percent of US Health Expenditures



* projected

Source: Centers for Medicare and Medicaid Services, 2002

Impact of Generic Drugs

- ◆ In US, 50-70% less expensive than brand name drugs
- ◆ Global sales increased by 24% in 2003 – compared with 8% sales growth for brand name drugs (*source: IMS Health*)
- ◆ In US, generics represent over half of filled prescriptions
- ◆ In US, UK, Canada, and Germany, generics account for 30% of drugs dispensed by volume (*source: IMS Health*)

Generic Drug Development Timeline

- Making or buying active ingredient and developing formulation *6-18 months*
- Bioequivalence testing *6-12 months*
- FDA approval *18-30 months*

- *Total time* *3-5 years*

- *Total cost (out-of-pocket)* *\$1-2 million*

Opportunities and Challenges for Generic Drug Companies

Opportunities

- ◆ Global effort to contain rising health care costs
- ◆ Many top selling branded drugs due to come off patent
- ◆ Biogenerics/biosimilars (EU in 2006; US in 2007 est)
- ◆ Change in Medicare drug benefit in US in 2006

Challenges

- ◆ Decline in output of top pharma companies
- ◆ Authorized generics
- ◆ Significant consolidation of generic industry

Mergers, Acquisitions, and Consolidation in the Generic Industry

Why

- ◆ Demand for generic product cost savings
- ◆ Upsurge in patent expirations
- ◆ Strength of leaders (e.g. Teva, Sandoz, Mylan)
- ◆ Generic drug price stability; prevent price erosion
- ◆ Increase market penetration
- ◆ Achieve economies of scale in development, production, and distribution (“internationalization” of the generic industry resulting in move to low-cost sites)

Novartis



Teva

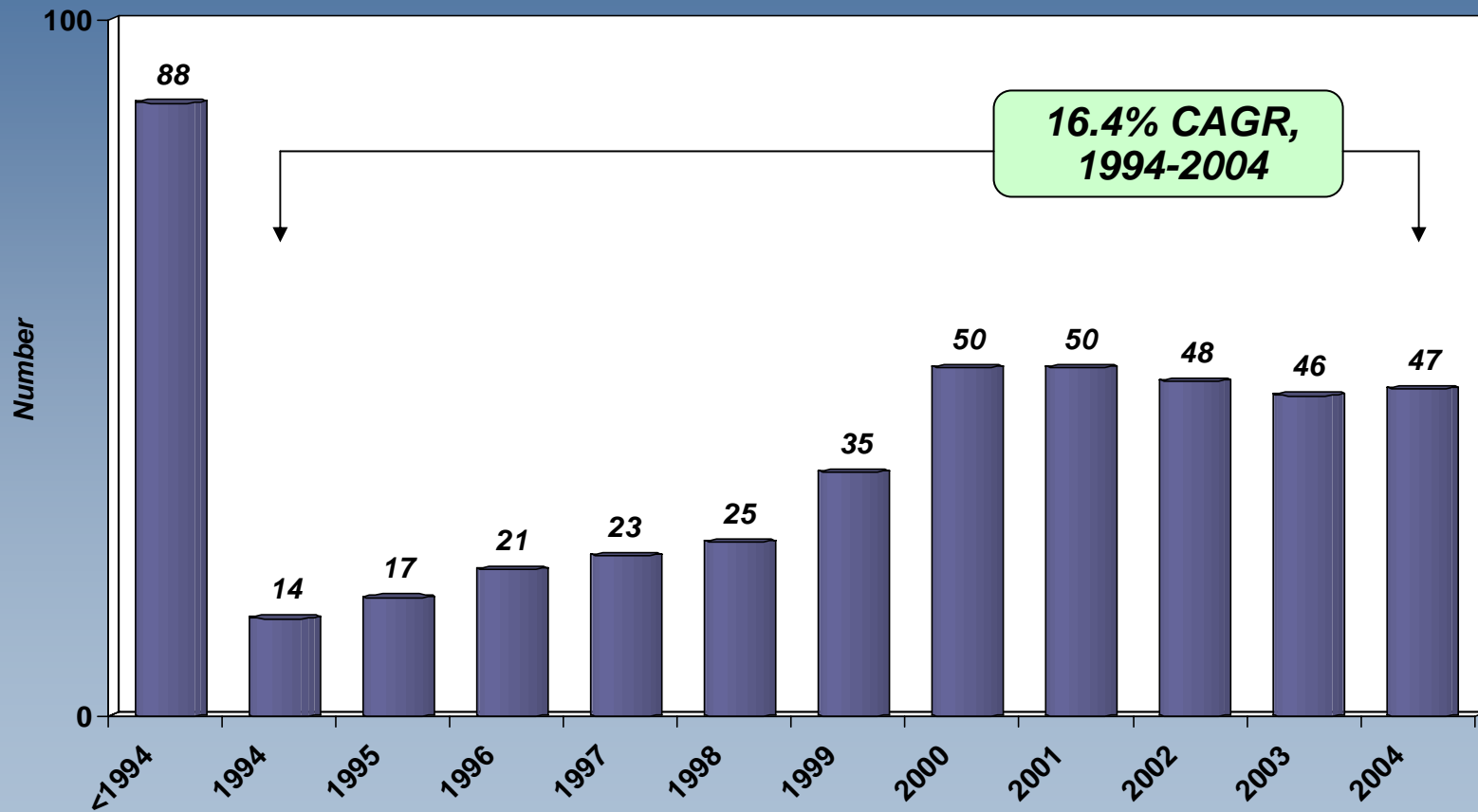


*The Environment for
Innovation in Israel*

Current Environment in Israel: Opportunities and Challenges

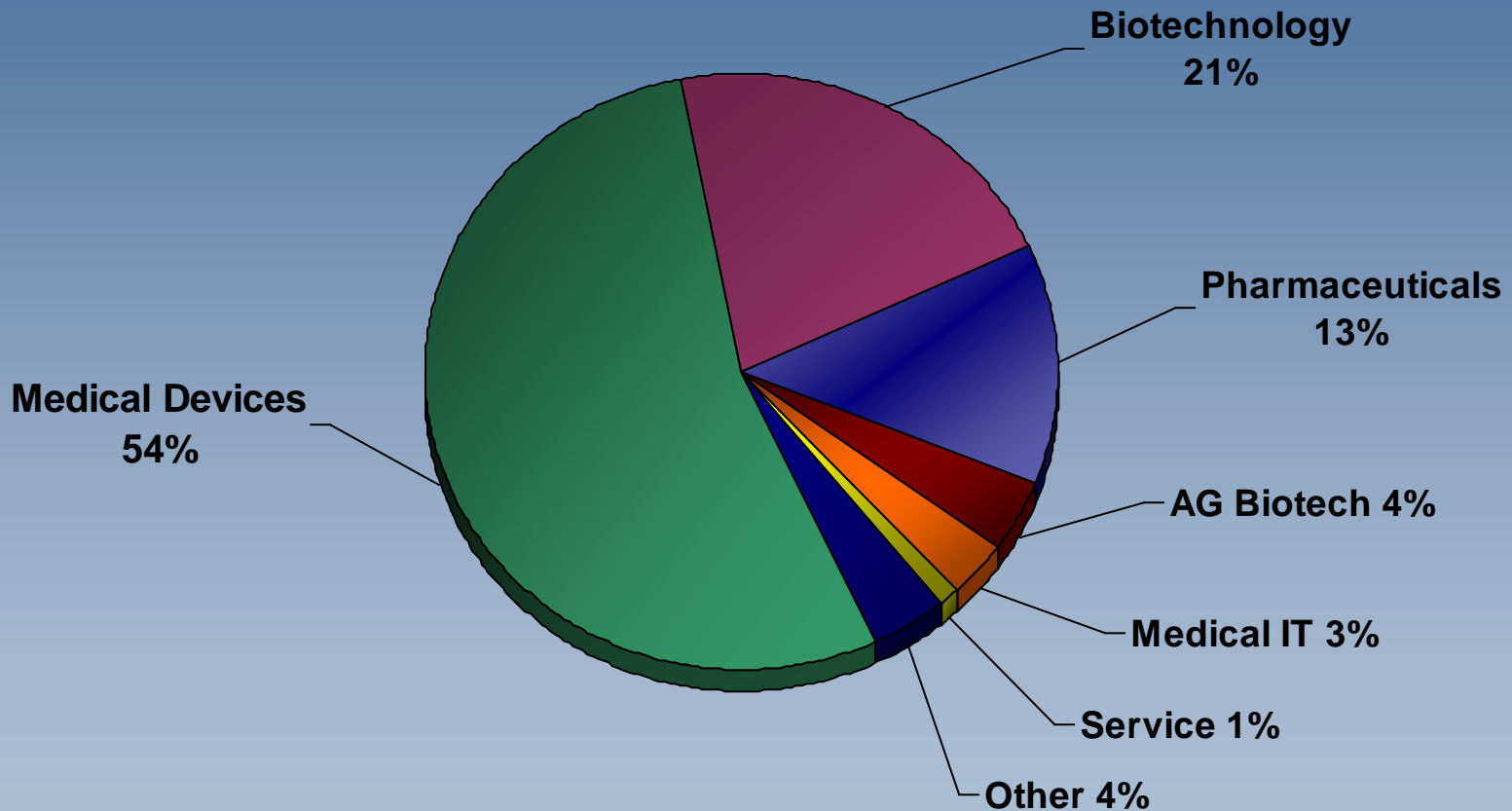
- ◆ Robust generic industry – nascent innovative/biotechnology industry
- ◆ Strong public and academic sector capabilities
- ◆ Creation of innovation clusters and regional incubators (e.g. JBC)
- ◆ Government support of innovation (e.g. amendment of tax rules for foreign investors)

Number of Israeli Life Science Companies Founded



Source: Israeli Life Sciences Industry Database
http://www.ilsj.org.il/industry_profile.asp

Sectors of Israeli Life Sciences Industry

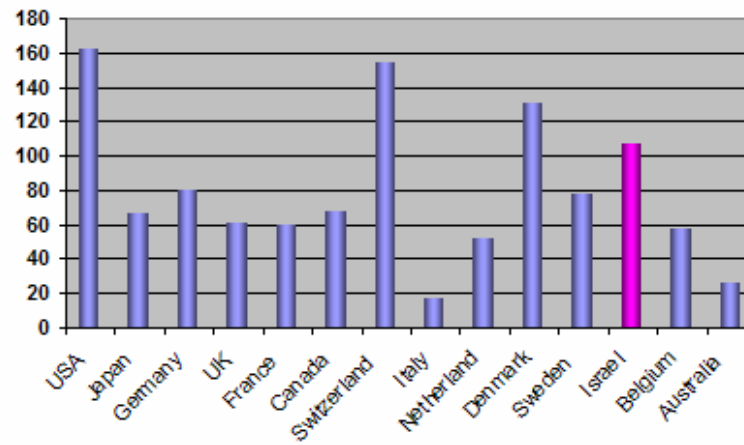


Source: Israeli Life Sciences Industry Database
http://www.ilsj.org.il/industry_profile.asp

Israel Ranks High Globally in Life Science Patents

Figure 11

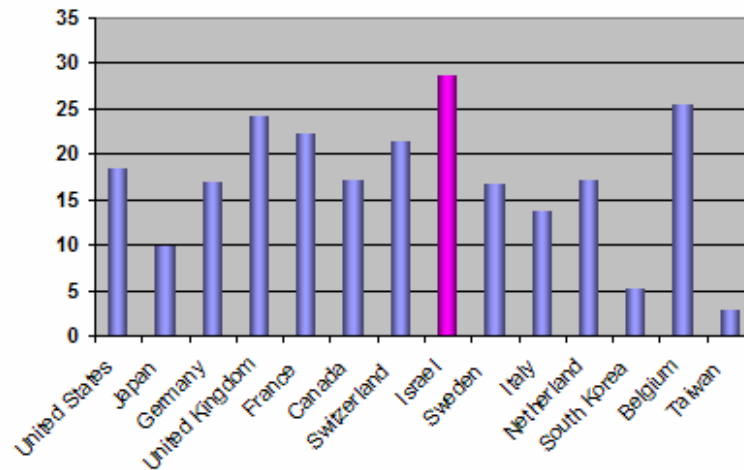
Number of BioPharma Patents per Million Capita



Source: www.uspto.gov, Analysis: ILSI ©

Figure 12

Life Science Patents
% of Total Patents Registered



Source: www.uspto.gov, Analysis: ILSI ©

Barriers to Innovation: Israel Comprises 1/200th of Global R&D Spend – Why?

- ◆ In general, IP laws favor generic industry
 - Govt's narrow interpretation of WTO TRIPS agreement
 - Supplementary Protection Certificate System, intro 1998, (similar to 1984 DPC-PTR Act in USA) under-leveraged
- ◆ Non-optimal tech transfer environment (contrast with 1980s Bayh/Dole and Stevenson/Wydler Acts in USA) hampers public-private partnerships (esp. govt bodies and industry)
- ◆ Restrictive cost containment and reimbursement policies (e.g. France, Canada) inhibit market presence and foreign investment
- ◆ Need for commitment to translational research (e.g. FDA Critical Path and NIH Roadmap) and regulatory assistance/transparency

Daily International Pharma Alert™

Published by FDAnews and Business Monitor International

TrackWise QMS: The Proven cGxP Solution used by 120 FDA Regulated Companies

TrackWise, the most modular and fully integrated solution to meet your FDA requirements: CAPA, Change Control, Complaints, Audit Mangement and more. No custom code required!

[Click Here](#)

TRACKWISE
The Ultimate
Tracking Software

✓ Lower
Regulatory
Exposure

100% 21 CFR
Part 11 Compliant!

[Click Here](#)



The Center for Professional Innovation & Education

For our current
course schedule

The Global Leader in Pharmaceutical, Biotech, Medical Device and Skin/Cosmetic Training

Vol. 3, No. 12

Wednesday, Jan. 18, 2006

Global Analysis

Asia

INDIA APPROVES 10-YEAR DRUG INDUSTRY PLAN

The Indian government has accepted a new ten-year plan set out by the National Competitiveness Council (NMCC) to help the domestic drug industry develop and improve its global competitiveness.

The plan is based on the premise that improving competitiveness — rather than protectionism or subsidies — is the way to help the pharmaceutical sector mature. Measures include improved training for medical workers and a new fund to provide financing for technological up-grades. Further, the plan calls for a reworking of various taxes that are stifling the industry's growth, and urges an increase in private/public partnerships.

The Confederation of Indian Industry believes that the country's drug industry could reach a value of US\$48bn in the next 10 years. This could be driven by generic drug exports and India's growing stature as a location for R&D offshoring.

However, industry watchers claim that the domestic market's competitiveness is the key to the market's ability to fulfil its potential. It is claimed that consolidation and new incentives for innovation would stimulate this process.

NEW!...

Pharma Online

Business Monitor
International's
Pharmaceuticals &
Healthcare Service
features:

- Quarterly market surveys
- 5-year forecasts
- Daily analyses
- Competitive intelligence

[Click here for a
FREE trial ▶▶▶](#)

**Managing
CAPA
Systems**

TrackWise QMS: The Proven cGxP Solution used by 120 FDA Regulated Companies

TrackWise, the most modular and fully integrated solution to meet your FDA requirements: CAPA, Change Control, Complaints, Audit Mangement and more. No custom code required!

[Click Here](#)



Smaller Classes • The Best Instructors • Proven Results



Third Annual

Medical Device Quality Congress

May 2-4, 2006

Leading the Way to Better Performance with Quality Systems Compliance

San Diego, CA

Vol. 3, No. 29

Friday, Feb. 10, 2006

Global Analysis

Asia

INDIAN PLANS EXPANSION OF BIOTECH INDUSTRY

India is planning to create 10 new biotech parks by 2010 primarily through public-private schemes, according to the Department of Biotechnology. The country already has large-scale biotechnology facilities in Hyderabad, Bangalore, Mumbai and Pune. Although India has yet to develop a novel biotech drug, the government forecasts that the sector has the potential to generate US\$5bn in revenue by 2010 and create one million jobs.

To help foster growth, the government has launched a National Biotechnology Development Policy. One priority is increasing the number of PhD programmes in the life sciences in order to create a larger pool of skilled scientists. The Indian government need look no further than Singapore, where the government has invested US\$2bn attracting promising scientific talent to the country, and one-third of PhD students undertaking research are foreigners.

Many industry observers have also called for greater tax incentives for biotech, which is an intensely research-based industry. As a result, Indian companies often invest up to 20-30% of their operating costs on R&D. Government support, especially for small and medium-sized companies in the early stages of product development, will be the key to sustaining sector development. UK-based biotech companies can receive tax credits representing 40-50% of R&D costs.

Bottom Line . . .

- **Ability to operate in a stable and commercially rewarding environment increases chances of collaboration and shared growth.**

- **R&D flourishes in an environment where regulatory processes are predictable and transparent and stimulate innovation.**

What Government Must Do to Foster Innovation

- **Ensure adequate IP protection.**
- **Avoid restrictive pricing policies.**
- **Promote technology transfer.**
- **Create regulatory consistency and transparency.**

Conclusions

Conclusions

- ◆ **Research based pharma firms must meet the demand for innovative new drugs in the face of rising R&D costs and growing cost containment pressure.**
- ◆ **Government must work to create an environment that provides incentives to innovate while controlling health care spending and ensuring patient access to new medicines.**
- ◆ **Industry and government must work together to meet the challenge.**

Tufts Center for the Study of Drug Development

Tufts University, Boston, Massachusetts, USA

Kenneth I Kaitin, Ph.D., Director

Website

<http://csdd.tufts.edu>

email

kenneth.kaitin@tufts.edu

30th
anniversary
1976–2006

Tufts Center for the Study of Drug Development