

The logo for PhAMA, featuring the word "PhAMA" in white, bold, sans-serif font. The "Ph" is on a dark blue background, and "AMA" is on a red background.

**PhAMA**

Innovative Medicines for Malaysia

# 1ST NATIONAL BIO-THERAPEUTICS CONGRESS – PUTTING PATIENT FIRST

**22 NOVEMBER 2014**

# The rising costs in healthcare – Can Biosimilars help?

Dr. Paul Cornes

# **Dr Paul Cornes**

## **Conflict of interest**

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- **Salary received:**
  - **United Kingdom National Health Service**
- **Honoraria received:**
  - **Roche**
  - **Janssen**
  - **Sandoz**
  - **Lilly**
  - **European Generics Association**
  - **Teva**
  - **Hospira**

# *The rising costs in healthcare - can Biosimilars help?*



**Dr Paul Cornes,  
Consultant Oncologist,  
Bristol Haematology & Oncology Centre**



**Comparative Outcomes Group**



**ESO Task Force Advisory Board on  
Access to Innovative Treatment in  
Europe**


**European School of Oncology  
Piazza Indipendenza, 2  
6500 Bellinzona - Switzerland**

**[paul.cornes@yahoo.co.uk](mailto:paul.cornes@yahoo.co.uk)**



# Question

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- **Is there sufficient money in the health system to afford innovation in medicine?**
  
  - **please chose your best response:**
    1. **No – we do not have the budget to introduce innovation**
    2. **Unsure**
    3. **Yes – we have the chance to increase spending on innovative treatments**
- 

# There is a cost to cancer care

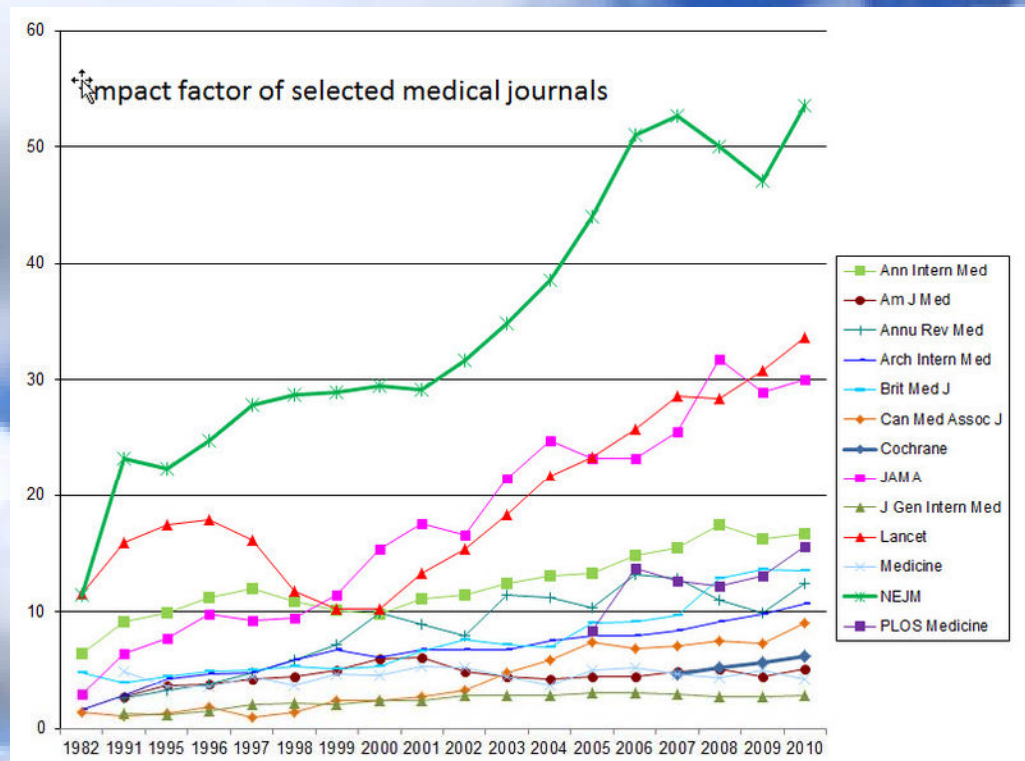
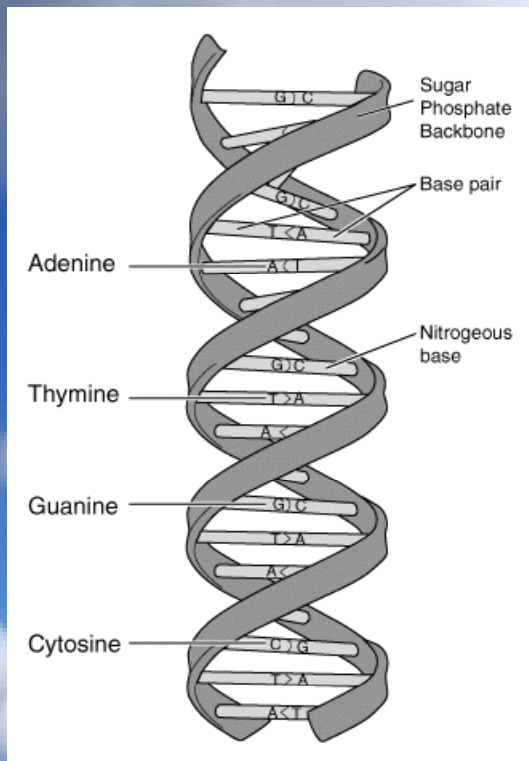


***“Think about health spending as not consumption but investment”***

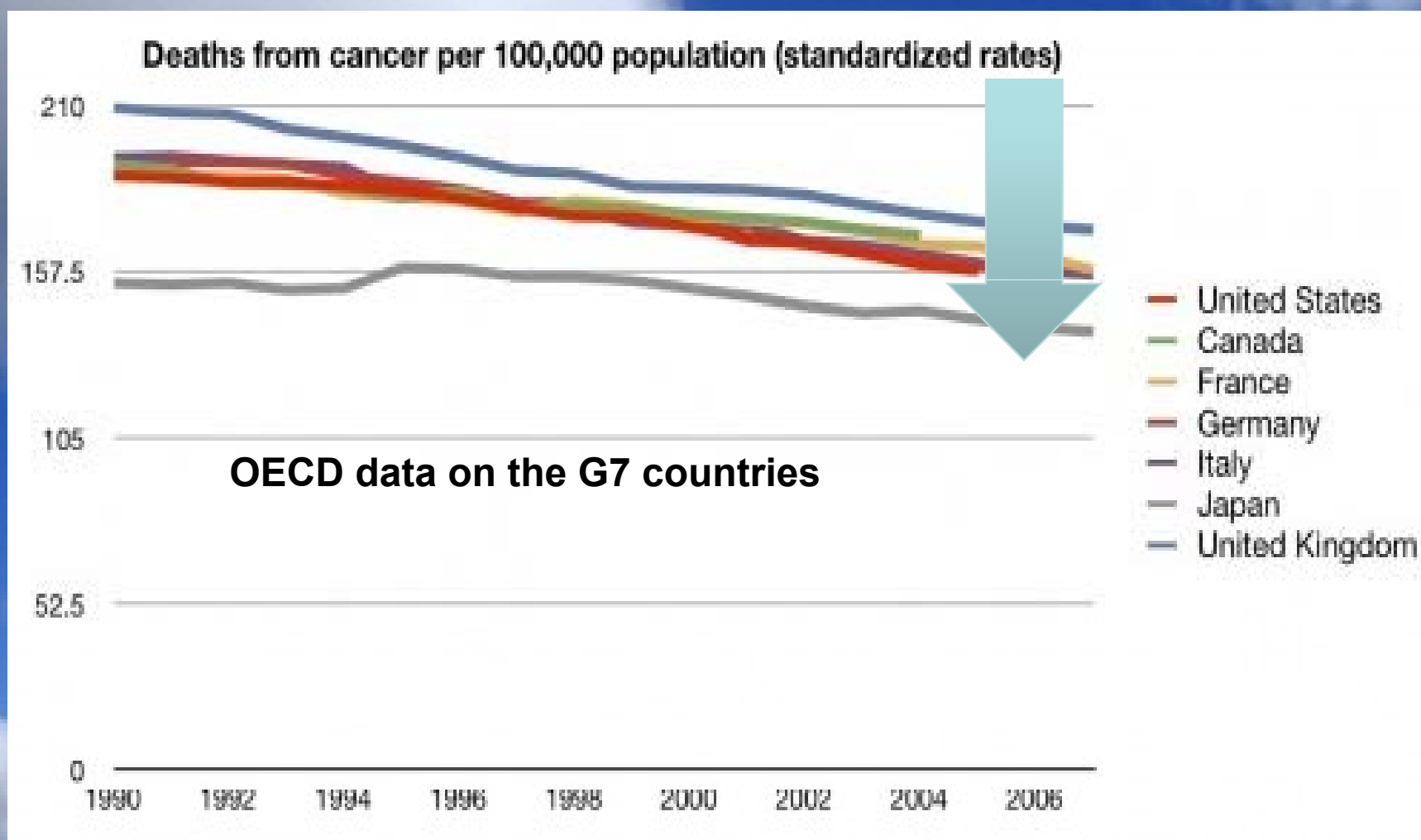
**David E. Bloom,  
professor of economics and  
demography at Harvard**

# Good news for medicine

- Basic cancer science is paying back on its investment
- One medical paper a minute is added to the PubMed US National Library of Medicine



# Good news for cancer treatment: Cancer survival is improving





# Good news for cancer treatment: Cancer survival is improving

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## NEWS HEALTH


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29 April 2014 Last updated at 00:00

### Half of cancer sufferers 'live a decade or more'

COMMENTS (178)

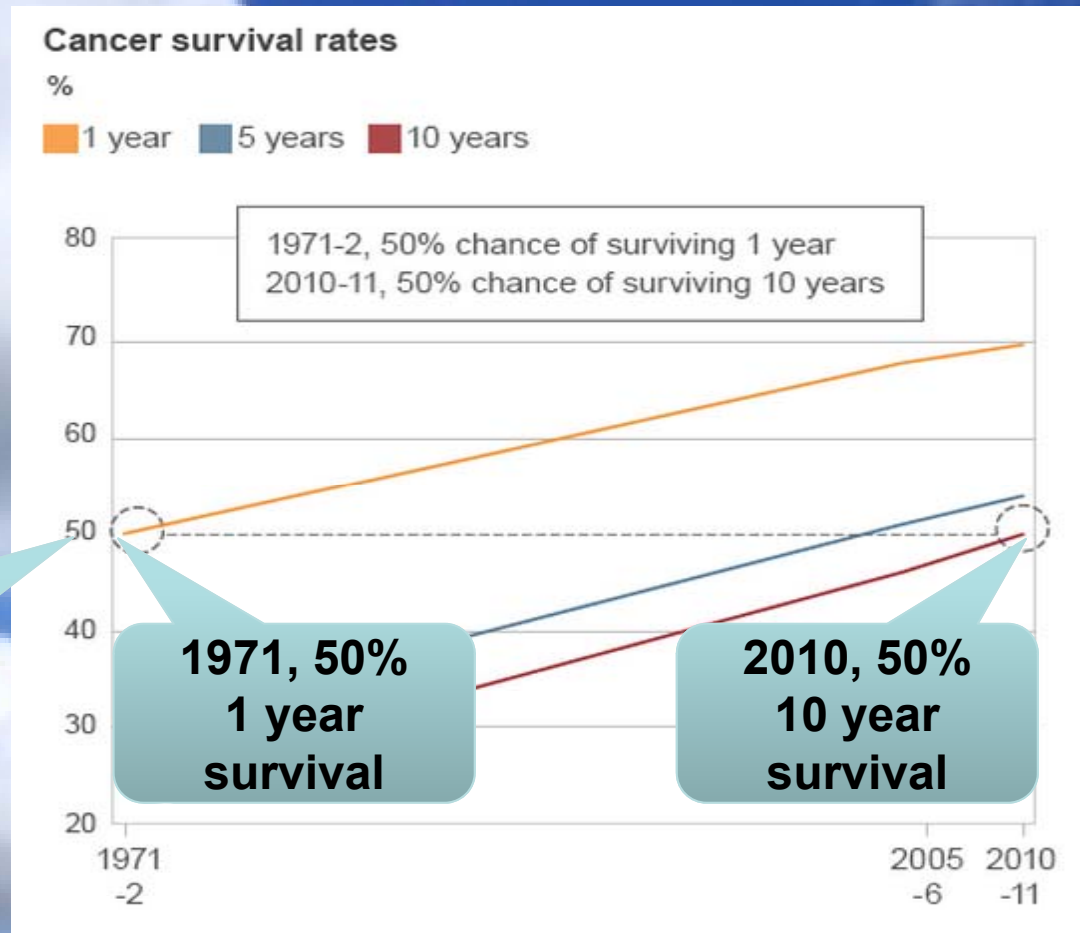
By Nick Triggle  
Health correspondent, BBC News



**Median Survival with Cancer in the UK has risen 10-fold since 1971**

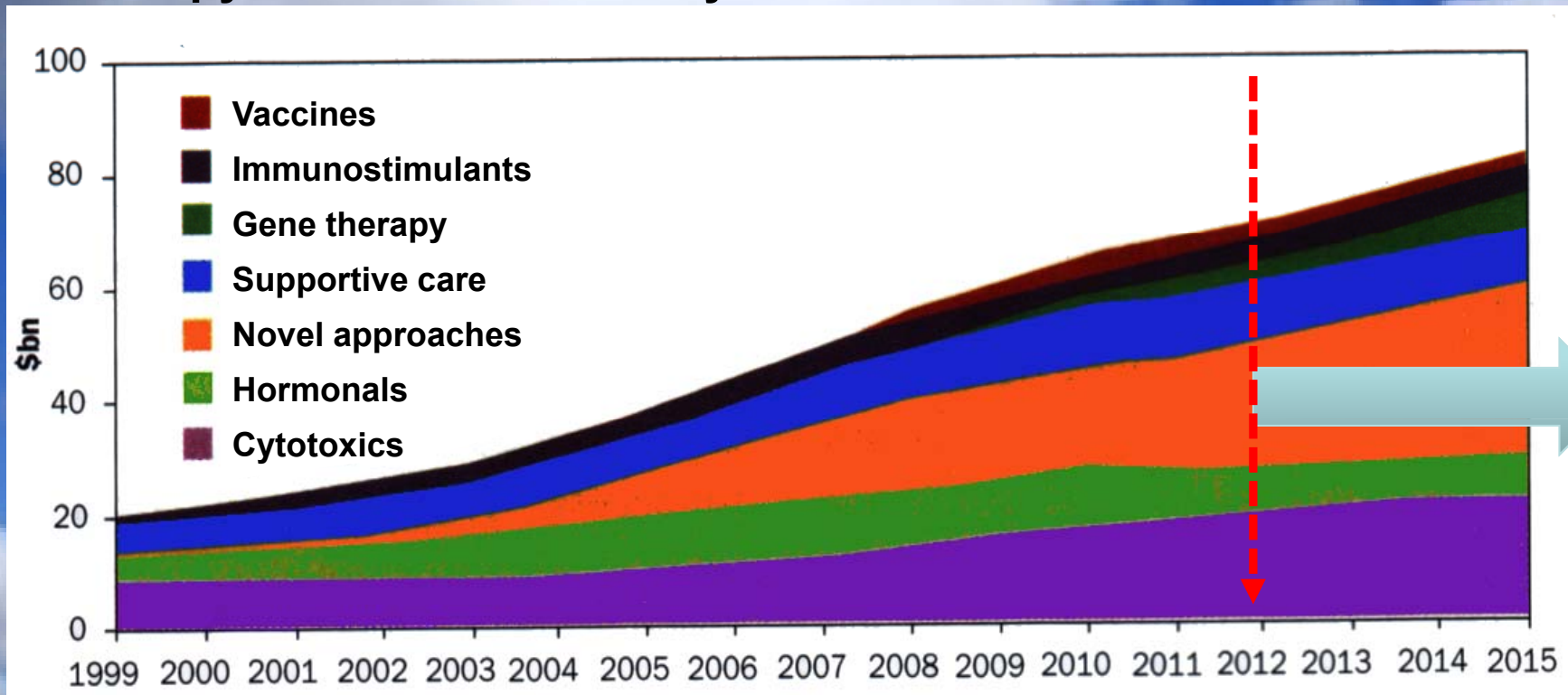
Half of people in England and Wales now being diagnosed with cancer will survive at least a decade - double the rate in the early 1970s, figures show.

Related Stories



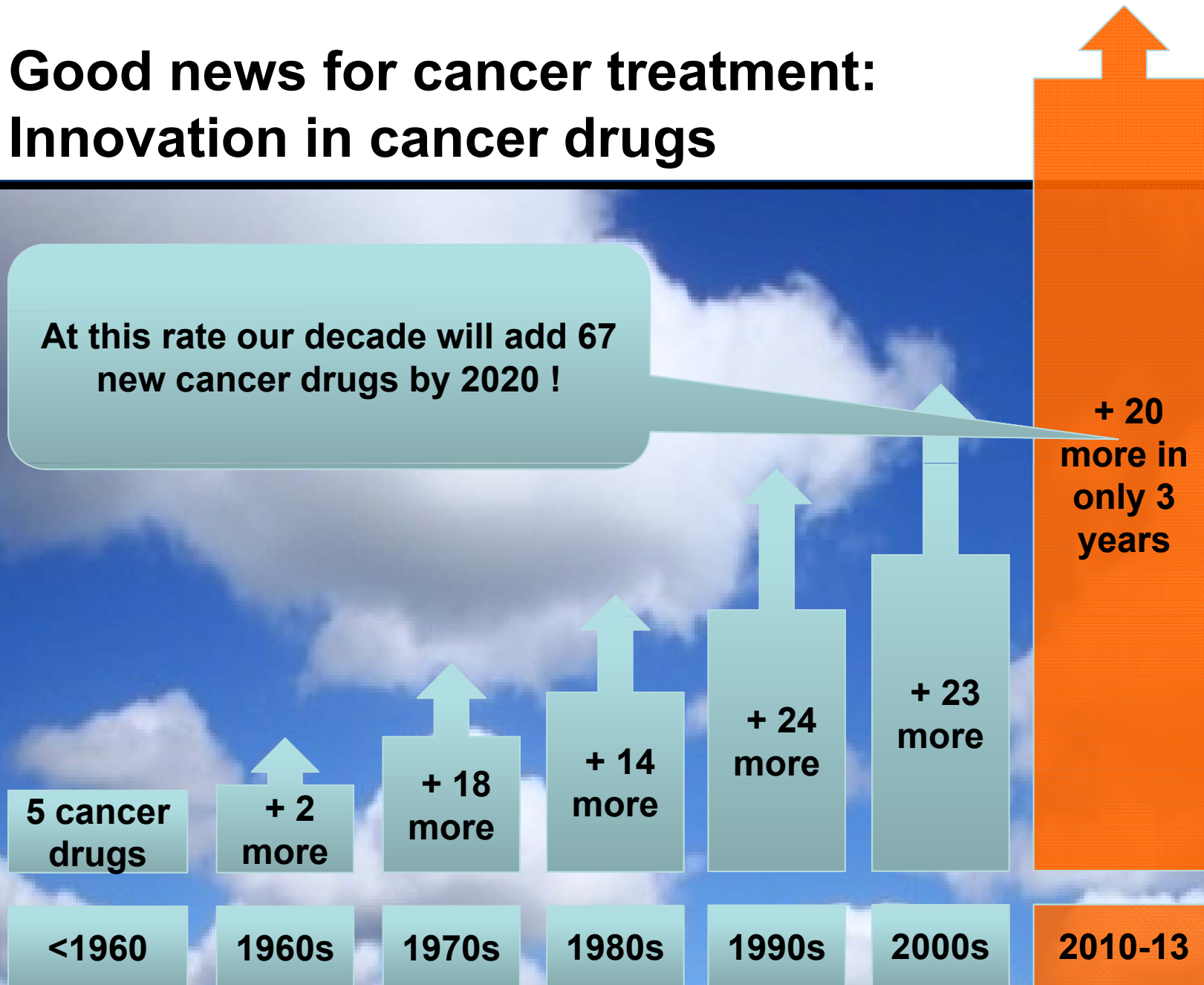
# Good news for cancer treatment

- This investment in innovation means that novel targeted biologic approaches now dominate drug development
- It is predicted that 2012 was probably the year where biologic therapy use outnumbered cytotoxic treatments



# Good news for cancer treatment: Innovation in cancer drugs

At this rate our decade will add 67 new cancer drugs by 2020 !





Exploration

Innovation Dr

# Good news for cancer treatment: Survival impact of some targeted therapies

REVIEWS

Targeted therapy in rare cancers—adopting the orphans

John Munoz and David Sidransky

**Abstract** Targeted therapy in rare cancers is widely considered to be a model of precision oncology. However, emerging data suggest that this approach may be less effective than expected, and that the benefits of targeted therapy may be limited to a subset of patients. This review discusses the challenges of targeted therapy in rare cancers and the potential for personalized medicine to improve outcomes.

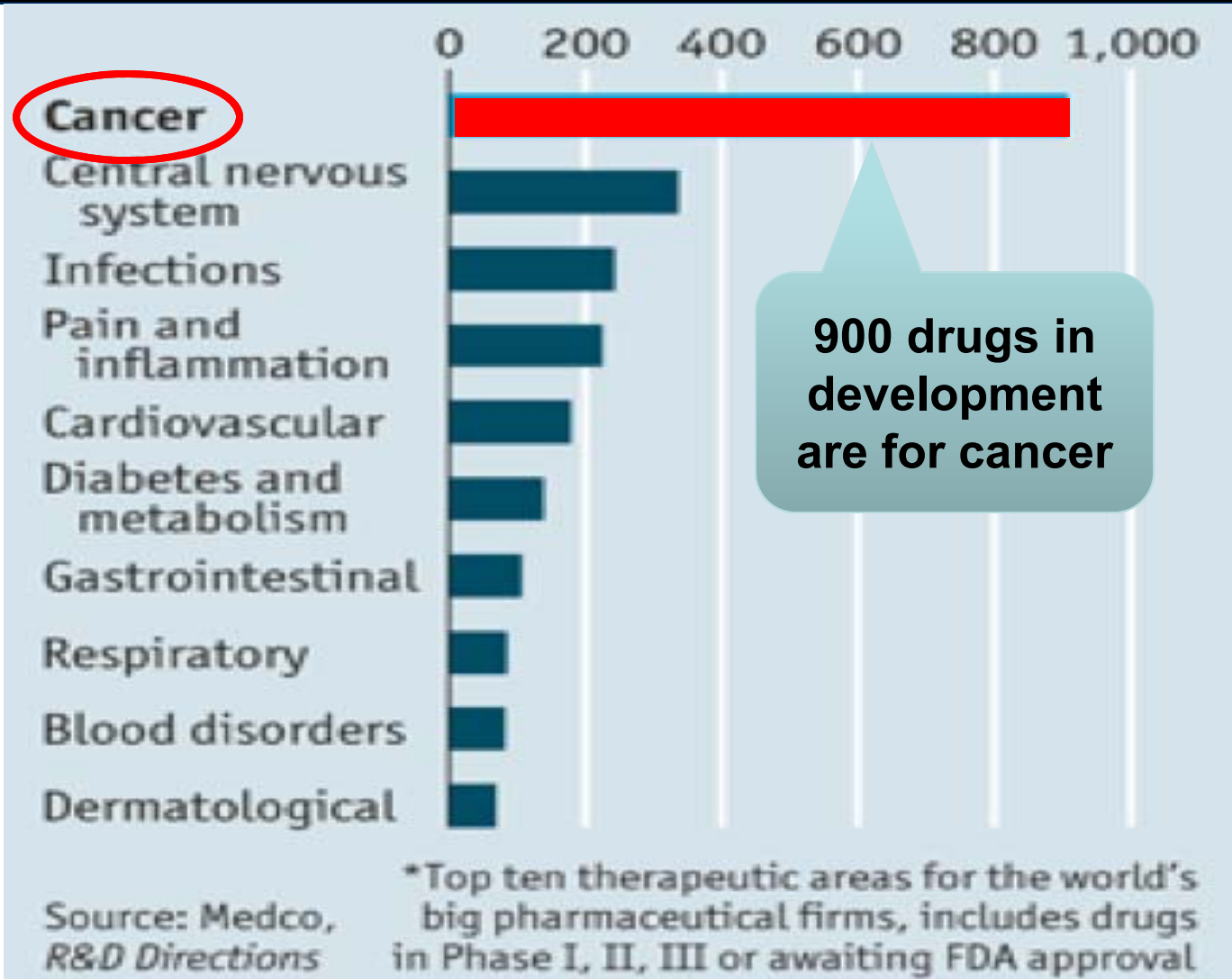
**Introduction** Targeted therapy in rare cancers is widely considered to be a model of precision oncology. However, emerging data suggest that this approach may be less effective than expected, and that the benefits of targeted therapy may be limited to a subset of patients. This review discusses the challenges of targeted therapy in rare cancers and the potential for personalized medicine to improve outcomes.

Cancer Disease	Old Model	Old Survival	Personalized Model	Personalized Survival
Acute promyelocytic leukemia	Chemotherapy	19 months	All trans retinoic acid	>58 months
Chronic myeloid leukemia	Chemotherapy	6 years	Imatinib	>22 years
Melanoma	Dacarbazine	<10 months	Vemurafenib	16 months
Medullary thyroid cancer	Chemotherapy	36 months	Vandetanib	Not reached
Gastrointestinal stromal tumour	Chemotherapy	12-18 months	Imatinib	Close to 5 years
Relapsed Hodgkin lymphoma	Chemotherapy	1.2 years	Brentuximab vedotin	22.4 months

data from Munoz, J. et al (2012) Targeted therapy in rare cancers—adopting the orphans Nat. Rev. Clin. Oncol. doi:10.1038/nrclinonc.2012.160. Table from The Value of Medical Innovation. <http://valueofinnovation.org/a-world-free-from-cancer/#ref3>, Accessed April 29, 2014

# Good news for cancer treatment

Drugs in development, 2010





Exploration

Innovation Dr

# Bad news for cancer

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## The Lancet Oncology Commission

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### Delivering affordable cancer care in high-income countries

*Richard Sullivan, Jeffrey Peppercorn, Karol Sikora, John Zalcberg, Neal J Meropol, Eitan Amir, David Khayat, Peter Boyle, Philippe Autier, Ian F Tannock, Tito Fojo, Jim Siderov, Steve Williamson, Silvia Camporesi, J Gordon McVie, Arnie D Purushotham, Peter Naredi, Alexander Eggermont, Murray F Brennan, Michael L Steinberg, Mark De Ridder, Susan A McCloskey, Dirk Verellen, Terence Roberts, Guy Storme, Rodney J Hicks, Peter J Ell, Bradford R Hirsch, David P Carbone, Kevin A Schulman, Paul Catchpole, David Taylor, Jan Geissler, Nancy G Brinker, David Meltzer, David Kerr, Matti Aapro*

Elkin EB, Bach PB. Cancer's next frontier: addressing high and increasing costs. JAMA 2010;303:1086-1087.  
Meropol NJ, Schrag D, Smith TJ, et al. American Society of Clinical Oncology guidance statement: the cost of cancer care. J ClinOncol 2009;27:3868-3874.

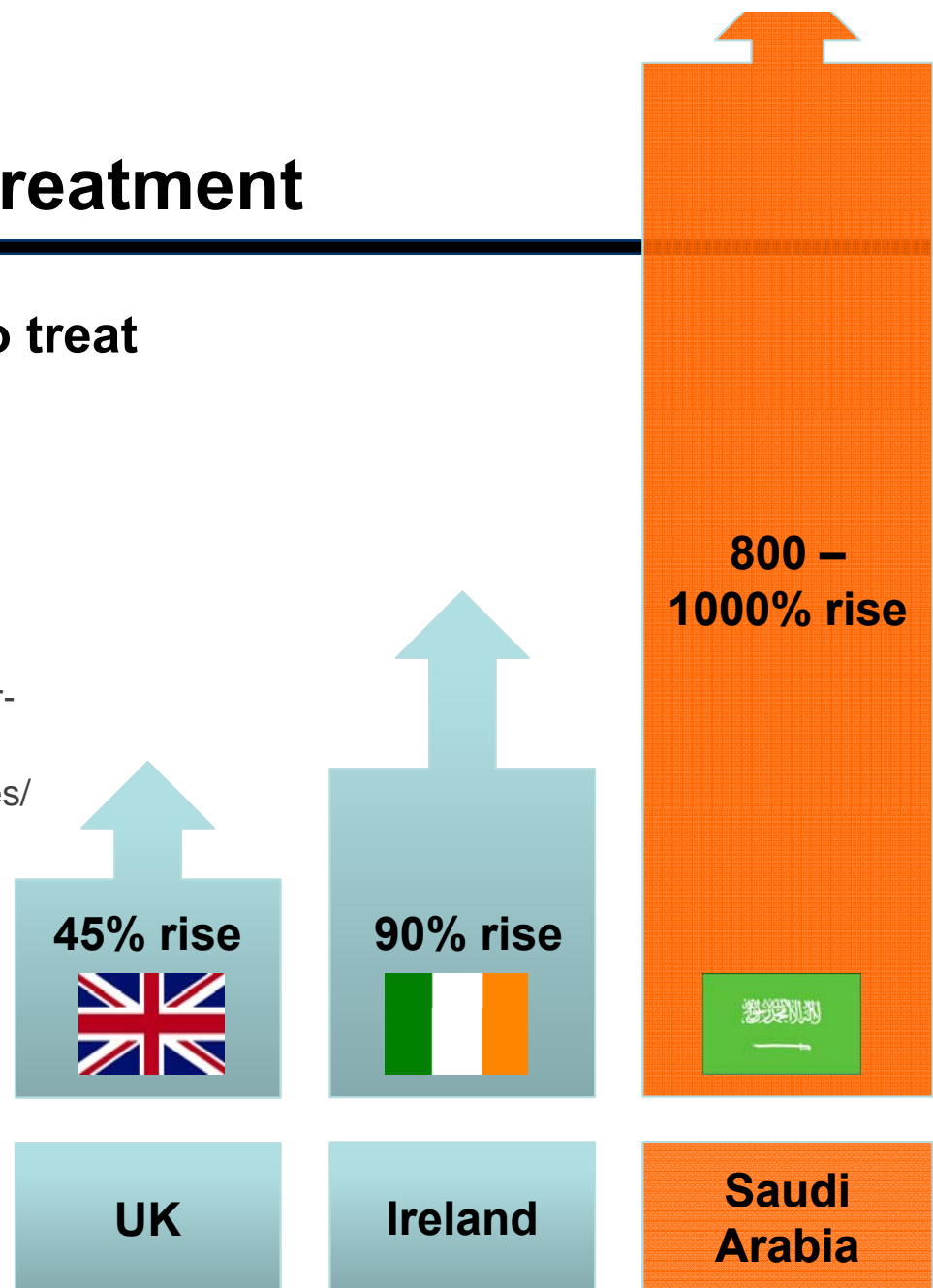


# Bad news for cancer treatment

- There will be more cancer to treat as the population ages

- **Expected rise in 20 years**

- <http://info.cancerresearchuk.org/news/archive/pressrelease/2011-10-28-NHS-burden-as-cancer-cases-to-jump-by-45-per-cent>
- <http://www.breakingnews.ie/archives/2006/0607/ireland/potentially-fatal-cancer-cases-predicted-to-double-by-2020-262312.html>
- Ibrahim E, et al. Current and future cancer burden in Saudi Arabia: meeting the challenge. Hematol Oncol Stem Cell Ther. 2008 Oct-Dec;1(4):210-5



# Bad news for cancer treatment

- **Innovative drug development is slow and expensive**
- **From 5000 - 10000 compounds in pre-clinical trials:**
  - **only 0.1% reach clinical trial stage**
  - **of these, only 10-20% are finally approved**
- **It takes 15 years from the target discovery to the market at 1.4 Billion Euro / drug**
  - Adams CP et al: Estimating the cost of new drug development: Is it really 802 million dollars? Health Aff (Millwood) 2006;25:420-428
  - ABPI. Delivering value to the UK: the contribution of the pharmaceutical industry to patients, the NHS and the economy. Updated. <http://www.abpi.org.uk/our-work/library/industry/Pages/310114.aspx>. Accessed May 12th, 2014



1330	10	1650	PCOT	22.0	2020	22.0-	250	TK	
10	12.70	10-	650	MEDIA8	555	6	655-	0.10	THITY
25	25.75	25-	2.75	RS	150	152	150-	0.20	US
355	350	350-	0.24	SAFARI	264	260		204	ZHICO
05	2	05-	0.0	TRAF	037	030	036-	0.10	APURE
4.74	400	4.74-	0.50	UBC				10	DAIDO
11	11.0	11-	0.70	ACL	302	304	302-	0.50	HTC
6.75	630	630-	0.20	AEOHTS	42	460		47	KSL
005	020	0.0-	100	AITCO				650	LST
1.70	1.75	1.65-	05	ASL	120	125	125-	05	MALEE
06	07	06-	10	ASP	322	324	324-	0.25	MFO
065	0.70	0.65-	055	BC				100	OISHI
5.25	5.25	5.25-	0.25	BLS	1.0	1.00	1.00-	100	PS
0550	05	05-	1.50	CHG		33	3250-	450	POPPUI
3200	32.75	32.75-	0.25	FNS		11	060-	130	PR
1050	1000	10.70-	00	GRK		10	100-	0.50	SAP
0.25	0.30	0.25-	006	KEST		0	0-	3.00	SINOH
204	206	206-	10	KOI		100	1.25-	0.75	SFP
0550	50	0550-	1000	KX		25	25.25-	0.25	SORKON
30.75	30	30.75-	4.75			24	2.850-	450	SAC
202	4	4-	0.5				15.7-	0.04	TC
300	290	300-	0.5					1.70	TF
450	450	450-	0.05				15-	0.01	TIPCO
0.30	0.70	0.30-	0.07				70-	0.10	TUF
5.00	52	5.00-	6				50-	7.75	TVO
000	050	050-	2.10				20-	0.10	TWFP
1550	1550		1.5				11-	0.05	WIC
0.10	0.30	0.20-	0.01				10-	0.25	WON
1.25	1.25	1.20-	0.55				2.50	WJ	
0.25	0.25	0.25-	0.10				0.15	W-CWI	



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LATE NEWS  
WALL STREET  
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90th YEAR—No. 216

NEW YORK CITY, THURSDAY, OCTOBER 24, 1929.

22 PAGES

THIRTEEN CENTS

## WALL ST. IN PANIC AS STOCKS CRASH

### Attempt Made to Kill Italy's Crown Prince

#### ASSASSIN CAUGHT IN BRUSSELS MOB; PRINCE UNHURT

Royal Squire Was Shot  
in Last Week on Via  
Nazario Sabotage' Trail

Princess, Doubt Moved,  
Falls Into Prince's  
Arms and Escapes Hit

BRUSSELS, Oct. 23.—An assassin was caught today in a mob in Brussels, Belgium, after a chase that lasted for several hours. The assassin, a man named ...

#### Hollywood Fire Destroys Films Worth Millions

ATTEMPT MADE ON LIFE



#### CARNEGIE CHARGE OF PAID ATHLETES BOUSES COLLEGES

#### FEAR 52 PERISHED IN LAKE MICHIGAN; FERRY IS MISSING

Consolidated Studios Are  
Sung by Florence Field  
in One-Minute Picture  
Record Includes Many  
New Talcott Productions

CHICAGO, Oct. 23.—A ...

#### HOOVER'S TRAIN HALTED BY AUTO PLACED ON RAILS

#### PIECE OF PLANE LIKE DITEMAN'S IS FOUND AT SEA

Wreckage Picked Up In  
Lakes; Crash Was  
Down With 22 Aboard

CHICAGO, Oct. 23.—A ...

#### High Duty Group Gave \$700,000 to Coolidge Drive

Grandly Agree Rates Won't  
Up Due to His Anti-  
Smoking Propaganda  
Favors More Lobbying to  
Keep Out 'Vices' With

WASHINGTON, Oct. 23.— ...

#### STOCKS CRASH IN RUSH TO SELL; BILLIONS LOST

FOR MORE LIBERTIES



#### SOMEONE NAMED AS HEAD OF NEW EXCHANGE BANK

NEW YORK, Oct. 23.— ...

#### WARDER SOUGHT TO KEEP SEA TRIP SECRET, AID SAYS

NEW YORK, Oct. 23.— ...

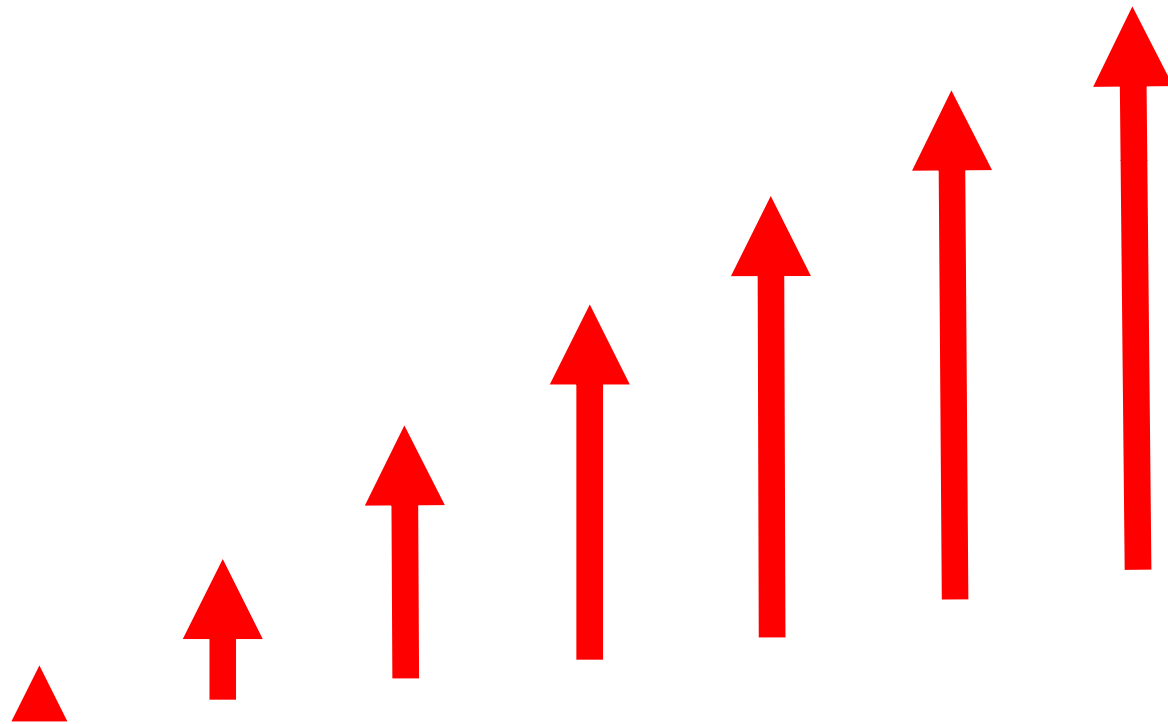


TIME 13th October, 2008

# ASCO 2009 Meeting emphasis: individualised care and cost-effectiveness

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USA Medical insurance costs are rising faster than earnings and general inflation



# Cost of USA cancer care 1963 to 2004

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Cancer treatment spending, in billions



# Medicaid expenditures (\$ billions) for outpatient prescription drugs

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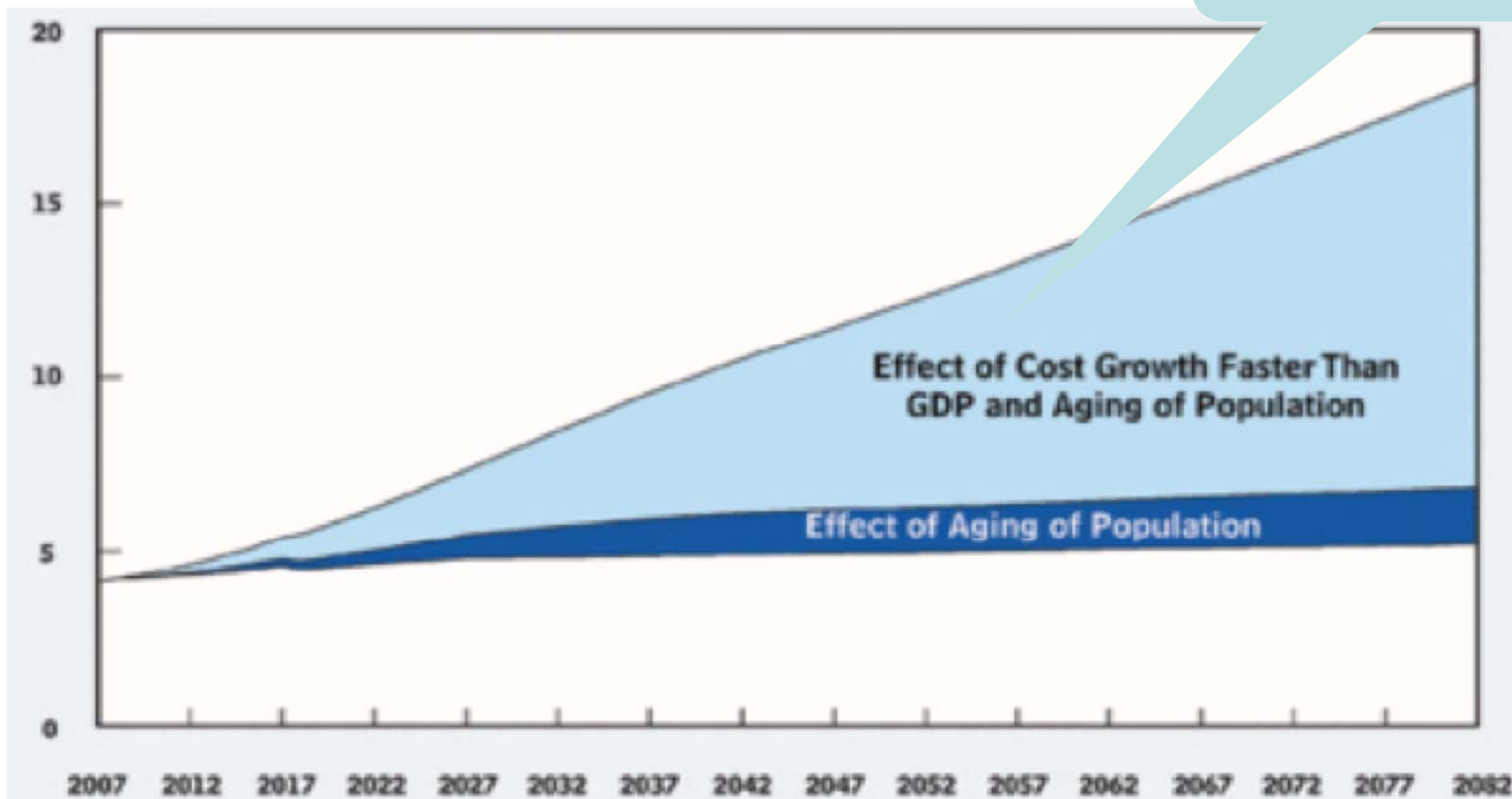
US\$

**In 2003, Medicaid spent \$33.7 billion on drugs (19% of national spending for drugs and more than 10% of the Medicaid budget)**



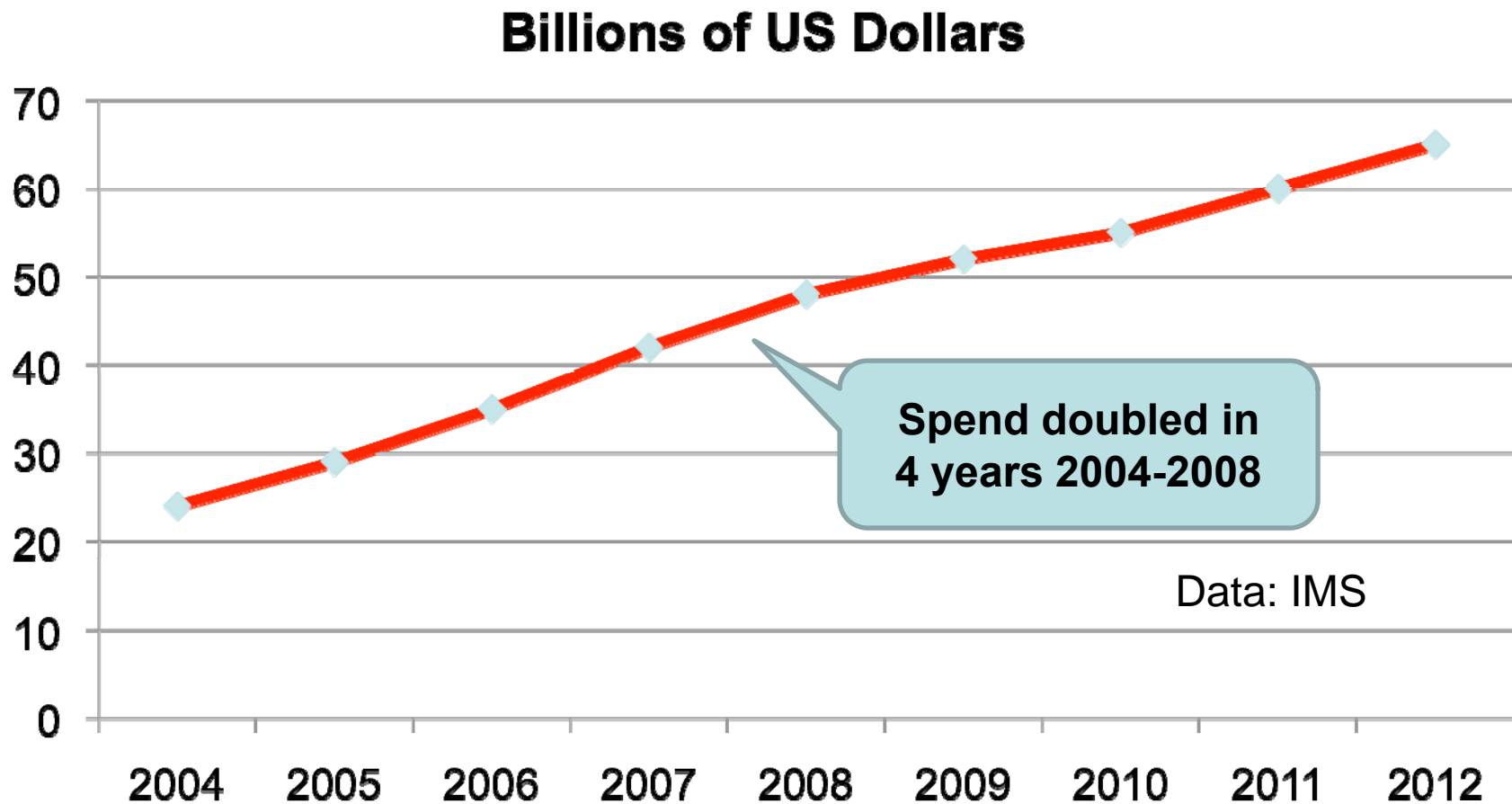
# Planning for the future: what will happen to costs?

What is the driver for increased spending: ageing populations or medical treatment?

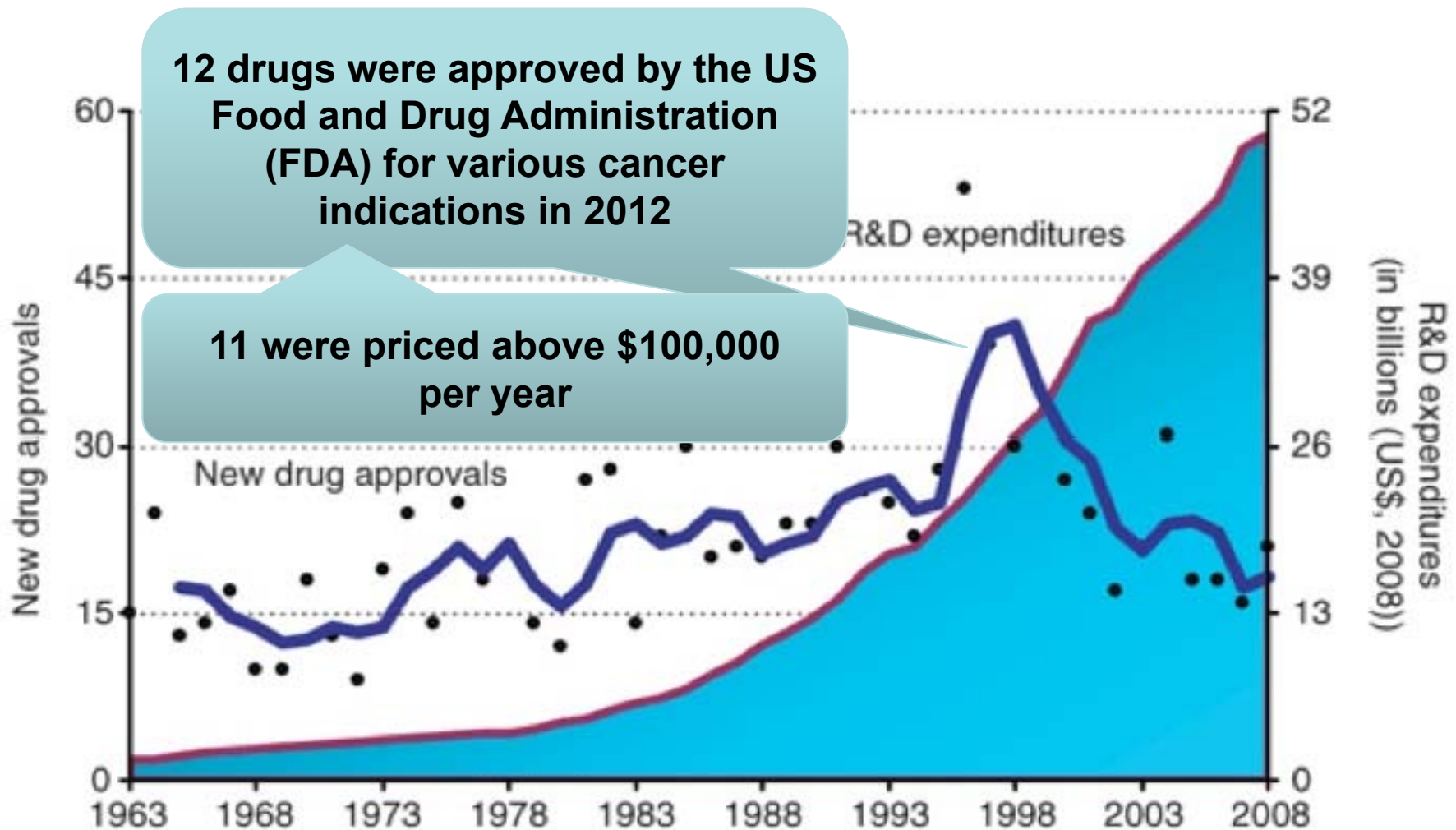


# The world spends more each year for cancer treatment

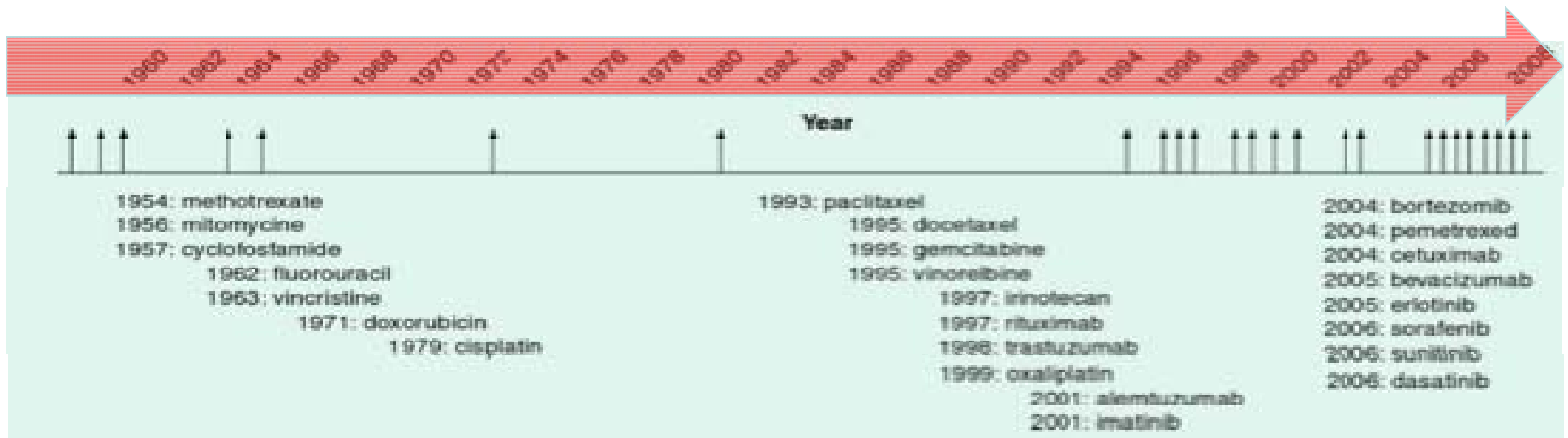
- Global spend on oncology drugs: projected for 2010-12



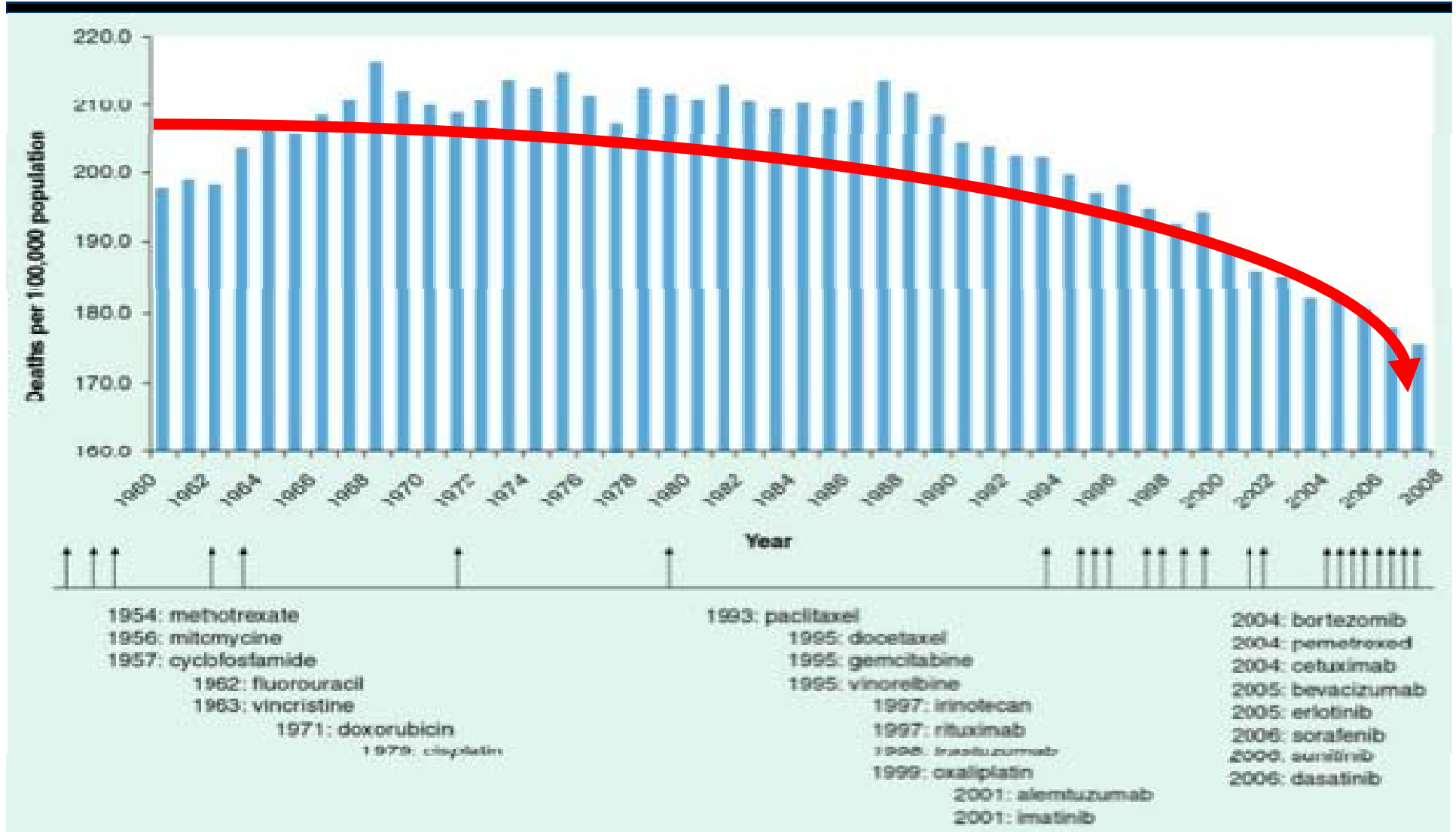
# Innovation is expensive



# Timeline of novel cancer drug approval



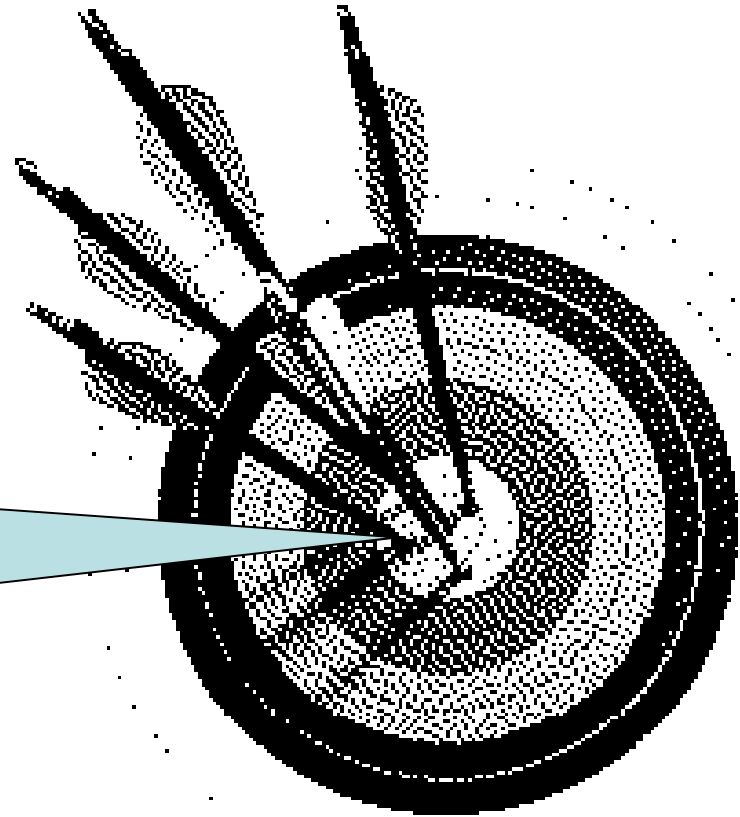
# Association of novel drugs and cancer mortality



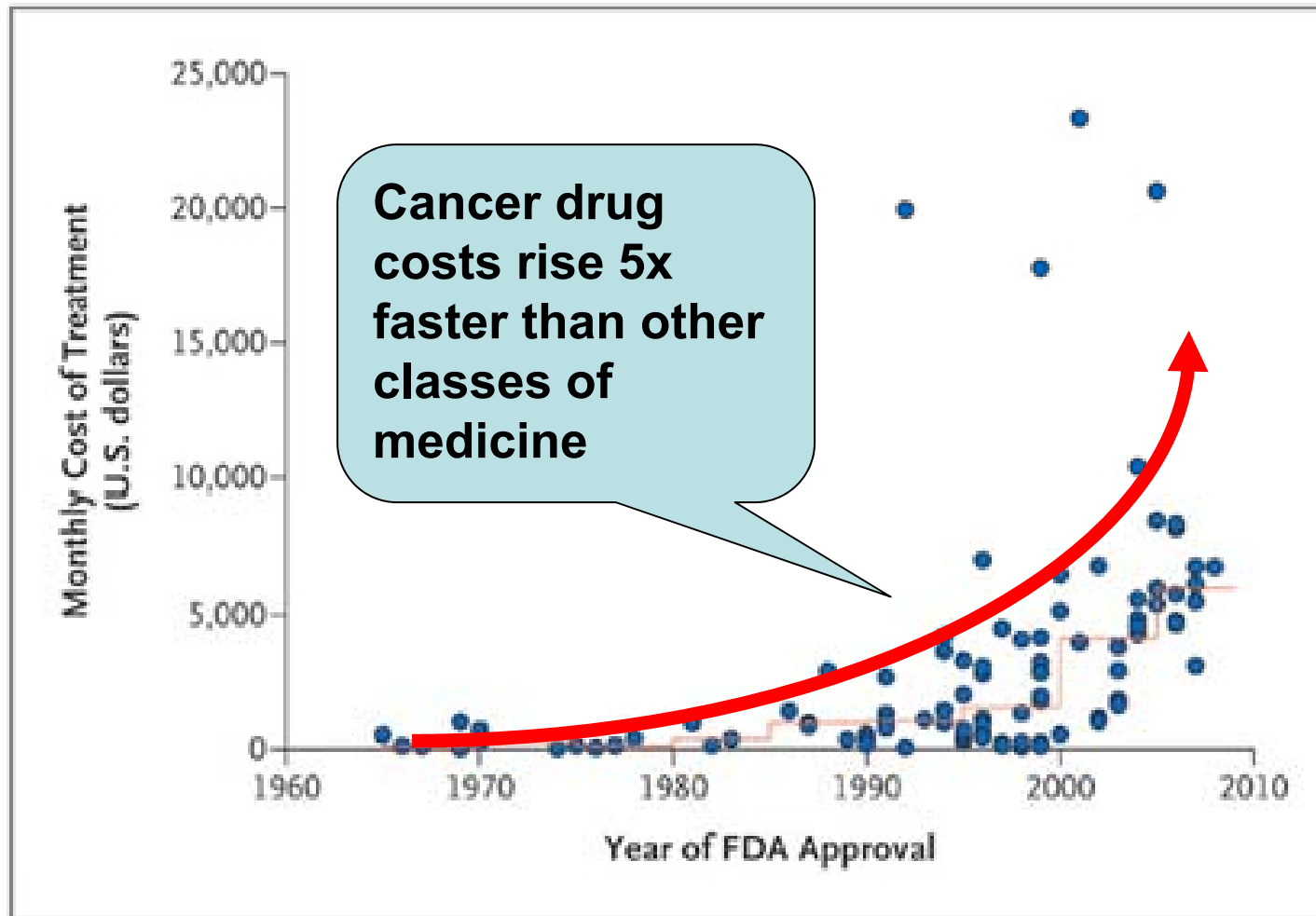
# Association of novel drugs and cancer mortality

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**Estimated - new medicines have accounted for 50-60% of the increase in cancer survival rates since 1975**



# Cost of cancer drugs by year of approval



Limits on Medicare's ability to control rising spending on cancer drugs

Bach P. N  
Engl J Med  
2009;  
360:626-633

# What are policy-makers trying to do?

Health Care

## Will Health Costs Bankrupt America?

02.23.11, 06:00 PM EST

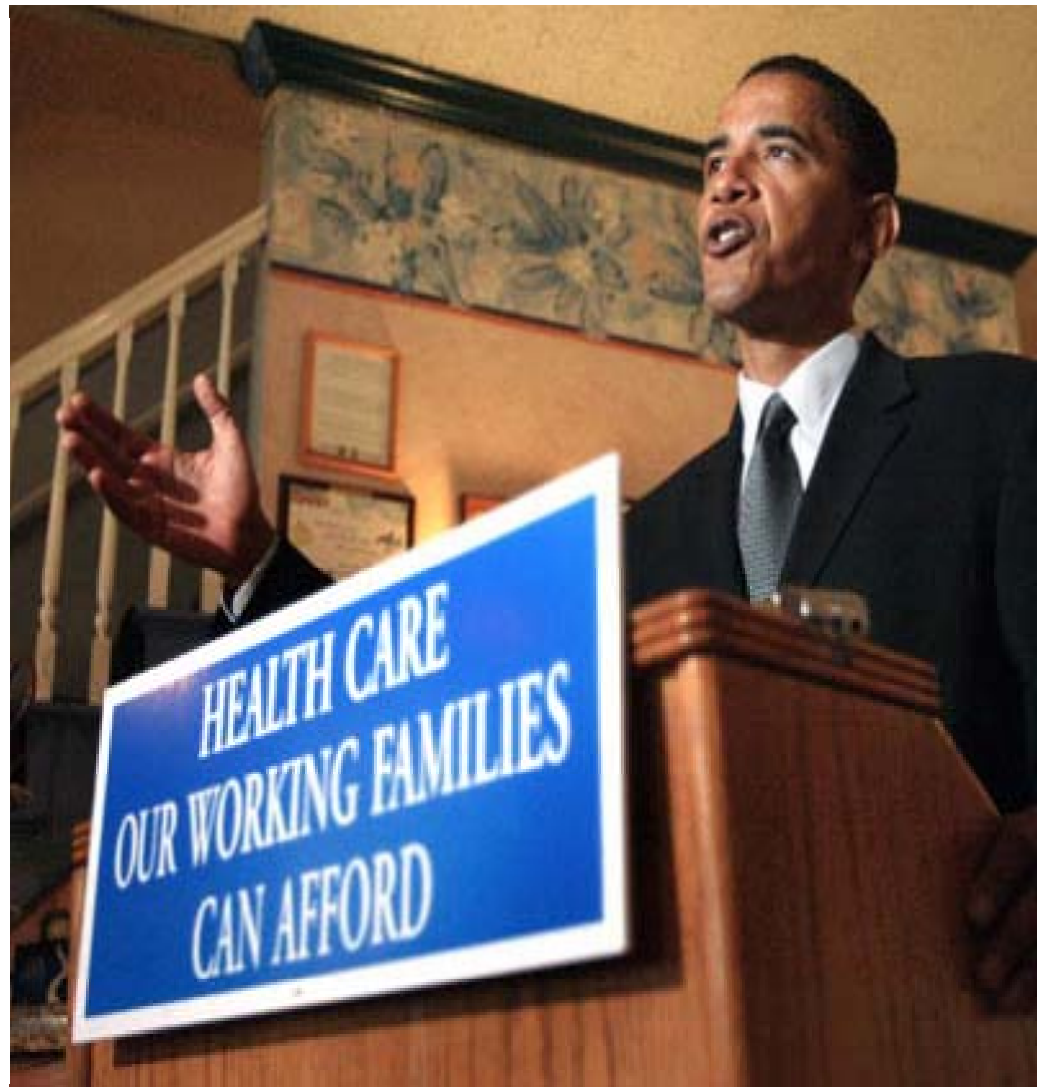
Forbes Magazine dated March 14, 2011

What kept going up even in the depths of the worst recession since the 1930s? Health spending.

A forbes.com conversation with Robert Langreth, Avik Roy, David Whelan, Matthew Herper--and our audience.

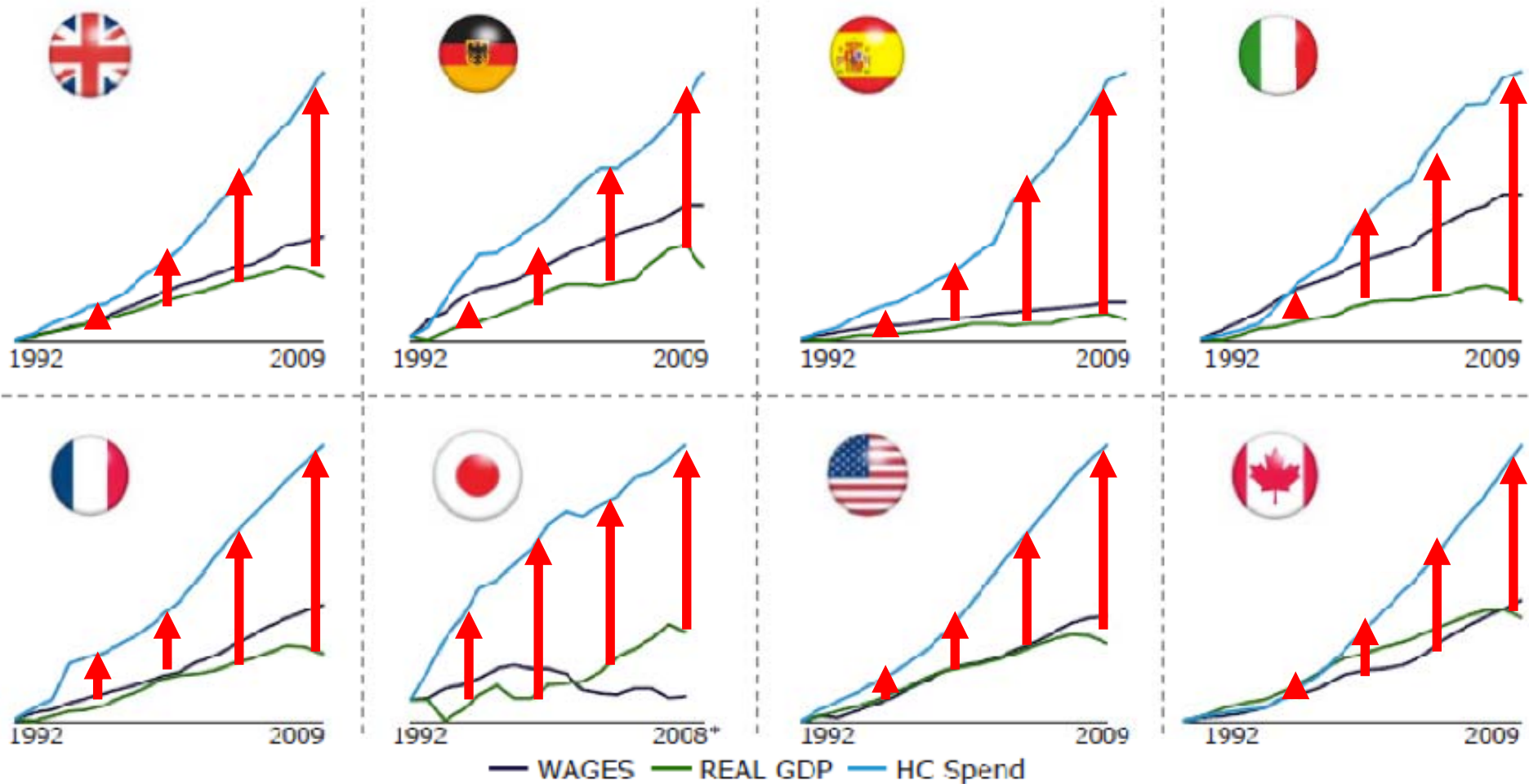
What kept going up even in the depths of the worst recession since the 1930s? Health spending. It rose 4% in 2009 to an alltime record of 17.6% of gross domestic product. We are far above every other nation in health spending but don't have the longevity to show for it. Health costs are by far the biggest threat to the nation's fiscal health in the long run.

Health care costs are increasing at an annual rate of 7% a year, which if sustained will bankrupt Medicare in nine years and increase the nation's overall annual health care tab to \$4 trillion in 10 years.





# Medical Cost Inflation puts health services at jeopardy



Walsh K. Biosimilars' utilization and the role payers do play in driving uptake in Europe: an industry perspective. Biosimilar Medicines 11th EGA International Symposium, April 2013. Accessed 5th March, 2014

# There is no evidence that spending more will consistently improve health

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1 January 2013, Vol 158, No. 1>

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**Reviews** | 1 January 2013

### The Association Between Health Care Quality and Cost: A Systematic Review

Peter S. Hussey, PhD; Samuel Wertheimer, MPH; and Ateev Mehrotra, MD, MPH

[\[+\] Article and Author Information](#)

*Ann Intern Med.* 1 January 2013;158(1):27-34

Text Size: [A](#) [A](#) [A](#)

[Article](#) [Figures](#) [Tables](#) [References](#) [Comments](#)

**Background:** Although there is broad policy consensus that both cost containment and quality improvement are critical, the association between costs and quality is poorly understood.

**Purpose:** To systematically review evidence of the association between health care quality and cost.

**Data Sources:** Electronic literature search of PubMed, EconLit, and EMBASE databases for U.S.-based studies published between 1990 and 2012.

**Study Selection:** Title, abstract, and full-text review to identify relevant studies.

Hussey PS et al. The Association Between Health Care Quality and Cost: A. *Ann Intern Med.* 1 January 2013;158(1):27-34

**There is also no evidence that simple budget cuts will consistently improve health**

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# Focus care to where it helps us live longer and live better

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**“Estimates suggest that as much as \$700 billion a year in health care costs do not improve health outcomes**

**They occur because we pay for more care rather than better care”**

- **Peter Orszag, director of the White House Office of Management and Budget, May 2009 interview with NPR**

– <http://www.factsforhealthcare.com/whitepaper/HealthcareWaste.pdf>

# Education to promote cost-effective care

*“billions of euros are wasted, say researchers, because doctors prescribe branded drugs when a generic equivalent is just as good”*

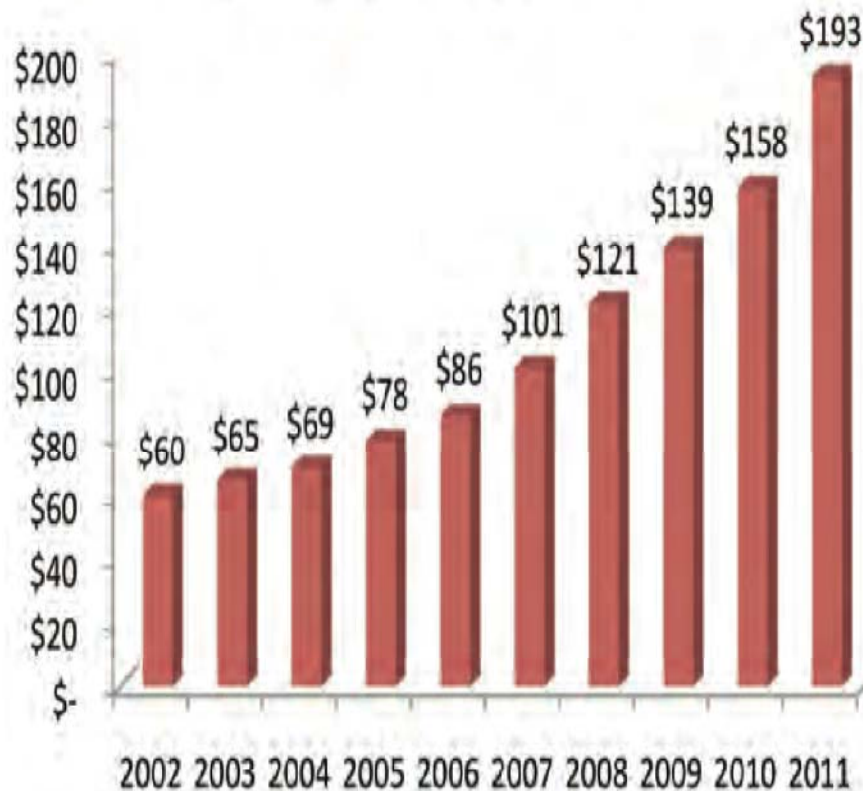
DrugWatch



No-name heroes  
can save Europe billions

→ Anna Wagstaff

# USA – annual savings from generics in billions USD



## Generic Drugs Saved Consumers \$1 Trillion

Consumer Health World — 03 August 2012



Consumers saved more than \$1 trillion over the last decade — and \$193 billion in 2011 alone — through their use of generic drugs, according to a new report published by Generic Pharmaceutical Association (GPhA), an industry trade organization.

Using data compiled by IMS Institute for Healthcare Informatics, the **Generic Drugs Cost Savings Study** reveals that the use of cheaper generic versions of expensive brand-name prescription drugs results in

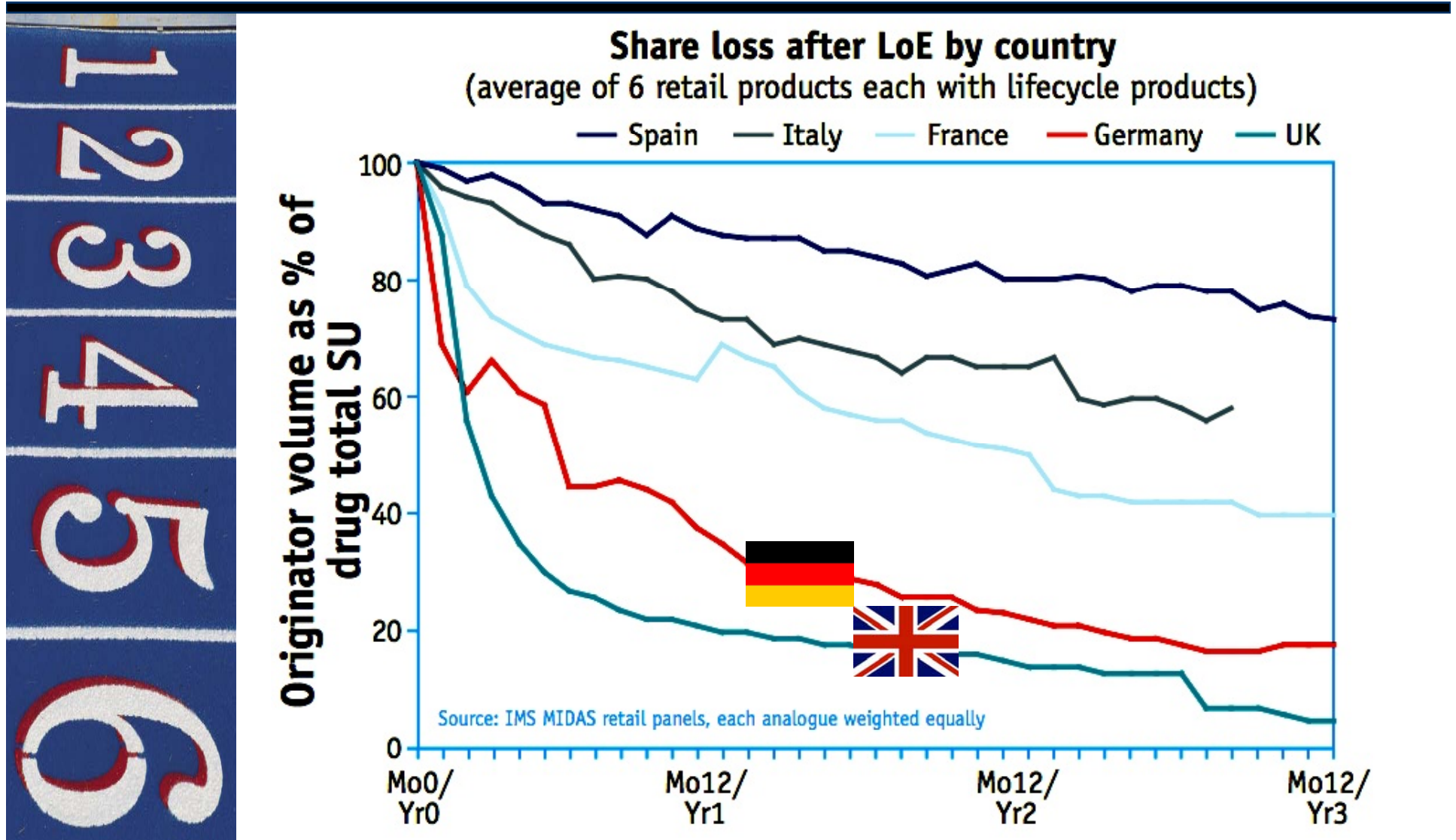
nearly \$1 billion of savings every other day.

# 1 trillion dollars in 100 dollar notes looks like



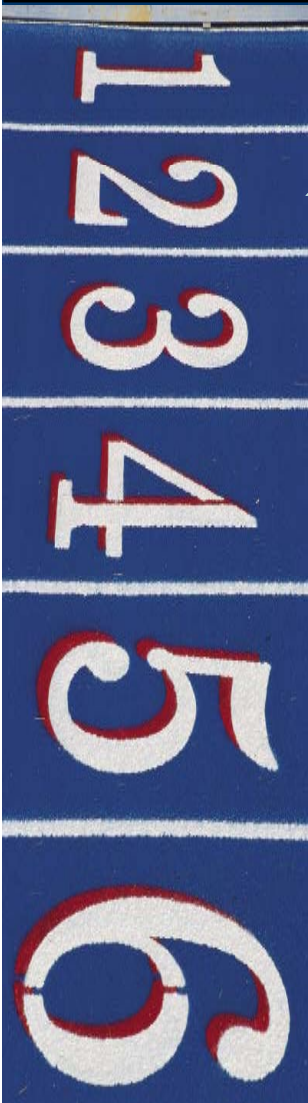
<http://www.kiplinger.com/article/business/T043-C000-S001-14-ways-to-spend-1-trillion.html> Cited 1 July 2013  
[http://americandigest.org/mt-archives/5minute\\_arguments/the\\_awesome\\_awfulness\\_of.php](http://americandigest.org/mt-archives/5minute_arguments/the_awesome_awfulness_of.php). Cited 1 July 2013

# Speed of uptake of generics differs by country within the EU

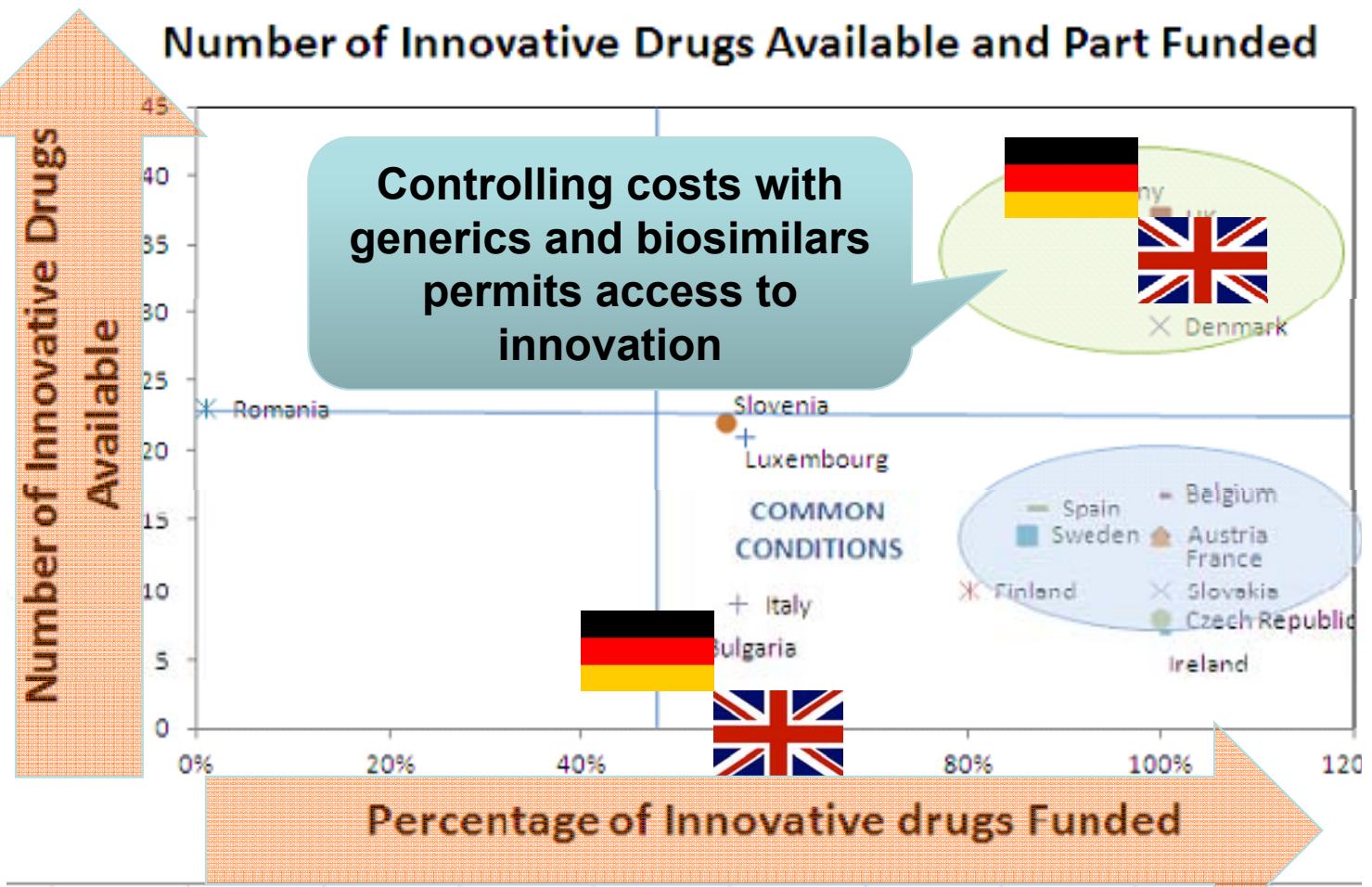




# Access to innovative drugs differs by country within the EU



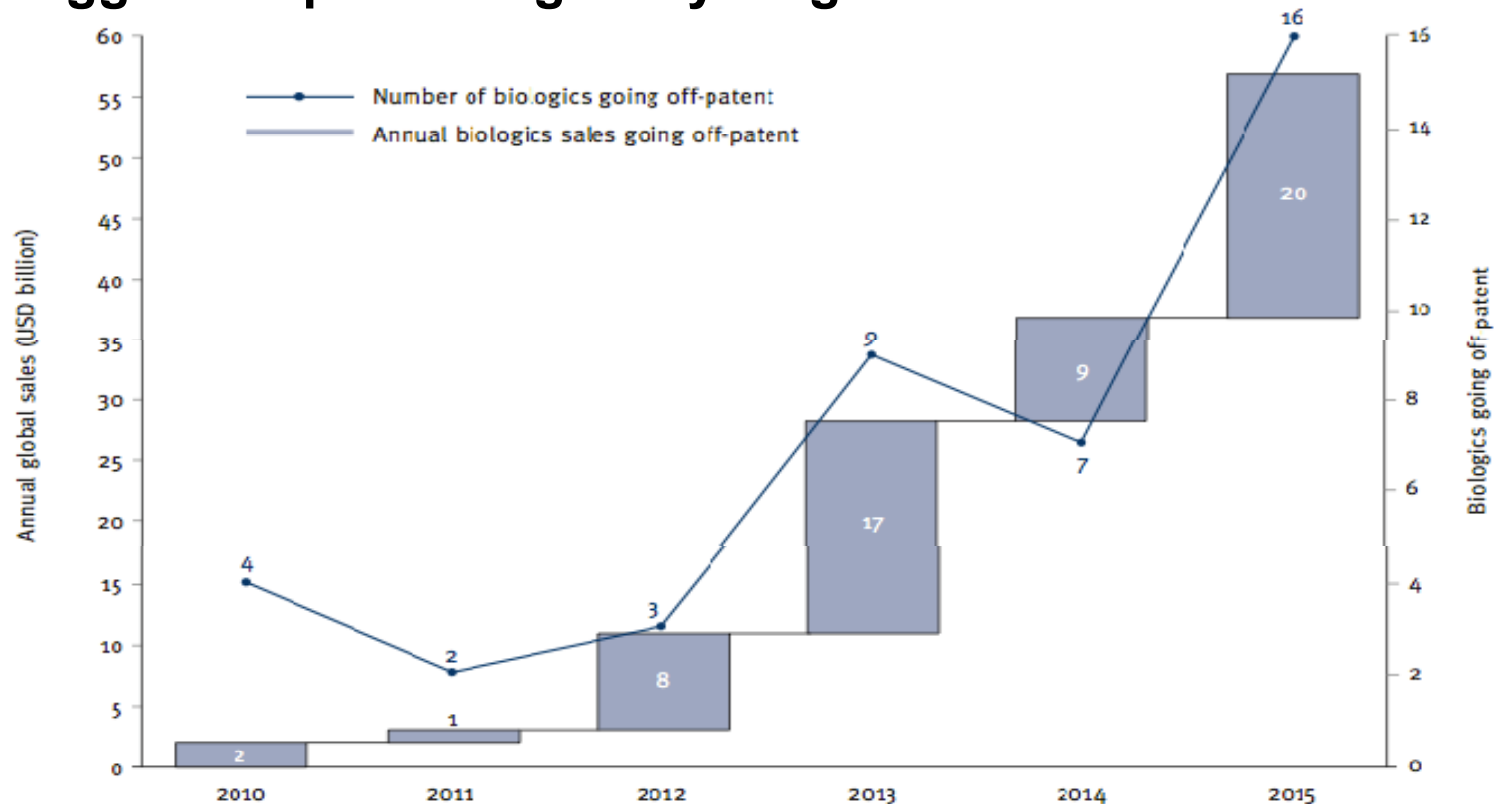
Number of Innovative Drugs Available and Part Funded



Source: IHS Global Insight, service PharmOnline International, 2012

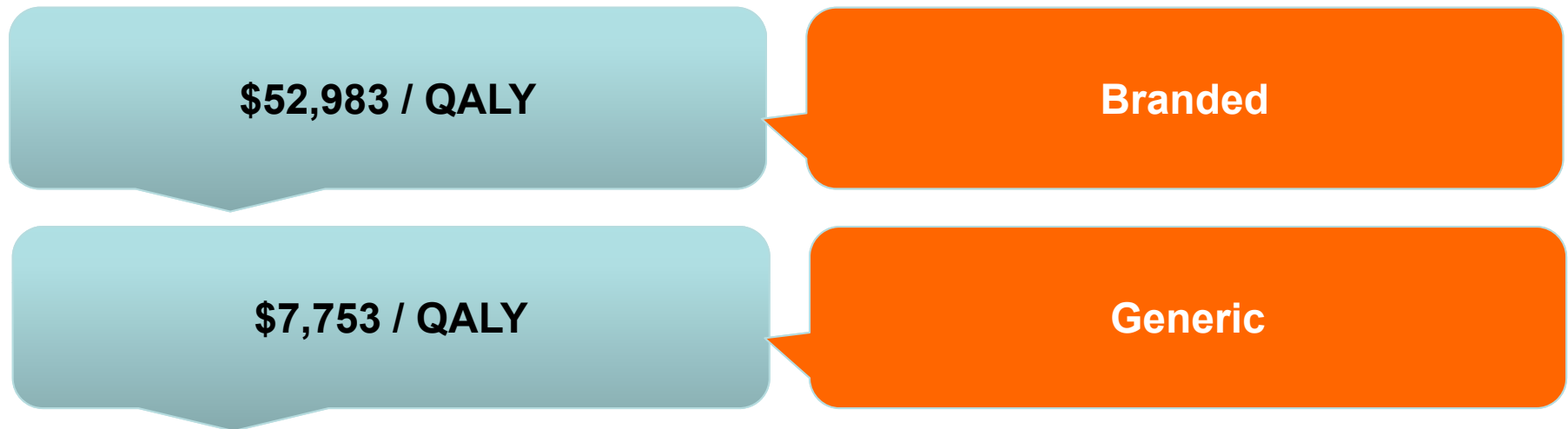
# Biosimilar medicines

Time to consider biosimilar use is now – the number and value of biologic drugs set to lose patent protection per year to 2015 suggests rapid savings may be gained to reinvest in better care



# Generics bring treatments into reimbursement that might otherwise be unaffordable

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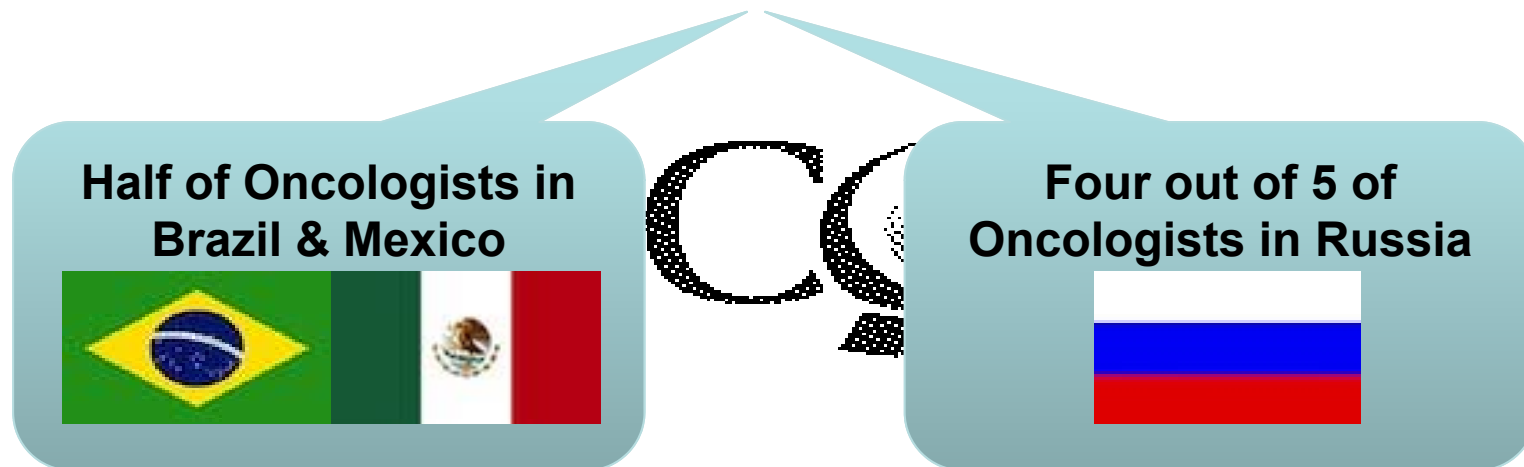


- **Shrank WH, The use of generic drugs in prevention of chronic disease is far more cost-effective than thought, and may save money. Health Aff (Millwood). 2011 Jul;30(7):1351-7**

# Cost and access: A survey of Oncologists - USA



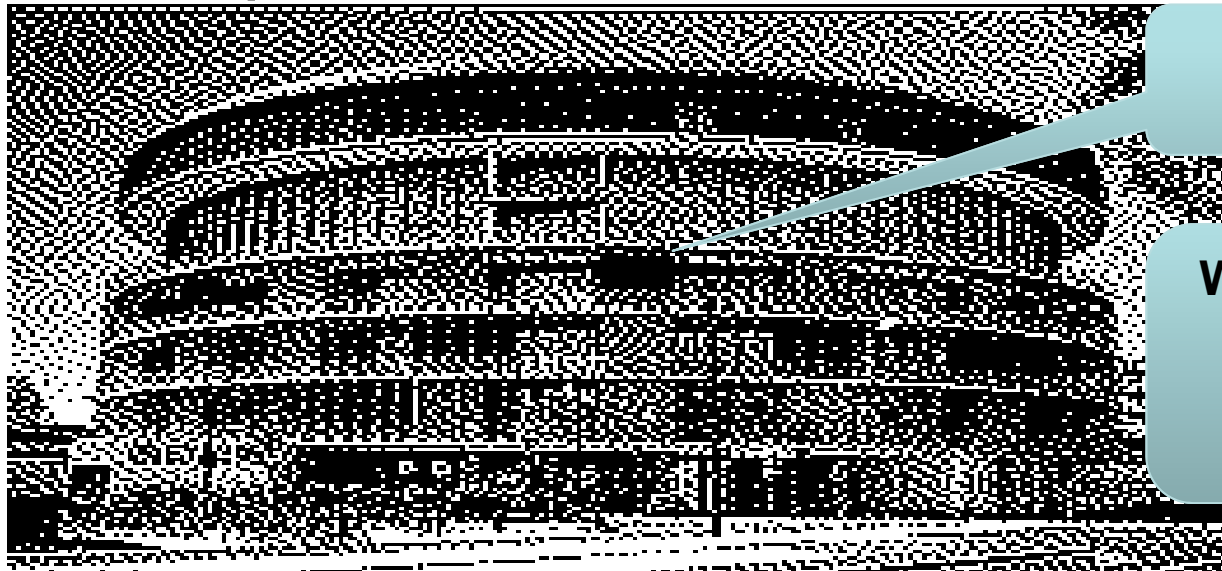
- Even in the wealthiest countries there are barriers to accessing the best treatment
- **A third of US Oncologists would offer more trastuzumab to breast cancer patients if a lower cost biosimilar was available!**
  - Lammers, PE et al. Barriers to the use of trastuzumab for HER2+ breast cancer and the potential impact of biosimilars: A physician survey in the United States and emerging markets. J ClinOncol 32:5s, 2014 (suppl; abstr 610)



# Savings from biosimilars - Sweden

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- Skane University Hospital in Sweden
- Annual saving of €650,000 (6 million SEK)
- From Switching to biosimilar Human Growth Hormone Omnitrope from the original biologic, Somatropin



**With no loss of efficacy**

**With no no serious or unexpected adverse drug reactions**

# Savings from biosimilars - UK

---

- **University College London Hospitals NHS Trust also indicate the substantial cost savings possible when switching all patients in a single center from originator rhGH to biosimilarrhGH, with annual savings estimated as in excess of £200,000 / Euro 240,000**
  - Thakrar K, Bodalia P, Grosso A. Assessing the efficacy and safety of Omnitrope. Br J Clin Pharm. 2010;2:298–301



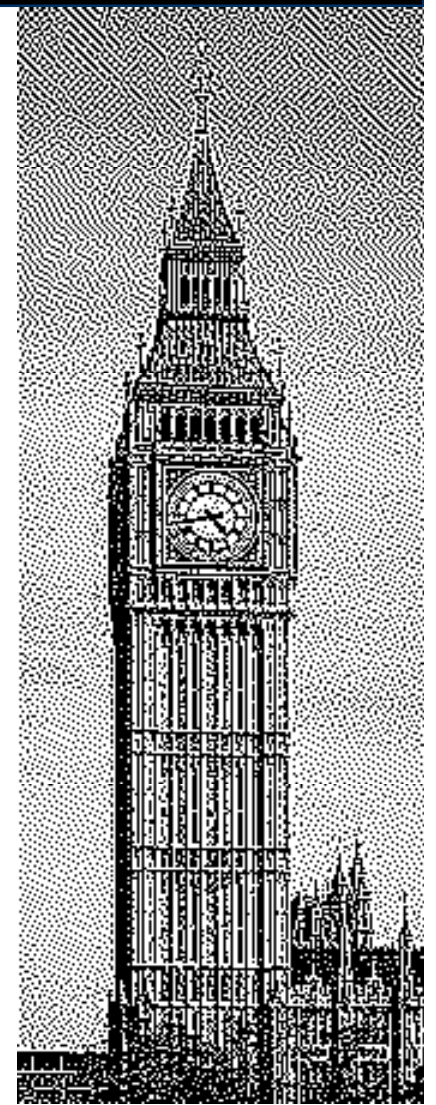
Thakrar K, Bodalia P, Grosso A. Assessing the efficacy and safety of Omnitrope. Br J Clin Pharm. 2010;2:298–301

# Savings from biosimilars - London

- Savings from biosimilar G-CSF switch in London
- G-CSF purchasing cost £3.3 million per year in 2010

**£2 million saving from biosimilar switch predicted by 2012**

- Antony Grosso, London Procurement Programme, September 2012, quoted in PereGascón et al. Support Care Cancer. 2013; 21: 2925–2932. Published online 2013 August 1. doi: 10.1007/s00520-013-1911-7



# Data from UK indicates biosimilars expand access to G-CSF



**UK G-CSF volume growth**  
Percent change vs. previous year

**Sept 2008  
Biosimilar  
G-CSF  
approved**

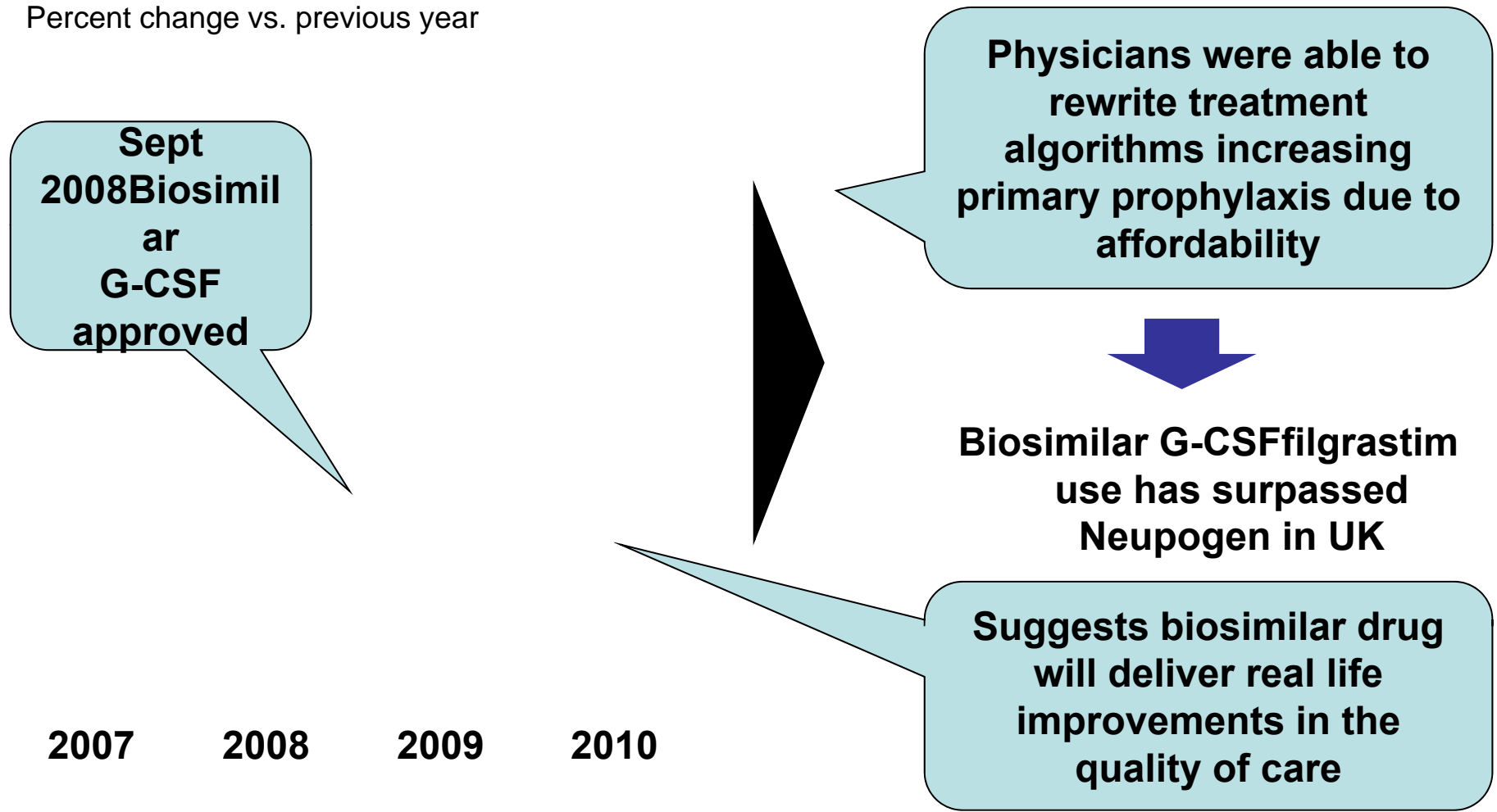
**2007      2008      2009      2010**



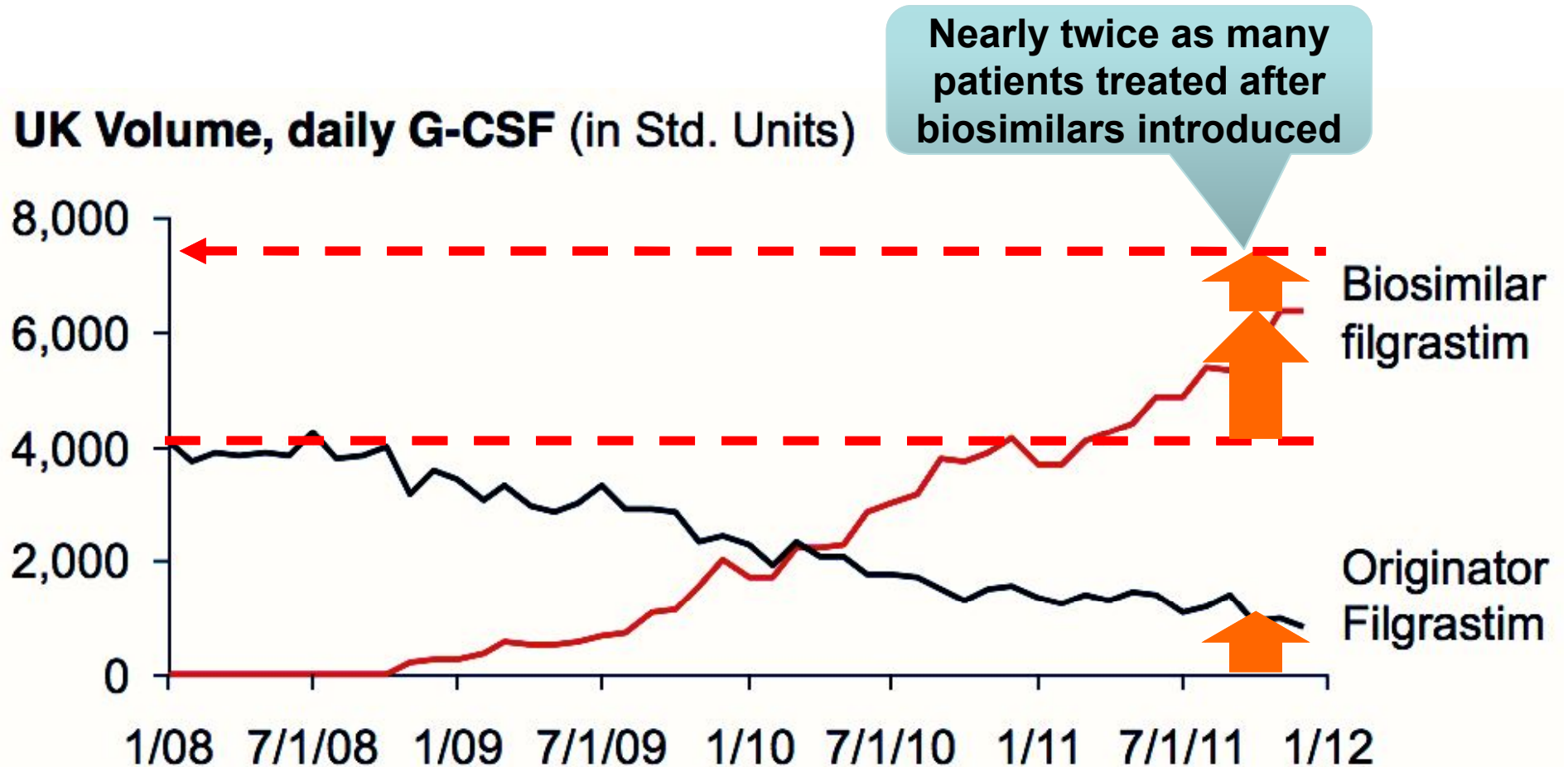
# Data from UK indicates biosimilars expand access to G-CSF



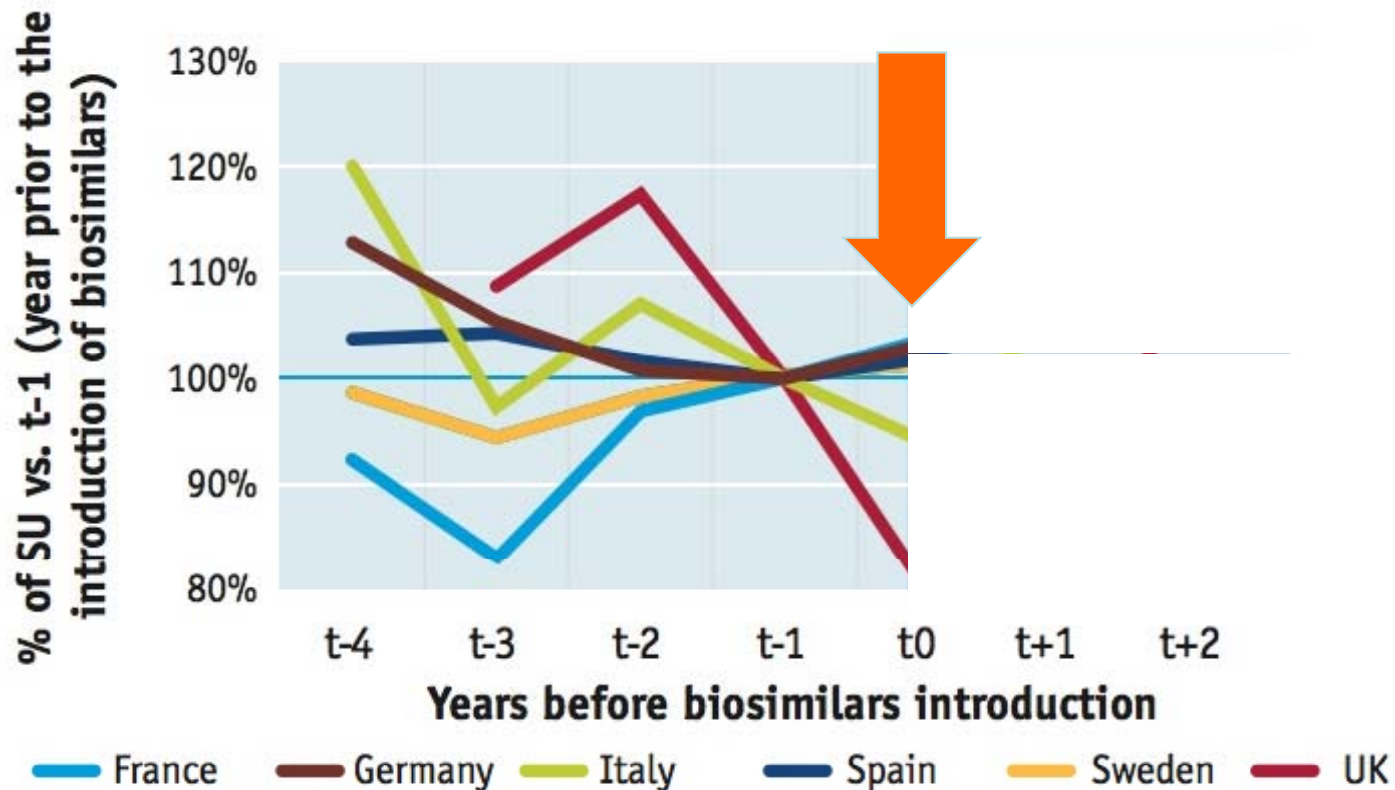
**UK G-CSF volume growth**  
Percent change vs. previous year



# Biosimilars improve the standard of care



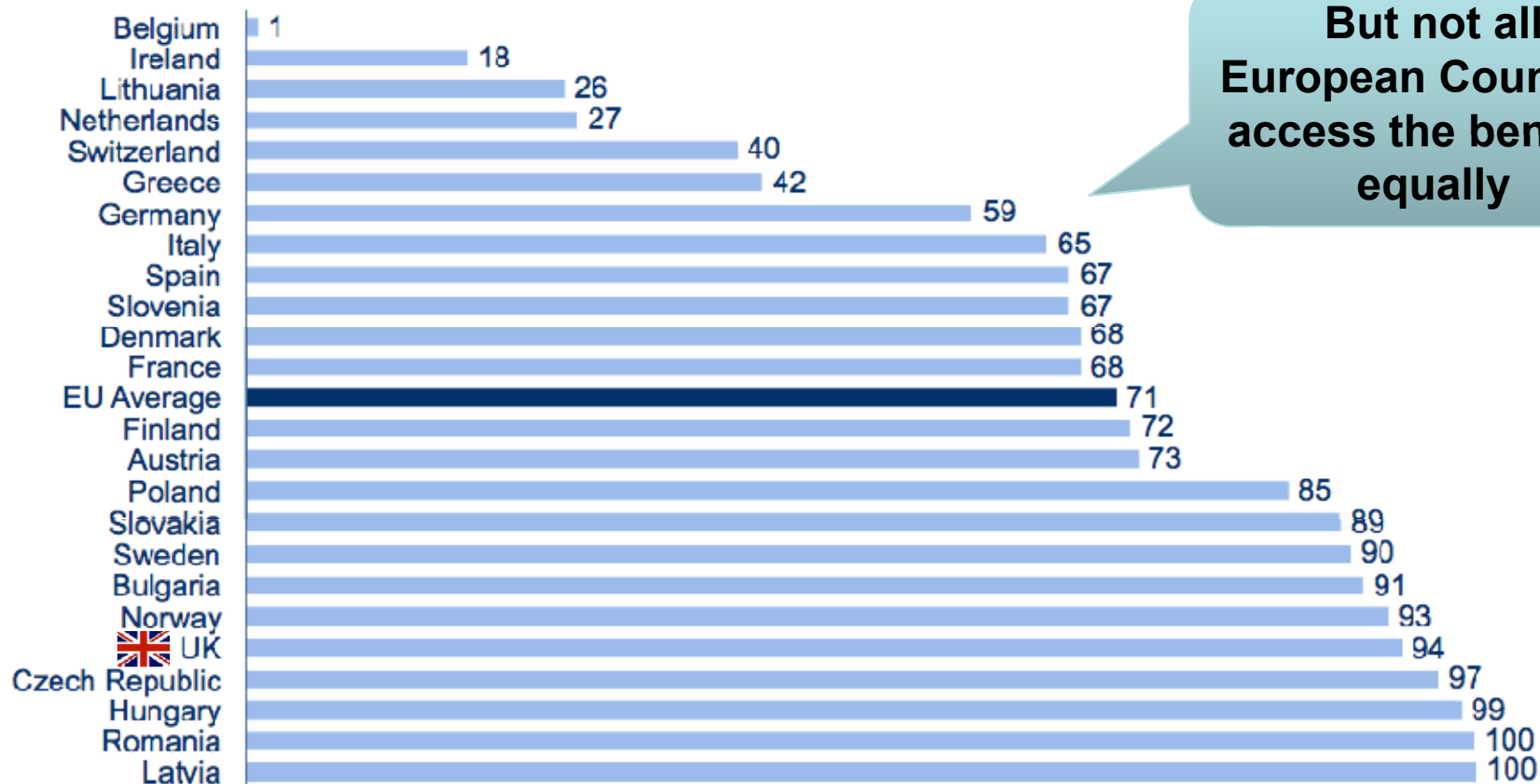
# Biosimilars bring treatments into reimbursement that might otherwise be unaffordable



- **Trends in use of white cell growth factors - G-CSF before and after biosimilar introduction in the EU**
  - IMS Health. Shaping the biosimilars opportunity: A global perspective on the evolving biosimilars landscape. December 2011.  
[http://www.imshealth.com/ims/Global/Content/Home%20Page%20Content/IMS%20News/Biosimilars\\_Whitepaper.pdf](http://www.imshealth.com/ims/Global/Content/Home%20Page%20Content/IMS%20News/Biosimilars_Whitepaper.pdf)

# Biosimilars improve the standard of care

- % of G-CSF as biosimilars vs Neupogen in Europe, Feb 2013



Source: IMS MIDAS, Feb 2013, quoted in - Walsh K. Biosimilars' utilization and the role payers do play in driving uptake in Europe: an industry perspective. Biosimilar Medicines 11th EGA International Symposium, April 2013. Accessed 5th March, 2014

# There is no doubt: even in rich nations - Savings drive increased access to treatment !

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- Savings from biosimilar G-CSF switch in Southern Health Care region in Sweden (population 1.7 million)

Five-fold increase in daily G-CSF usage

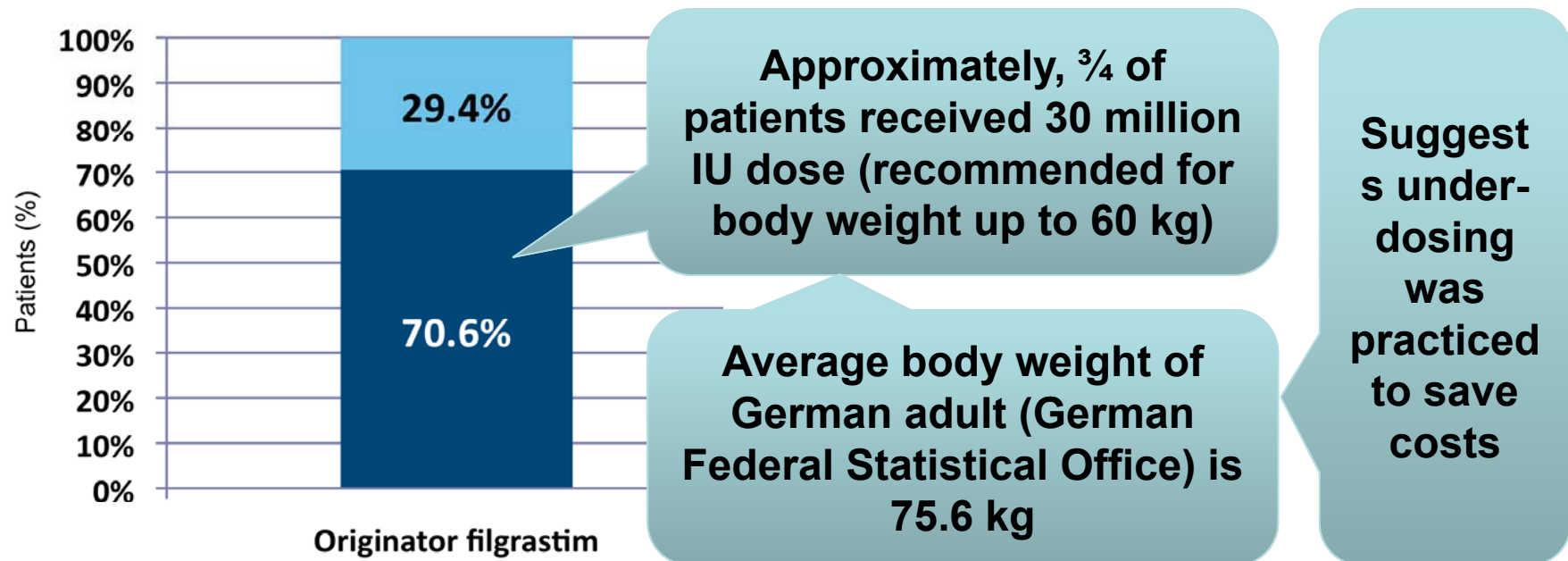
But still net savings of €2 million

This represents a saving of 4–5% of the total drug budget



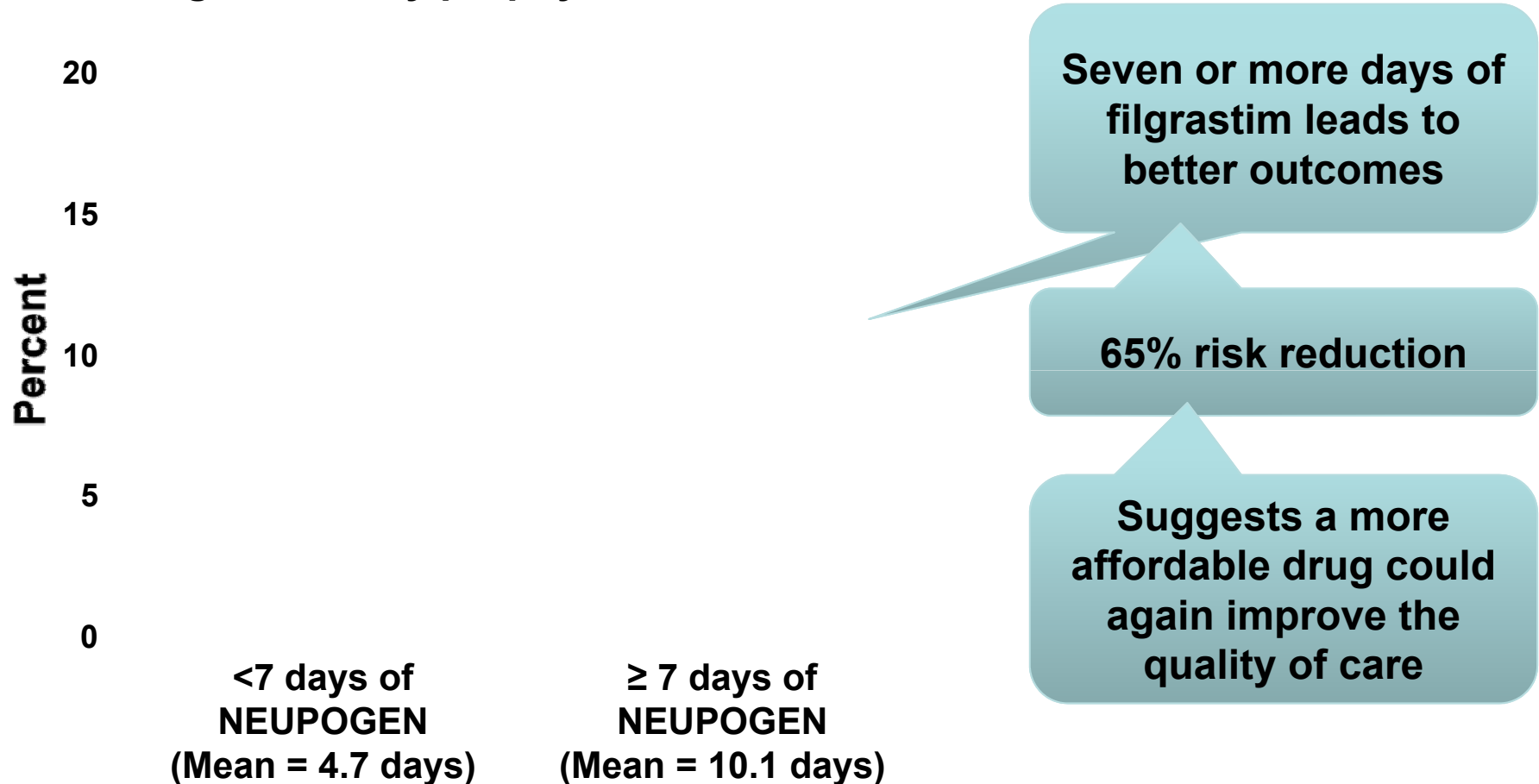
# Cost saving steps with expensive drugs can compromise outcomes

- Prescription data of statutory health insurance members in Germany with G-CSF prescriptions between January 2008 and July 2010 were evaluated (originator filgrastim, n = 8726; biosimilar filgrastim, n = 4240)
  - Hadji et al. Int J Clin Pharmacol Ther. 2012;50:281-9.



# Duration of G-CSF use may affect the quality of care

Incidence of febrile neutropenia in patients receiving secondary prophylaxis



# Biosimilar use is increasing

**Estimated biosimilar market potential: 2009 value of products whose patents expected to expire between 2009-2019. In absolute value**



Rovira J et al, for the European Commission (Directorate-General for Enterprise and Industry) - The impact of biosimilars' entry in the EU market.  
[http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars\\_market\\_012011\\_en.pdf](http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_market_012011_en.pdf)

Estonia	9,4
Finland	207,9
France	3.432,5
Germany	3.200,5
Greece	279,8
Hungary	195,2
Ireland	193,9
Italy	1.912,6
Latvia	17,6
Lithuania	17,3
Luxembourg	14,7
Netherlands	365
Norway	207,3
Portugal	52,1
Romania	188,4
Slovakia	124,2
Slovenia	49,5
Spain	1.828,0
Sweden	462,0
Switzerland	353,7
UK	1.351,0





# Potential EU savings from biosimilar use

- Höer A. Saving money in the European healthcare systems with biosimilars. GaBI Journal 2012;1(3-4):120-6
- **Methods:** using a sequential approach, we calculated the savings through the use of biosimilars for 8 of the 28 EU nations - France, Germany, Italy, Poland, Romania, Spain, Sweden and UK
- **Results:**
  - The use of biosimilars is expected to result in overall savings between Euros 11.8 billion and Euros 33.4 billion between 2007 and 2020, with largest savings expected for France, Germany and UK.
  - Biosimilar monoclonal antibodies - 1.8 to 20.4 billion Euros
  - Biosimilar erythropoietins - 9.4 to 11.2 billion Euros
  - Biosimilar GCSF - 0.7 to 1.8 billion Euros



# Potential USA savings from biosimilar use

Estimated Savings from Biogeneric Competition by Treatment Category  
35 Percent Average Price Discount, 2010-2029, \$ billions

Appendix 2A

	Erythropoietins	TNF Blockers	Insulin & Insulin Analogs	Cancer Antibodies	Interferons	Interleukins	Monoclonal Antibodies	Recombinant Hormones	Recombinant Proteins	Small Molecule	Thrombolytics	Vaccines	Other
2010													
2011		2.67											
2012		2.57											
2013		2.57											
2014		2.58											
2015		2.58		4.11									
2016		2.58		4.12									
2017	7.68	2.58		4.12									
2018	7.69	2.59		4.13									
2019	7.70	2.59		4.13									
2020	7.70	2.59	3.94	4.13									
2021	7.71	2.59	3.94	4.14									
2022	7.72	2.00	3.95	4.14									
2023	7.73	2.60	3.95	4.15									
2024	7.73	2.60	3.95	4.15									
2025	7.74	2.60	3.96	4.15									
2026	7.75	2.61	3.96	4.16									
2027	7.76	2.61	3.96	4.16									
2028	7.76	2.61	3.97	4.17									
2029	7.77	2.61	3.97	4.17									
Total	100.45	49.23	39.55	62.13	39.55	0.50	27.23	6.41	377.72				

Predicts 378 Billion USD saved by 2029

"...generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans \$67 billion to \$108 billion over 10 years and \$236 billion to \$378 billion over 20 years."

Dr. Robert J. Shapiro, former Under Secretary of Commerce - report released February 11, 2008

[http://www.youtube.com/watch?v=gAW56\\_4gxS8](http://www.youtube.com/watch?v=gAW56_4gxS8)

# The predicted savings from biosimilars makes them a priority for cost-effective care

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- Paul Cornes. The economic pressures for biosimilar drug use in cancer medicine. *TargOncol* (2012) 7 (Suppl 1):S57–S67. DOI 10.1007/s11523-011-0196-3

- <http://www.targoncology.com/doi/10.1007/s11523-011-0196-3>

*Targ Oncol* (2012) 7 (Suppl 1):S57–S67  
DOI 10.1007/s11523-011-0196-3

PERSPECTIVES

"...generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans \$67 billion to \$108 billion over 10 years and \$236 billion to \$378 billion over 20 years."

## The economic pressures for biosimilar drug use in cancer medicine

Paul Cornes

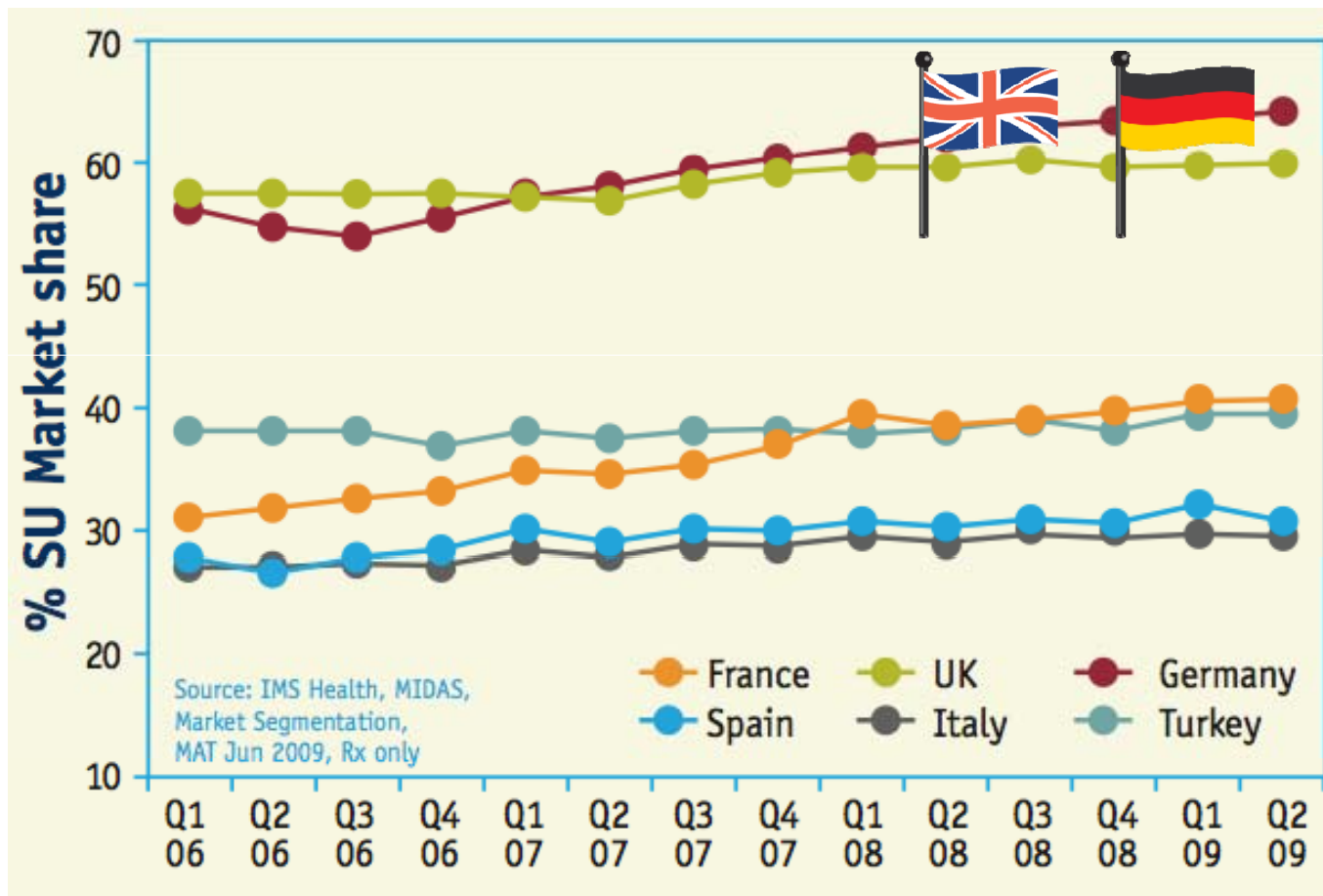
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# There is no consistent model for governments to promote generic & biosimilar medicines



Differing rules & incentives for use of generic medicines across EU markets leads to different market forces

Rules and Incentives																	
Market Rules	Mandatory price reduction	✓	✓					✓		✓	✓					✓	
	Patient co-pay		✓	✓			✓			✓	✓	✓	✓			✓	
	Price referencing			✓	✓	✓	✓			✓		✓	✓	✓	✓		
	Pharmacy-level substitution				✓	✓				✓	✓		✓	✓			✓
Market Incentives	At the pharmacy				✓	✓			✓	✓	✓		✓	✓			✓
	With the health insurers						✓			✓							
	With wholesalers										✓						
	With payers	✓	✓			✓											
	Favouring brands							✓					✓				
	Favouring generics	✓		✓			✓		✓		✓				✓	✓	✓

# Contrasting generic medicines volume penetration in key countries



# There is no consistent model for governments to promote generic & biosimilar medicines

Rules and Incentives			
Market Rules	Mandatory price reduction		
	Patient co-pay	✓	
	Price referencing	✓	
	Pharmacy-level substitution		✓
Market Incentives	At the pharmacy		✓
	With the health insurers	✓	
	With wholesalers		
	With payers		
	Favouring brands		
	Favouring generics	✓	✓

Perhaps the physicians' leadership is the missing driver





# CAN WE AFFORD THE WAR ON CANCER?

Immunotherapy vaccines could extend survival in a handful of cancers. But personalizing treatment, payers argue, is not sustainable. Where should the line be drawn?

BY ED SILVERMAN

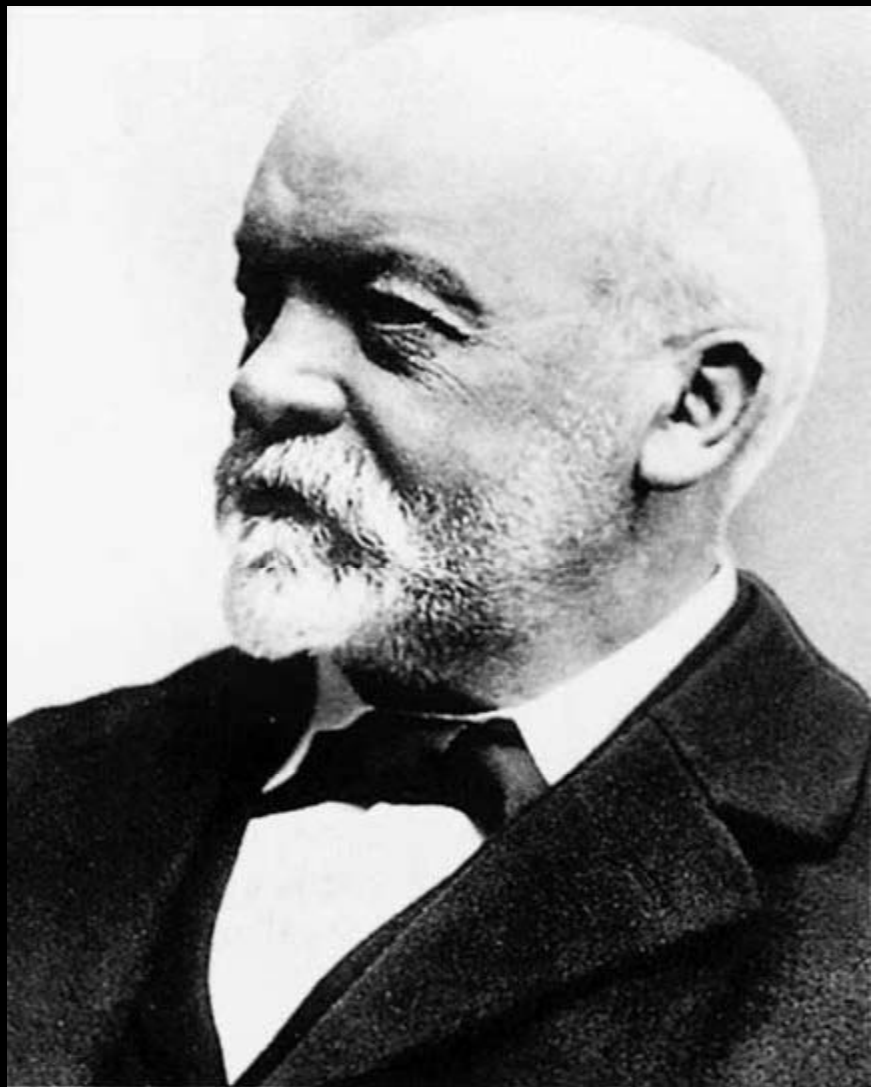
**T**wo years ago, the U.S. Food and Drug Administration took a step that some thought would never occur — it approved the sipuleucel-T (Provenge) vaccine for late-stage prostate cancer. The move came after a protracted episode involving allegations of conflicts of interest among a pair of FDA advisory committee members who reviewed the

tending a life by 4.1 months is worth the price of Provenge. It has also prompted larger questions about the underlying technology and the need to develop more vaccines.

Provenge is made by culturing a patient's immune cells with a recombinant antigen. The individualized product is then infused back into the patient, activating the immune system to target and attack the cancer. This "immunotherapy" underscores the move toward personalized



# Economics – we need both innovation and value to access better cancer treatment



Gottlieb Daimler



Henry Ford

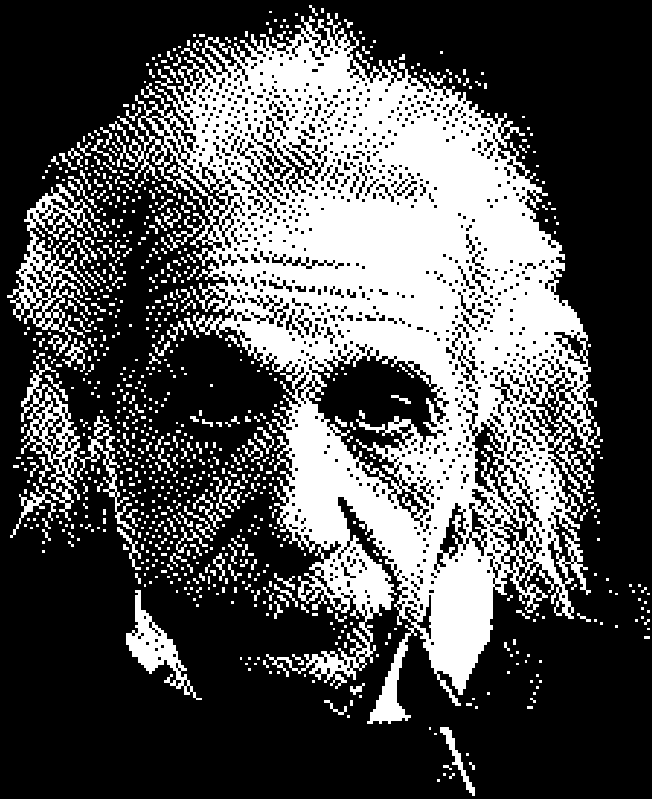




***“ We understand that we doctors should be and are stewards of the larger society as well as of the patient in our examination room ”***

*Dr. Lowell E. Schnipper,*

*Chief of Hematology/Oncology Beth Israel Deaconess Medical Center  
Chairman of ASCO task force on value in cancer care*



*Albert Einstein*

***Strive not to be a success,  
but rather to be of value***

# Question

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- **Is there sufficient money in the health system to afford innovation in medicine?**
  
- **please chose your best response:**
  1. **No – we do not have the budget to introduce innovation**
  2. **Unsure**
  3. **Yes – we have the chance to increase spending on innovative treatments**

The logo for PhAMA, featuring the word "PhAMA" in white, bold, sans-serif font. The "Ph" is on a dark blue background, and "AMA" is on a red background.

**PhAMA**

Innovative Medicines for Malaysia

# 1ST NATIONAL BIO-THERAPEUTICS CONGRESS – PUTTING PATIENT FIRST

**22 NOVEMBER 2014**