

# *Biotech and Advanced Therapies: A Pharma Renaissance*

Dr Claude Farrugia  
Vice-President Communications, EIPG

# These are troubled times.....



€90bn Irish bailout ends in turmoil.  
Now Europe fears crisis will spread

● Taoiseach at bay as Dublin's ruling coalition disintegrates ● Fears rise that Portugal and Spain may need financial aid ● Massive international rescue plan does little to calm markets



Warning that UK 'may never recover' if Greece exits euro



**ELEZIONI.** Il voto premia Berlusconi e l'ex comico. Nessuno ha i numeri per governare  
**Italia, e adesso?**

Grillo primo partito: «Niente inciuci». Silvio risorge. Pd sotto choc. Monti ko Senato senza vincitori. Camera al centrosinistra. Ma Alfano contesta i dati

Subito scelte chiare o a perdere il Paese



**The Washington Post** Politics Opinions Local Sports National World Business Tech

## Why today's Cyprus bailout could be the start of the next financial crisis

Posted by Neil Irwin on March 16, 2013 at 4:08 pm **16 March 2013**

It is a bad day to have your money deposited in a bank in the Mediterranean island nation of Cyprus. And it may just mean some bad days ahead for the rest of us.

Early Saturday, the nation reached an agreement with international lenders for bailout help. Part of the agreement: Bank depositors with more than 100,000 euros (\$131,000) in their accounts will take a 9.9 percent haircut. Even those with less in savings will see their accounts reduced by 6.75 percent. That's right: Anyone with money in a Cypriot bank will have significantly less money when the banks open for business Tuesday than they did on Friday. Cypriots have reacted with this perfectly rational reaction: lining up at ATM machines to try to get as much money out in the form of cash before the money they have in

*These are troubled times.....*



.....and pharma is not 'immune'.

## TOP 10 COMPANIES

Many big drug companies are seeing their sales decline

	SALES <sup>a</sup> (\$ BILLIONS)	12-MONTH CHANGE IN SALES
Pfizer	\$51.9	-8.6%
Novartis	50.8	2.0
Merck & Co.	40.9	6.8
Sanofi	38.9	-0.9
Roche	35.0	2.7
AstraZeneca	34.5	-5.4
GlaxoSmithKline	33.6	-1.8
Johnson & Johnson	26.8	-4.5
Abbott Laboratories	25.8	4.1
Teva	24.0	-3.4
<b>TOTAL</b>	<b>\$362.2</b>	<b>-1.2%</b>
<b>GLOBAL MARKET</b>	<b>\$857.3</b>	<b>3.5%</b>

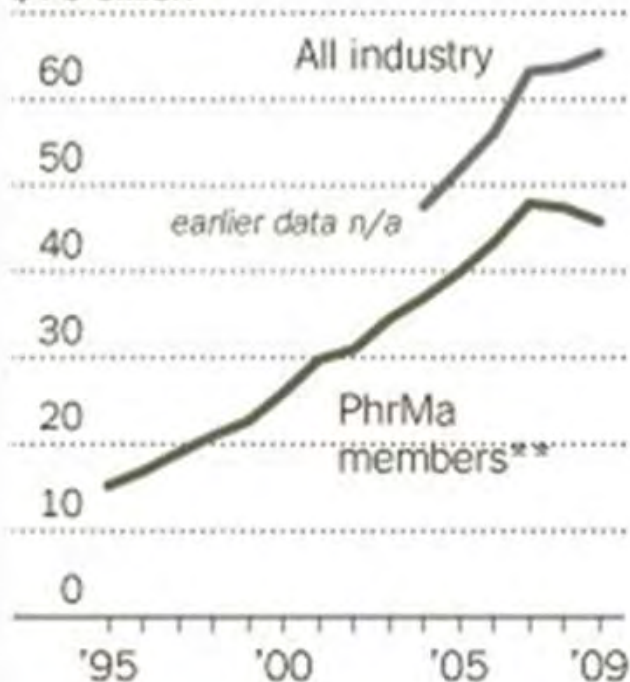
<sup>a</sup> For the 12 months ending on June 30, 2012.

**SOURCE:** IMS Institute for Healthcare Informatics

.....and pharma is not 'immune'.

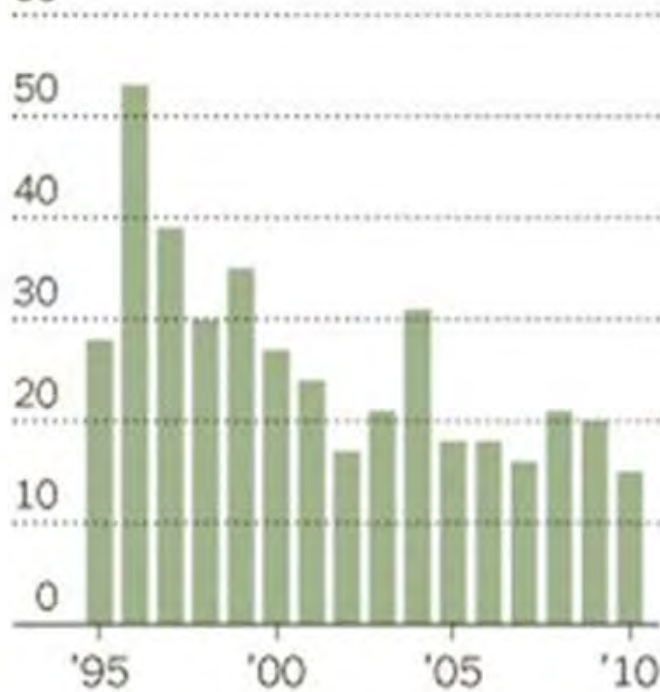
**PHARMACEUTICAL R&D EXPENDITURES**

\$70 billion

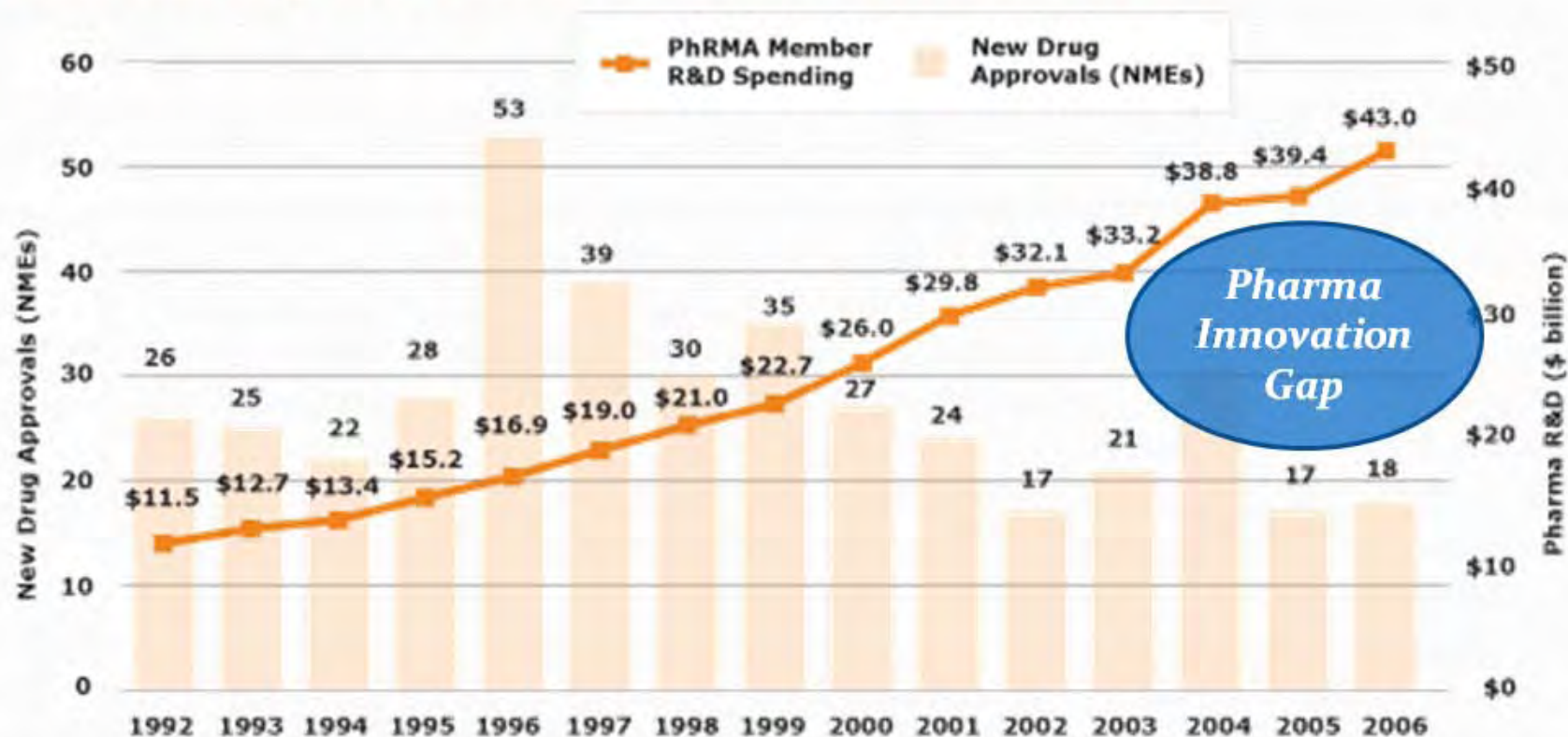


**NEW DRUGS APPROVED\***

60



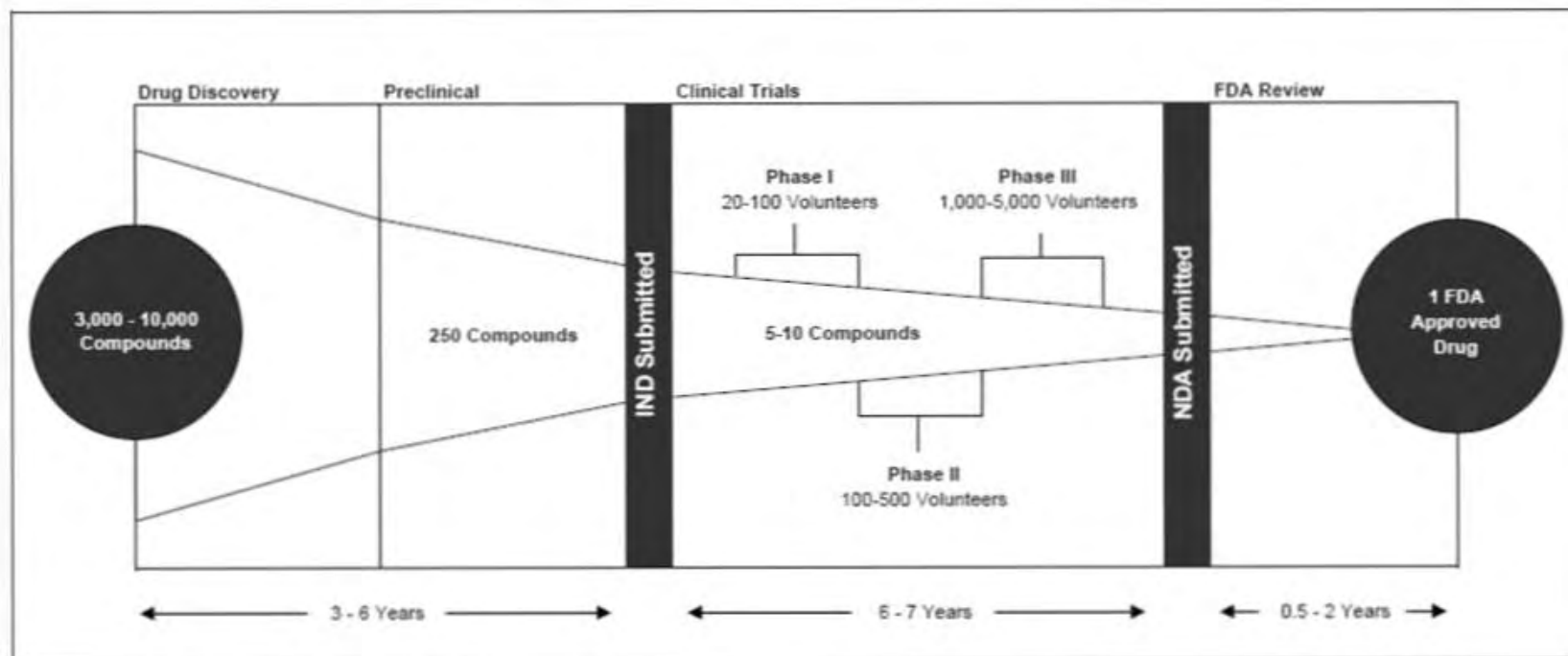
.....and pharma is not 'immune'.



Source: Burrill & Company; US Food and Drug Administration

# Drug Development: Costly and Lengthy

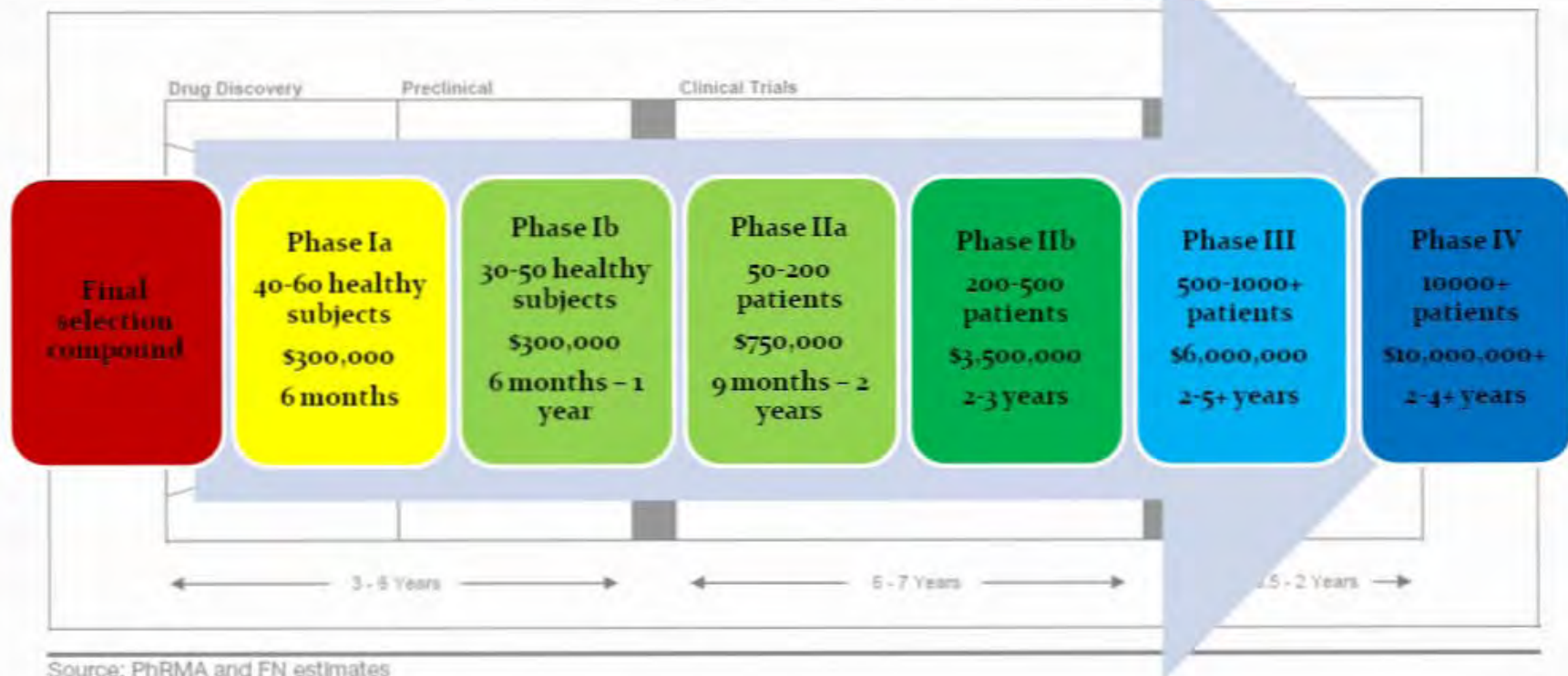
Number of Compounds to Produce a New Drug



Source: PhRMA and FN estimates

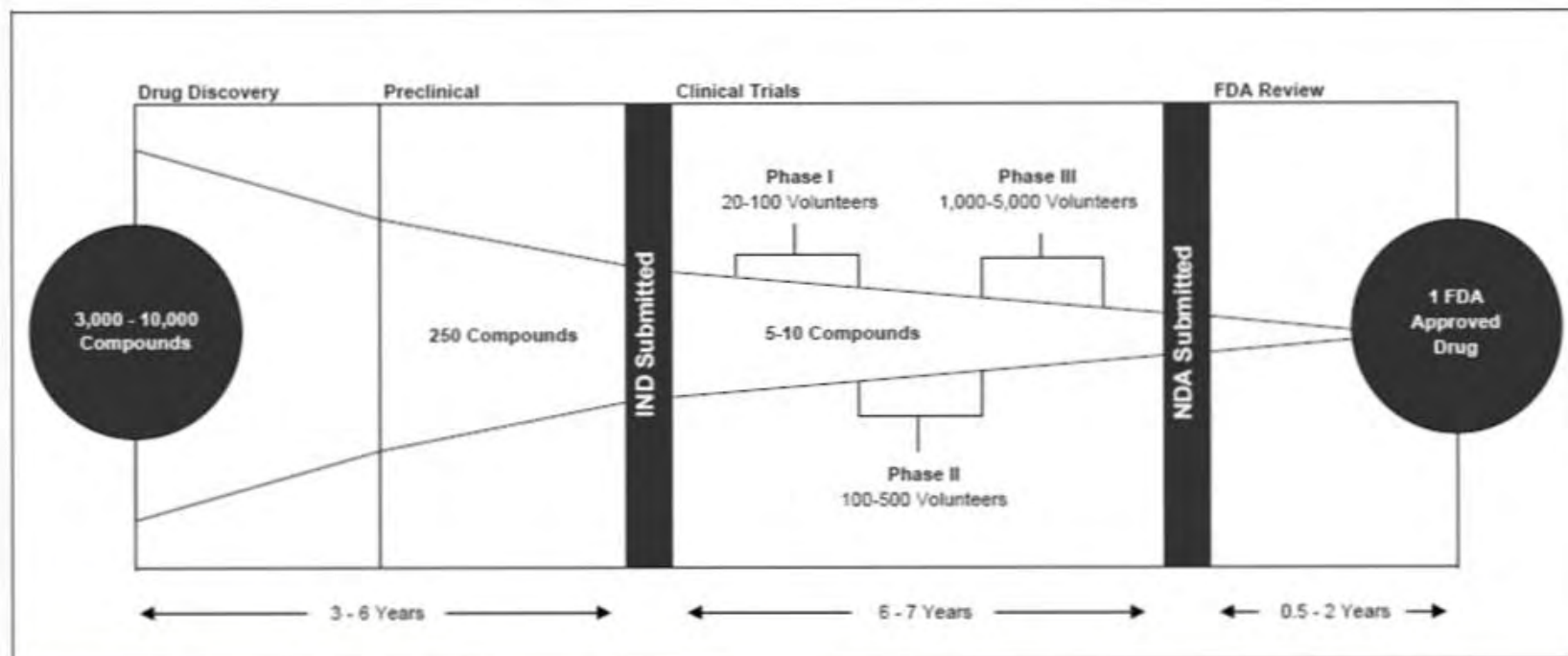
# Drug Development: Costly and Lengthy

Number of Compounds to Produce a New Drug



# Drug Development: Costly and Lengthy

Number of Compounds to Produce a New Drug



Source: PhRMA and FN estimates

*10-15 years from start to launch*

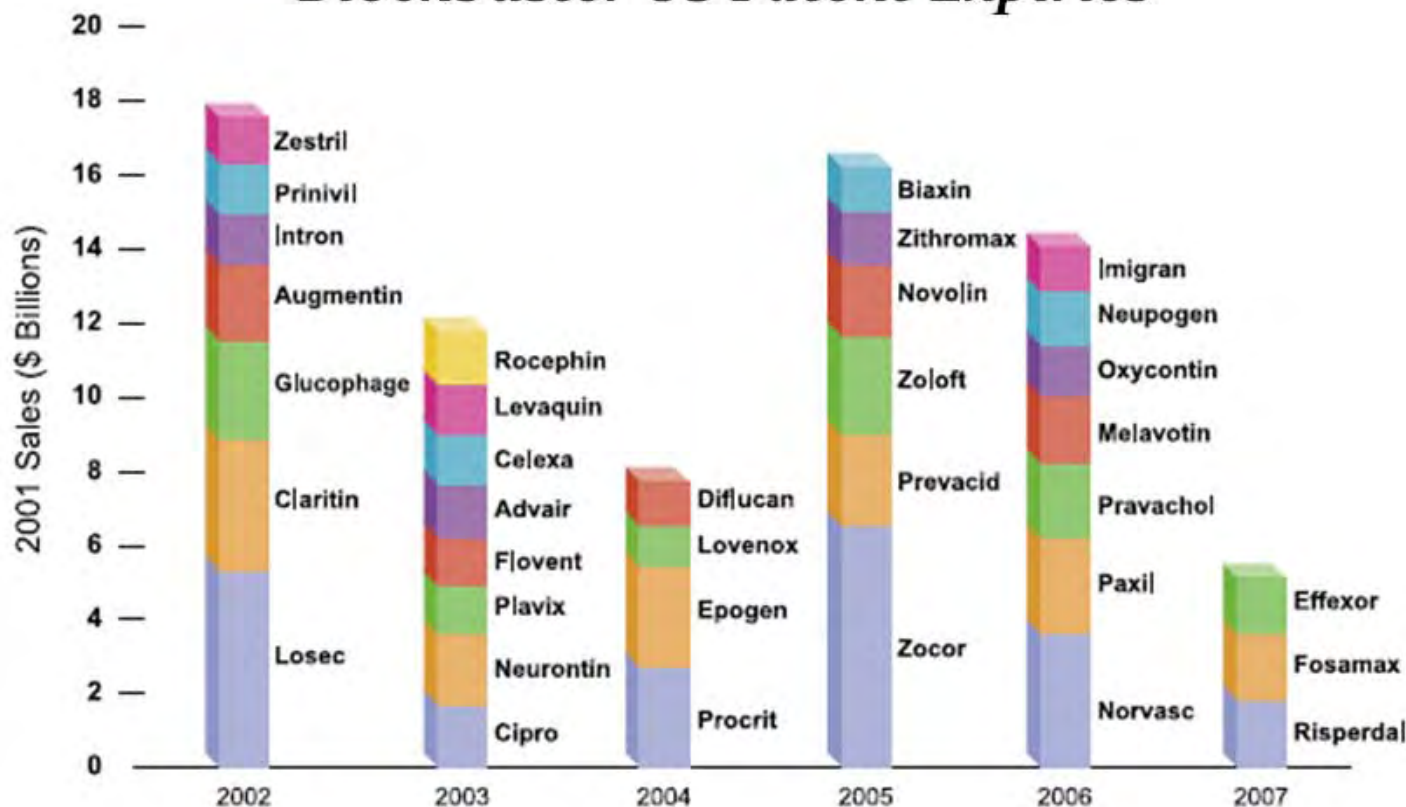
# *Just to put things in perspective...*



*10-15 years from start to launch*

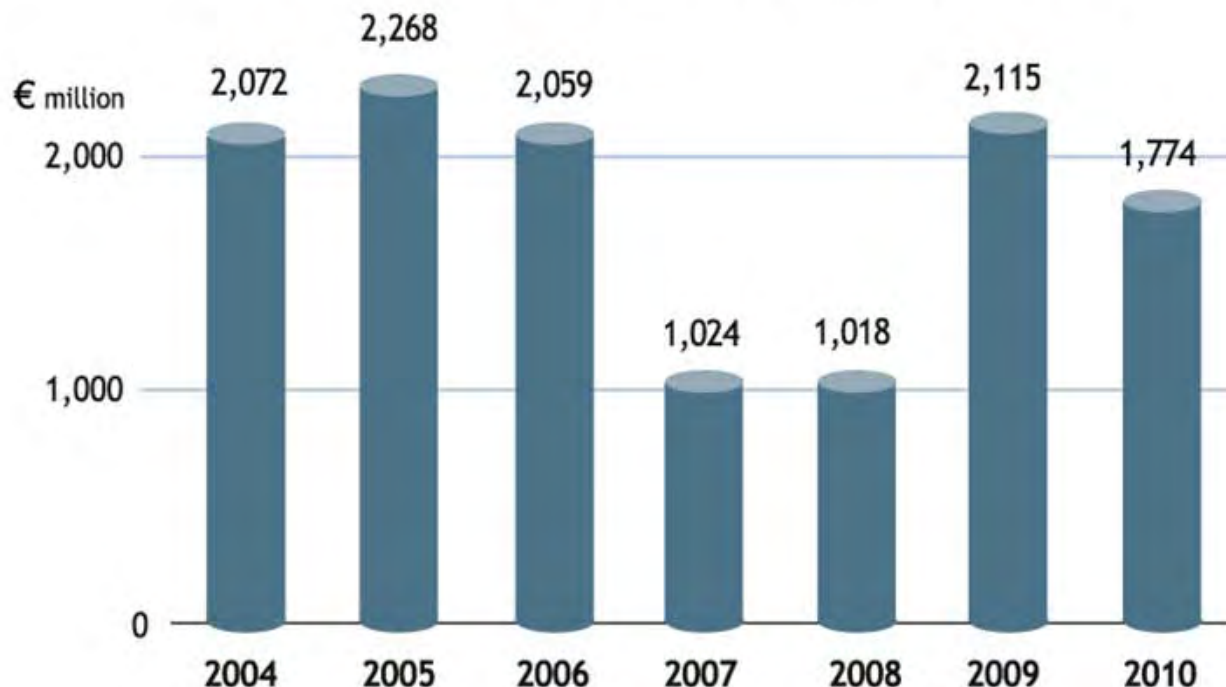
# The Patent Cliff: A Race Against Time

## Blockbuster US Patent Expiries



# The Patent Cliff: A Race Against Time

*Annual Sales Volume in the EU  
becoming available for competition*



# The Patent Cliff: A Race Against Time

## TOP 10 PRODUCTS

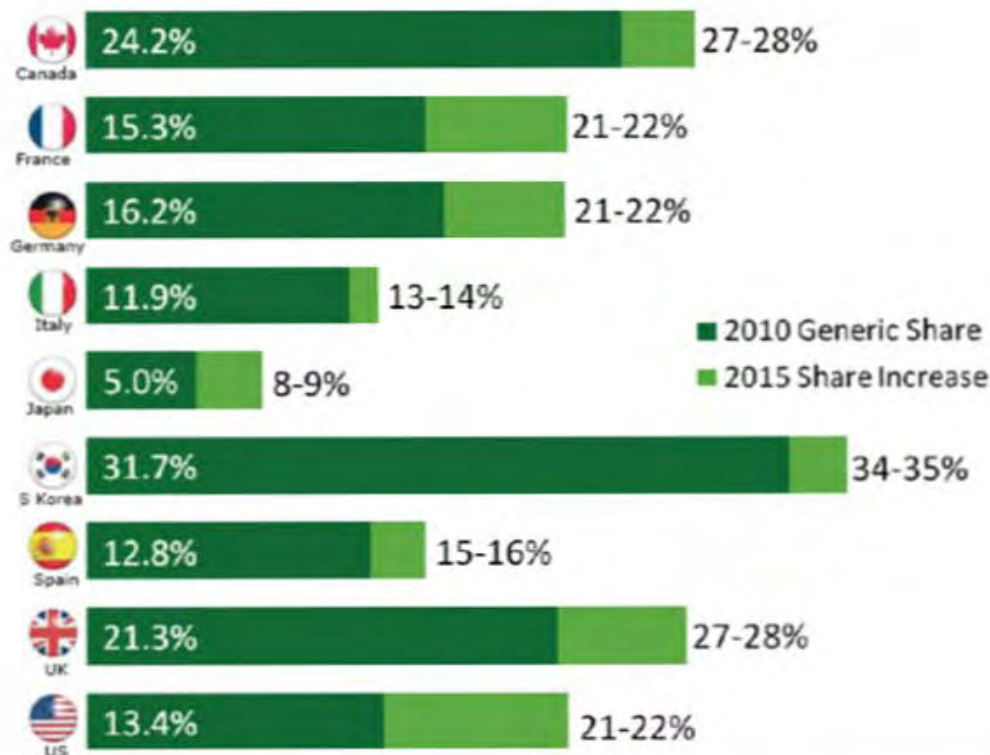
Sales are declining for many of the world's top pharmaceuticals

BRAND NAME	COMPOUND	MARKETER	INDICATION	SALES <sup>a</sup> (\$ BILLIONS)	12-MONTH CHANGE IN SALES
Lipitor	Atorvastatin	Pfizer	Hypercholesterolemia	\$9.5	-24.6%
Seretide	Fluticasone & salmeterol	GlaxoSmithKline	Asthma	8.7	-0.4
Plavix	Clopidogrel	BMS & Sanofi	Atherosclerotic events	8.4	-8.3
Crestor	Rosuvastatin	AstraZeneca	Hypercholesterolemia	8.1	8.8
Humira	Adalimumab	Abbott Laboratories	Rheumatoid arthritis	7.5	17.0
Nexium	Esomeprazole	AstraZeneca	Acid reflux disease symptoms	7.4	-10.2
Remicade	Infliximab	Janssen Biotech	Crohn's disease, rheumatoid arthritis	7.0	9.2
Enbrel	Etanercept	Amgen & Pfizer	Rheumatoid arthritis	6.9	7.6
Seroquel	Quetiapine	AstraZeneca	Bipolar disorder & schizophrenia	6.6	-8.2
Abilify	Aripiprazole	BMS & Otsuka	Schizophrenia	6.6	11.4
<b>TOTAL</b>				<b>\$76.7</b>	<b>-2.3%</b>

<sup>a</sup> For the 12 months ending on June 30, 2012. SOURCE: IMS Institute for Healthcare Informatics

# The Patent Cliff: A Race Against Time

## Developed Markets Generic Share



Source: IMS Market Prognosis, Apr 2011

# The Patent Cliff: A Race Against Time

## SOLUTION

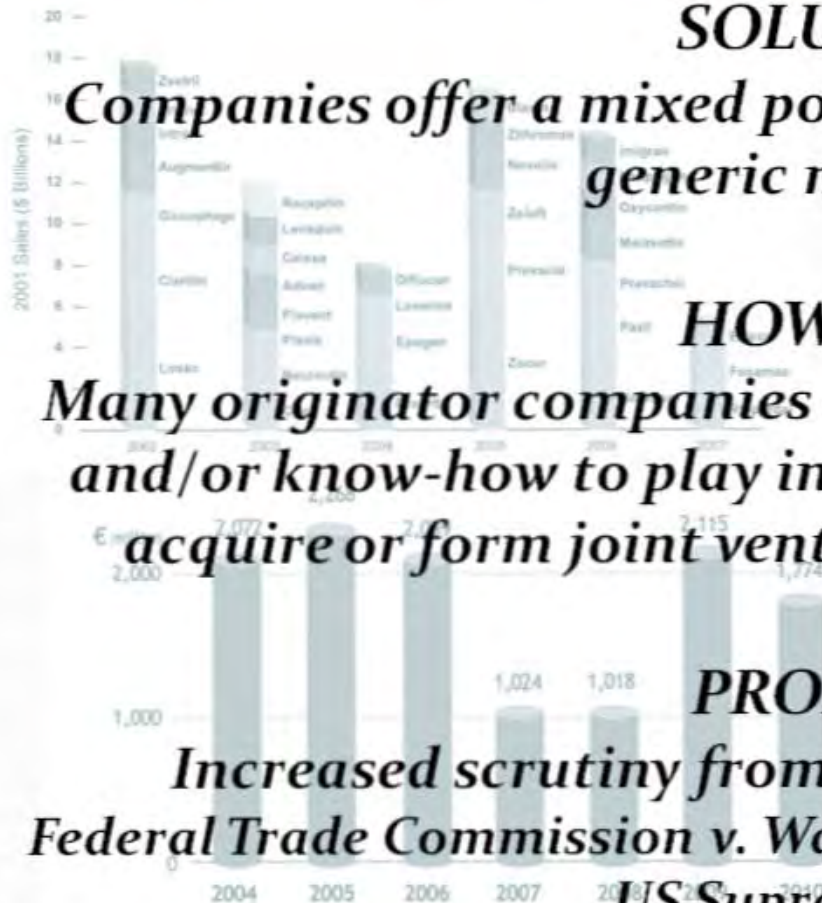
*Companies offer a mixed portfolio of new medicines and generic medicines.*

## HOWEVER

*Many originator companies do not possess the experience and/or know-how to play in the generic space, and must acquire or form joint ventures with existing players.*

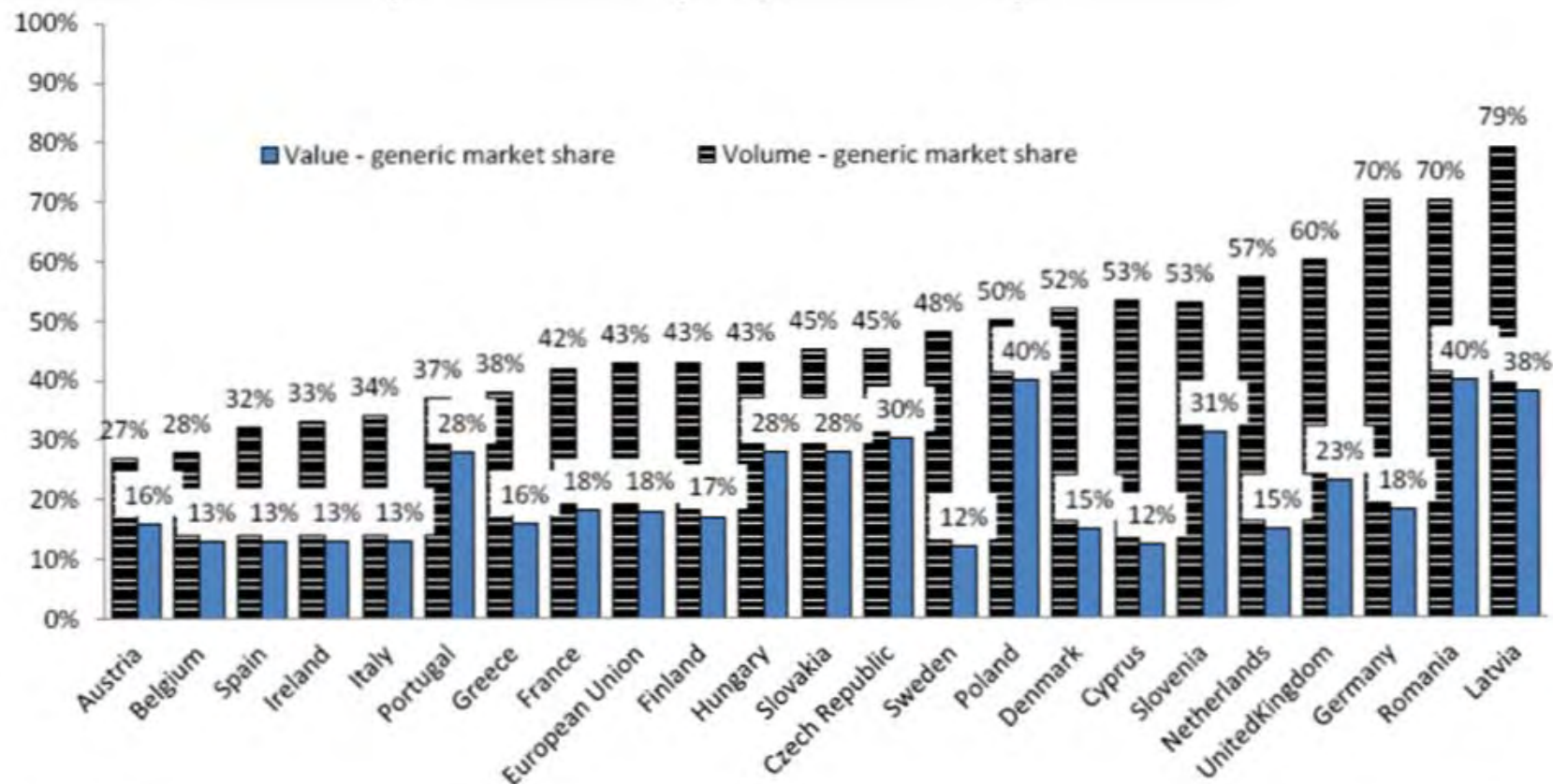
## PROBLEM

*Increased scrutiny from competition watchdogs.  
Federal Trade Commission v. Watson Pharmaceuticals Inc et al.,  
US Supreme Court*



# Are we prepared to pay?

*In Europe, generics make up almost one half of volume sales, but merely a fraction of value sales*



## *Are we prepared to pay?*

*“Europe must ensure that it doesn’t slip into a position where it simply focuses on acquiring medicines at the lowest possible cost. This will destroy the incentivisation for innovation, and will ultimately lead to a loss of the breakthrough opportunities of new medicine research. The importance of this industry to health, healthy ageing, and economic growth is just too great to run that risk.”*

*(Richard Bergström, Director General EFPIA)*



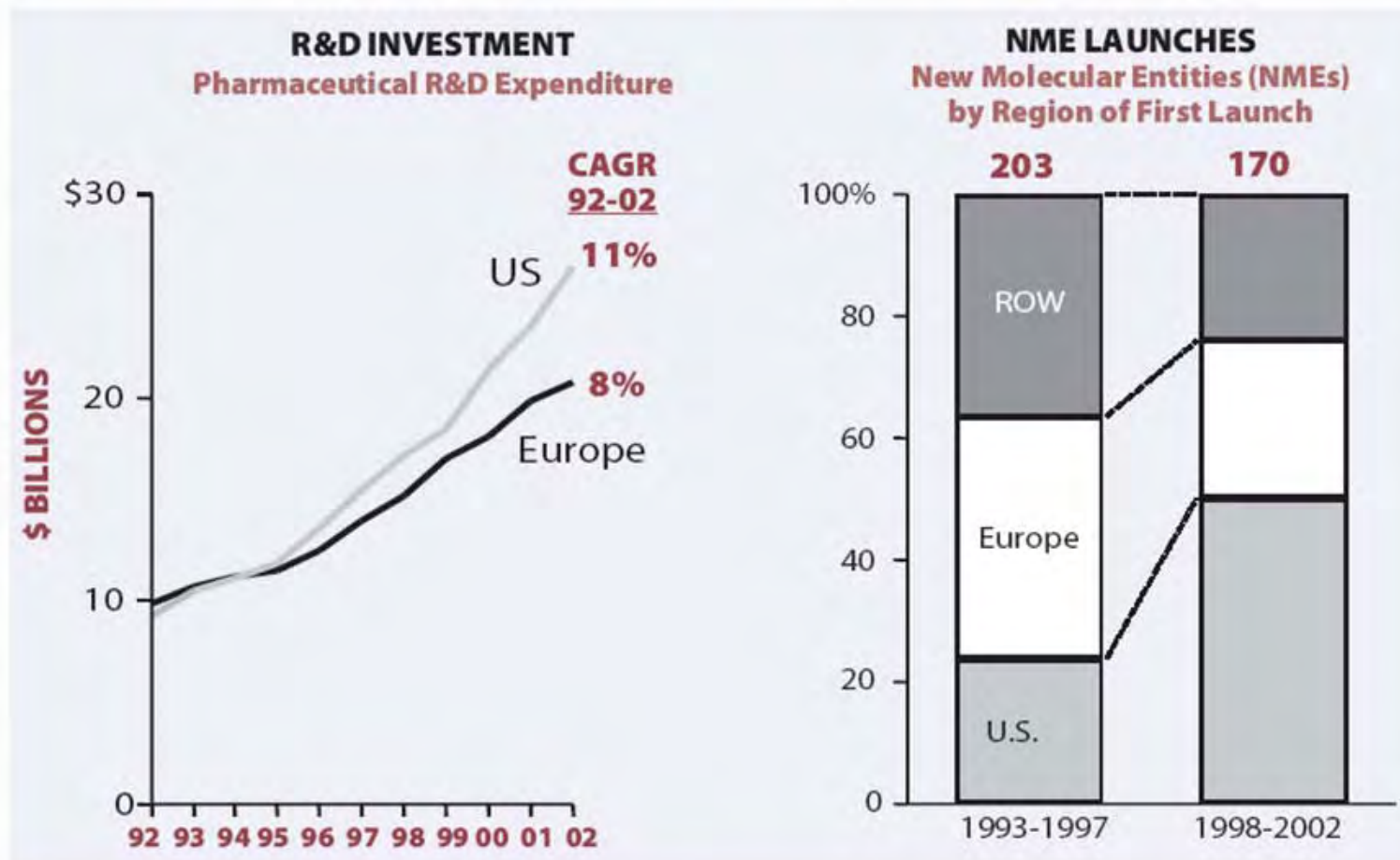
# Are we prepared to pay?

*“Europe has unfortunately slipped in terms of its willingness to pay for innovation. ... We’re now at a point where we have to take the view and I think face the reality that really it’s about the U.S. and, excitingly anew, it’s about Japan in terms of where innovation should be driven.”*

*(Sir Andrew Witty, CEO GlaxoSmithKline)*

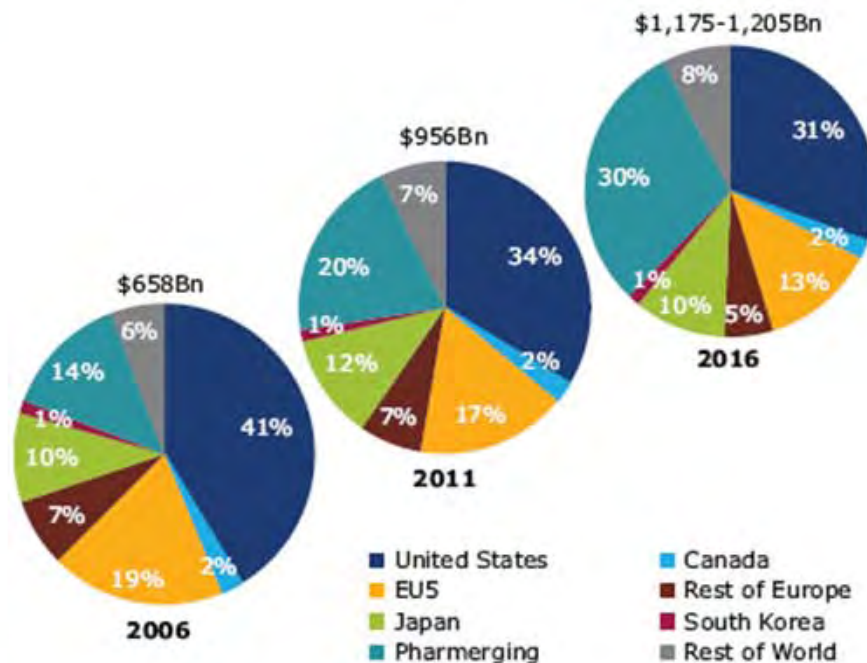


# Where have we heard this before?



# Enter the Global Markets.

Spending by Geography



Source: IMS Market Prognosis, May 2012

# Enter the Global Markets.

RANK	2006	INDEX
1	United States	100
2	Japan	35
3	 France	13
4	 Germany	13
5	 China	9
6	 Italy	8
7	 Spain	6
8	 UK	6
9	 Canada	6
10	Brazil	5
11	Australia	3
12	Mexico	3
13	South Korea	3
14	Russia	3
15	 India	2
16	 Turkey	2
17	 Netherlands	2
18	 Belgium	2
19	 Greece	2
20	 Poland	2

RANK	2011	INDEX
1	United States	100
2	Japan	36
3	 China	21
4	Germany	14
5	 France	12
6	 Brazil	9
7	 Italy	9
8	 Spain	7
9	Canada	7
10	 UK	7
11	 Russia	5
12	 Australia	4
13	 India	4
14	 South Korea	4
15	 Mexico	3
16	Turkey	3
17	 Poland	2
18	 Venezuela	2
19	 Netherlands	2
20	 Belgium	2

RANK	2016	INDEX
1	United States	100
2	 China	39
3	 Japan	36
4	 Brazil	15
5	 Germany	13
6	 France	11
7	Italy	8
8	 India	7
9	 Russia	7
10	 Canada	6
11	 UK	6
12	 Spain	5
13	 Australia	4
14	 Argentina	4
15	 South Korea	4
16	 Mexico	3
17	 Venezuela	3
18	 Turkey	3
19	 Indonesia	2
20	 Poland	2

  Change in ranking over prior 5 years

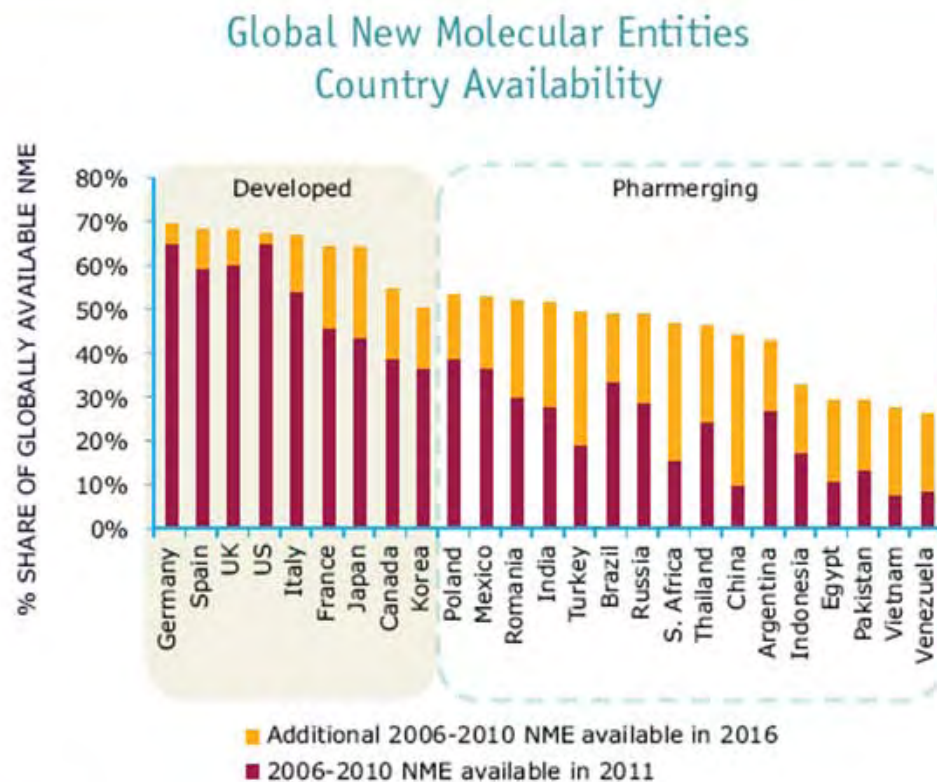
Source: IMS Market Prognosis, May 2012

## Appendix notes

Ranking in all years based on spending in constant US\$ at Q4 2011 exchange rates.

Index in each year based on ratio of country spending to U.S. spending (in constant US\$) in the year.

# Enter the Global Markets.



Source: IMS Institute for Healthcare Informatics, May 2012

## ***Global markets are not European***

- Diverse healthcare systems
- Fragmented markets
- Complex regulatory systems
- Cultural and language barriers
- Increased competition (local and global)
- Varied infrastructure
- Highly dynamic situation

# Global markets are not European

Figure 2: The Wealth Pyramid across the emerging markets (adapted from Prahalad and Lieberthal, 1998).

Purchasing power parity		Population in millions		
	In U.S. dollars	China	India	Brazil
Have a lot	Greater than \$20,000	2	7	9
Have	\$10,000 to \$20,000	60	63	15
Have less	\$5,000 to \$10,000	330	125	27
Have not	Less than \$5,000	800	700	105

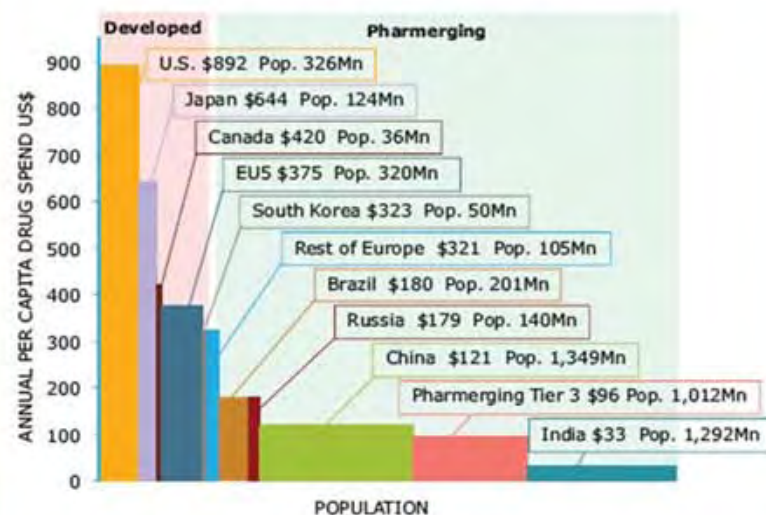
# Global markets are not European

Volume Growth and Populations  
With >\$5,000/Year Income by Country in 2016



Source: Institute for Healthcare Informatics, IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

2016 Pharmaceutical Spend Per Capita  
2005\$ and Population



Source: IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

# ***Global markets are not European***

## **Intellectual Property**

- Indian patent law allows for compulsory licensing if *“reasonable requirements of the public with respect to the patented invention have not been satisfied; the patented invention is not available to the public at a reasonably affordable price; or the patented invention has not been worked in the territory of India”*.
- 2012: Indian patent office authorised Natco Pharma to make and sell generic sorafenib (Nexavar, Bayer AG) whilst still under patent, paying 7% of its net (reduced) sale in royalties to Bayer.
- Trastuzumab (Herceptin, Roche), ixabepilone and dasatinib (Ixempra and Sprycel, Bristol-Myers Squibb) under consideration.

# ***Global markets are not European***

## **Price control:**

- *China:* In 2013 cut prices of more than 400 medicines by up to 20%.
- *India:* In 2012 widened scope of price controls to 348 medicines from 74. In 2013, proposes that prices of patented medicines be based on the country's per capita income.
- *"Most countries follow some form of price control. We need to ensure that expensive drugs are available at affordable rates to the poor."*

*(D.S. Kalba, Secretary, Pharmaceutical Department)*

# Global markets are not European

*“The danger of pushing the prices of prescription drugs down, down, down is that at some point the business model of developing these drugs will lose its attractiveness. .... India is becoming very reluctant to respect IP for Western companies and that is becoming a challenge for us.”*

*(Marijn Dekkers, CEO Bayer)*



# Global markets are not European

Global Spending, 2011 and 2016



Source: IMS Institute for Healthcare Informatics, IMS Market Prognosis, May 2012

Pharmerging Spending and Growth



Source: IMS Institute for Healthcare Informatics, IMS Market Prognosis, May 2012

## Changes in the industry: a renaissance

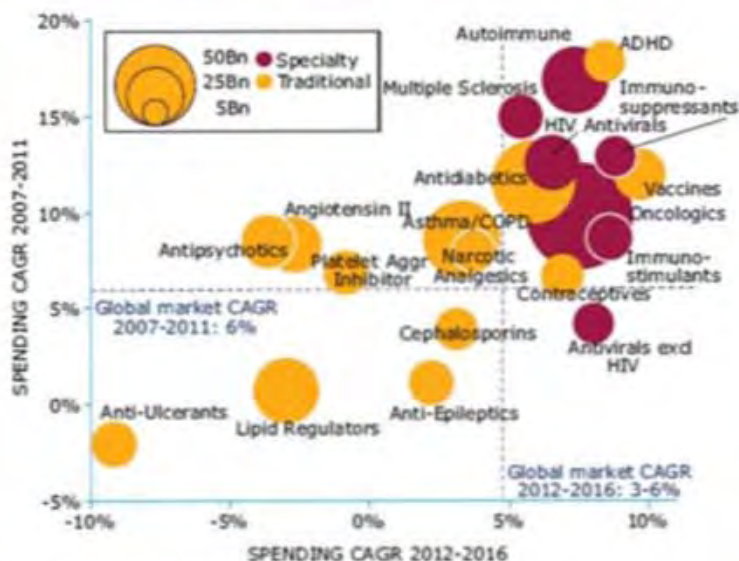
*"I really believe that in the future, companies like Novartis are going to be paid on patient outcomes as opposed to selling the pill. ... Many health-care systems around the world are under intense financial pressure and would prefer to pay for a patient who is actually getting a result and feeling better. ... The industry needs to spend more money on R&D and less on sales and marketing."*

*(Joseph Jimenez, CEO Novartis)*



# Changes in the industry: a renaissance

Spending and Growth in Leading Therapy Areas



Source: IMS Institute for Healthcare Informatics, May 2012

Spending in 2016



Source: IMS Institute for Healthcare Informatics, May 2012

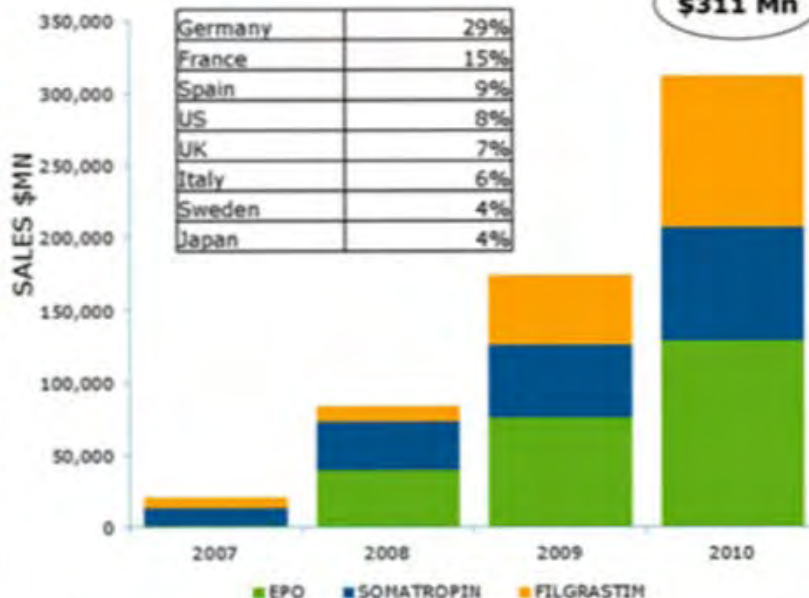
# Changes in the industry: a renaissance

Biosimilar penetration in Europe embryonic;  
potential in USA post 2014

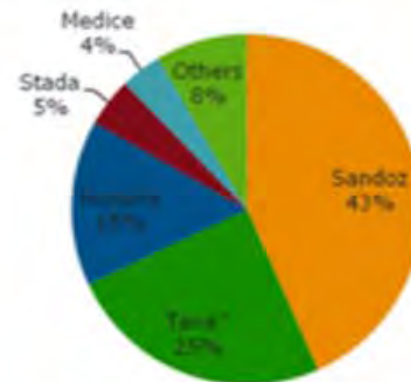
For R&D based companies is going to be an established market play

% share of global biosimilars

Germany	29%
France	15%
Spain	9%
US	8%
UK	7%
Italy	6%
Sweden	4%
Japan	4%



Biosimilars: Top players (US\$)



Source: IMS Health, MIDAS, MAT Dec 2010; USA (Omnitrope) + Europe + Australia. \*Teva = Teva + Ratiopharm

# Changes in the industry: a renaissance

*“It’s not like engineering where the iPhone 5 follows on from the iPhone 4. Coming up with a new drug requires skill, insight and luck. .... But we are on the verge, potentially, of a new wave of pharmaceutical innovation.”*

*(Kenneth Frazier, CEO Merck & Co)*



# *European industrial pharmacists*

## *Q1 2013: Annus horribilis*

- GSK to close financial services operations in Cork (Ireland), 94 jobs to go
- MSD to close facility in Rathdrum (Ireland); 280 jobs to go
- Actavis Malta to close R&D unit by end 2013; 64 jobs to go
- AstraZeneca to close Alderly Park (UK), overhaul R&D, cut about 1,600 jobs; 2,300 job cuts in sales and administration; total of 5,050 jobs by 2016
- Eli Lilly to lay off 1,000 US sales jobs
- TEVA to reduce manufacturing footprint, job losses in Israel likely over next five years
- AbbVie to fire mid-hundreds of sales force for heart drugs

## *European industrial pharmacists*

- *A changing workplace:*
  - drug discovery in Europe, drug development and commercialisation in far East, registration and marketing in Europe or North America
  - drug discovery , development and commercialisation in far East, and then registered and marketed in Europe
- Logistical challenges to avoid shortages of supply
- Challenges to safeguard quality, safety and efficacy
  - Temperature control of biologicals in transportation
  - Falsified medicinal products

# Falsified Medicinal Products

	2008	2009	2010	2011
Number of cases	3,207	3,368	1,812	2,494
Number of articles	8,891,056	11,462,533	3,200,492	27,460,538
Provenance Top 3	India (51.6%)	UAE (73.7%)	India (93.2%)	China (68.2%)
	Syria (36.4%)	India (22.6%)	China (4.7%)	India (28.2%)
	UAE (8.7%)	China (1.4%)	Hong Kong (0.9%)	Hong Kong (1.5%)

*European Commission Taxation and Customs Union*

# *European industrial pharmacists*

## **Seven Skill Sets Necessary to Operate in the Pharmaceutical Industry of the Future**

- 1) Ability to Manage Decentralized Intellectual Capital Resources
- 2) Ability to Work in Joint Ventures and Across Divisions, Cultures and Countries
- 3) Ability to Integrate an Understanding of Intellectual Property Laws, Scientific Expertise and Business Strategy
- 4) Ability to Spur Creativity While Managing Commercially
- 5) Knowledge and Insight on the Decision-Making Dynamics of Payers
- 6) Expertise in the Functioning and Decision-Making of Regulatory Agencies
- 7) Human Resource Skills to Help Transform Pharmaceutical Companies



## *European Industrial Pharmacists Group*

- The main objective of EIPG is to promote and uphold the importance and role of the industrial pharmacist within the pharmaceutical industry.
  - Promote the modern pharmaceutical industry to observers and more importantly to young pharmacists
  - Ensure that educational standards meet the needs of the industrial pharmacist in the industry of 2020
  - Provide mentoring and coaching to young pharmacists who need career advice



# European Industrial Pharmacists Group



*“Formerly, when religion was strong and science weak, men mistook magic for medicine; now, when science is strong and religion weak, men mistake medicine for magic.”*

**Thomas Szasz**