

Transforming Big Pharma

Assessing the
Strategic Alternatives

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TRANSFORMING BIG PHARMA

Assessing The Strategic Alternatives

I. How Pharma Differs from Other Industries

II. Pharma's Strategic Options

III. Prospects for New Products



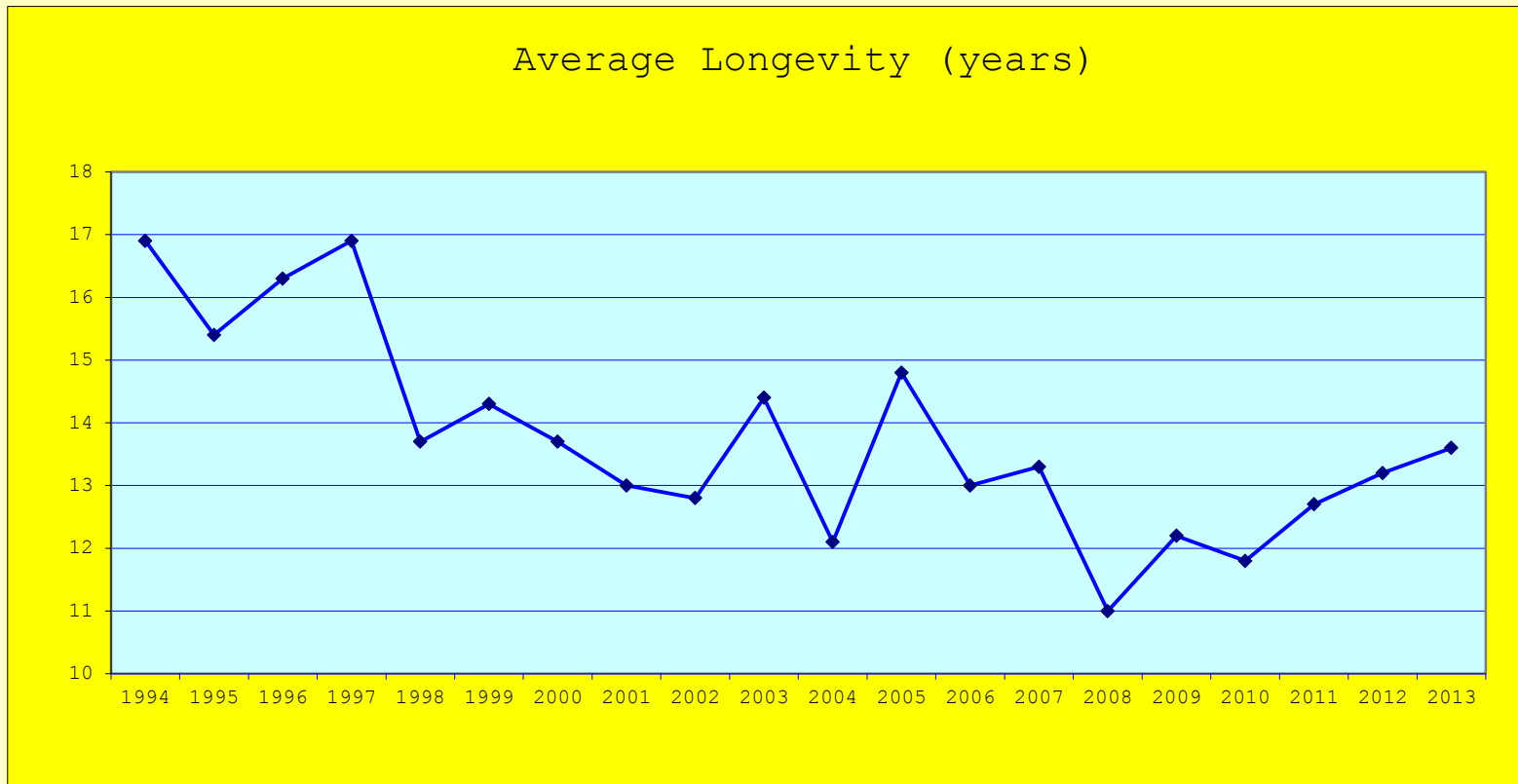
I . HOW PHARMA DIFFERS FROM OTHER INDUSTRIES



LONGEVITY

- Average time to peak sales

for top 50 globally best-selling products



Source: John Ansell Consultancy



COST STRUCTURES : SMALL MOLECULES

1ry care/

Small molecule

■ R & D	16.5%
■ Cost of goods	13.2%
■ Sales & marketing	35.0%
■ General & administrative	8.0%
■ Total	72.7%
■ Margin	27.3%

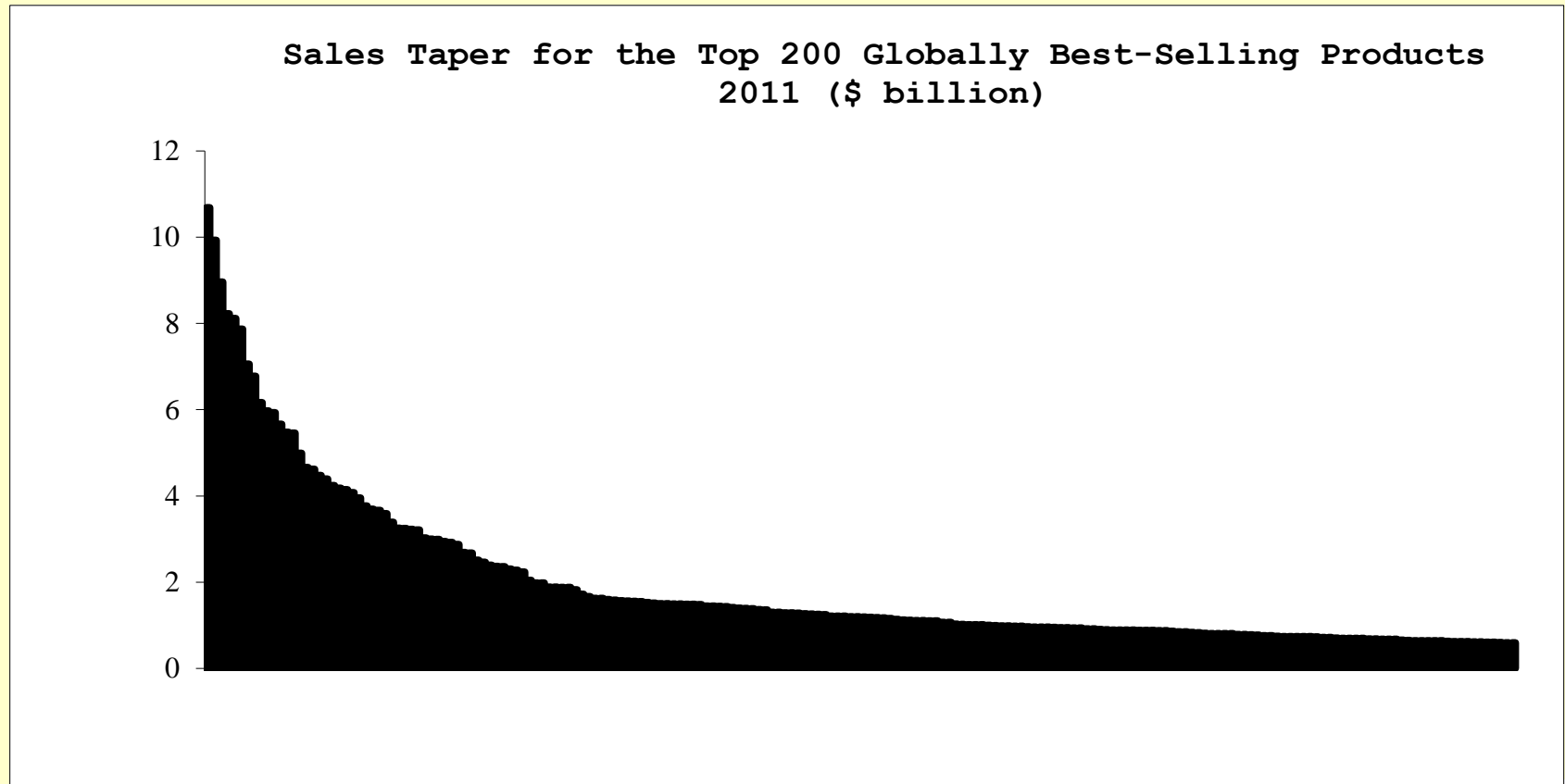
Source: James, B, Big Pharma: The Beginning of the End or the End of the Beginning? p 10, Decision Resources, Inc. Spectrum, Pharmaceutical Industry Dynamics, May 2003/John Ansell Consultancy

COST STRUCTURES: SMALL VS LARGE MOLECULES

molecule	Primary care/ small molecule	Specialist/ Large
■ R & D	16.5%	similar
■ Cost of goods	13.2%	often greater
■ Sales & marketing	35.0%	<10%
■ General & administrative	8.0%	similar
■ Total	72.7%	c.50%

Source: James B. *Big Pharma: The Beginning of the End or the End of the Beginning?* p 1
 ■ Margin 27.3% c.50%
 Decision Resources, Inc. Spectrum, Pharmaceutical Industry Dynamics,
 May 2003/John Ansell Consultancy

HOW CONCENTRATED IS THE PHARMA INDUSTRY?



Source: John Ansell "Transforming Big Pharma" Gower Publishing, 2013

II. PHARMA'S STRATEGIC OPTIONS



MAJOR STRATEGIC OPTIONS FOR PHARMA

- Focussing down
- Diversification
- M&A
- Demergers
- More emphasis on emerging countries
- Develop new products

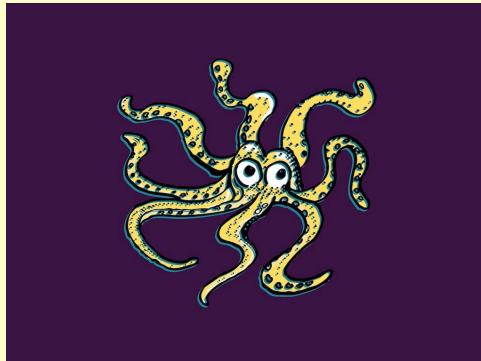


A CONUNDRUM



down

or



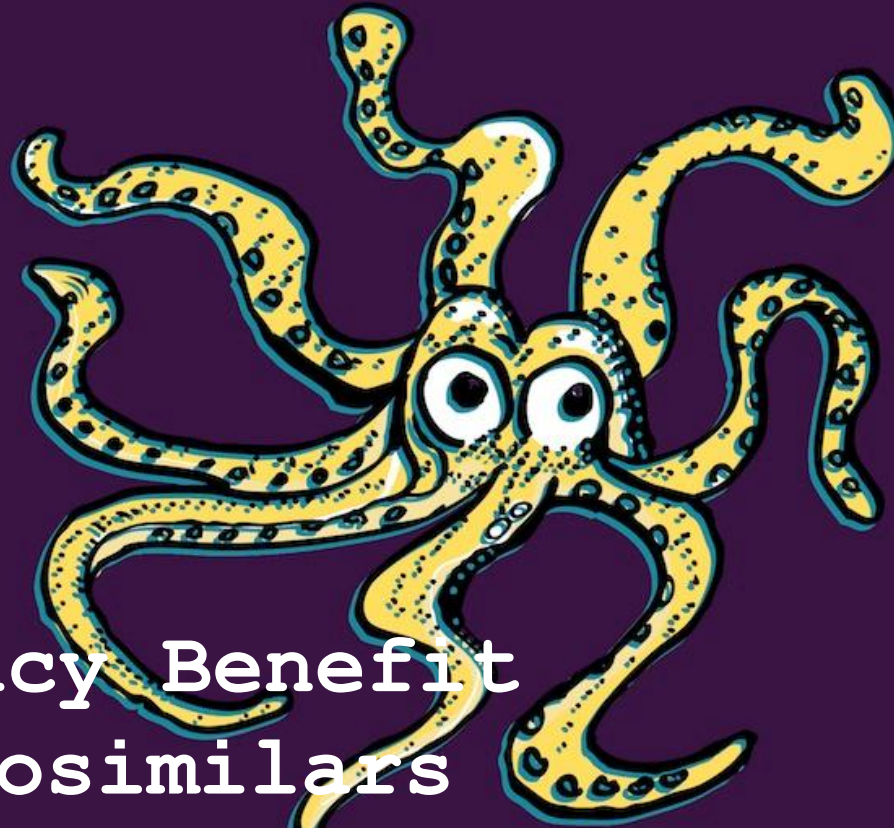
diversify?

DIVERSIFICATIO

N

OTC

Generics



Pharmacy Benefit
Biosimilars
Management (PBMs)

MAJOR STRATEGIC OPTIONS FOR PHARMA

- Focussing down
- Diversification
- M&A
- Demergers
- More emphasis on emerging countries
- Develop new products



III. PROSPECTS FOR NEW PRODUCTS



III. PROSPECTS FOR NEW PRODUCTS

- i. Trends in Numbers Launched
- ii. Trends in Quality
- iii. Trends in Attrition Rates
- iv. Getting a True Fix on Sales Potential
- v. Getting a True Fix on Profitability

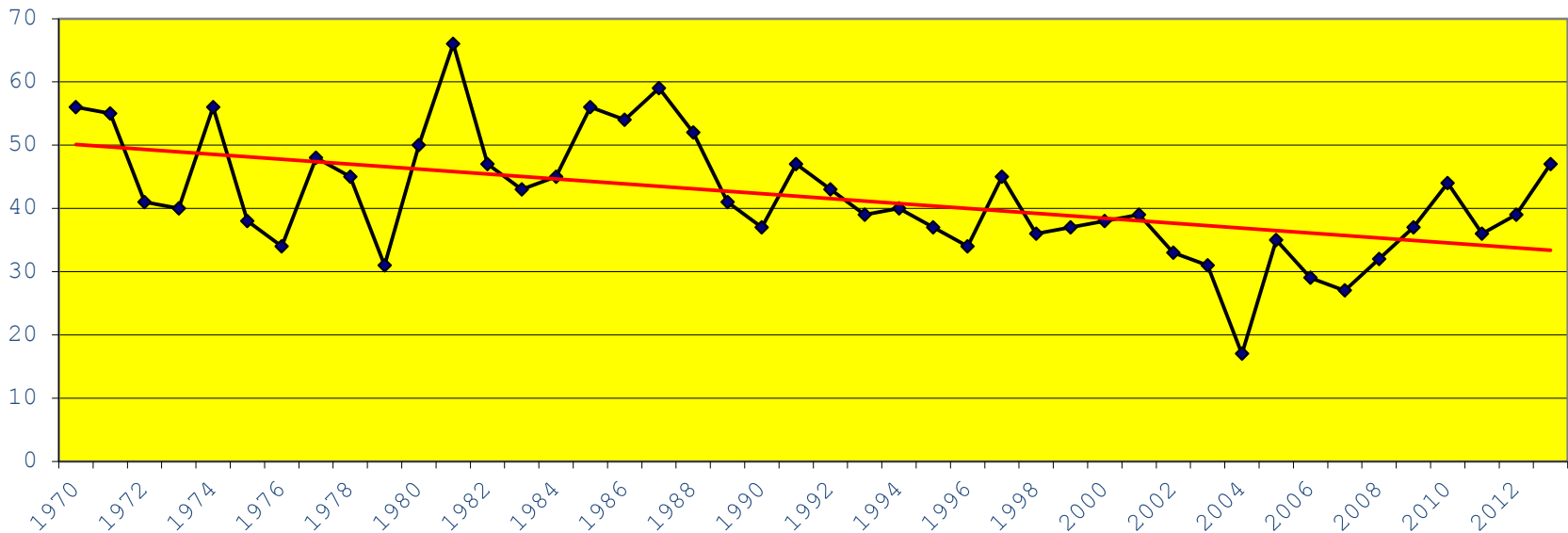


i.

Trends in New Product Quantity



GLOBAL FIRST LAUNCHES FOR NEW PRODUCTS 1970-2013



Source: John Ansell Consultancy.

Based on data from CMR International (1990-2000), Pharmaprojects (2000-2013).



GLOBAL FIRST LAUNCHES FOR NEW PRODUCTS 2000-2013

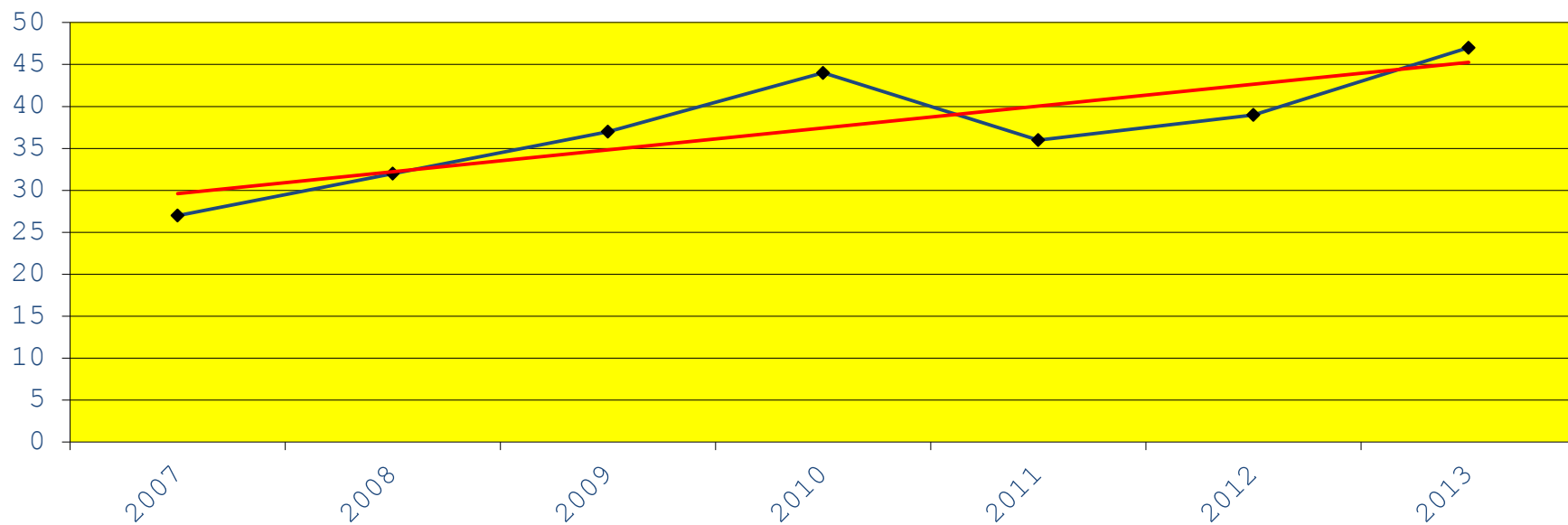


Source: John Ansell Consultancy.

Based on data from CMR International (1990-2000), Pharmaprojects (2000-2013).



GLOBAL FIRST LAUNCHES FOR NEW PRODUCTS 2007-2013

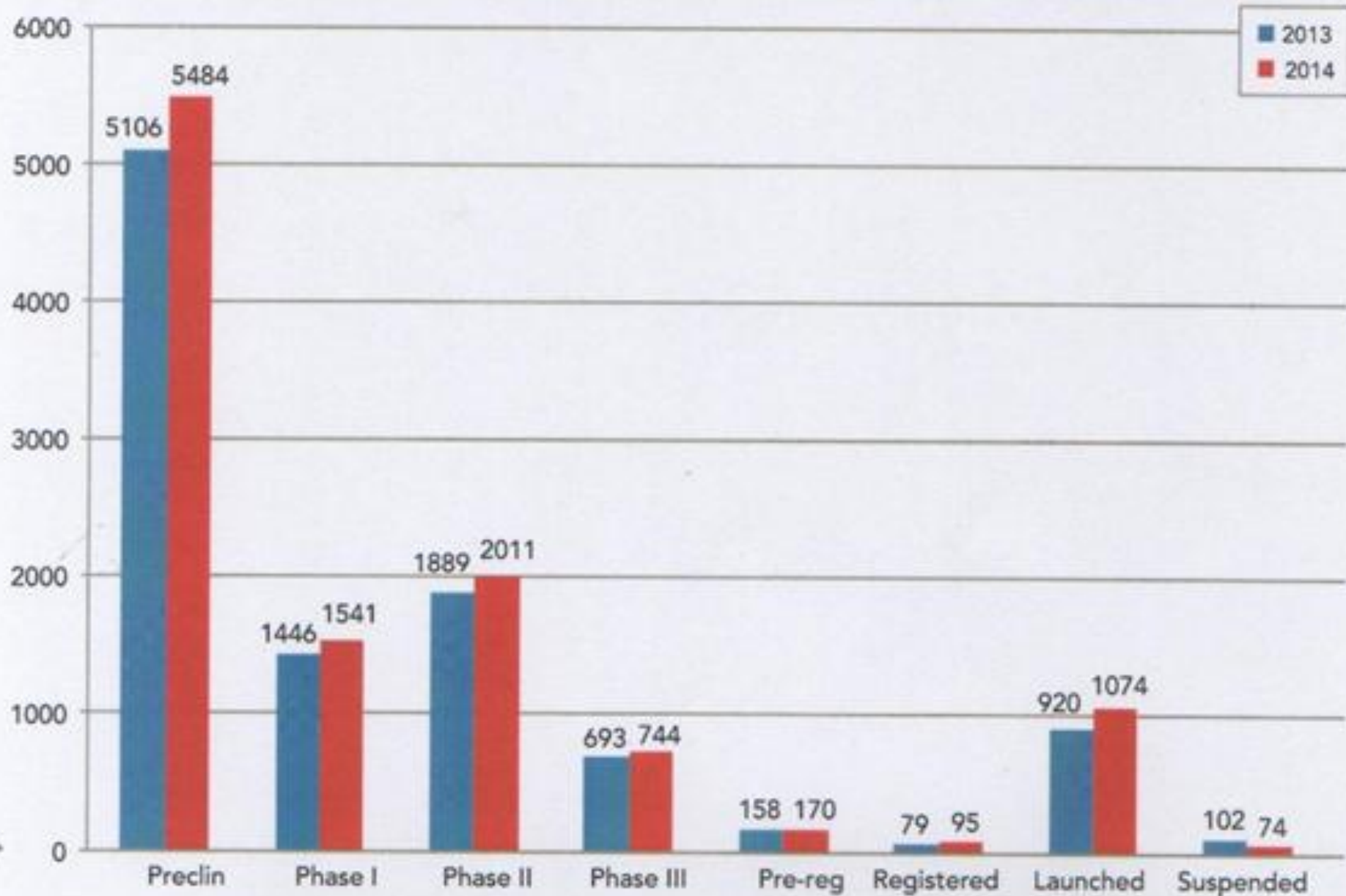


Source: John Ansell Consultancy.

Based on data from CMR International (1990-2000), Pharmaprojects (2000-2013).

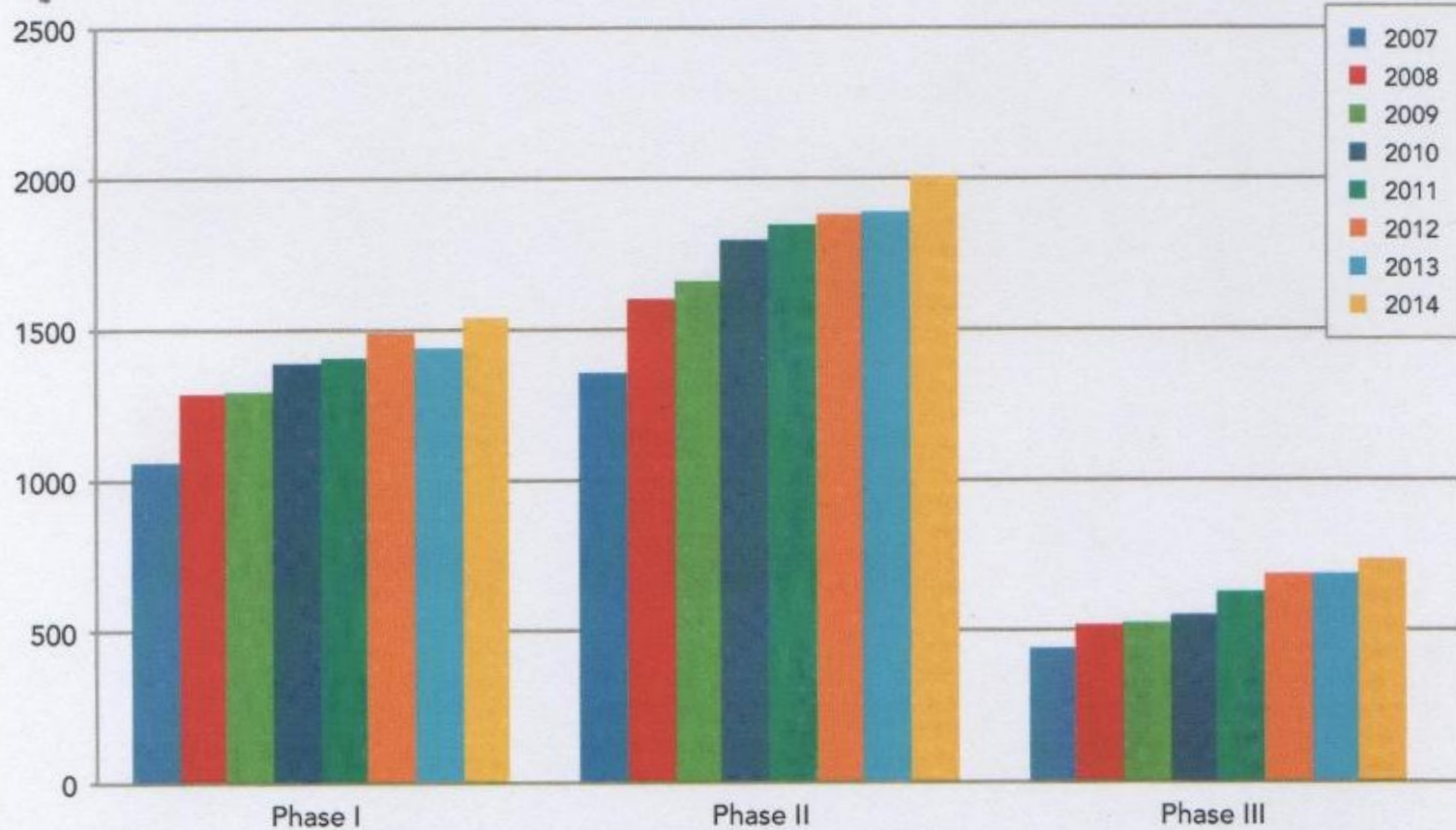


Figure 2. Pipeline By Development Phase



Source: Pharmaprojects® Pipeline®, January 2014

Figure 3. Clinical Phase Trends 2007-2014



Source: Pharmaprojects® Pipeline®, January 2014

ii.

New Product Quality:

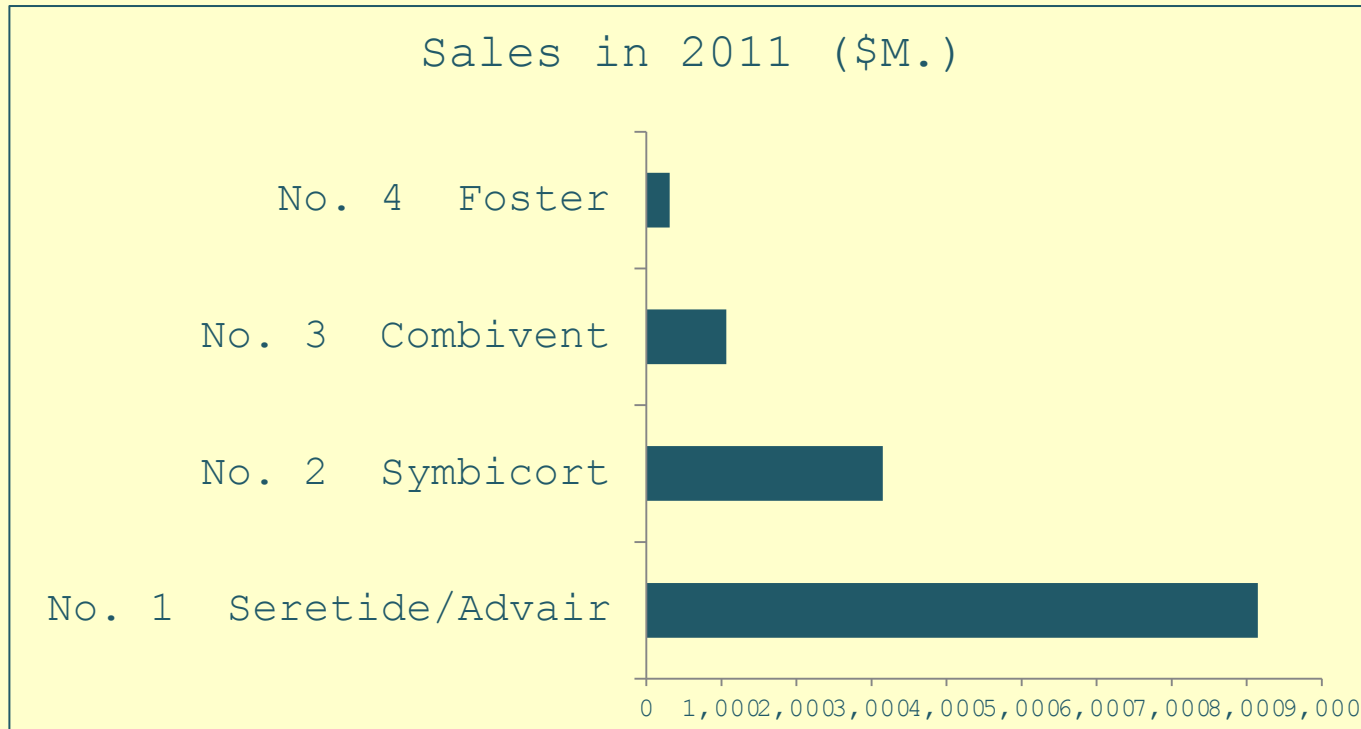
Will tomorrow's products
be as good as today's ?



AIMING LOW WITH ME-TOO PRODUCTS



ME-TOO RESPIRATORY COMBINATIONS – DIMINISHING RETURNS



No. 5 Dulera and No. 6 Flutiform – even less impact

Source: John Ansell Consultancy



BLOCKBUSTERS FIRST LAUNCHED IN ORPHAN INDICATIONS

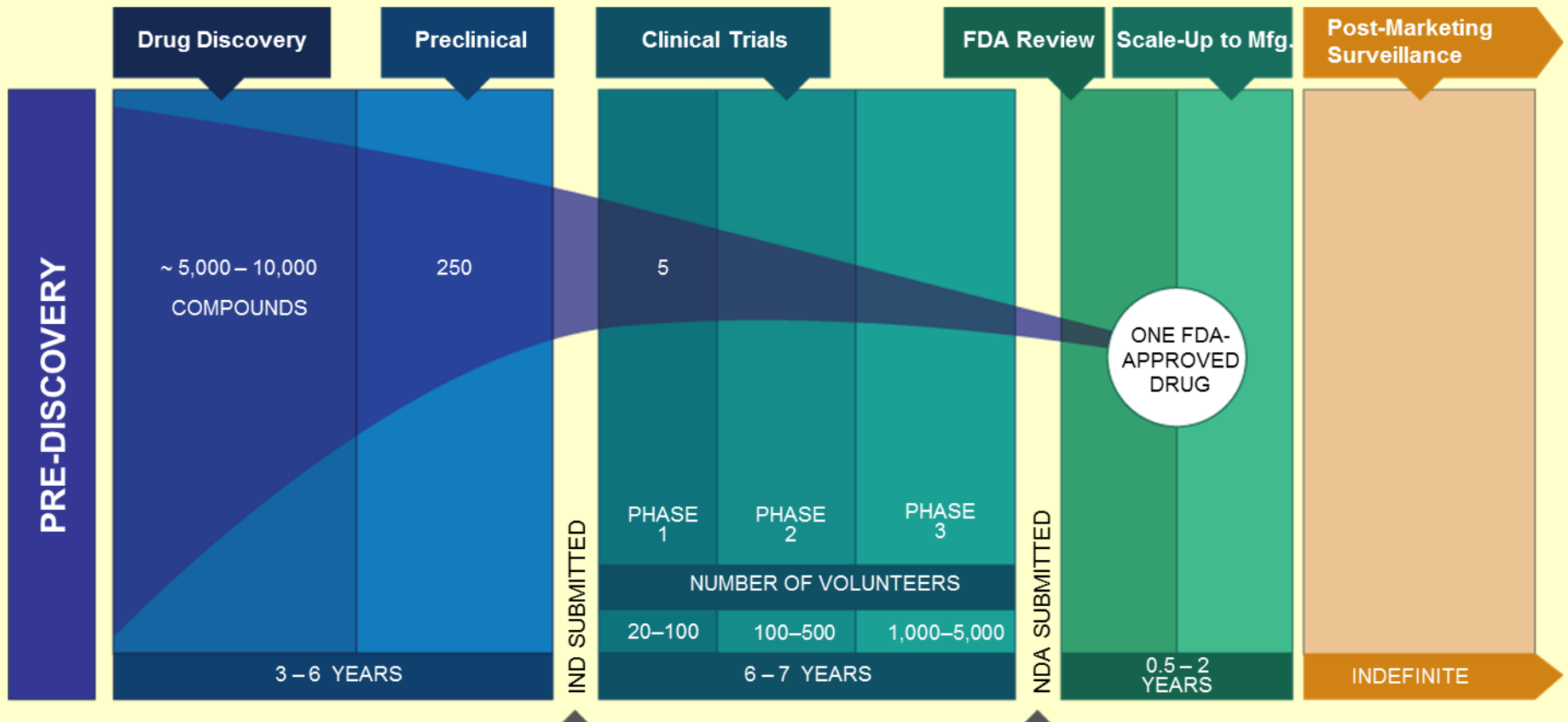


iii.

What's happening on
Attrition in New Product
Development?



CLASSICAL PORTRAYAL OF ATTRITION THROUGH R&D



Source: PhRMA, Biopharmaceuticals in Perspective Facts and Figures 2012 (Washington, DC: PhRMA, March 2012)



PERCENTAGE OF PROJECTS PROGRESSING: PHASE I → MARKET (FDA)

1990 → 14%
2005 → 8%



PERCENTAGE OF PROJECTS PROGRESSING: PHASE ~~III~~ → MARKET (FDA)

1990 → 80%
2005 → 50%





Merck to Withdraw Vioxx Because of Heart Risks

Painful Withdrawal for Makers of Vioxx

Pulling of Arthritis Drug Raises Questions on Marketing, Safety Risks

By Brooke A. Masters and Marc Kaufman

Washington Post Staff Writers

The Washington Post

Vioxx maker knew of problems early

“Vioxx makers knew of drug's dangers three years before recall, says UW study”



Analysis

Nature Reviews Drug Discovery **10**, 428-438 (June 2011) |

doi:10.1038/nrd3405

The productivity crisis in pharmaceutical R&D

Fabio Pammolli^{1,4}, Laura Magazzini^{2,4} & Massimo Riccaboni^{3,4} [About the authors](#)

top

Advances in the understanding of the molecular basis of diseases have expanded the number of plausible therapeutic targets for the development of innovative agents in recent decades. However, although investment in pharmaceutical research and development (R&D) has increased substantially in this time, the lack of a corresponding increase in the output in terms of new drugs being approved indicates that therapeutic innovation has become more challenging. Here, using a large database that contains information on R&D projects for more than 28,000 compounds investigated since 1990, we examine the decline of R&D productivity in pharmaceuticals in the past two decades and its determinants. We show that this decline is associated with an increasing concentration of R&D investments in areas in which the risk of failure is high, which correspond to unmet therapeutic needs and unexploited biological mechanisms. We also investigate the potential variations in productivity with regard to the regional location of companies and find that although



PAMMOLI ET AL.

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ENABLING TECHNOLOGIES: FROM COMBINATORIAL CHEMISTRY



ENABLING TECHNOLOGIES: FROM HIGH THROUGHPUT SCREENING (HTS)

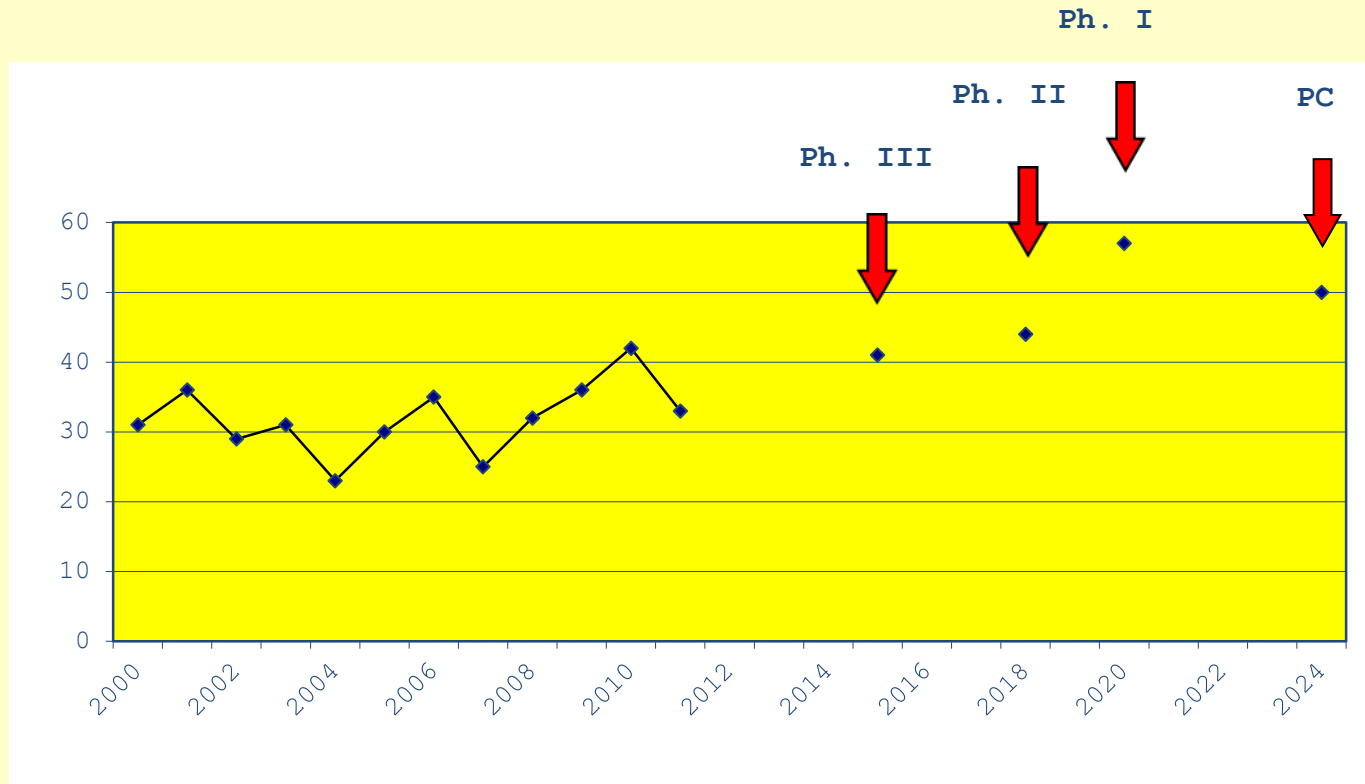


PRODUCTS ORIGINATING FROM HTS

Products Originating From HTS



PROJECTIONS FROM NO. PROJECTS NOW IN DEVELOPMENT AT EACH PHASE



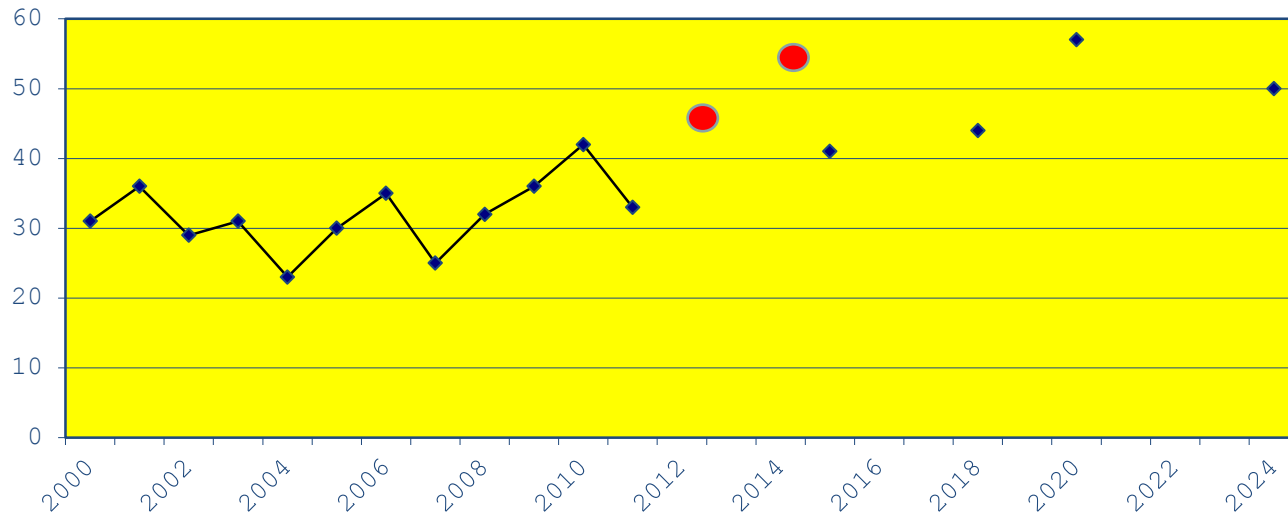
Source: Ansell, J., "Transforming Big Pharma", Gower Publishing, based on Citeline/Pharmaprojects data



HOW ARE WE DOING SO FAR?

Global new products
launches:

2012: 39 2013: 47



iv.

Getting a True Fix on
New Product Sales
Potential





UNDERFORECASTING SALES

Annual review
edition
headlines

1992 - annus horribilis

1993 - a year to retrench, restructure,
rethink

1994 - an end or a beginning ?

1999 Will R&D provide jam tomorrow ?

2000 Exciting times or just an ongoing
slog ?

2002 Looking back at an uncertain
future

2003 The old order comes to an end

2004 Misery loves company





"One of the Company's most exciting new products is CLARITIN, approved in 17 overseas markets with U.S. approval expected soon. When fully established, the product is projected to generate sales of \$200-to-\$300 million annually."

- Schering Corporation (1989)

Peak sales: \$3.159 billion





"Abilify has a solid shot at success, but our \$1.4 billion projection by 2007 is insufficient to move Bristol-Myers Squibb's underlying revenue growth in any given year beyond 2003" *ICIS 2003*

Reached sales of \$4.991 billion by 2011





"we would expect Nexium to achieve rapidly (and within two years) a 20 per cent+ share of the Losec franchise with corresponding sales of more than \$1 billion."
(see securities)

Peak sales reached: \$5.216 billion





Could have sales of \$1
billion "in four or
five years' time"
Scrip 1996

Peak sales of \$5.026
billion in 2010!



Seretide[®]
salmeterol/fluticasone propionate

ADVAIR DISKUS[®] 100/50
(fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder)

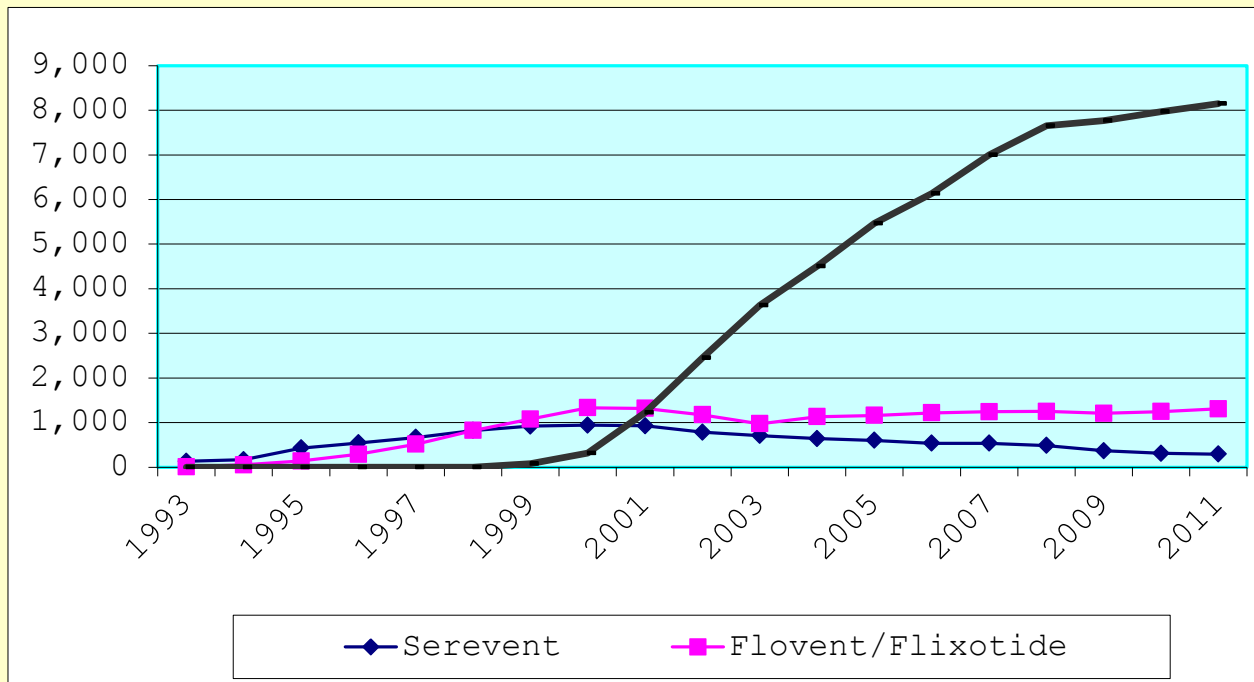
“Analysts see huge potential for Advair/Seretide in the US, particularly in light of its successful start elsewhere ... By 2003, global sales predictions for the combination product are in the region of £1-1.5 billion.” *Scrip 2001*



Seretide[®]
salmeterol/fluticasone propionate

ADVAIR DISKUS[®] 100/50
(fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder)

Global Sales of Advair/Seretide and its Component Products



Source: John Ansell Consultancy based on ex-company sales



“Aricept could easily make sales in excess of \$500 million a year” – A.G. Edwards, Pharma Letter, 1996)

Sales peaked at \$4.4 billion
in 2009 !

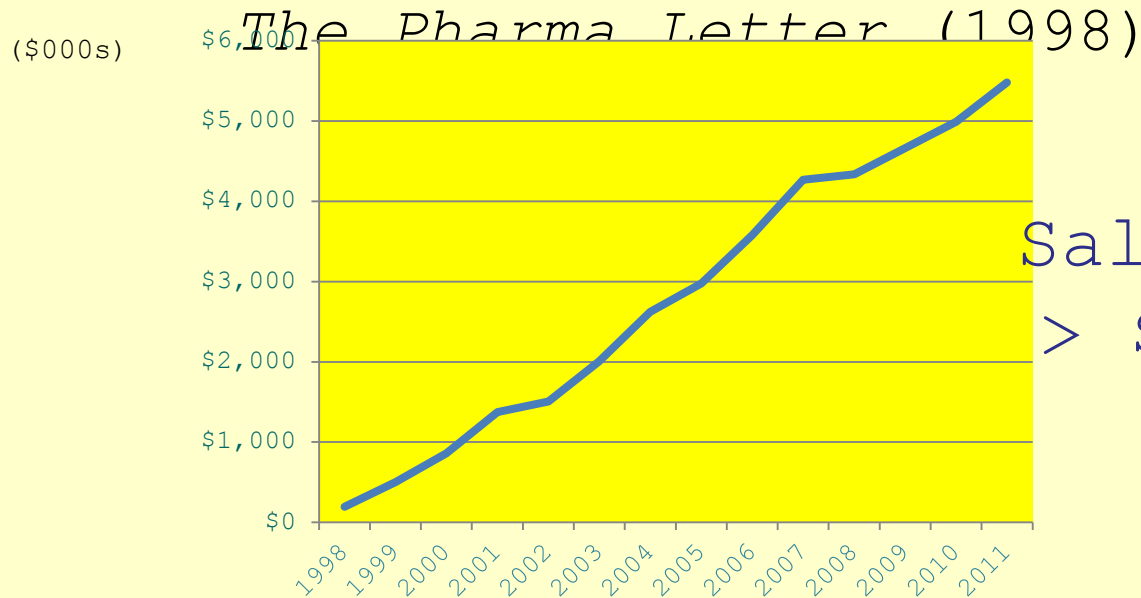


TABLET DAILY
SINGULAIR[®]
(montelukast, MSD)

Target the **Dual Pathways** of Asthmatic Inflammation



Annual sales could reach: 'over \$500 million within a few years'



Sales peaked at
> \$5 billion !





“Analysts feel that clopidogrel has the potential to become a blockbuster product, breaking the \$500 million mark...”

The Pharma Letter (1998)

Sales peaked at \$9.6
billion !





"first peak-sale estimates of \$500 million
were off by a factor of 25"
- Freda Lewis-Hall, Pfizer
Economist Pharma Summit, London (2011)



v.

Getting a True Fix on
New Product
Profitability



Returns on Research and Development for 1990s New Drug Introductions

Henry Grabowski,¹ John Vernon¹ and Joseph A. DiMasi²

¹ Department of Economics, Duke University, Durham, North Carolina, USA

² Tufts Center for the Study of Drug Development, Tufts University, Boston, USA

Abstract

Background: Previously published research by the authors found that returns on research and development (R&D) for drugs introduced into the US market in the 1970s and 1980s were highly skewed and that the top decile of new drugs accounted for close to half the overall market value. In the 1990s, however, the R&D environment for new medicines underwent a number of changes including the following: the rapid growth of managed-care organisations; indications that R&D costs were rising at a rate faster than that of overall inflation; new market strategies of major firms aimed at simultaneous launches across world markets; and the increased attention focused on the pharmaceutical industry in the political arena.

Objective: The aim of this study was to examine the worldwide returns on R&D for drugs introduced into the US market in the first half of the 1990s, given that there have been significant changes to the R&D environment for new medicines over the past decade or so.

Results: Analysis of new drugs entering the market from 1990 to 1994 resulted in findings similar to those of the earlier research – pharmaceutical R&D is characterised by a highly skewed distribution of returns and a mean industry internal rate of return modestly in excess of the cost of capital.

Conclusions: Although the distribution of returns on R&D for new drugs continues to be highly skewed, the analysis reveals that a number of dynamic forces are currently at work in the industry. In particular, R&D costs as well as new drug introductions, sales and contribution margins increased significantly compared with their 1980s values.

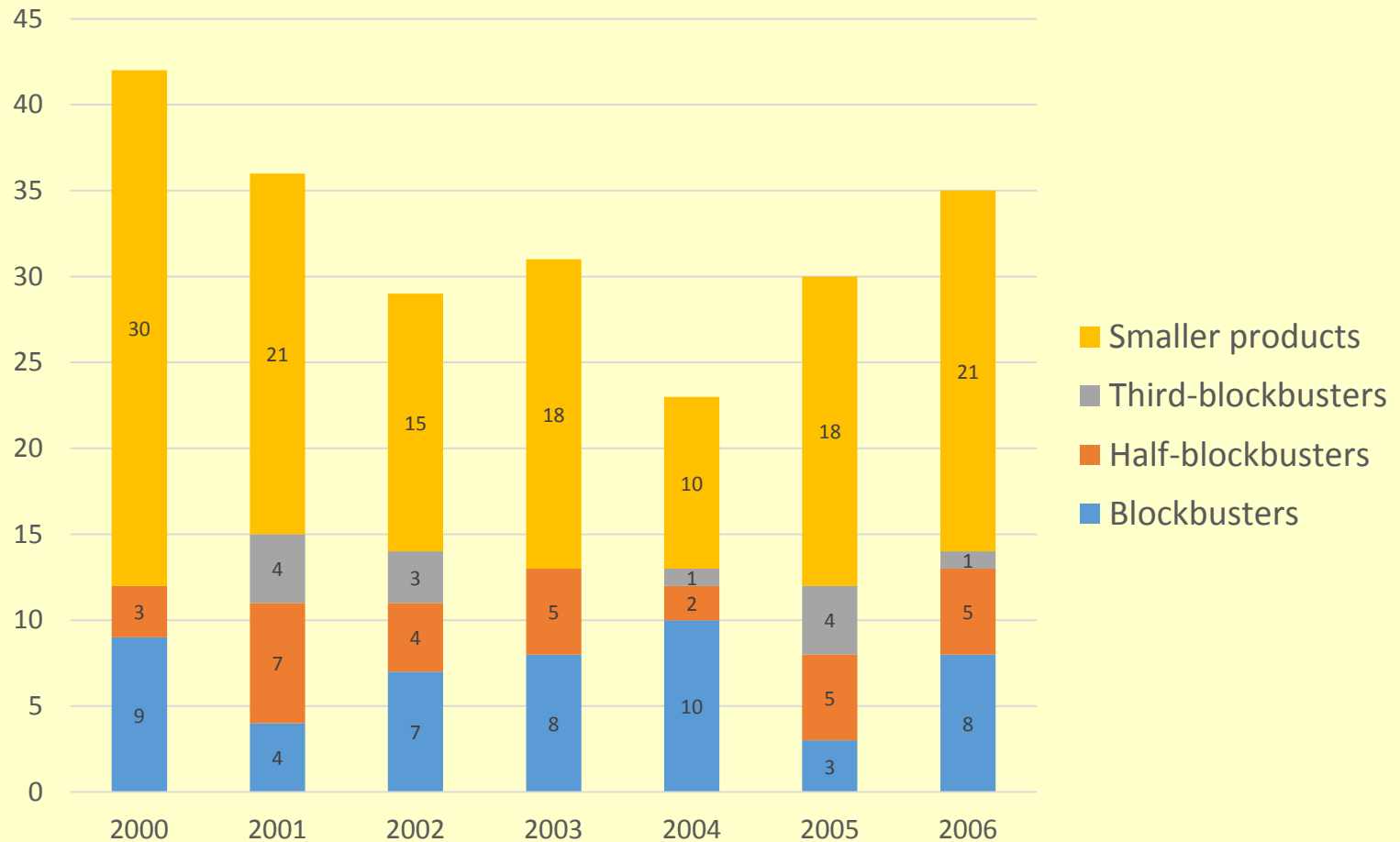
Competition in the research-based pharmaceutical industry centres on the introduction of new drug therapies. In this paper, we examine the returns on research and development (R&D) for new drug entities introduced into the US market in the first half of the 1990s. This research work builds directly on earlier analyses of returns on R&D for the 1970s and 1980s introductions performed by Grabowski and Vernon.^[1,2]

Our prior analyses indicate that this industry has exhibited very skewed distributions of returns. In this regard, several significant new classes of drug therapies have been introduced since the late 1970s. Early movers in these classes have obtained the highest returns on R&D. We found that the top decile of new drugs accounted for close to half of the overall market value associated with all the new drug introductions in our 1970s and 1980s' samples.

2002
assessment:
only 30% of
new products
covered their
20\$0s
reassessment:
down to 20%



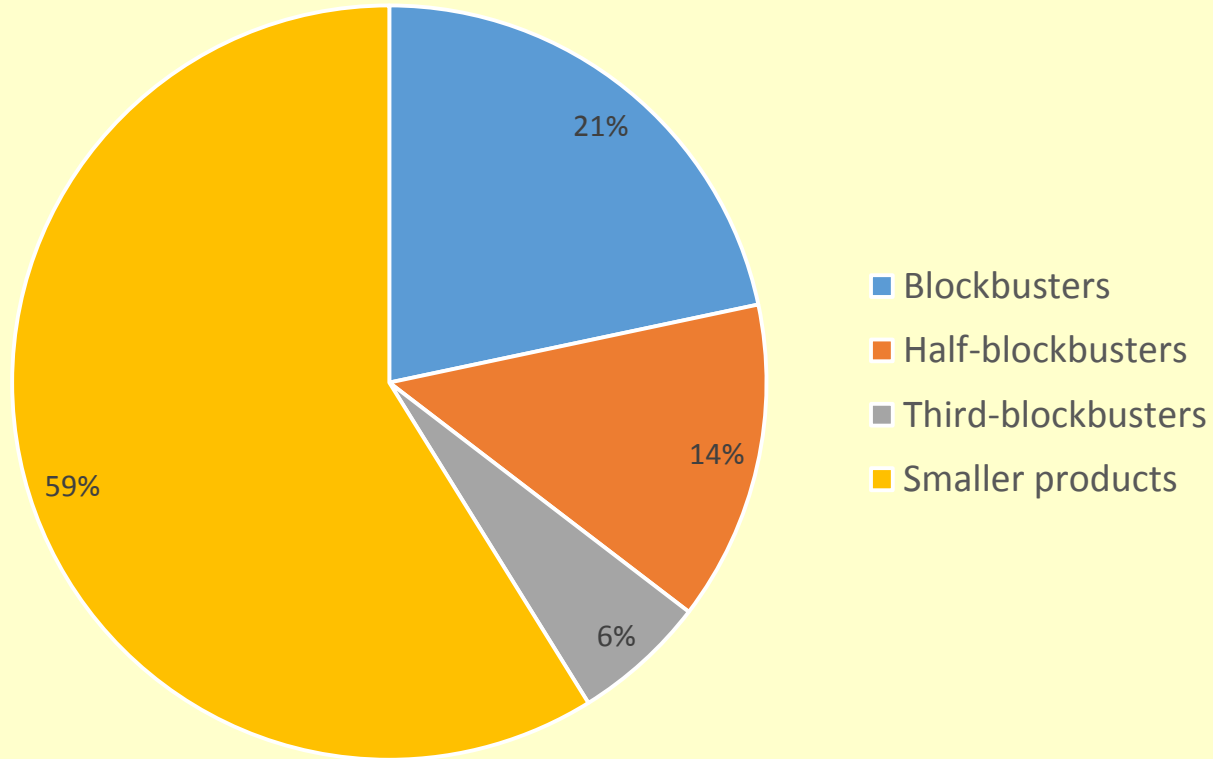
HOW NEW PRODUCTS FIRST LAUNCHED 2000-06 HAD PERFORMED BY 2013



Source: John Ansell Consultancy; based on ex-company sales.



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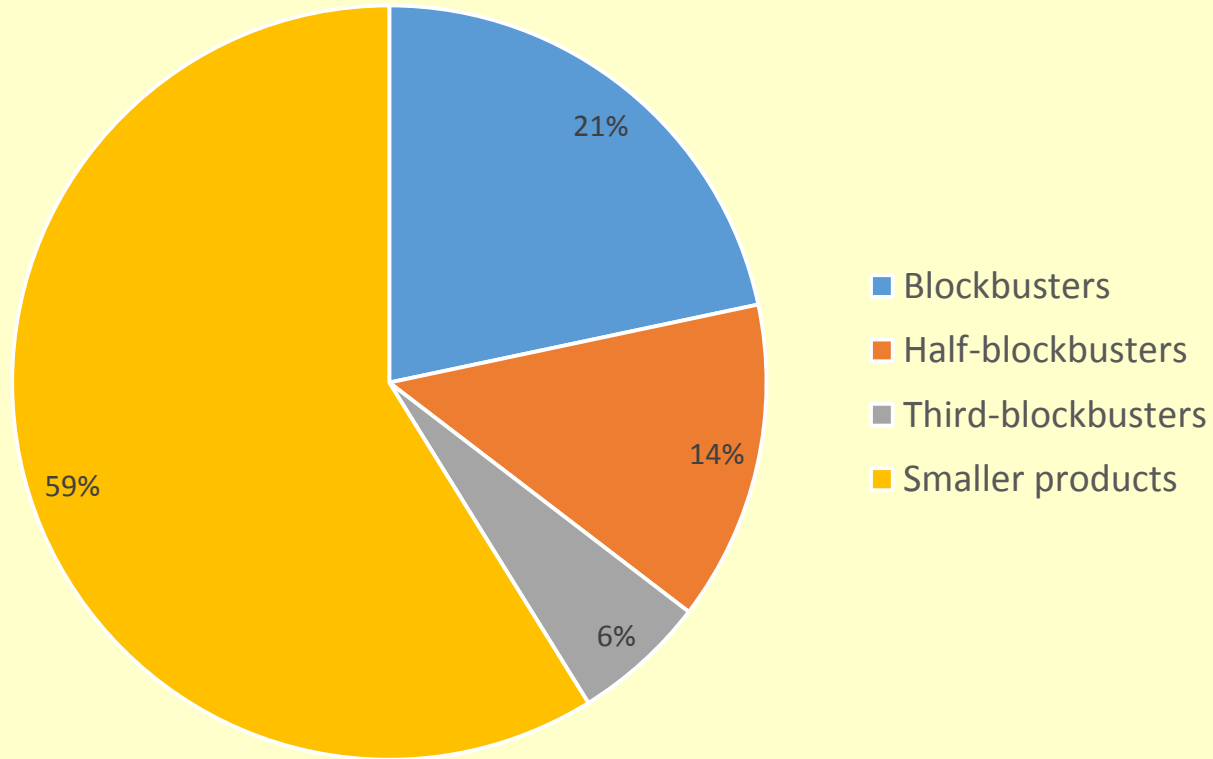
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2002
assessment:
only 30% of new
products
covered their
2010
costs
reassessment:
down to 20%

2014 survey:
Of all new products
first launched
2000-06
so far **21%** have
become
BLOCKBUSTERS!



HOW NEW PRODUCTS FIRST LAUNCHED 2000-06 HAD PERFORMED BY 2013



Source: John Ansell Consultancy



Product sales

	Year to December 31, 2013 S'M
VYVANSE	1,227.8
ELAPRASE	545.6
LIALDA/MEZAVANT	528.9
REPLAGAL	467.9
ADDERALL XR	375.4
VPRIV	342.7
INTUNIV	334.9
PENTASA	280.6
FIRAZYR	234.8
FOSRENOL	183.4
XAGRID	99.4
Other product sales	136.1
Total product sales	4,757.5



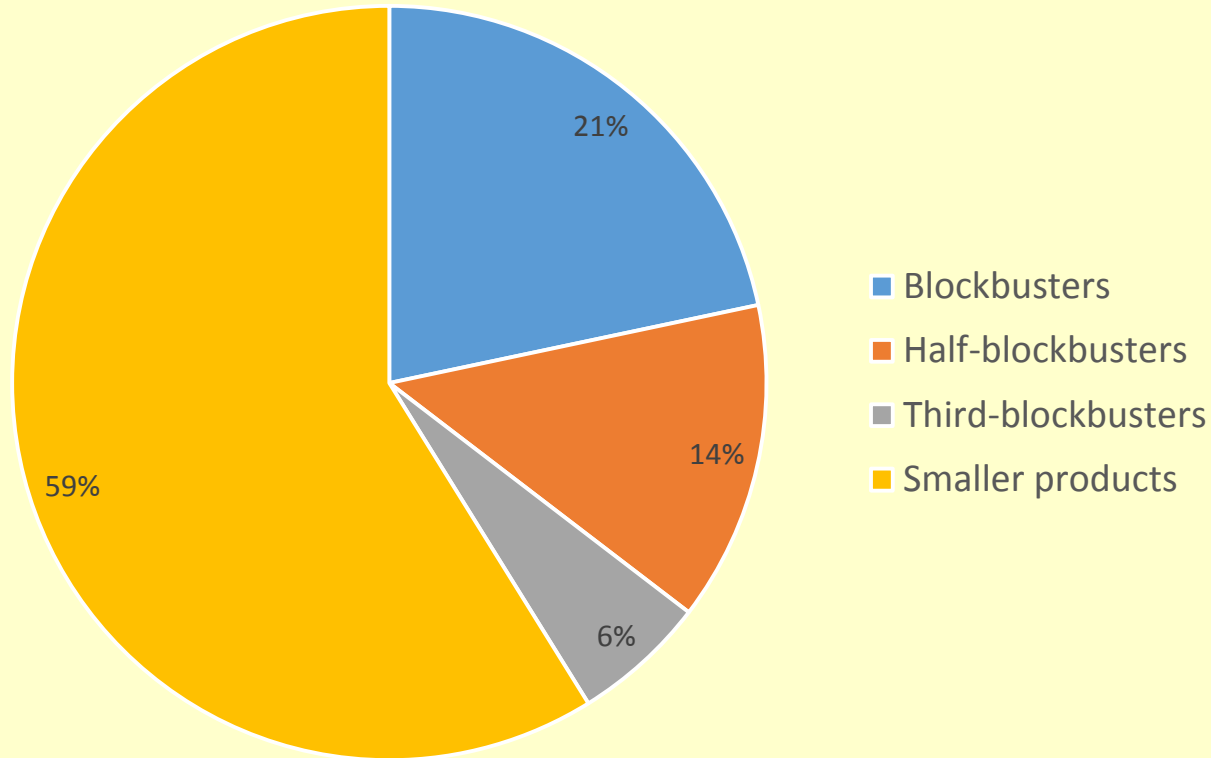


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HOW NEW PRODUCTS FIRST LAUNCHED 2000-06 HAD PERFORMED BY 2013

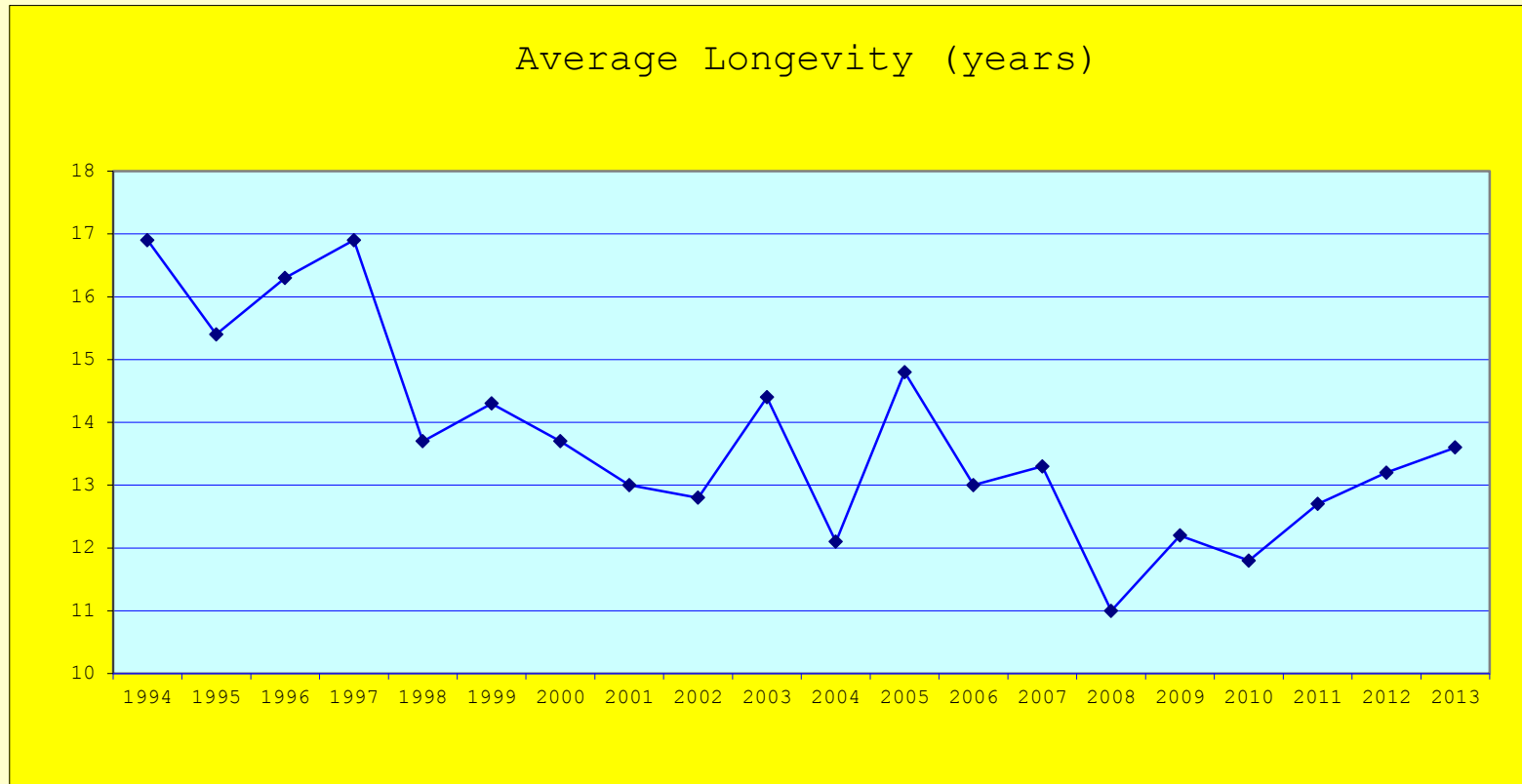


- At very least, 35% of new products are profitable
- > 40% are likely eventually to prove profitable.

LONGEVITY

- average time to peak sales

for Top 50 globally best-selling products



Source: John Ansell Consultancy

