

# Challenges for New Drug Development in a Changing Economic Environment

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# Current Concerns for Pharmaceutical Development

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- Patents on many high revenue products are expiring
- Marketplace is highly competitive and reimbursement environment is increasingly restrictive
- 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.



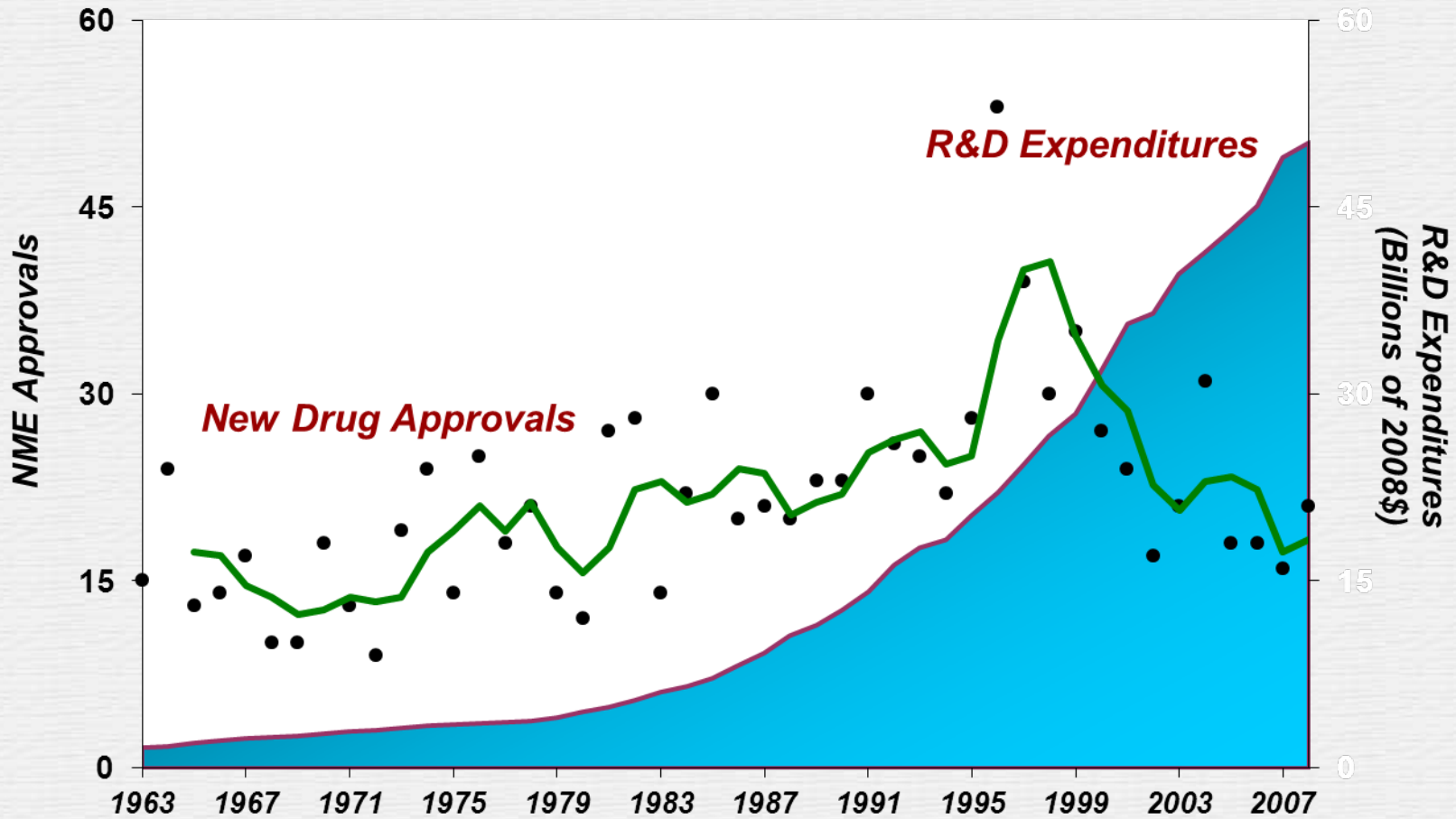
# Agenda

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- Trends in R&D costs
- Clinical development and approval phase times
- Greater technical risks: clinical phase transition probabilities and clinical approval success rates
- Development of “me-too” drugs



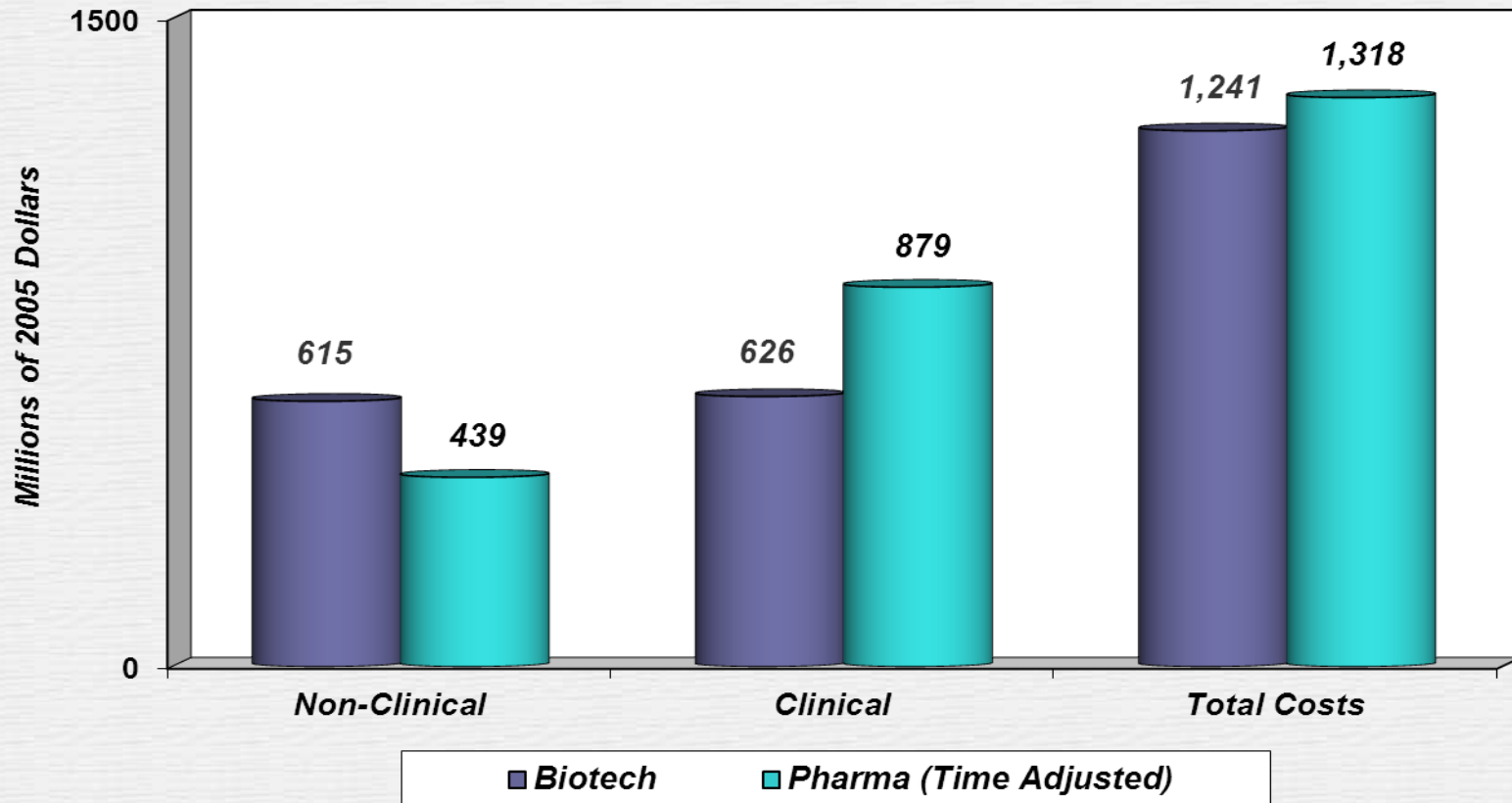
# New Drug Approvals and R&D Spending



*R&D expenditures are adjusted for inflation; curve is 3-year moving average for NMEs*



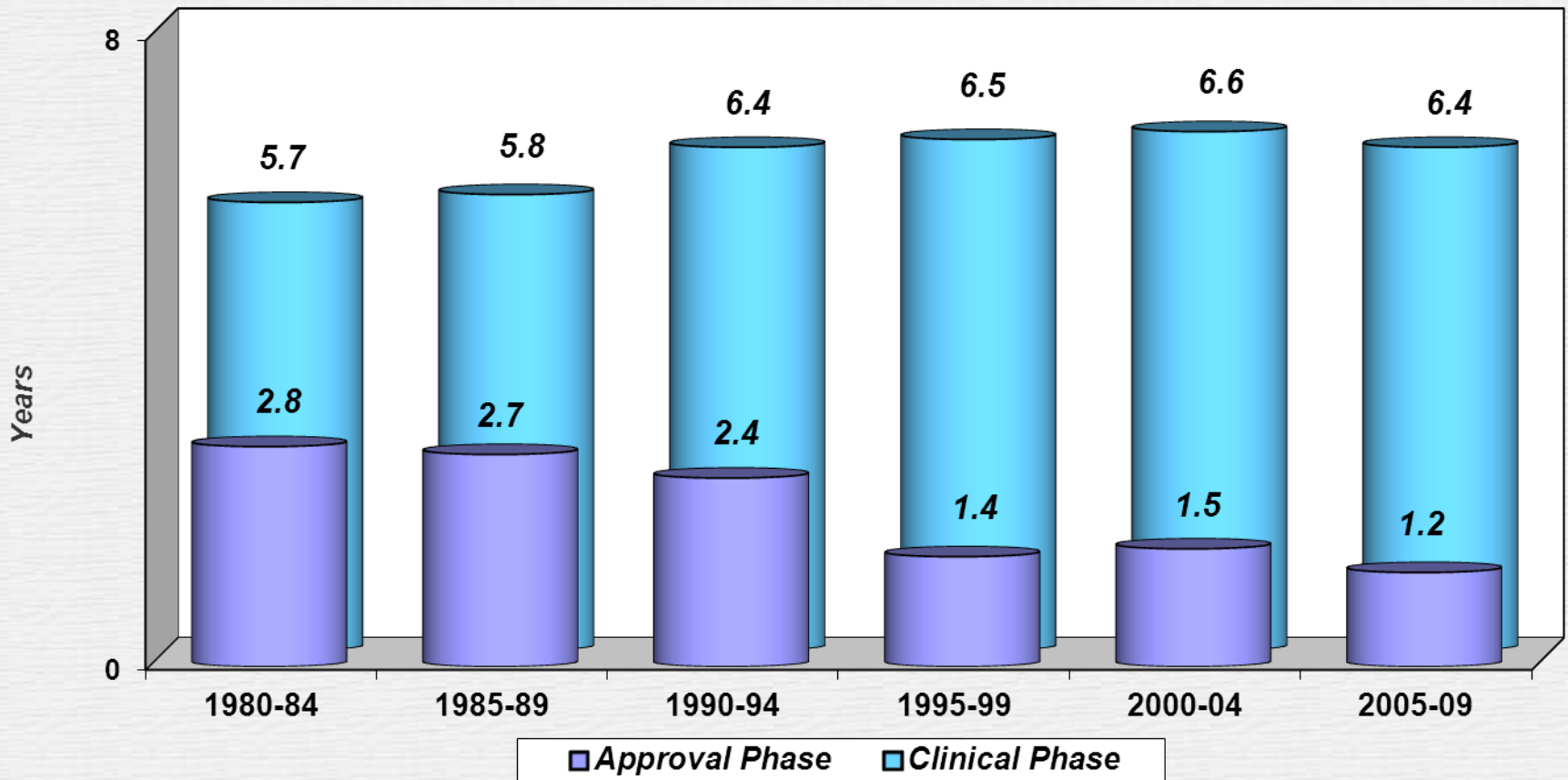
# R&D Cost per Approved Molecule Compared: Biotech vs. Pharma



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



# Clinical and Approval Times over Three Decades

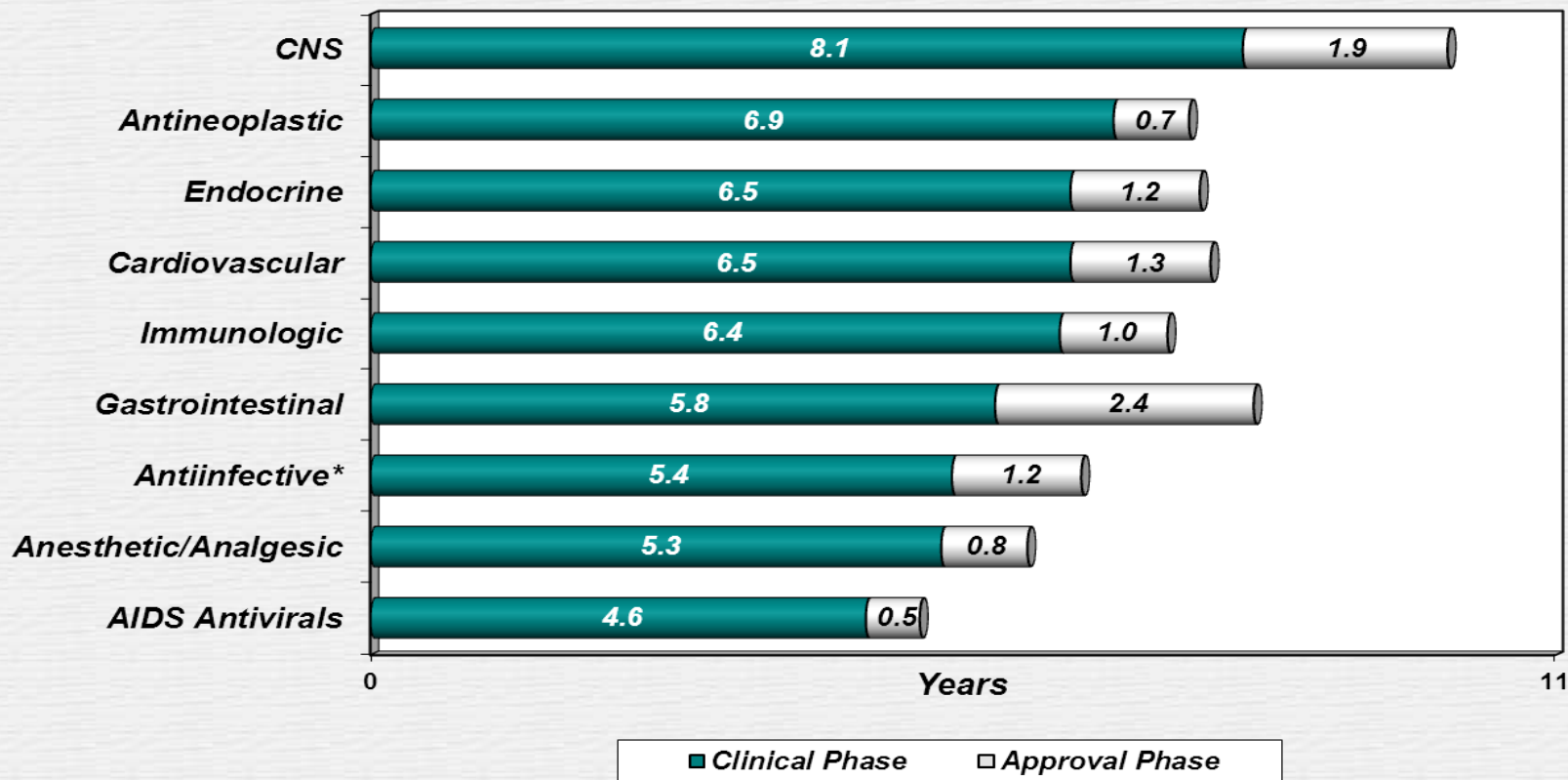


Source: Kaitin & DiMasi, *Clin Pharmacol Ther*, 2011;89(2):183-188



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# Clinical and Approval Times Vary Across Therapeutic Classes, 2005-09

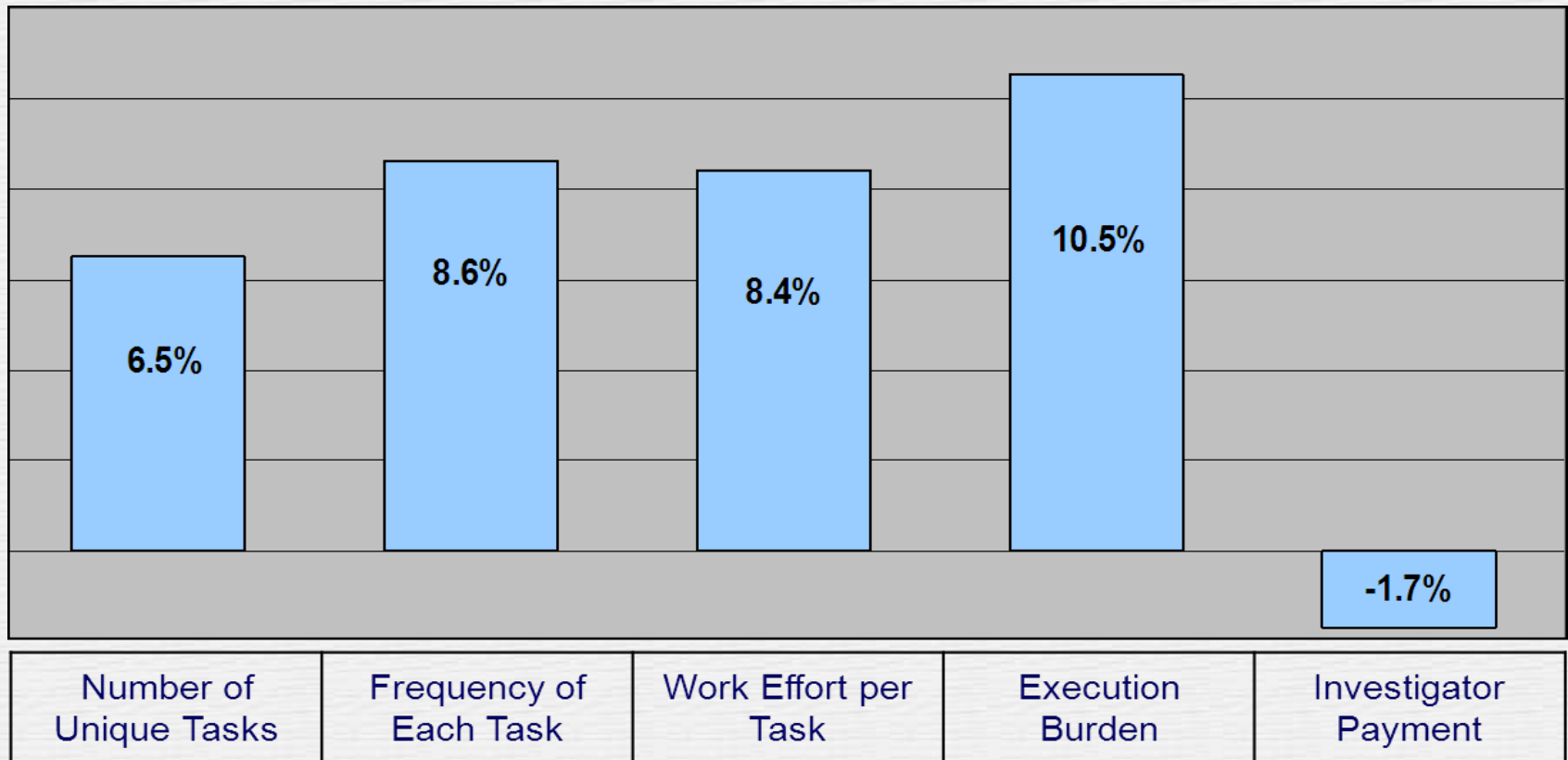


\* excludes AIDS antivirals

Source: Kaitin & DiMasi, *Clin Pharmacol Ther*, 2011;89(2):183-188



# Protocol Design Trends: Increased Tasks, Frequency, Effort, & Complexity

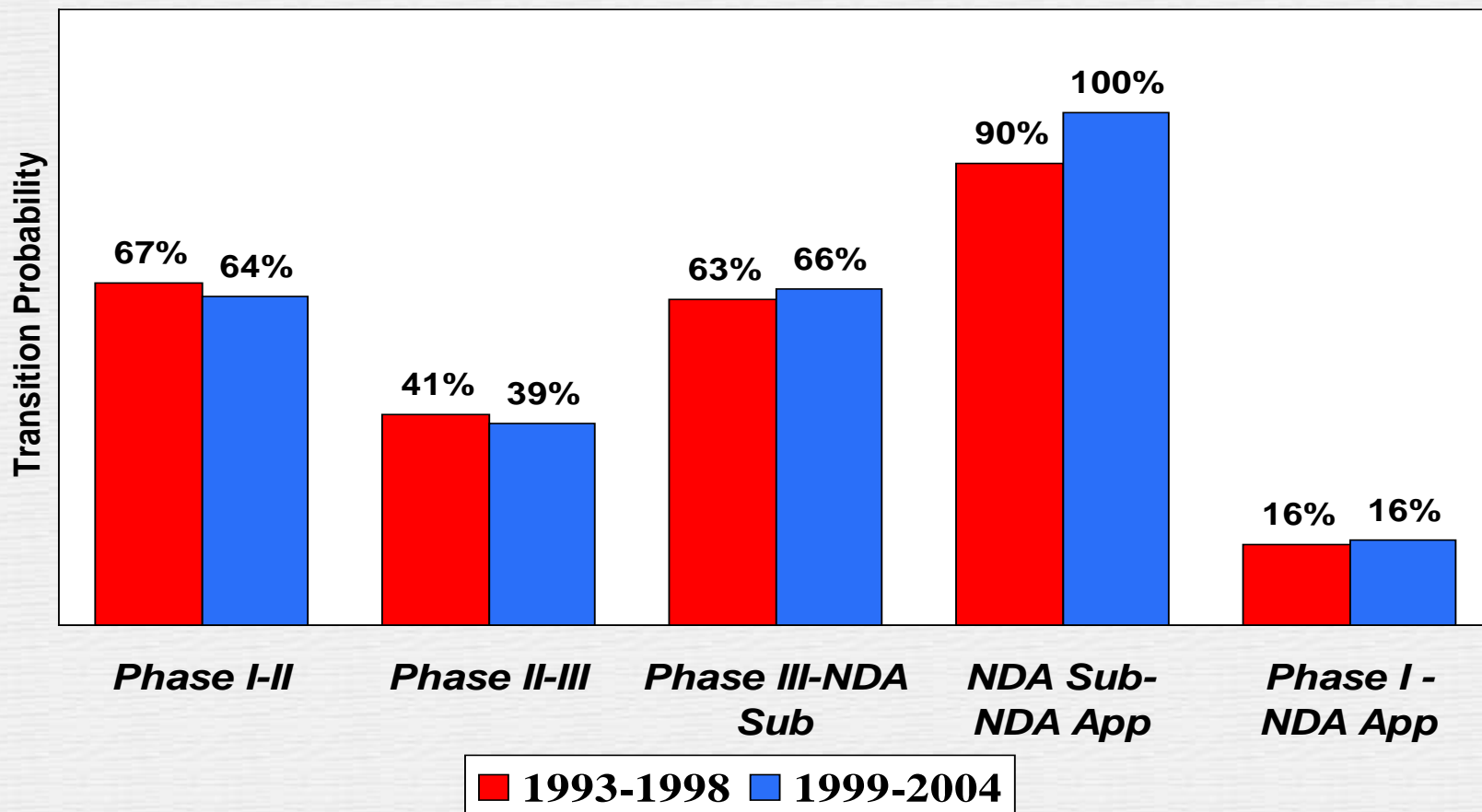


Source: Getz et al., *American Journal of Therapeutics*, 2008;15:450-457



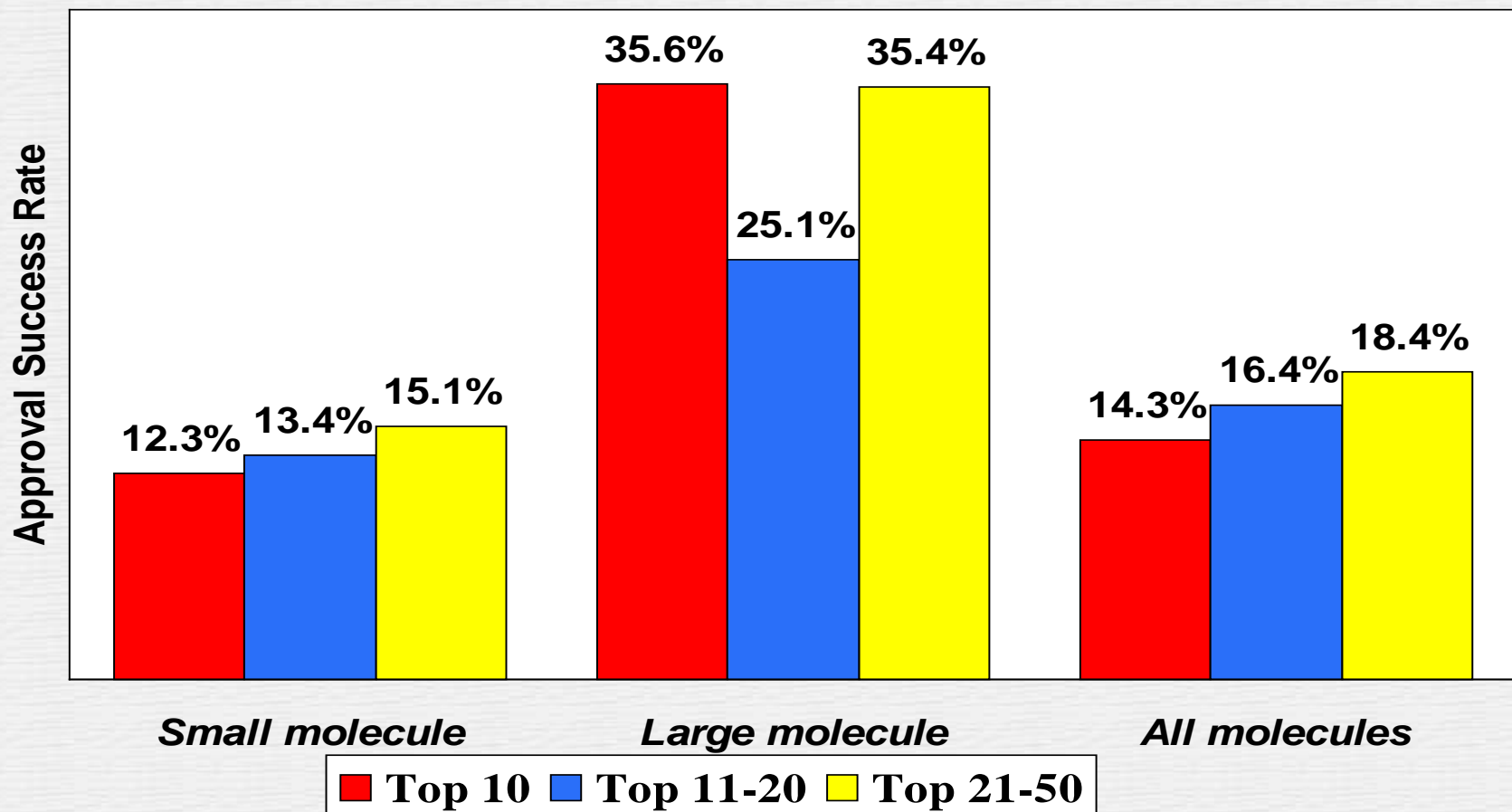
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# Phase Transition Probabilities for Self-Originated Drugs of Leading Firms



Source: DiMasi et al., *Clin Pharmacol Ther* 2010;87(3):272-277

# Clinical Approval Success Rates for Self-Originated Drugs by Molecule Type and Firm Size

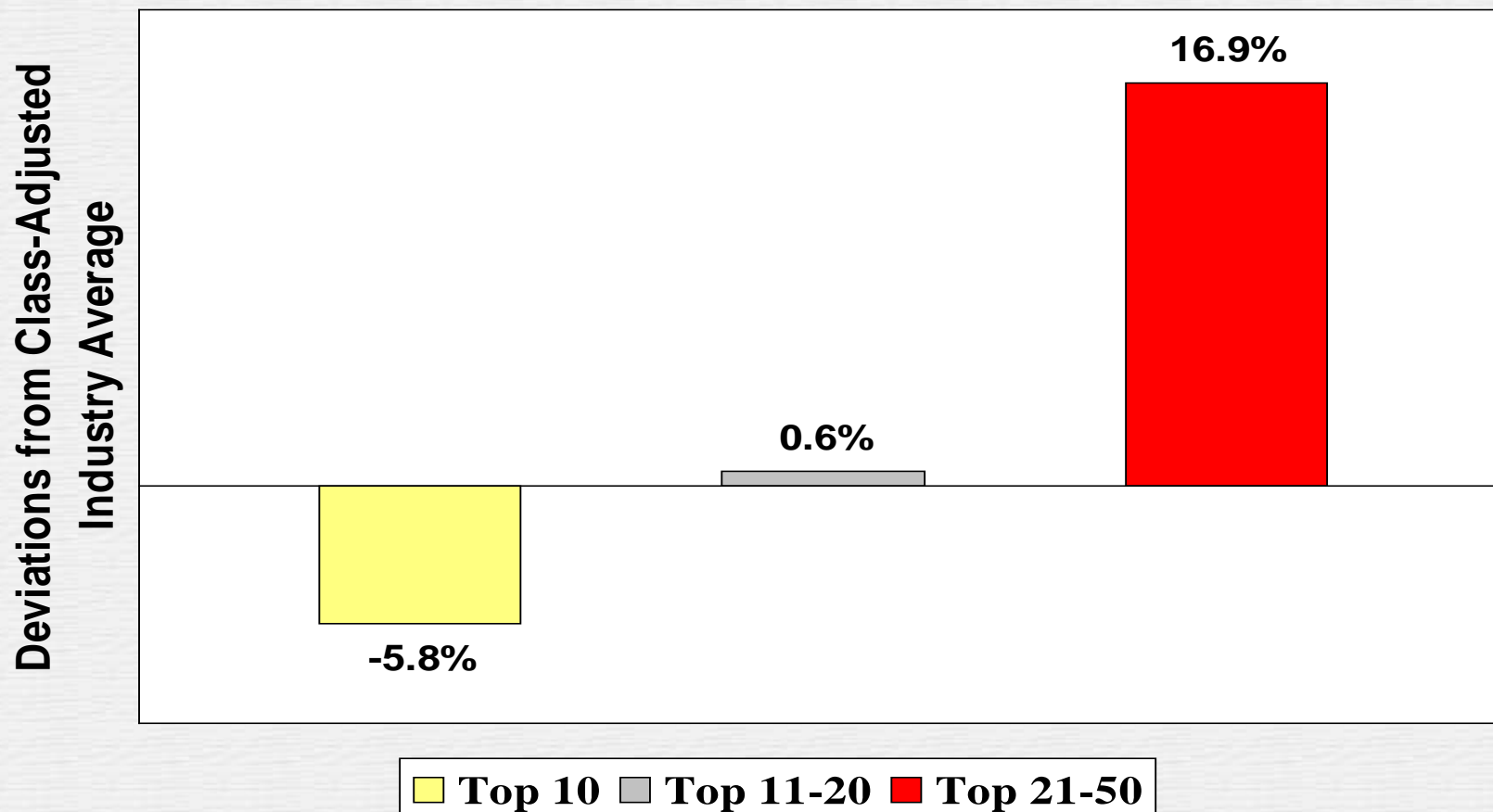


Source: Tufts CSDD



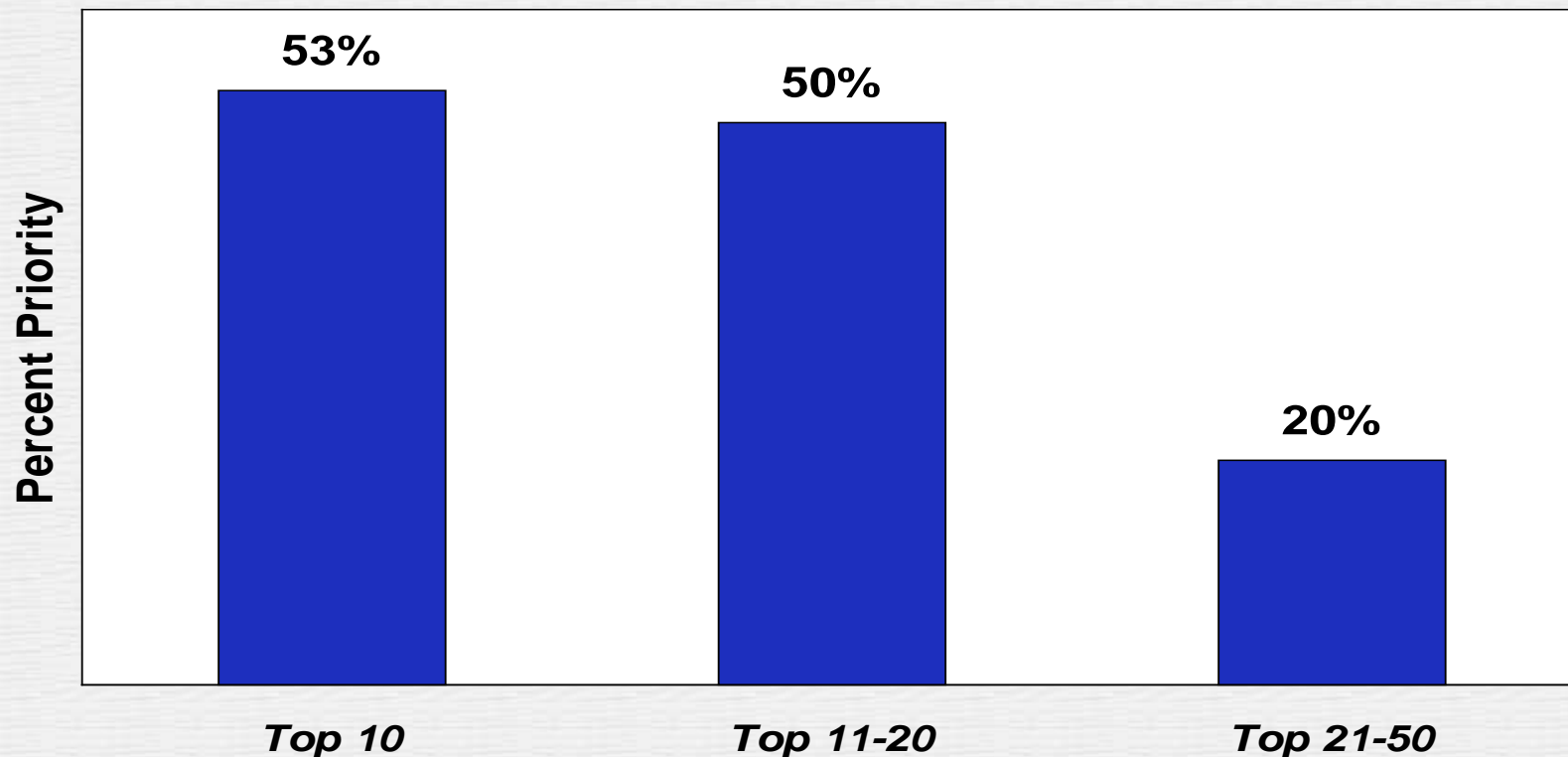
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# Therapeutic Class Adjustments for Approval Success Rates of Self-Originated Drugs by Firm Size



Source: Tufts CSDD

# Therapeutic Significance Ratings for Non-Orphan Approved Drugs by Firm Size



Approvals from success rates dataset; first tested in humans, 1993-2004

Source: Tufts CSDD

# Sales Levels by Firm Size for Drugs First Tested in Humans from 1993 to 2004 with 2009 Sales in the List of Top 200 Drugs for 2009<sup>a</sup>

<i>Sales Rank</i>	Top 10 (n=24)	Top 11-20 (n=17)	Top 21-50 (n=7)
Mean	100	99	106
Median	94	83	115
<i>Sales (millions \$)</i>			
Mean	1,711	1,778	1,461
Median	1,257	1,366	1,070

Source: Medical Advertising News  
<sup>a</sup> Drugs approved from 2000 to 2007



# Drivers of High Cost, Low Success Drug Development

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- Chronic use and complex indications
- Protocol design complexity
- Patient recruitment/retention
- High cost discovery/research tools
- Poor preclinical screens and predictive models
- Regulatory demands
- Market oriented studies



# ***The Economics of Me-too Drug Development: Imitation or a Competitive Race?***

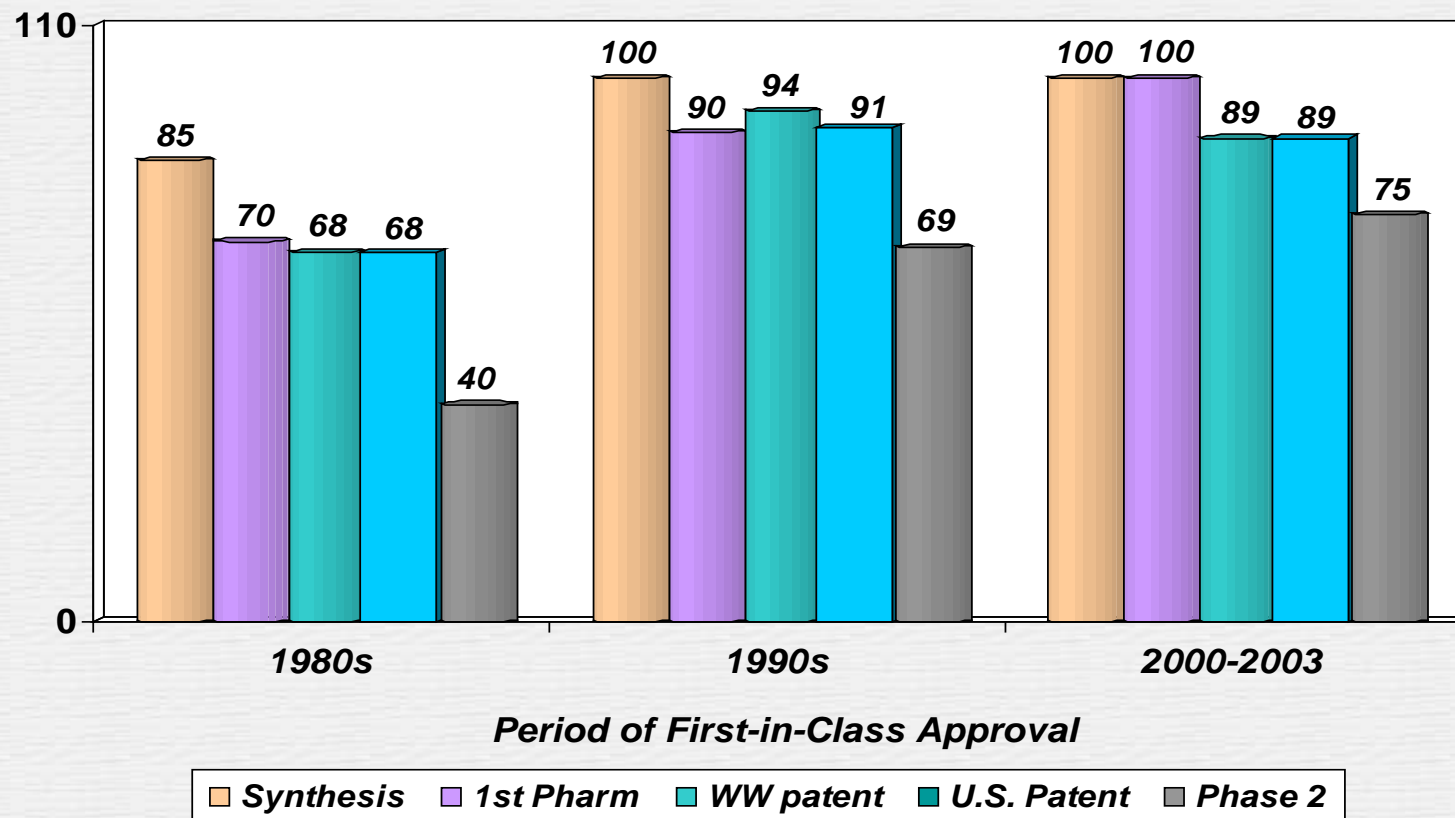


# Period of Market Exclusivity for First-in-Class Drugs (time to first me-too approval)



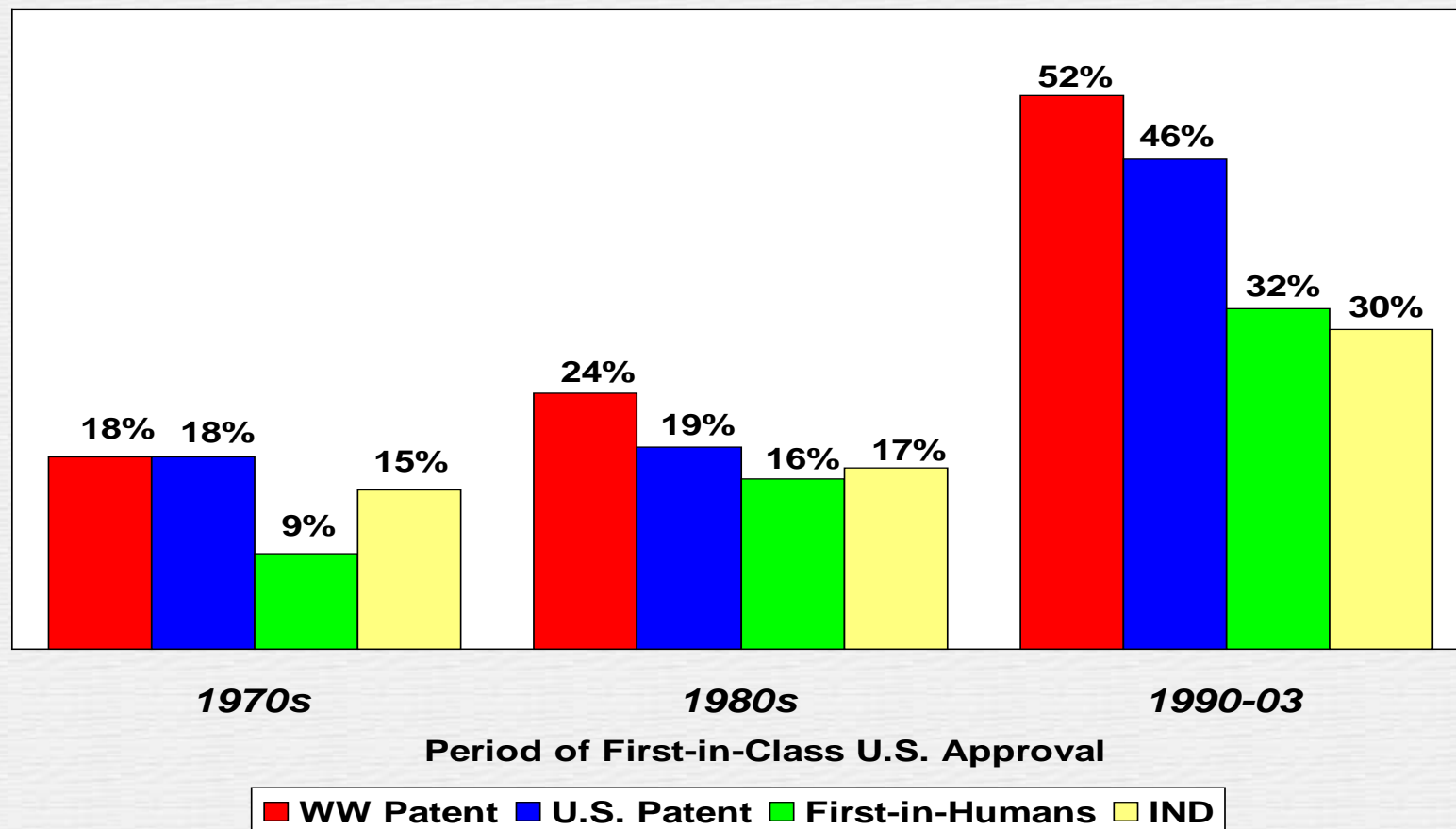
Source: DiMasi and Faden, *Nature Reviews Drug Discovery* 2011;10(1):23-27

# Percent of Me-Too Drugs Having Reached Milestone Before First-in-Class Approval



Source: DiMasi and Faden, *Nature Reviews Drug Discovery* 2011;10(1):23-27

# Percent of Me-Too Drugs Reaching Milestone Before First-in-Class Drug Reached the Same Milestone



Source: DiMasi and Faden, *Nature Reviews Drug Discovery* 2011;10(1):23-27

# Conclusions

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- Time to market is very lengthy, albeit relatively stable
- Clinical trial out-of-pocket costs continue to increase
- Development risks have also been increasing
- Development of “me-too” drugs is better described as a race to market, rather than post hoc imitation
- Focus on stratified and personalized medicine, if successful, may reduce market sizes but lessen price competition
- Increasing demands for comparative data on clinical effectiveness and costs will increase pressures on developers

