

The Economic and Social Return to Innovation in Medicines

BIO 2005 Session:
Drug Pricing, the Return to Innovation and Industry Development

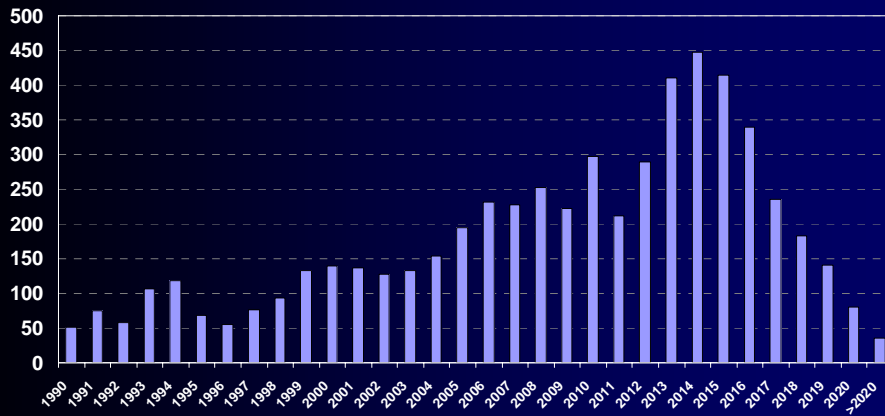
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Maturity in Pharmaceuticals and the Biotech Revolution

- Pharmaceuticals is a maturing industry
 - Innovation in 1970s, 1980s and 1990s brought forth blockbusters
 - Patents on these drugs are now expiring
 - Many molecular approaches to a given therapeutic problem (including 'me too' drugs)
 - Deepening competition in many therapeutic groups
 - This characteristic of a mature industry

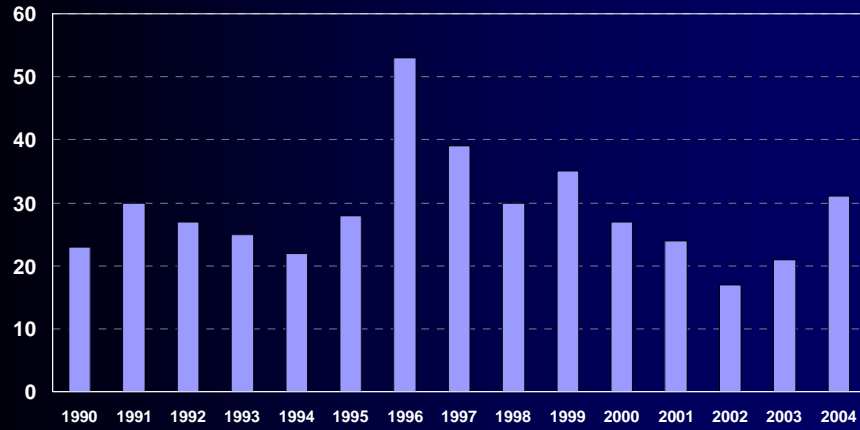
Chart 1. Drug Patent Expiries, USA, 1990-2020
(Number of patents; IMS Patent Focus Database, November 2004)



An Industry Reshaped by New Technologies

- But pharmaceuticals is also in the midst of a technological revolution
 - 'Low hanging fruit' from chemical trial and error method of drug discovery picked
 - New scientific and technological basis of drug discovery
 - Based on better understanding the molecular basis of disease
 - Genomics and proteomics
 - Advanced drug search tools and platforms
 - Towards individually targeted treatments
 - Declining research productivity in the transition
 - The rising cost of developing new drugs, by current methods

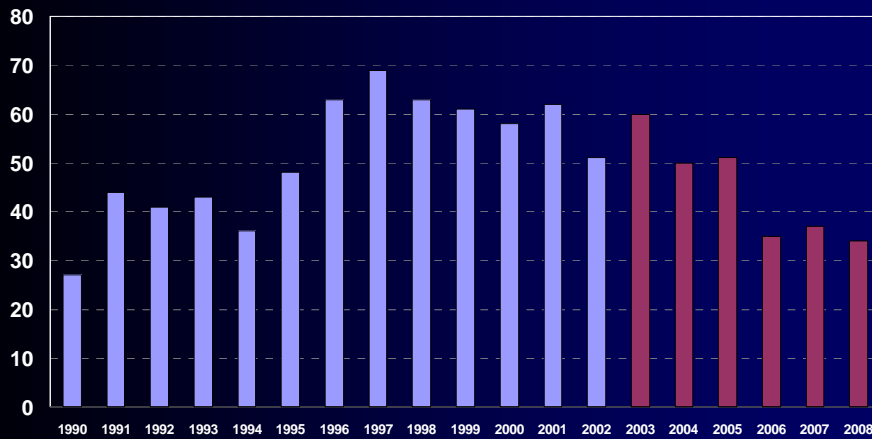
Chart 2. New Molecular Entities Approved by the FDA, 1990 to 2004



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Chart 3. Number of New Drugs Launched Globally, 2003-2008 (Lehman Brothers, *Pharma Pipelines*, various years)



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Financing Technological Change in a Mature Industry

- Implications of these trends for financing the technological revolution
 - Growth rate of drug company revenues slowing
 - Generic and other competition puts pressure on unit prices
 - Pharmaceutical companies are a major source of funding for biotech
 - Many biotech companies aim to achieve direct access to pharma revenue, by becoming drug companies
- How can we ensure optimum development of the new technologies?

The Social Value and Cost of New Medicines

- Over the 20th century new medicines have brought massive social benefits
- Likely that new targeted medicines will also have great social benefits
- How can we reap the social benefits, at the least social cost?
- This reduces partly to:
 - How to provide an adequate return to innovation to achieve technological development?
 - How to minimize social cost of providing that return?

Patents and the Return to Innovation

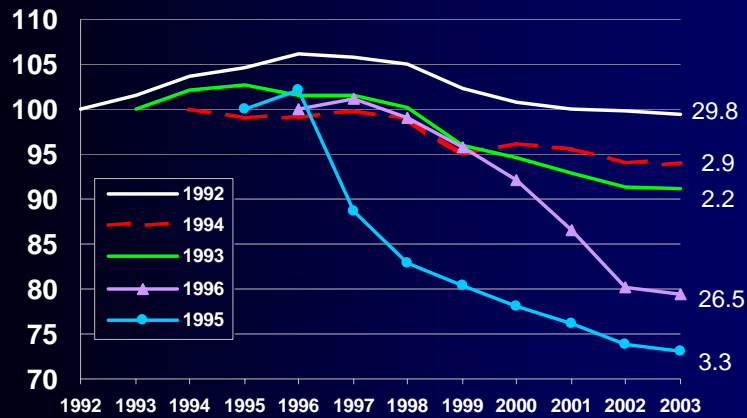
- As previously noted, competitive marginal cost pricing does not provide a return on R&D sunk costs
- The current response – patent protection for a given molecule
- The value of patents erode in competitive markets
 - Other molecules (including generics) compete during patent period
 - The market at work, in a maturing industry

Therapeutic Reference Pricing

- Increasing use of therapeutic reference pricing systems including generics (eg Australia)
- Reference pricing systems with generics
 - Equate prices for patented and generic drugs in a therapeutic group
 - Reduce prices for patented medicines
 - Divide market between patented and generic drugs
 - Do not achieve high market share for low price generics
- Hence they achieve neither objective
 - High returns for innovative drugs
 - Reduced costs through extensive use of low price generics
- Cost saving achieved through lower prices for patented drugs

Prices for Drug Cohorts on Australian Pharmaceutical Benefits Scheme, 1992-1996 Cohorts

(By year of listing; opening year = 100; Fisher price indexes)



Achieving a Return to Innovation at Least Social Cost: Three Approaches

1. Gear pricing towards truly innovative medicines
2. Recognize that factors other than pricing affect returns to innovation
3. Improve the effectiveness of the use of medicines

1. Separating Patented and Generic Medicines in Therapeutic Reference Pricing

- Competitive processes for high market share at lower prices for generics
- Alternative process for prices for patented drugs
 - Contribution to global return to innovation
 - Cost effectiveness analysis to determine relative prices
- Market competition based on prices to determine market shares

Opportunities for Drug Pricing and Pharmaceutical Budgets

- Most projections based on the past, not the future
 - Rapid growth in drug costs will not continue
 - Patent expiries / pause in new molecules approved
- Current stage of drug cycle offers opportunity to
 - Reduce costs by aggressive use of generics
 - Provide higher prices for truly innovative drugs (return to innovation)
 - Manage drug costs and spur innovation
- Opportunities for countries/regions to pursue this course

2. Not Only Prices Affect the Return to Innovation

- The return to innovation depends on discounted net revenues in relation to the cost of innovation
 - Depends on level and timing of sales
 - Marginal costs of production are fairly uniform
 - Marketing and other costs to market differ greatly across systems
 - Some centralised systems can offer lower cost to market
 - Hence they can provide a higher return to innovation for given prices
- Wrong to focus only on relative prices

Key Items as a Share of Sales, Ten Largest Pharmaceutical Companies: World and Australia (US SEC 10K reports and equivalent Australian filings)

	Global	Australia
	(Per cent of Sales)	
Sales	100	100
Cost of sales	29.0	65.0
Sales/Admin expense	41.6	24.1
EBIT R&D	29.3	10.7

Government and Industry Action to Increase the Return to Innovation, for Given Prices

- Ease of entry and sales of innovative medicines
- Measures to reduce the cost to market
 - Access in centralised systems
 - New methods in market systems
- Reducing the cost of R&D
- No guarantees of an adequate return on innovation

3. Improving the Use of Medicines

- Extensive testing of medicines before approval
 - Little knowledge of actual use after approval
- Actual use is far from optimal
 - Differential effect of blockbusters on patients
 - Adverse medical events
 - Waste/overuse of medicines in some cases
 - Failure to use medicines in many cases (social pattern of medical use)
- Targeted medicines can offer greater effectiveness
 - Require supportive policies

Opportunities to Improve Effectiveness of Use of Medicines

- New technologies offer major advances in effectiveness
 - Information systems
 - Prescribing and monitoring use
 - Information on existing diagnosis and treatment
 - Diagnosis of 'at risk' groups
 - More targeted treatments
 - Policy needs to focus on effective use of medicines

Conclusion

- Current stage of pharma/biotech provides an opportunity to
 - Reduce growth rate in drug budgets
 - Sustain return to innovation in new drugs
 - Reduce the social cost of providing that return
- Three policy approaches
 - Utilize generics and gear pricing towards innovative drugs
 - Reduce the cost to market for new drugs
 - Improve the effectiveness of drug use
- Potential health and industry development gains from pursuing this path

Presentation available at www.cfses.com