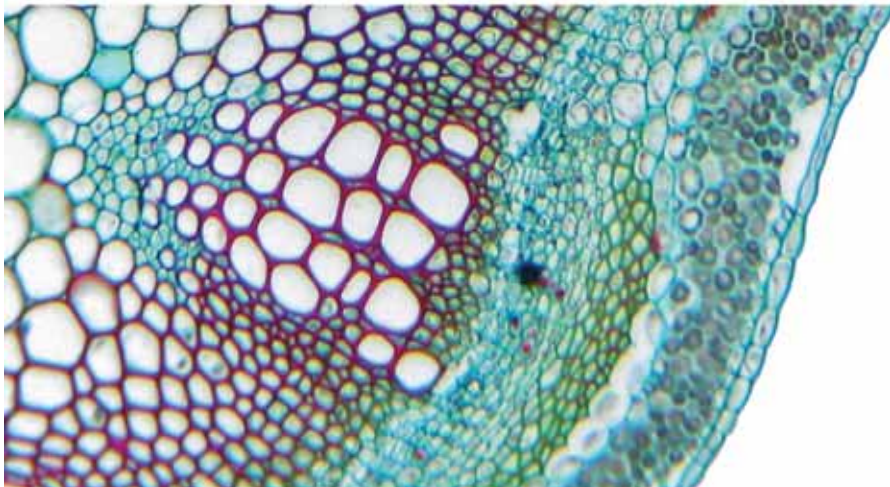
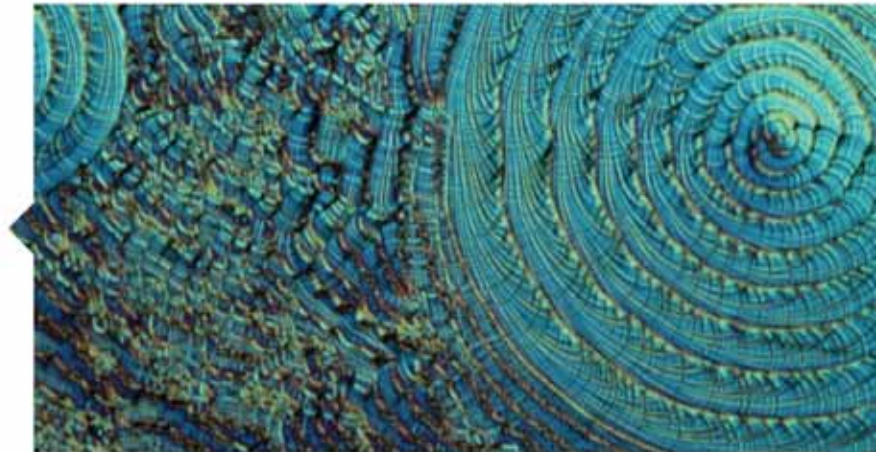


2010 Quintiles Executive Vision Forum
"Capitalizing on Convergence in *the New Health*"
June 29, 2010



**Breaking Out of Organizational
Silos: Bridging the Gap from
Development to Commercialization**

Pasquale Cetera

*VP, Portfolio Management and Strategy
Merck*

clinical | commercial | consulting | capital

Two Pivotal Questions ?



- > Can Pharma Companies “do well” while “doing good”?
- > Can Pharma Companies manage efficiently their R&D Portfolios?

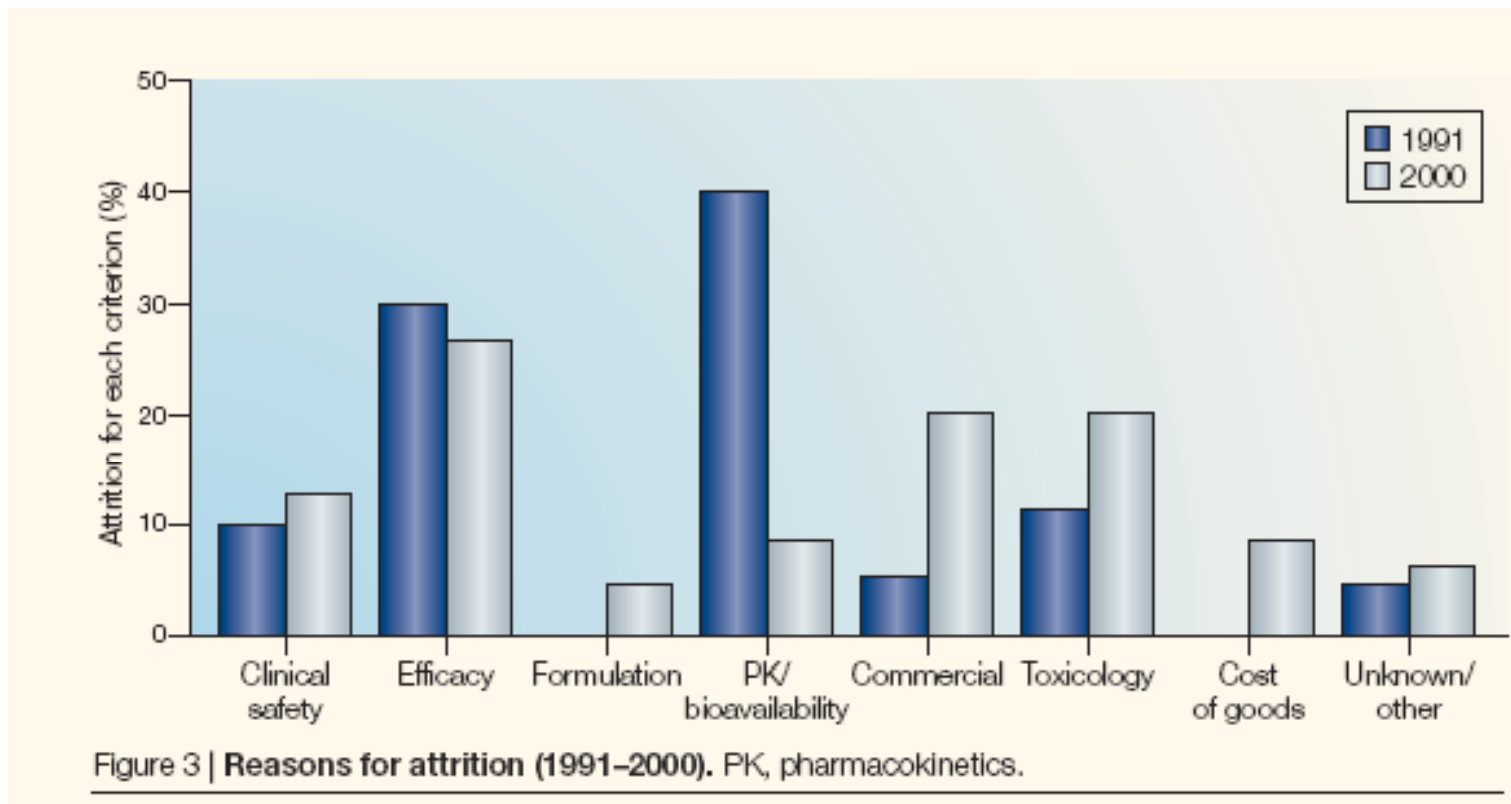
The R&D & Commercial Silos



- The Silo effect is characterized by
 - lack of timely cross-functional communication
 - absence of shared goals and incentives
 - different strategies and priorities
 - inward focus and operating in a vacuum (no customer-orientation)
 - fighting for resources (who should pay for a given PE study?)
 - lack of alignment on critical issues
- The silo effect is caused by
 - Complexity of integrating scientific and marketing data
 - Governance and Decision-making processes
 - Communication and Culture Gap
- Bridging the structural, cultural, process & communications gaps between R&D and Commercial challenges even the most skilled organizations



Growing Attrition due to “Commercial” Problems



The growing role of “Commercial” in R&D



1. Utilizing market data to eliminate commercially risky drugs and minimize costly development mistakes
2. Identifying and analyzing real-world evidence to support development initiatives
3. Engaging all customers in the drug development process
 - Development plans must consider more than regulators' requirements; they must be able to provide payers, providers and patients with reliable information about health outcomes
 - The medical and economic benefits of the new drug must be clear and the trials that assess these benefits must be transparent



The Paradox of Commercial Role for New Drugs



Commercial Expert Opinion is relatively unreliable.....

- The changing environment (new regulations, deeper pharmaco-economics, refined health care practices, scientific innovations & evolving customer expectations, etc.) is making commercial assessments more difficult
- Commercial people have no crystal ball and cannot assess new products without “approximation”
- Excessive portfolio rationalization might kill viable products too early and lead to a loss of serendipity
- Early data on efficacy and safety are not necessarily confirmed in Phase III and commercial assessments are therefore not entirely reliable

.... nevertheless it remains
“critically important“

The “Four Step” Approach



1. Target Identification
 - DOPs (Disease Opportunity Profile)
2. Lead Finding & Optimization
 - TCP (Target Candidate Profile)
3. Candidate Nomination
 - Alignment Meeting on TCP
4. POC Completion
 - Alignment Meeting on TPP

The benefits of Joint Brand Crafting



- Giving continuously a Commercial perspective on early projects, while understanding R&D challenges
- Performing commercial assessments and helping redirect funding from marginal projects to those with higher potential for success
- Gathering input from Commercial Franchises, Brand Teams, Market Access/P&R, Country and Regional Teams at critical decision gates
- Develop KOLs as new product champions and prepare for launch the market, product and company
- Provide alerts on generics, competitors and key market changes
- Assist in clinical trial design aligned with customers' needs and in selecting centers of excellence
- Operating with centralized approaches and standardized tools to ensure consistent approaches/assessments for
 - Projects in different therapeutic areas
 - Internal projects vs in-licensing opportunities

Pharma has a Trust Deficit !



- The Pharmaceutical Industry is also suffering from “Toxic Assets”
 - withdrawals of toxic new medicines
 - unjustified and growing high prices
 - launches of me-too products and line extensions
 - newly “invented” diseases
- “Drug companies want to turn every normal human experience into a diagnosable disease that’s treatable with their high-priced, patent- protected, brand-name drugs” (from NaturalNews.com)

Pharmaceutical Industry can “do well by QUINTILES doing good”!

- We need to be focused on finding ways to create value for both shareholders and society
- The belief that pharmaceutical companies must choose between doing good and being profitable is outdated
- We need to deeply understand that our responsibility to investors means being accountable to the society
- The role of JBC is central in this critical endeavor
 - The benefits of ComDev are clear, but “how to do it” is less clear
 - Transformation is needed, but it requires inventing new processes, re-defining the culture of both R&D and Commercial organizations
 - Each company will ultimately have to define its own model

Two Pivotal Questions ?



1. Can Pharma Companies “do well” while “doing good”?
2. Can Pharma Companies manage efficiently their R&D Portfolios?

Top Ten Criteria for Prioritization of Projects QUINTILES[®]

1. Unmet medical need
2. MoA validation
3. Regulatory Pathway
4. Peak Sales
5. Time and Cost for Development
6. Technical Difficulty
7. Value proposition
8. Competitive environment
9. Manufacturing complexity
10. Company Know-how / Expertise

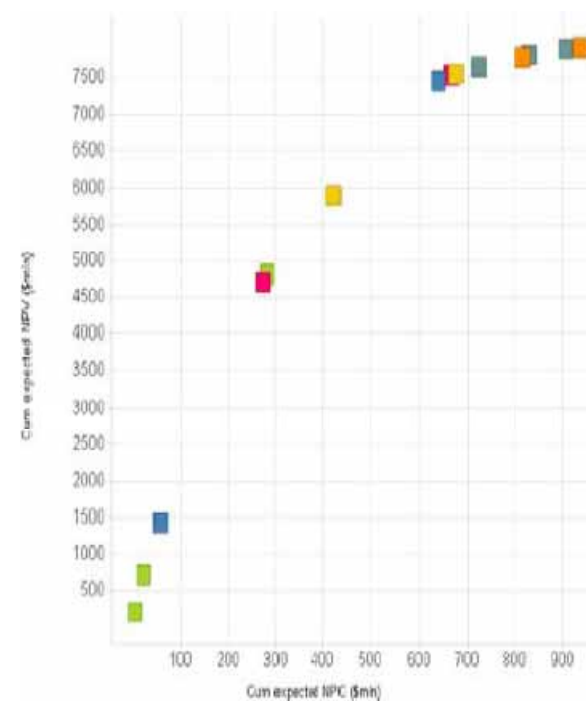


> Cost
> Sales
> PoS

Strategic Fit

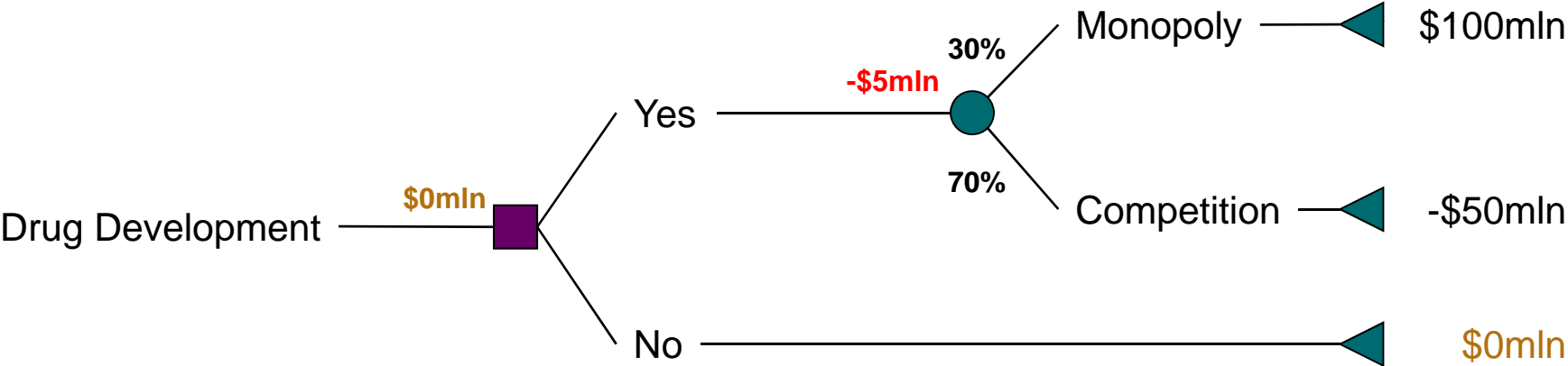
Three Levels of Decisions

- Decisions on individual experiments
 - VIR for late development
 - Vol for early development
- Decisions on Portfolio Rationalization
 - Risk / Reward Matrix and Creaming Curves
- Decisions on Portfolio Management
 - Long-term Strategies

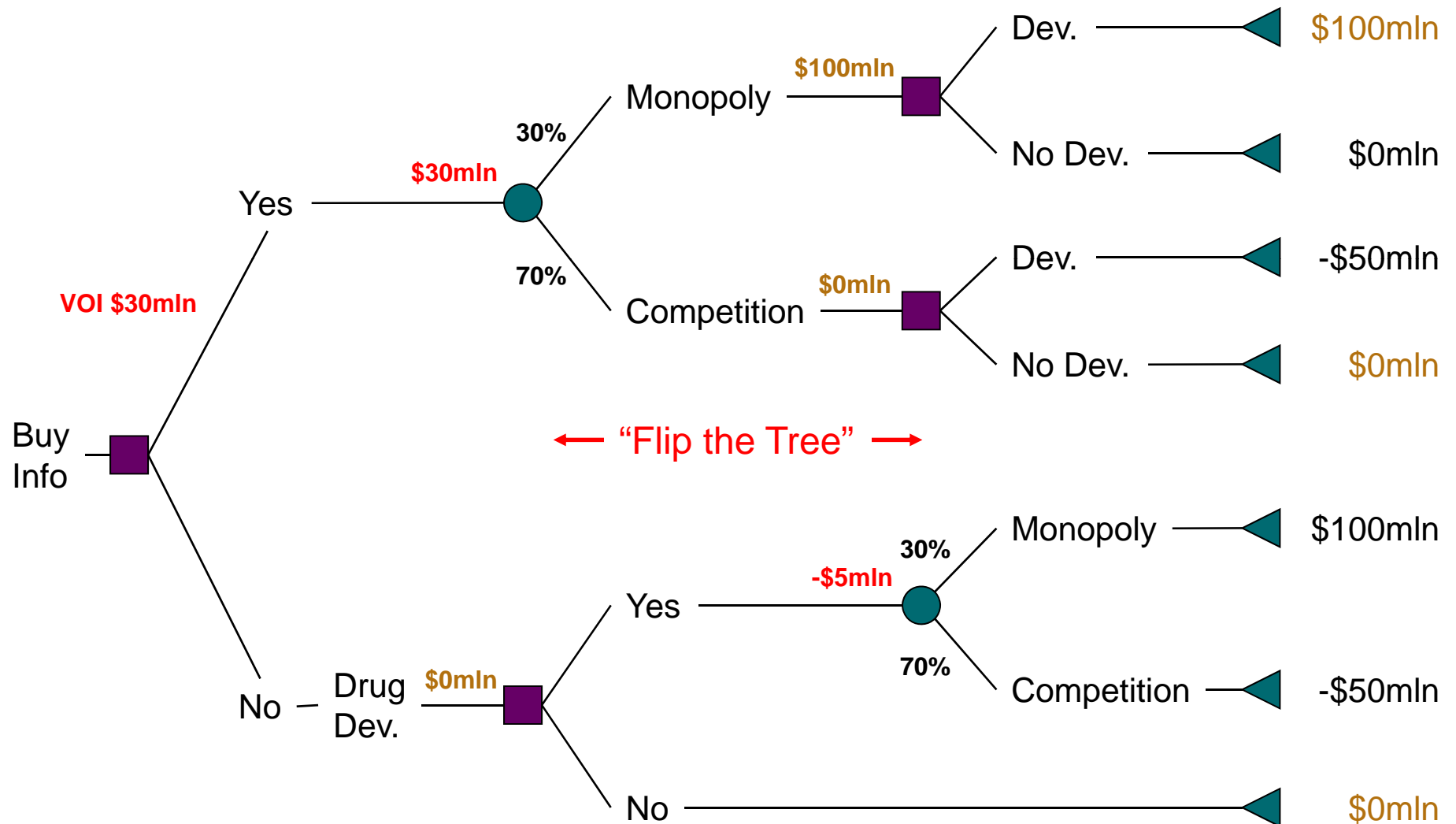


- GOAL: to develop new drugs in less than 6 years and have them approved in less than 1 year, while minimizing the number of projects killed in Phase III

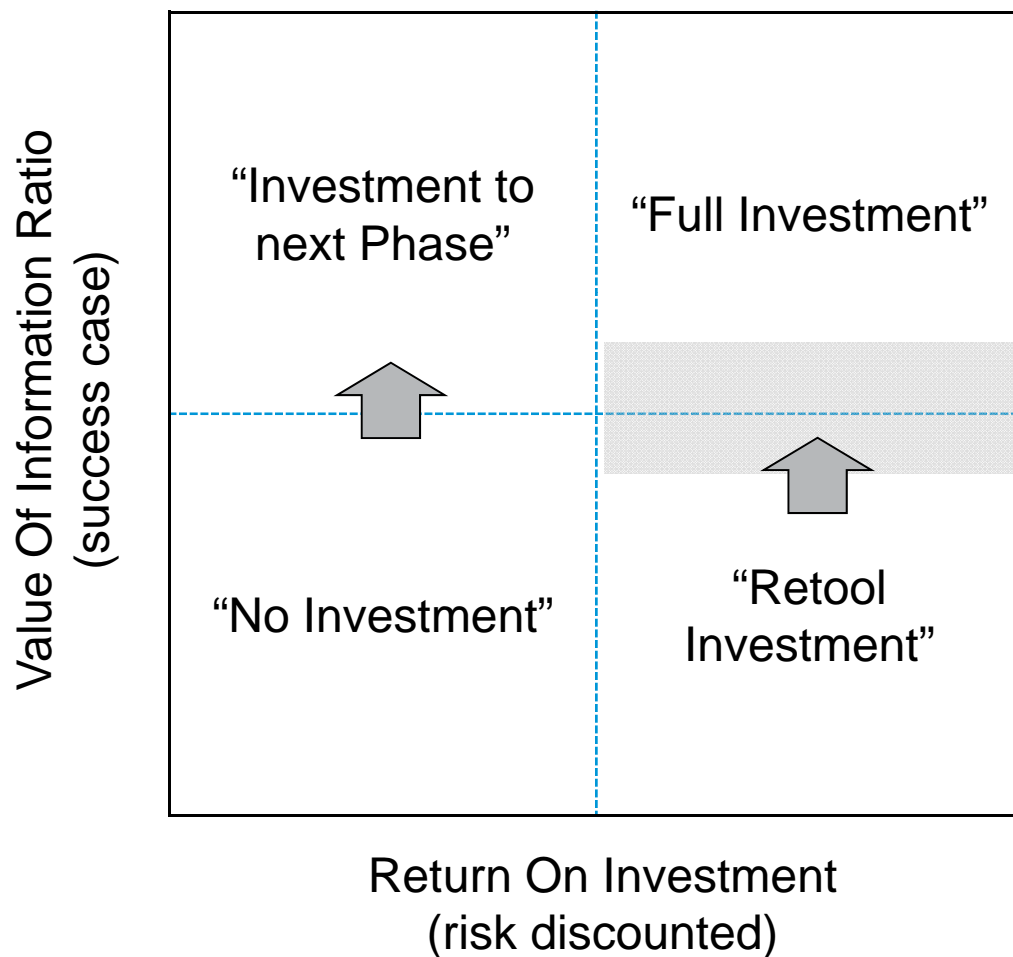
“Blind” Decision Making



VOI Based Decision Making



Value of Information

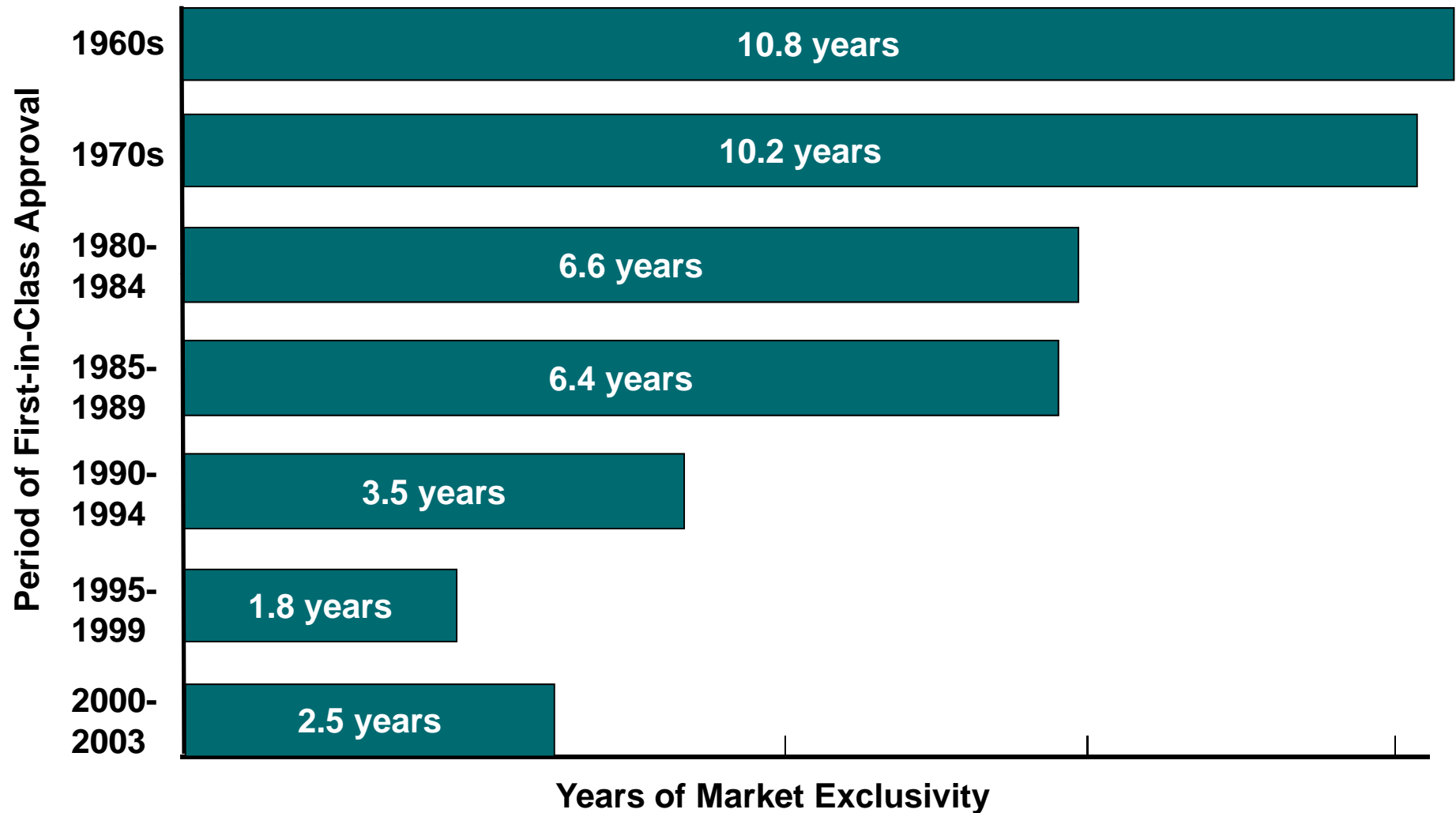


Portfolio Balance: the right Mix



- > FIC vs BIC
- > PC vs Specialty
- > Biologics vs Small Molecules
- > Global vs Regional

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



Source: Tufts Impact Report; Volume 11, Number 5; October 2009

Time to Market Entry for Follow on Products has Decreased



Average Time in Years to Market Entry for Second and Third Follow-on Drugs

	Time from 1st to 2nd Follow-on Drug		Time from 2nd to 3rd Follow-on Drug	
	Mean	Median	Mean	Median
1960s	13.5	16.1	8.3	5.1
1970s	5.7	4.2	5.2	3.7
1980s	3.8	3.5	2.8	2.0
1990s	2.7	2.0	2.2	1.3
2000-03	1.1	1.1	NA	NA

Note: First column refers to period of U.S. marketing approval for first entrant in class.

Source: Tufts Center for the Study of Drug Development, Impact Report, 2009: Vol 11, number 5

Fast followers worse than generics!

“We estimate that between-patent competition, most of which occurs while a drug is under patent, costs the innovator at least as much as within-patent competition, which cannot occur until a drug is off patent. The reduction in the present discounted value of the innovator’s return from between-patent competition appears to be at least as large as the reduction from competition within -patents, and may be much larger.”

THE DUAL EFFECTS OF INTELLECTUAL PROPERTY REGULATIONS:
WITHIN- AND BETWEEN- PATENT COMPETITION IN THE US
PHARMACEUTICALS INDUSTRY

Frank R. Lichtenberg & Tomas J. Philipson
Journal of Law & Economics – Oct.2002 (vol.45, N.S2; pp.643-672).

Discussion