

New R&D Strategies in The Research Based Industry

Boosting Productivity and ROI

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Current Realities for Pharmaceutical Developers

- ◆ Patents on many high revenue products are expiring
- ◆ Marketplace is highly competitive and reimbursement environment is increasingly restrictive
- ◆ Public support has declined
- ◆ There's a new regulatory regime in the U.S. and new regulatory hurdles
- ◆ Drug development process is long and risky and increasingly complex and expensive.



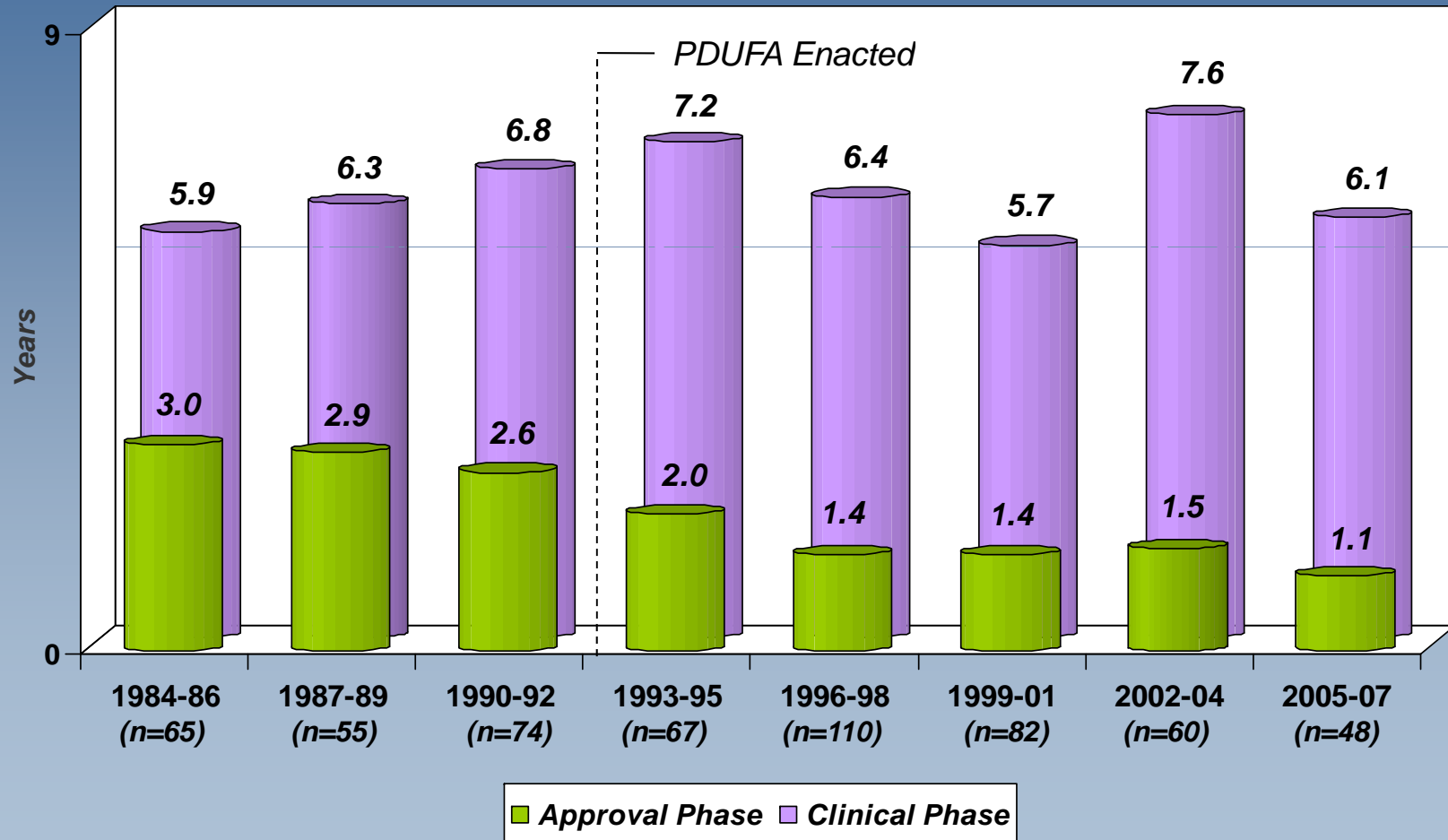
Major Pharma Patent Expirations

2009		2010		2011		2012	
<i>Product</i>	<i>Sales (\$MM)</i>	<i>Product</i>	<i>Sales (\$MM)</i>	<i>Product</i>	<i>Sales (\$MM)</i>	<i>Product</i>	<i>Sales (\$MM)</i>
Prevacid	3,514	Aricept	1,810	Lipitor	7,493	Singulair	3,327
Topamax	2,302	Cozaar/Hyzaar	1,454	Plavix	4,483	Enbrel	3,274
Lamictal	2,099	Protonix	1,132	Advair	4,321	Diovan	2,848
Valtrex	1,777	Taxotere	1,078	Seroquel	3,772	Lexapro	2,617
Flomax	1,485	Arimidex	729	Actos	2,957	Lovenox	2,539
Imitrex	1,312	Gemzar	722	Zyprexa	2,670	Viagra	1,046
Adderall	1,309	Xalatan	544	Levaquin	1,779	Geodon	989
Keppra	1,247	NovoSeven	497	Avapro	843	Detrol	905
CellCept	968	Combivir	407	Caduet	485	Provigil	867
Ambien CR	899	Mirapex	402	Femara	447	Zometa	796
Suboxone	468	Coreg CR	311	Xeloda	420	Avandia	676
All Others	2,335	All Others	3,260	All Others	2,366	All Others	4,584
Totals	\$19,715	Totals	\$12,346	Totals	\$32,036	Totals	\$24,468



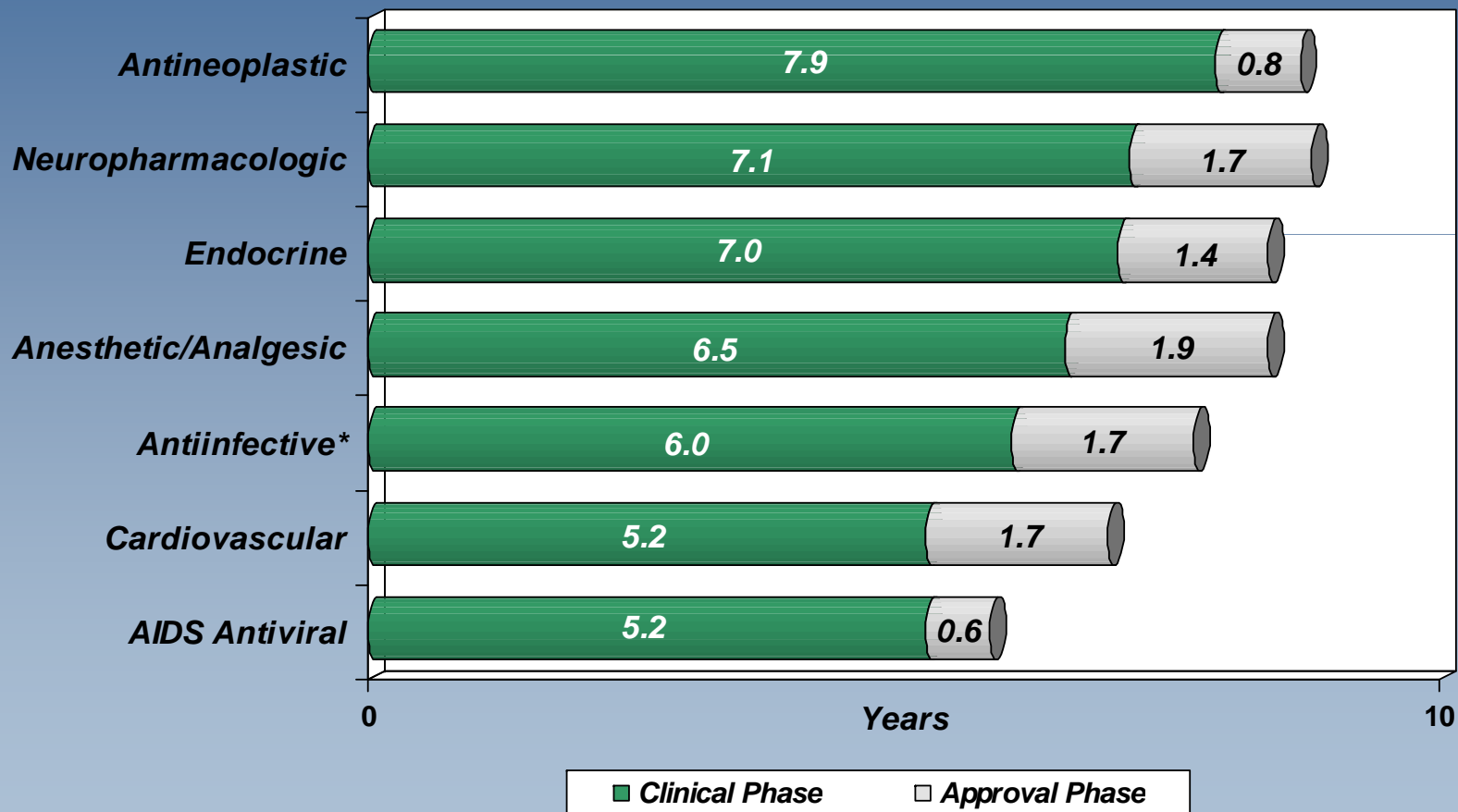
*Bringing a New Drug to
Market: Current Development
Metrics*

Clinical and Approval Times over Two Decades



Source: Tufts CSDD, 2009

Clinical and Approval Times Vary Across Therapeutic Classes, 2003-07



* excludes AIDS antivirals

Source: Tufts CSDD, 2009



Tufts Center for the Study of Drug Development

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Impact REPORT

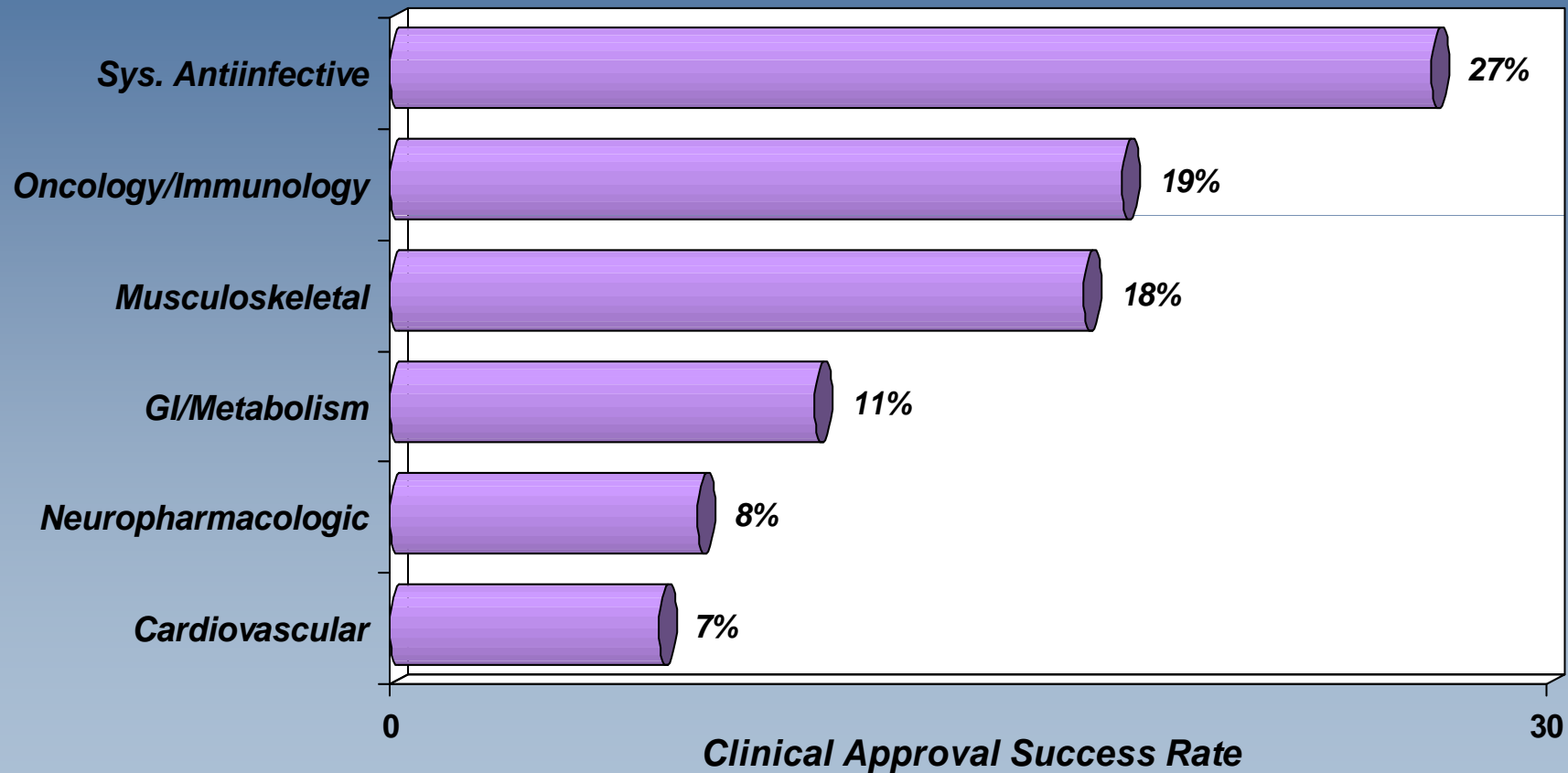
ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Large pharma success rate for drugs entering clinical trials in 1993-04: 16%

Share of licensed products in development portfolios peaked in 1999-01

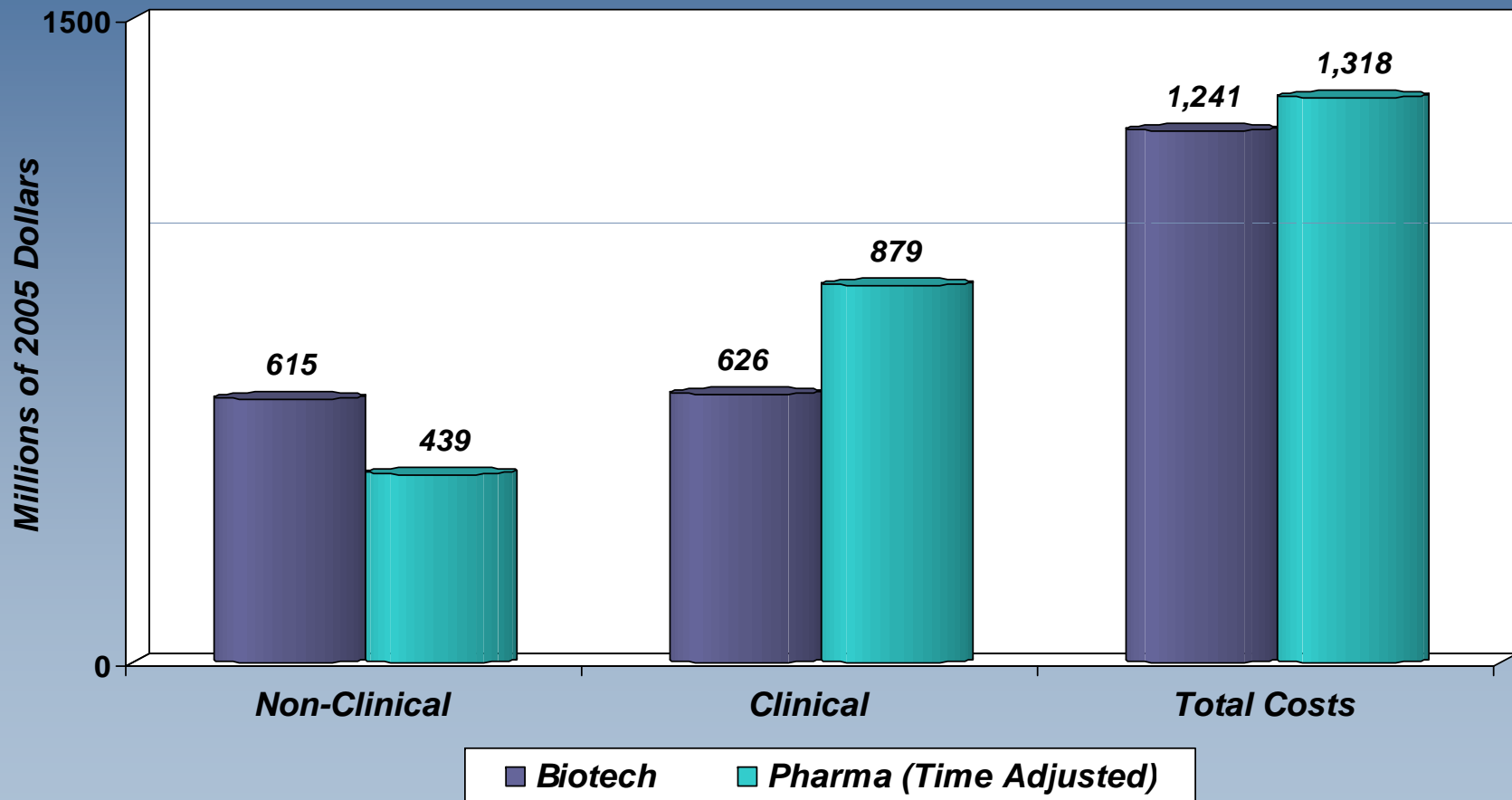
- Nearly three-quarters of the drugs in the portfolios of the top pharmaceutical firms that reached clinical testing from 1993-07 originated in and were developed by the firms.
- Of six specific broad therapeutic categories analyzed, oncologic/immunologic and central nervous system (CNS) had the greatest number of drug candidates entering clinical testing over the 1993-07 period.
- For the top 50 firms, the annual rate at which drugs enter clinical testing increased 31% from 1999-01 to 2002-07.
- Systemic anti-infectives had the highest clinical approval success rate for self-originated new drugs, with more than one-quarter of the drugs entering clinical testing during 1993-04 estimated to receive U.S. marketing approval.
- Less than 10% of cardiovascular and CNS drugs entering the clinical testing pipeline

Overall Clinical Approval Success Rate for NCEs has Dropped to 16%



Source: Tufts CSDD Impact Report, 11(4), Jul/Aug 2009

Capitalized Cost per Approved Biotech Product is Similar to that for Pharma



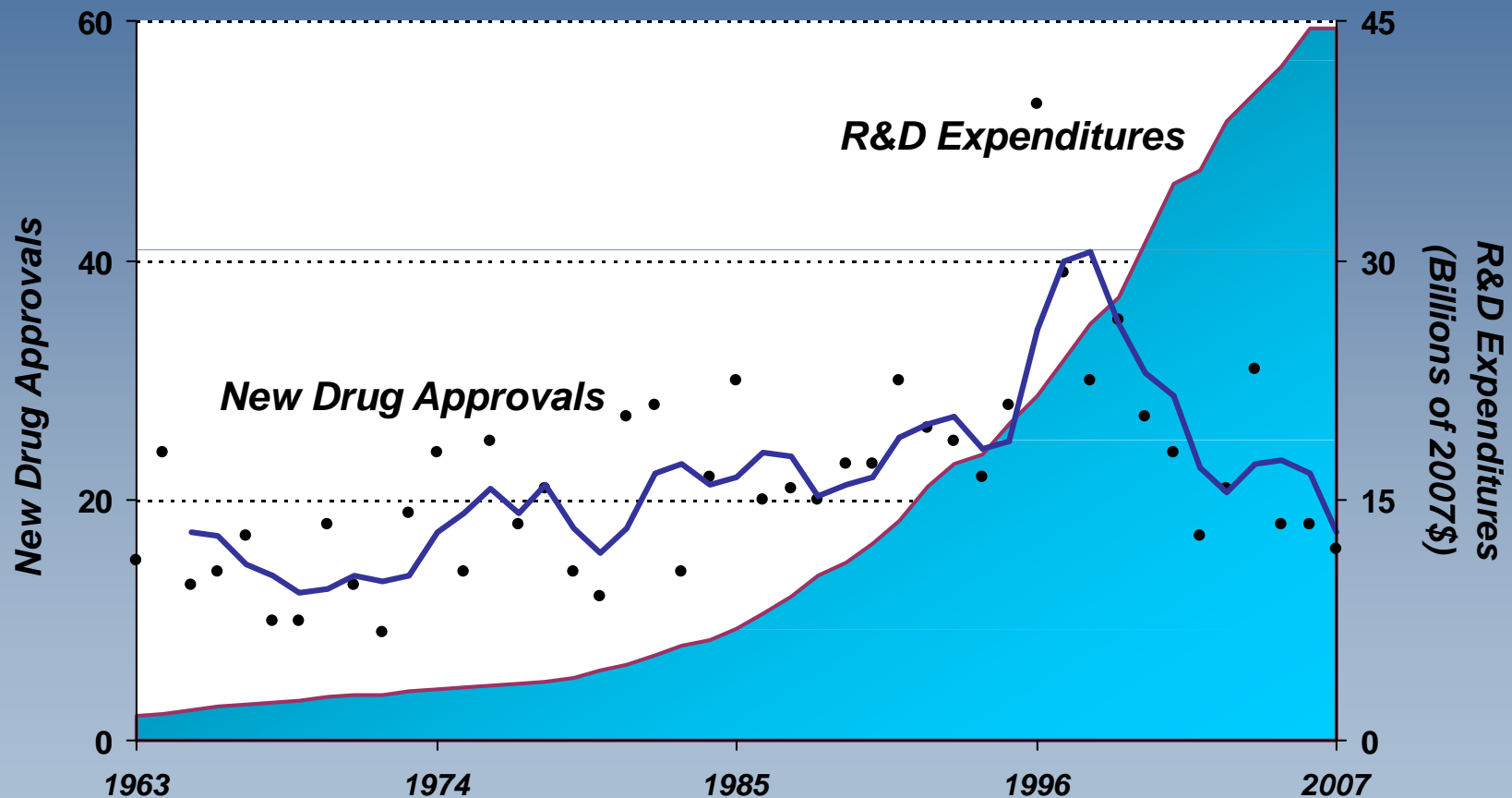
Source: DiMasi & Grabowski, *Managerial Decision Econ*, 2007;28:469-479

Drivers of Rising R&D Costs

- ◆ Chronic and complex indications
- ◆ Clinical trial size
- ◆ Protocol design complexity
- ◆ Patient recruitment/retention
- ◆ High cost discovery/research tools
- ◆ Regulatory demands
- ◆ Market oriented studies
- ◆ Late-stage attrition



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



* Trend line is 3-year moving average

R&D expenditures adjusted for inflation
Source: Tufts CSDD Approved NCE Database, PhRMA, 2008

*For the Research-Based
Industry
“Business as Usual”
is No Longer an Option*

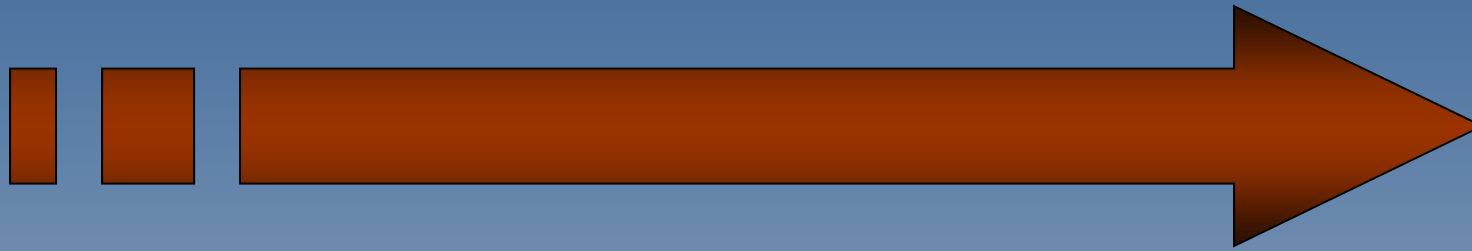
*Industry Focus on R&D
Efficiency and Performance:*

Merging Operational and
Strategic Objectives

Reported Success Factors – Best Practices of Top-Performing Firms

- Focus on core competencies, higher level of outsourcing, prioritize resources
- Active collaboration with global regulatory agencies
- Enhanced utilization of e-data management technologies
- Offshoring

Evolving Sponsor/CRO Relationship Structures



PROVIDER
(Transactional services)

Ad-Hoc

Capacity-based

Reactive, project task outsourcing

Larger operation, sponsor SOPs

Mid-management governance committee

Lowest-bid/Many Providers

PARTNER
(Multiple FSPs and Alliances)

Formalized

Virtual/Competency-based

Planned, portfolio outsourcing

Lean operation, coordination SOPs

Senior management committee

Few Partner-Providers



New R&D Strategies

- ◆ **M&As**
- ◆ **R&D Reorganization**
 - e.g., GSK (CEDDs ⇨ DPUs), Pfizer, Roche, Novartis, BMS, Sanofi Aventis
- ◆ **Partnerships**
 - With public and private research entities, academic institutions, and biotech companies
 - Large pharma/biotech (e.g., GSK and Concert)
 - Pharma/pharma (e.g., Merck & AZ [onc], GSK & Pfizer [HIV], Enlight Biosciences [JNJ, LLY, MRK, NVS, PFE])
 - Other (e.g., Lilly-Covance; Quintiles/NovaQuest; Lilly-Chorus; PDCs)
- ◆ **FIPCos ⇨ FIPNets (⇨ VIPNets)**
- ◆ **Generalized ⇨ targeted medicines**



Conclusions

- ◆ **The time, cost, and risk to bring a new medicine to market continue to represent formidable challenges for drug developers.**
- ◆ **These challenges have led to a heightened focus within the industry on R&D efficiency and performance, and on new strategies, including R&D re-org, partnerships, network relationships, and targeted medicine development.**

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