Biosimilars – can we do without them?

Dr Paul Cornes

Thursday 17th March, 2016
EAHP - Vienna

medicines for europe
better access. better health.

Dr Paul Cornes

Disclosures March 2016

- **Salary received:**
  - **United Kingdom National Health Service**
- **Honoraria received:**
  - **Accord Healthcare**
  - **Amgen**
  - **Bernstein**
  - **British Medical Journal**
  - **European Generics Association**
  - **Hospira**
  - **Janssen**
  - **Lilly**
  - **Merck Serono**
  - **Napp**
  - **Pharmaceutical Association of Malaysia**
  - **Pfizer**
  - **Roche**
  - **Sandoz**
  - **Teva**

These slides and their content were created by Dr Paul Cornes.

Please let me know if there are errors or omissions

Biosimilars – can we do without them?

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Comparative Outcomes Group

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

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Biosimilars – can we do without them?

Biosimilars – I can't imagine the world of medicine without them

There is a cost to cancer

cancer has the most devastating economic impact of any cause of death in the world.

WHO: Cancer world's top killer since 2010

The total economic impact of premature death and disability from cancer worldwide is $2.5 trillion.

Cancer causes the highest economic loss of all of the 15 leading causes of death worldwide

17 percent of all 'healthy' years lost in the European Union

170 million years of “healthy life” lost due to death and disability from cancer in 2008

Managing the costs of cancer will be the model we use for other diseases

Ref [1] www.usatoday.com/news/health/2008-12-09-cancer_N.htm [2] http://www.cancer.org/acs/groups/content/@internationalaffairs/documents/document/acspc-026203.pdf [3] Smith M. Life-Years Lost to Cancer More than 150 Million. http://www.medpagetoday.com/HematologyOncology/OtherCancers/35325. Accessed March 15, 2016 [4] Lopez G. Investing in Cancer Prevention and Control to Reduce Global Economic Burden. http://am.asco.org/investing-cancer-prevention-and-control-reduce-global-economic-burden. Accessed March 15, 2016

There is a cost to cancer
There is a cost to cancer care

"Think about health spending as not consumption but investment"

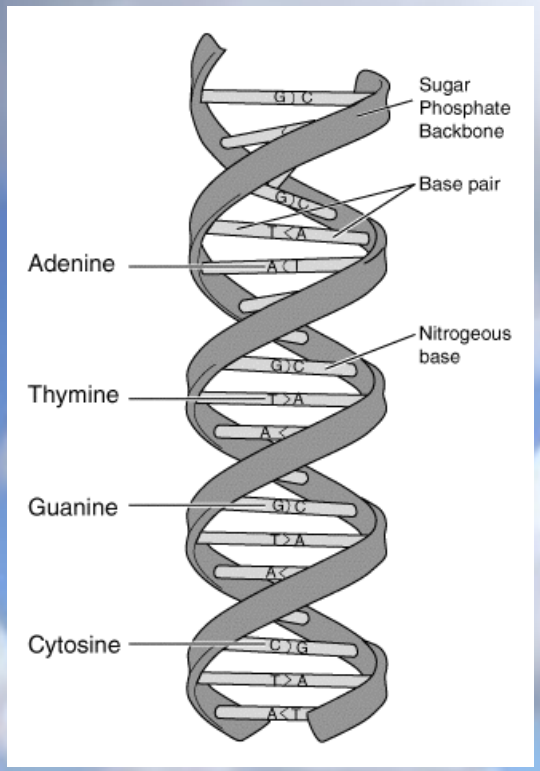
Spending is not a negative – it is a positive good

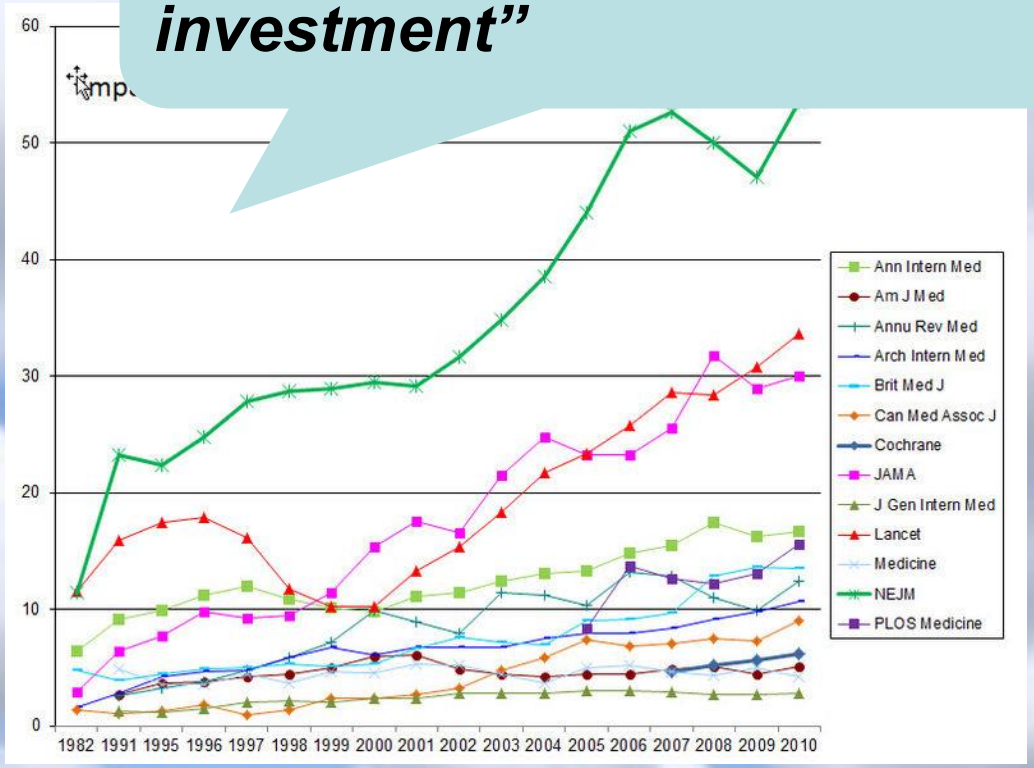
We are treating the worlds most important disease – its greatest killer

Good news for medicine

- **Basic cancer science is paying back on its investment**
- **One medical paper a minut**
  Library of Medicine

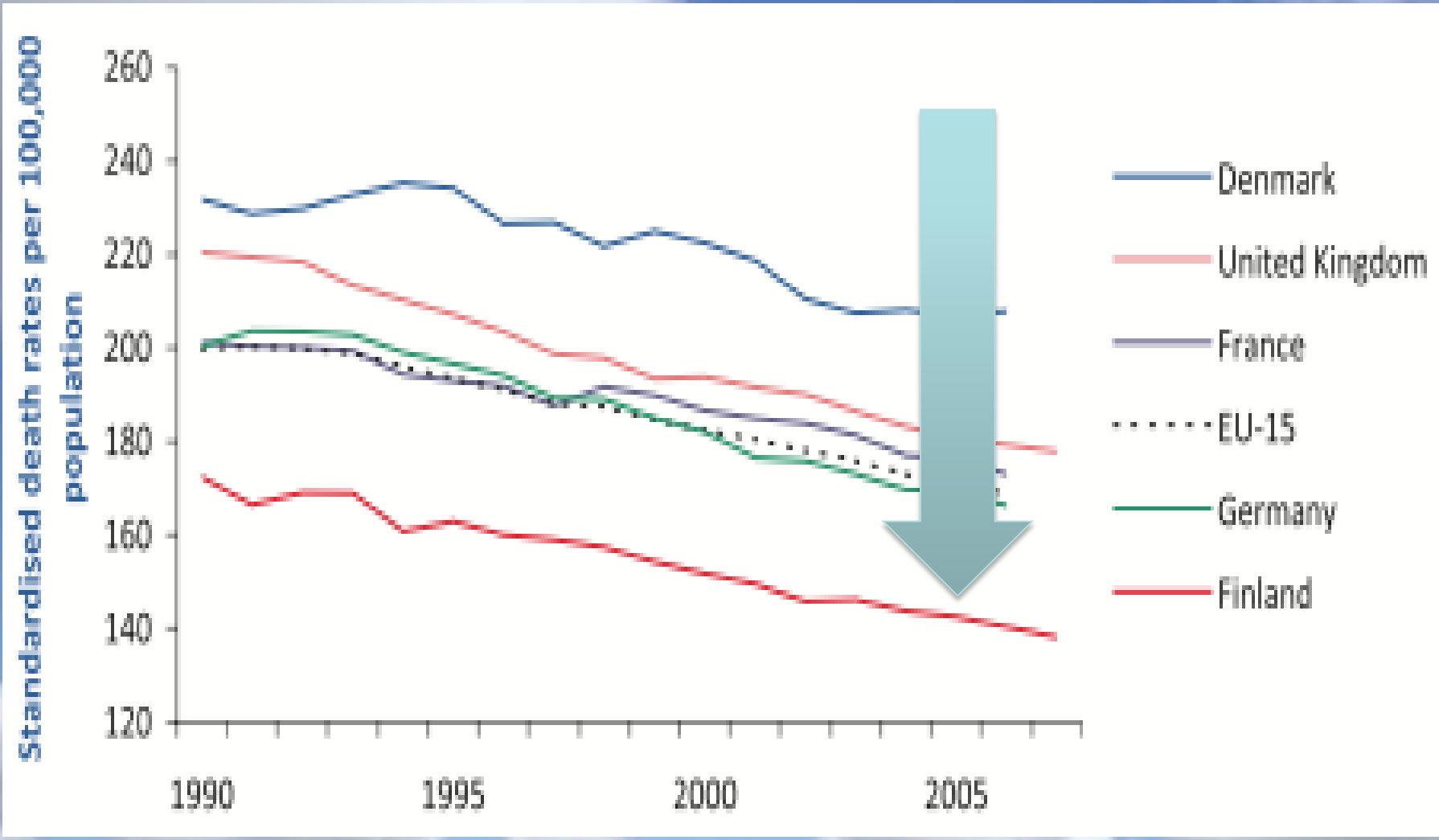
"Think about health spending as not consumption but investment"





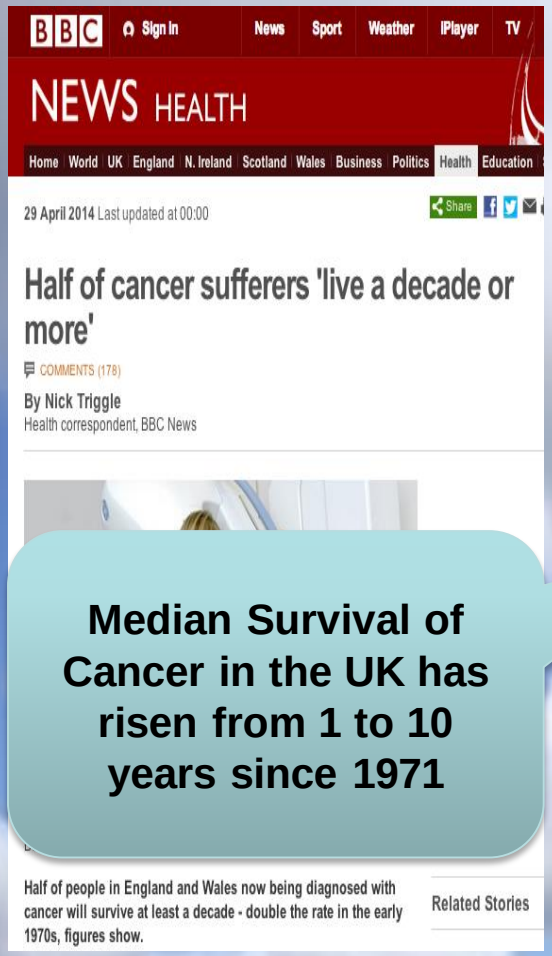
MEDLINE Citation Counts by Year of Publication. Available at http://www.nlm.nih.gov/bsd/medline_cit_counts_yr_pub.html, accessed 2012 Sept 11. Template:2010 - Impact factor of selected medical journals.jpg/credit

Good news for cancer treatment: worldwide – more people survive cancer



Ref: [1] WHO Health for all database [2] [2] Health and Social Care Information Centre. NHS Outcomes Framework. Nov 2014. www.hscic.gov.uk/catalogue/PUB15930/nhs-out-fram-ind-nov-14-comm.pdf. Accessed Jan 9, 2016

Good news for cancer treatment: Cancer survival is improving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29 April 2014 Last updated at 00:00

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Half of cancer sufferers 'live a decade or more'

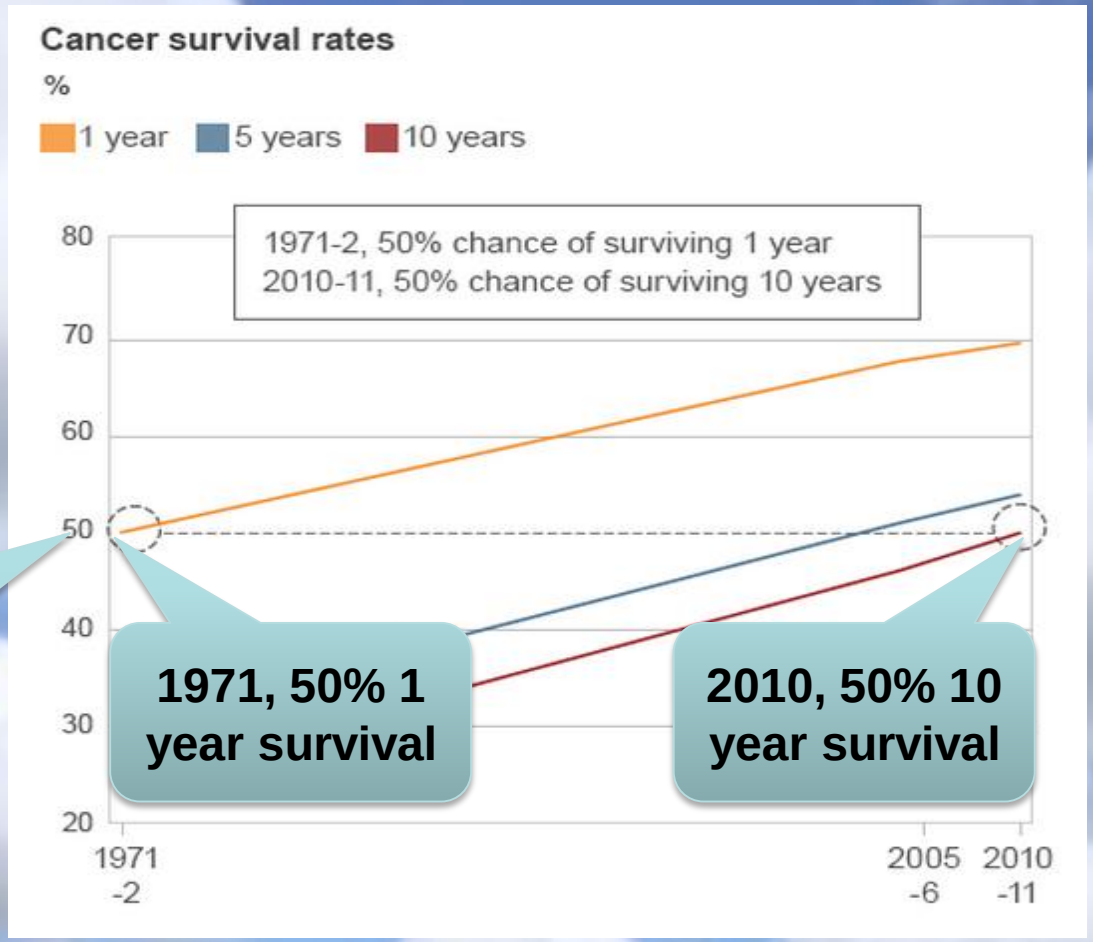
COMMENTS (178)

By Nick Triggle
Health correspondent, BBC News

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.

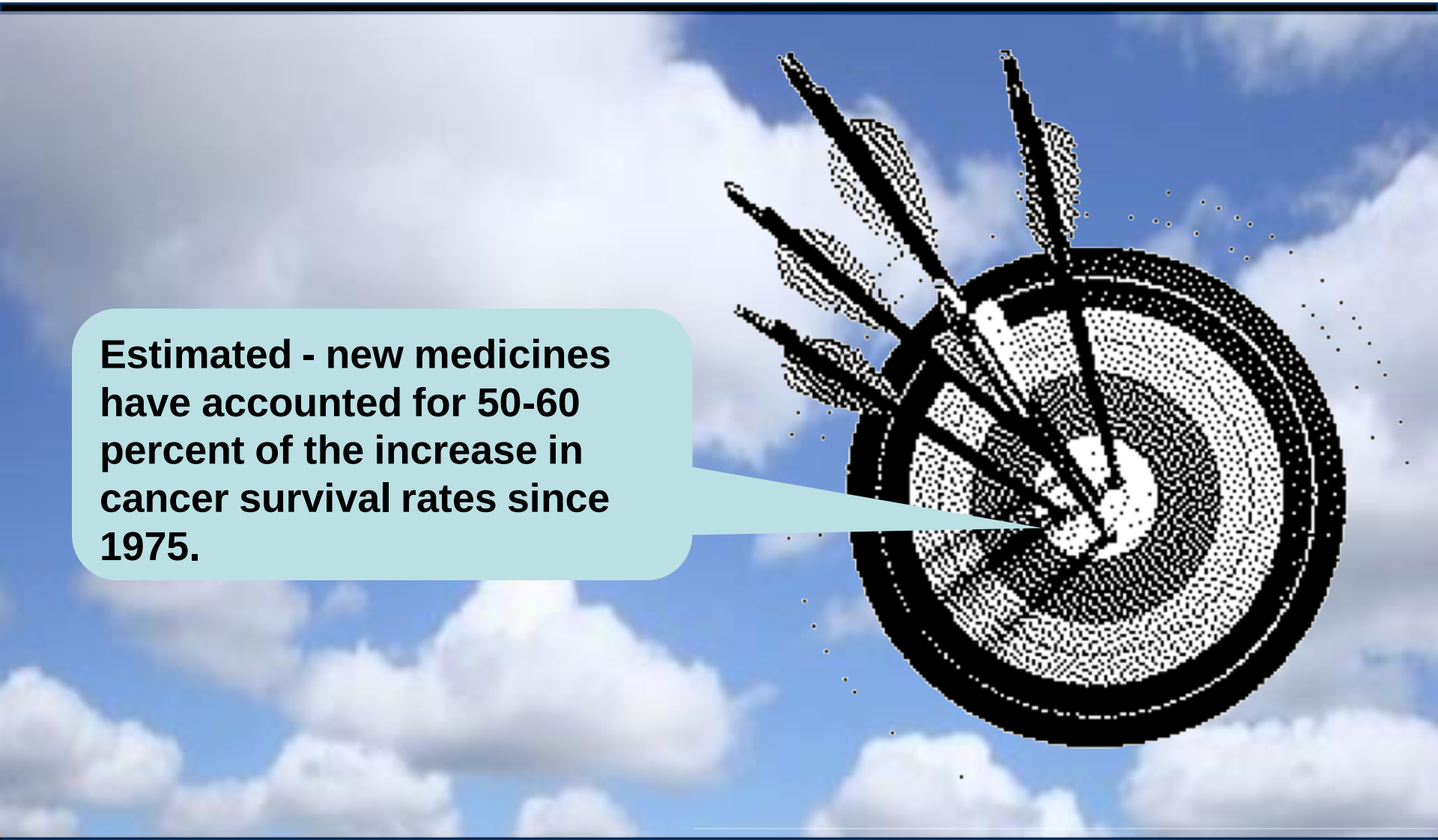
Related Stories

Median Survival of Cancer in the UK has risen from 1 to 10 years since 1971



Triggle N. Half of cancer sufferers 'live a decade or more'. BBC News April 29th, 2014. http://www.bbc.co.uk/news/health-27194823. April 29th, 2014.

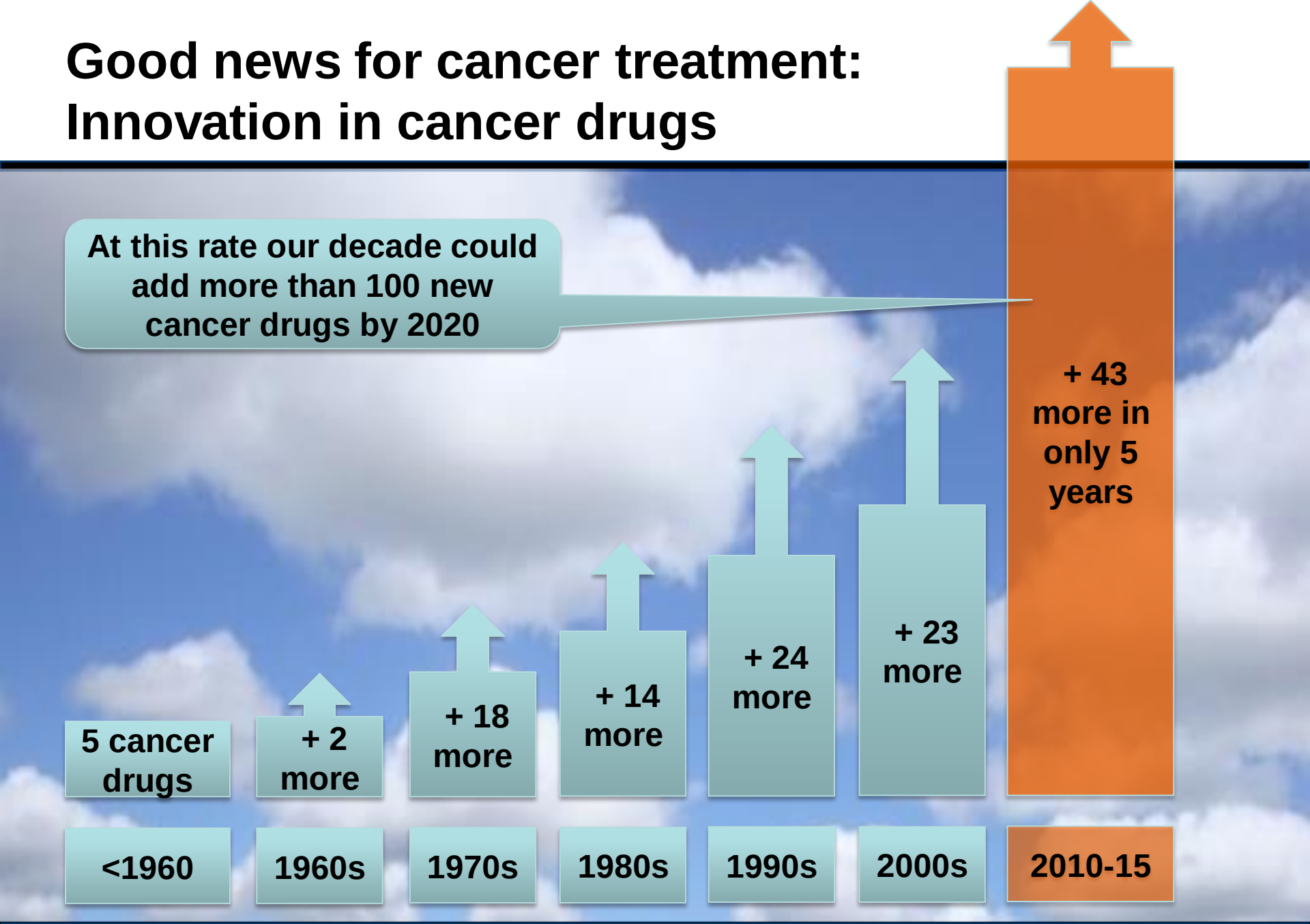
Cancer survival is improving



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

Lichtenberg Fr. The Expanding Pharmaceutical Arsenal in the War on Cancer. National Bureau of Economic research Working Paper No. 10328. February 2004.

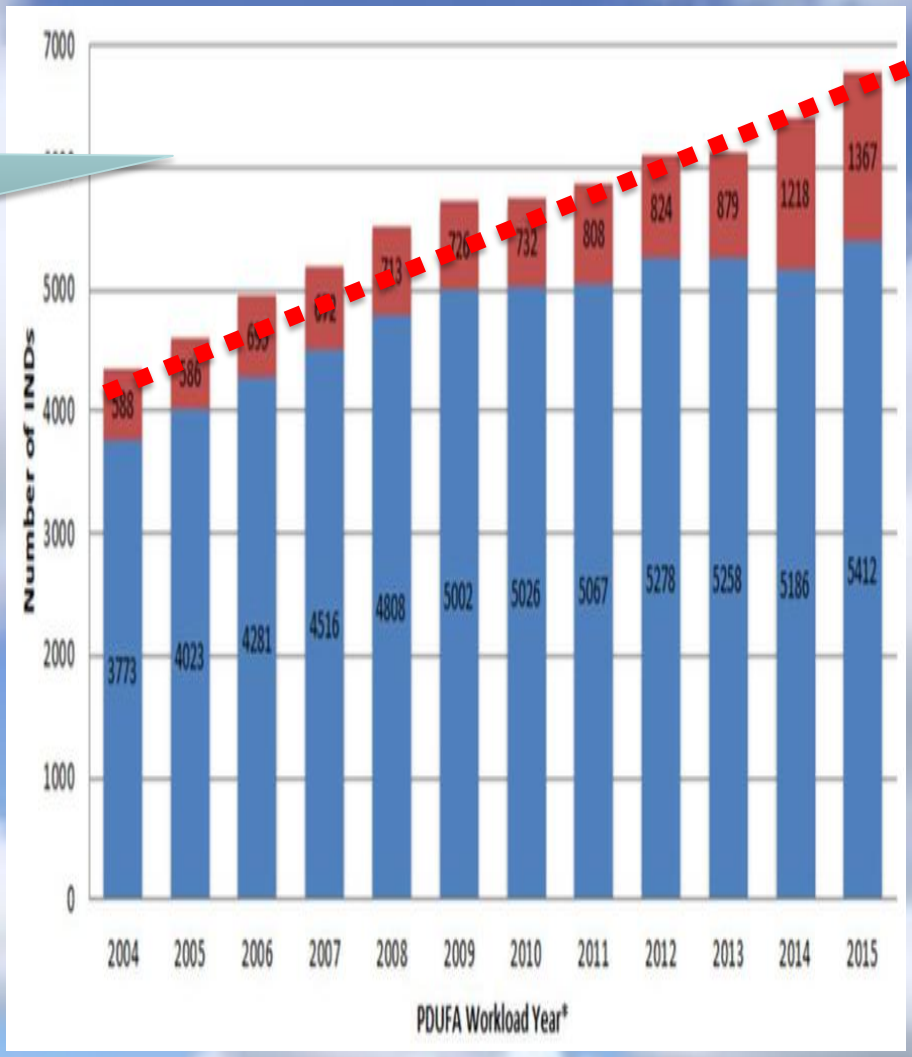
Good news for cancer treatment: Innovation in cancer drugs



Ref: [1] Cornes P. Pictogram created from data in - Savage P. Development and economic trends in cancer therapeutic drugs: Analysis of modern and historical treatment costs compared to the contemporary GDP per capita. J Clin Oncol 32, 2014 (suppl; abstr e17535) updated to 2014 with data from [2] 2014 New Drug Approvals Hit 18-Year High. Forbes Jan 2, 2015. URL: http://www.forbes.com/sites/bernardmunos/2015/01/02/the-fda-approvals-of-2014/ . Accessed Sept 23, 2015, updated to 2015 with [3] Thomas D. 2015 FDA Approvals: Highest Levels in Over a Decade. Biotech-now.org. 01/08/2016. http://www.biotech-now.org/business-and-investments/2016/01/2015-fda-approvals-highest-levels-in-over-a-decade. Accessed Jan 27, 2016

Good news for medical treatment: Innovation for all medicines is rising

Number of Commercial Investigational New Drugs by year at the US FDA



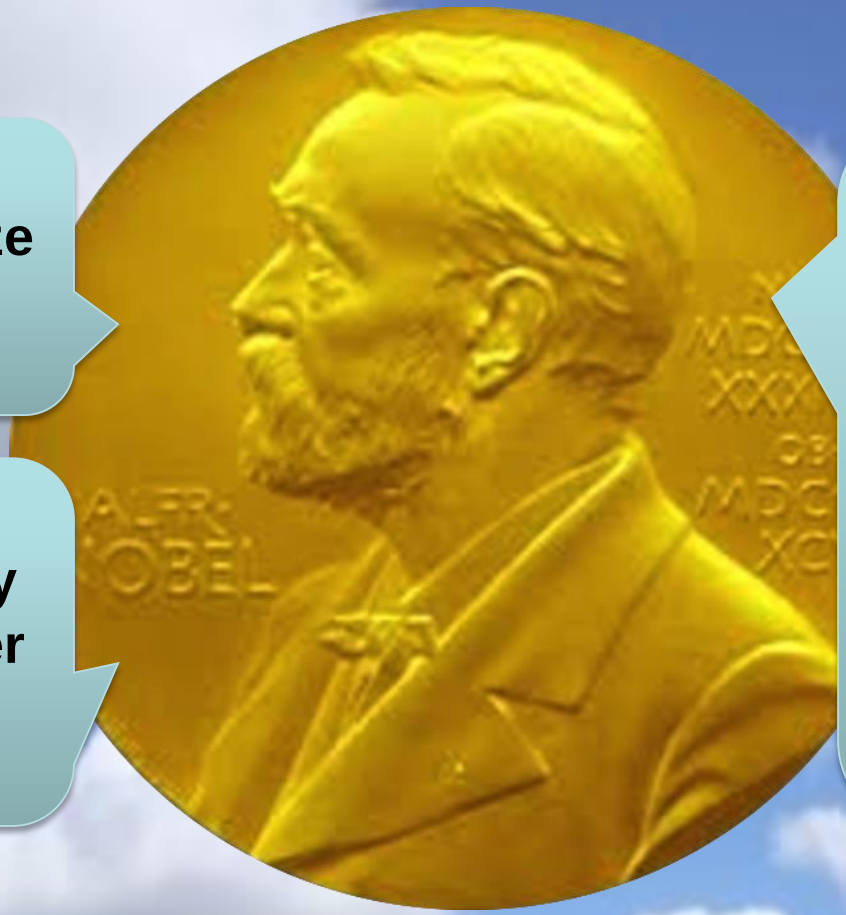
Refs: [1] John K. Jenkins. CDER New Drug Review: 2015 Update. Office of New Drugs Center for Drug Evaluation and Research. FDA/CMS Summit Dec14, 2015. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM477020.pdf. Accessed Jan 6, 2016 [2] Thomas D. 2015 FDA Approvals: Highest Levels in Over a Decade. Biotech-now.org. 01/08/2016. http://www.biotech-now.org/business-and-investments/2016/01/2015-fda-approvals-highest-levels-in-over-a-decade. Accessed Jan 27, 2016


Innovation Dr

Innovation - 1984

1984 Nobel Prize for Medicine

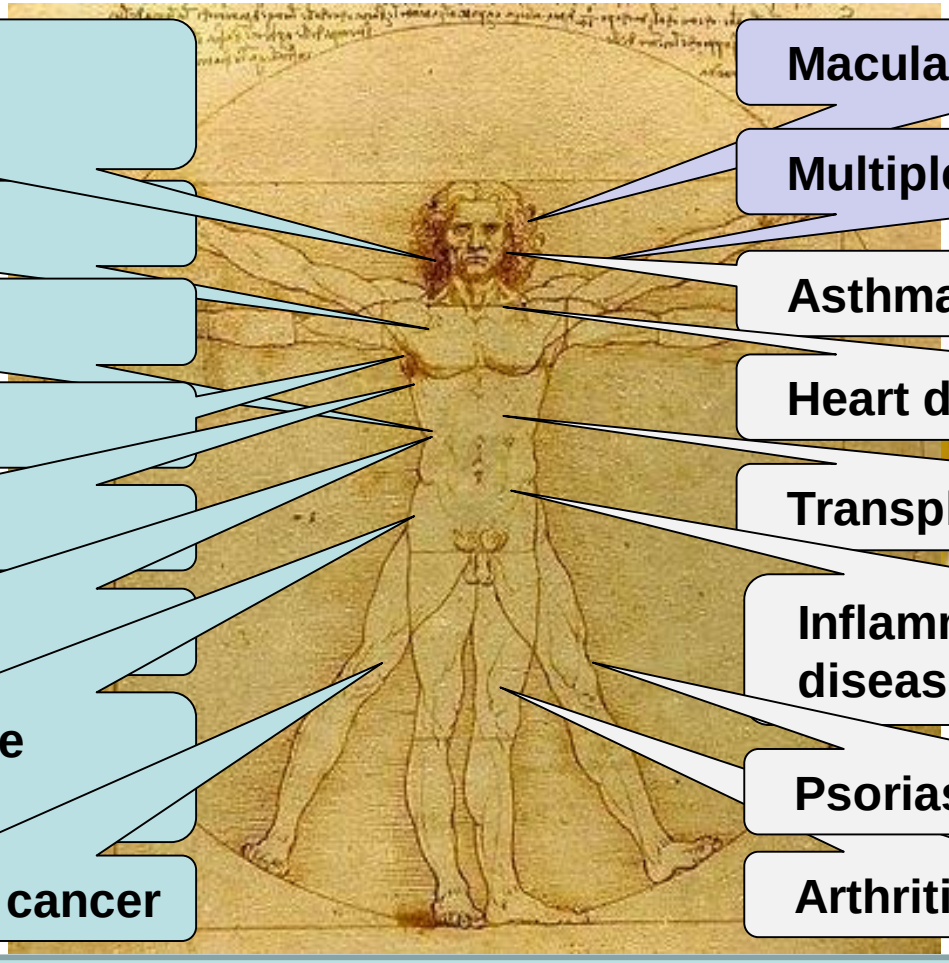
awarded jointly to Jerne, Köhler and Milstein



"for the discovery of the principle for production of monoclonal antibodies".

3 decades later

3 decades of Innovation:
1984 to 2016 Monoclonal antibody development

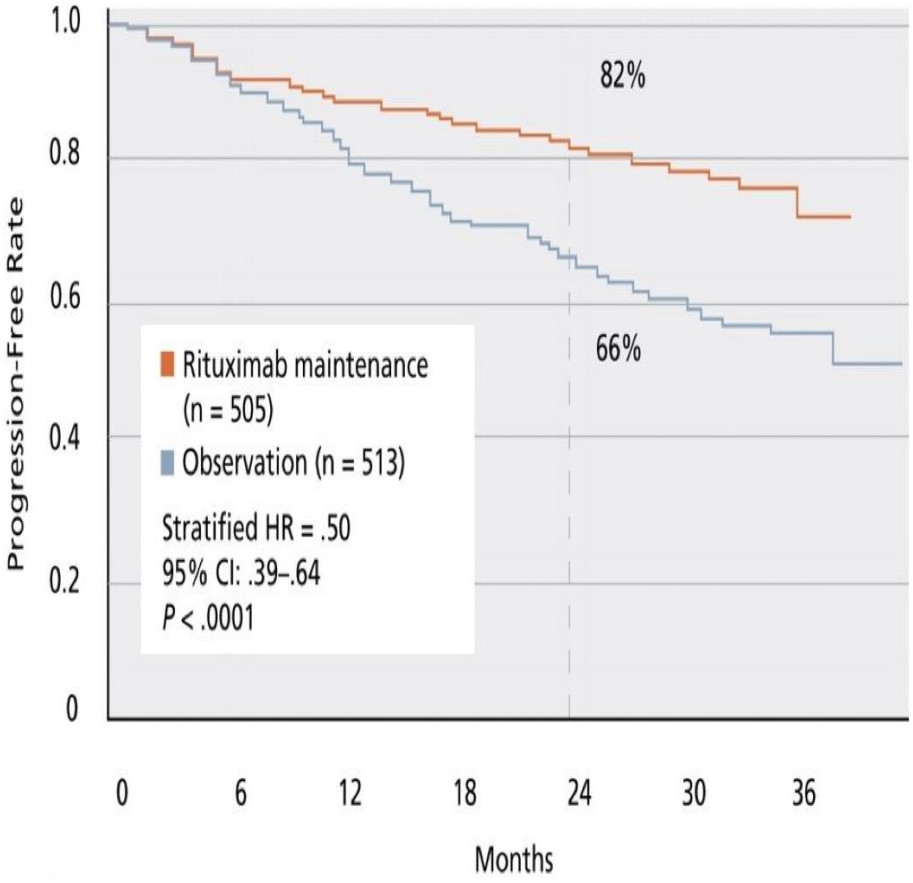


- Head and Neck Cancer
- Breast Cancer
- Bowel Cancer
- Leukaemia
- Lymphoma
- Ovary cancer
- Secondary bone cancer
- Melanoma skin cancer
- Macular Degeneration
- Multiple sclerosis
- Asthma
- Heart disease
- Transplant rejection
- Inflammatory bowel disease
- Psoriasis
- Arthritis

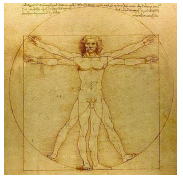
3 decades later

http://en.wikipedia.org/wiki/File:Da_Vinci_Vitruve_Luc_Viatour.jpg

Monoclonals in cancer - lymphoma

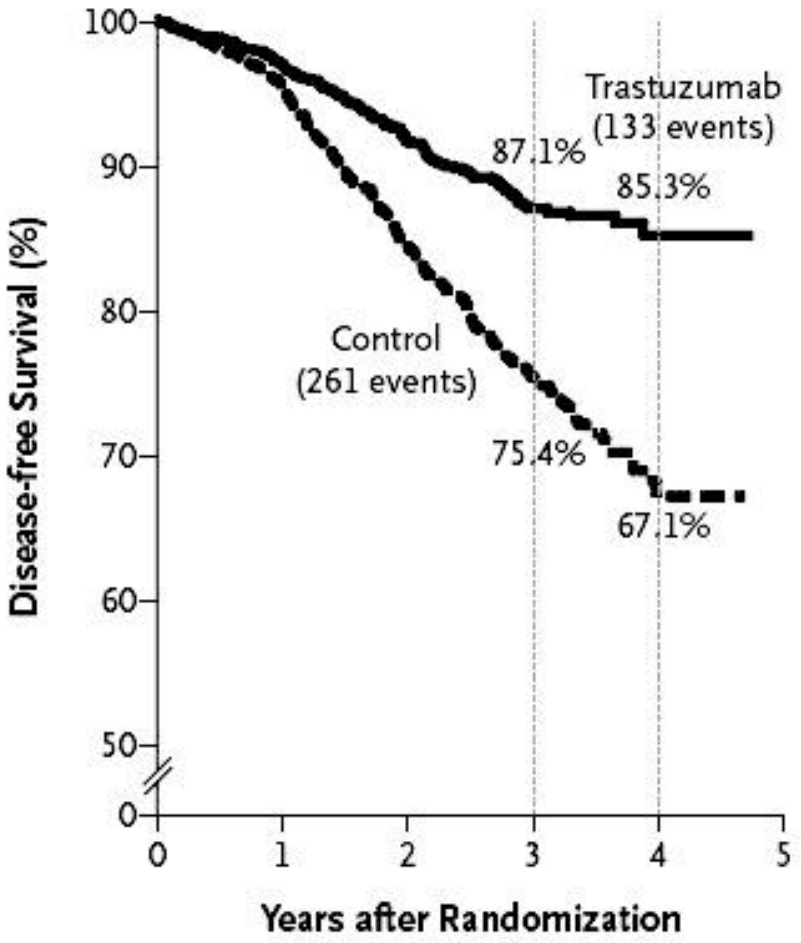


- **Rituximab**
  - **Halves lymphoma relapse**

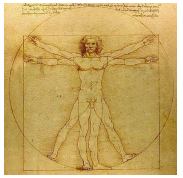


http://www.jnccn.org/content/8/Suppl_6/S-1/F3.large.jpg

Monoclonals in breast cancer

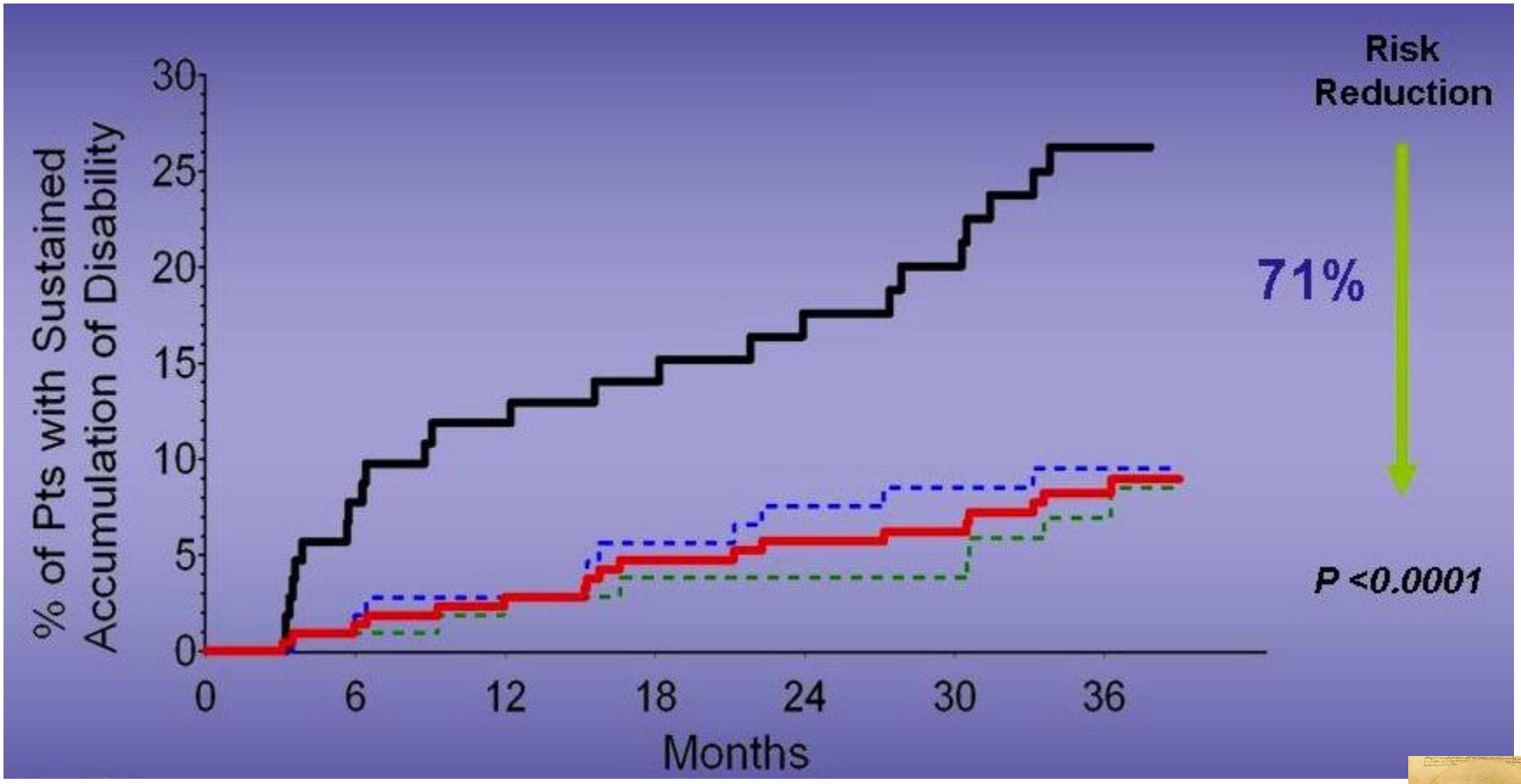


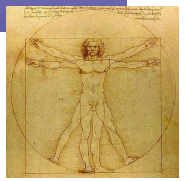
- **Trastuzumab**
  - **Halves the chance of relapse**
  - **Reduces death by 33%**



Romond EH, et al. NEJM. 2005;353:1673-1684

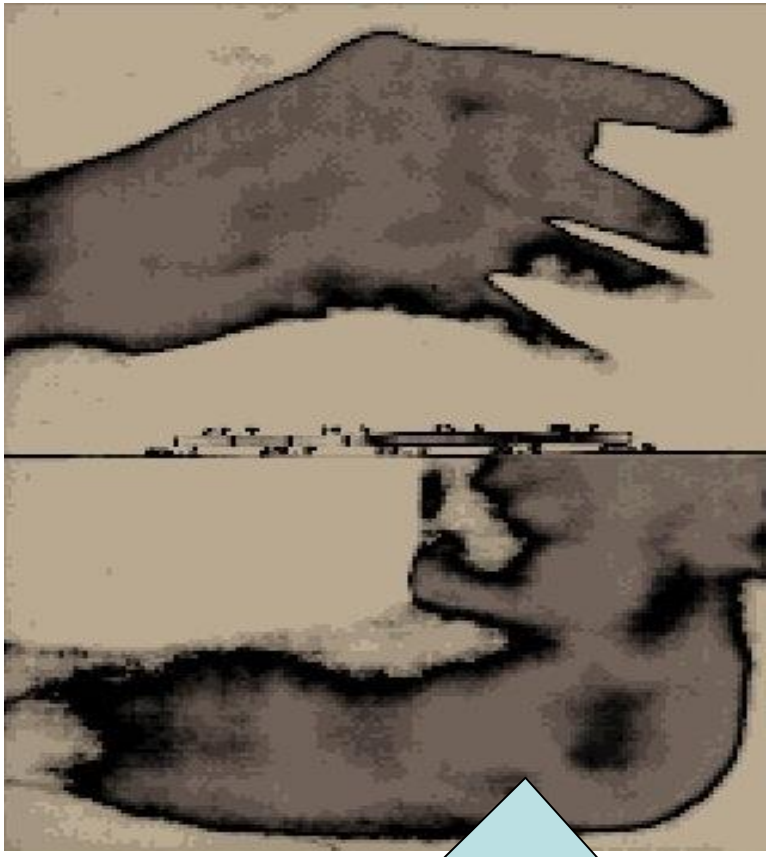
MAbs:
71% reduction in disability in multiple sclerosis





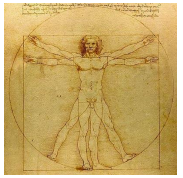
Ref: data - Campath-H1 vs interferon from http://users.ox.ac.uk/~path0116/tig/new1/mstrialfig.jpg. Accessed Jan 27, 2016

MAbs: Controlling rheumatoid arthritis



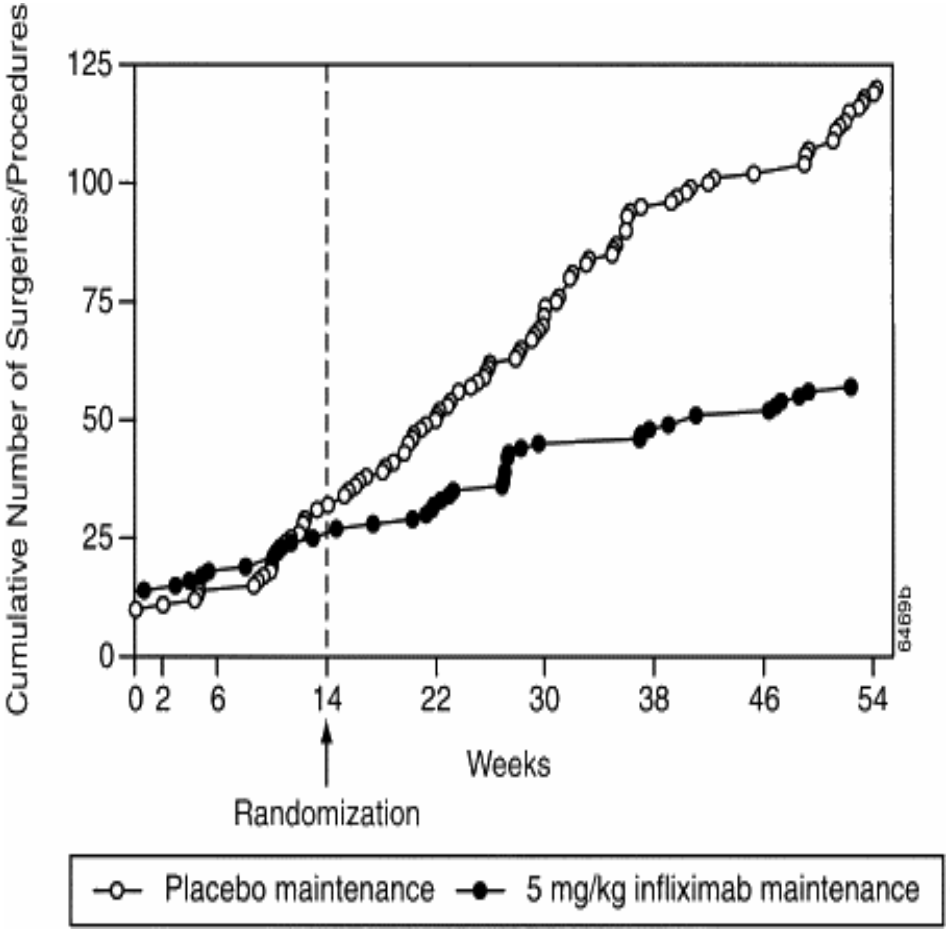
Thermal imaging of hand and elbow joints before……

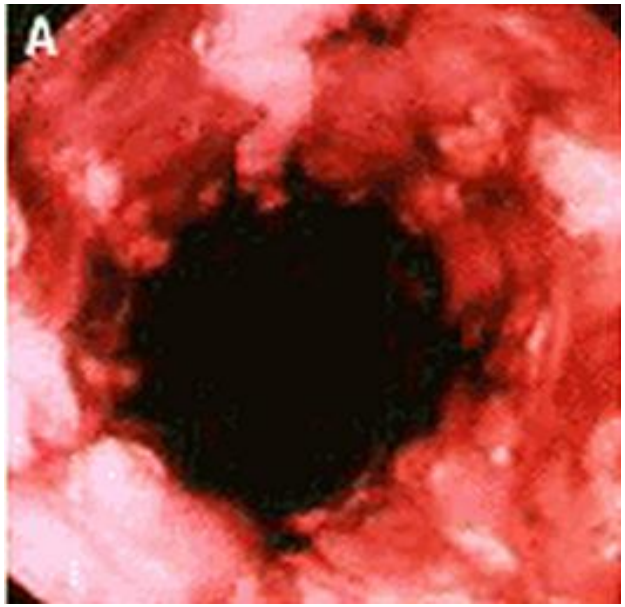
..and after Mab therapy



Ref: [1] Image from - http://users.ox.ac.uk/~path0116/tig/new1/thefg.gif. Accessed jan 27, 2016

MAbs - halves hospitalizations, surgeries, and procedures in fistulizing Crohn's disease

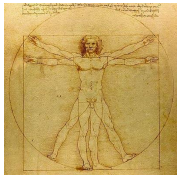




Infliximab

Ref [1] Lichtenstein GR. Infliximab maintenance treatment reduces hospitalizations, surgeries, and procedures in fistulizing Crohn's disease. Gastroenterology,Volume 128, Issue 4 , Pages 862-869, April 2005. http://en.wikipedia.org/wiki/File:CD_colitis.jpg

MAbs for psoriasis



Ref: [1] Sylvia Marecki & Peter Kirkpatrick. Efalizumab. Nature Reviews Drug Discovery 2004;3:473-474 . URL: http://www.epgpatientdirect.org/send_article.cfm/page/355/title/Biologicals

New targeted precision medicines are transforming cancer care

REVIEWS

Targeted therapy in rare cancers—adopting the orphans

Javier Munoz and Razelle Kurzrock

Abstract | Designation of a rare 'orphan' disease is usually conferred by a prevalence of one in 1,500 to 2,500 individuals. Increasingly, orphan diseases are also being defined by their molecular fingerprints. Rare diseases are uniquely challenging from a therapeutic standpoint; it is critical to modify clinical study design of treatments for orphan disorders as well as for the increasingly smaller molecular subsets within frequently occurring cancers. In spite of the immense challenges associated with developing a treatment for a rare disorder, some of the most groundbreaking therapeutic discoveries have been made in orphan malignancies. This situation may be because a limited number of driver molecular aberrations occur in rare disorders, which can be targeted by agents. Here, we describe drug-class examples of targeted therapies for orphan diseases, with particular emphasis on malignancies or tumour-prone nonmalignant conditions, as well as potential therapeutic strategies that can be adopted to treat these orphan conditions.

Introduction

Cancer is one of the most common causes of death worldwide.[1] Treatment of metastatic disease has yielded only modest results, and most patients succumb to their disease. To a large extent, these dismal outcomes are probably because cancer consists of hundreds of molecular disease subsets, each requiring its own personalized treatment approach. Therefore, the standard paradigm of classifying patients by histology alone, and treating large unselected groups of patients with the same treatment

rare diseases as "life-threatening or chronically debilitating diseases that are of such low prevalence that special combined efforts are needed to address them."[2] ESMO defines rare tumours as those with an incidence of fewer than six per 100,000 persons per year.[3] The United States Orphan Drug Act defines as orphan diseases as conditions "for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will [be] recovered

Chemotherapy era vs. targeted medicines era

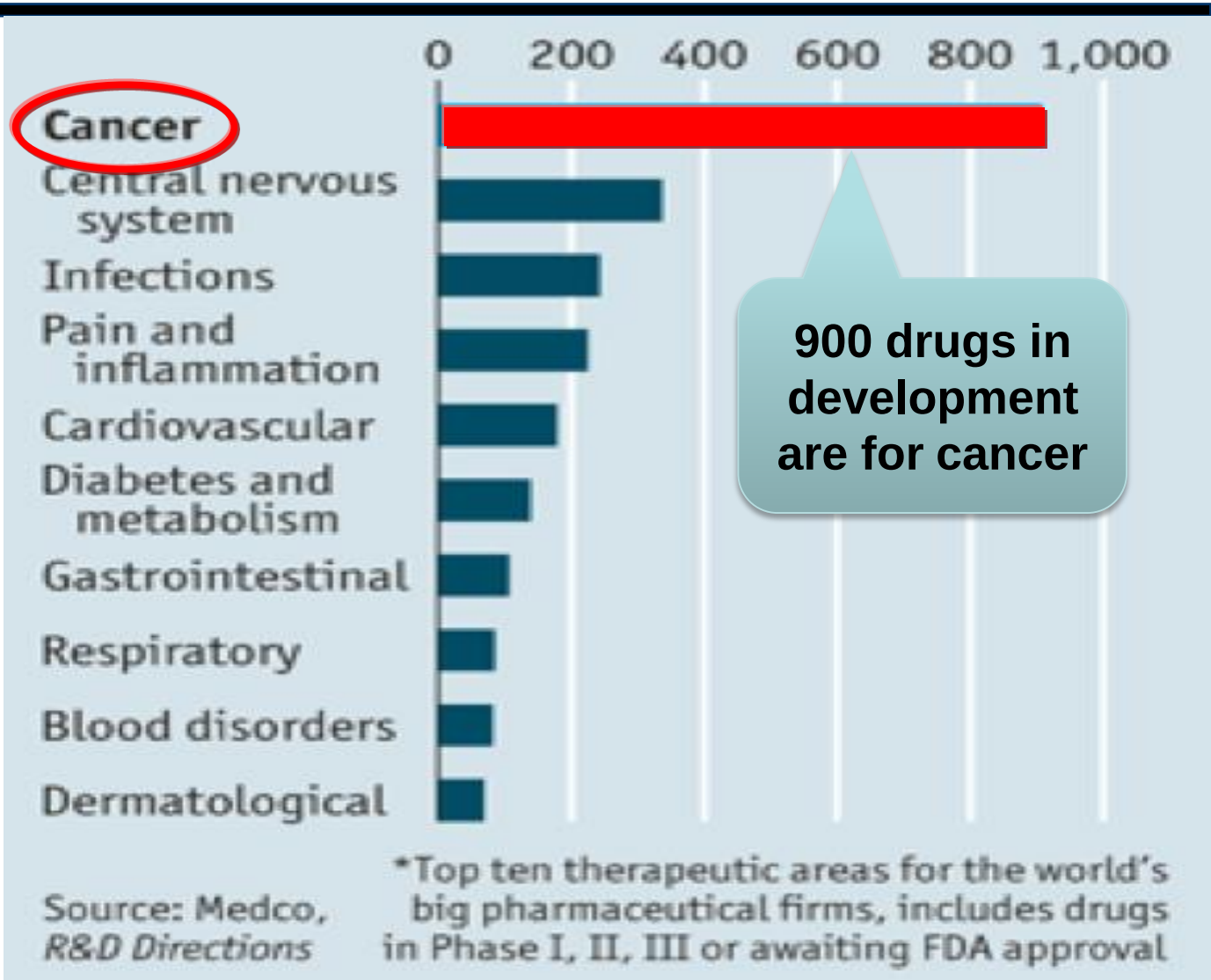
Examples where survival has more than tripled

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

[1] Munoz and Kurzrock. *Nat Rev Clin Oncol*. 2012;9(11):631-42.
[2] The Value of Medical Innovation. http://valueofinnovation.org/a-world-free-from-cancer/#ref3 [Accessed May 2015].

Good news for cancer treatment

Drugs in development,



The costly war on cancer. The Economist. 2011 May 26. http://www.economist.com/node/18743951

Biologics

~~Biosimilars~~ – can we do without them?

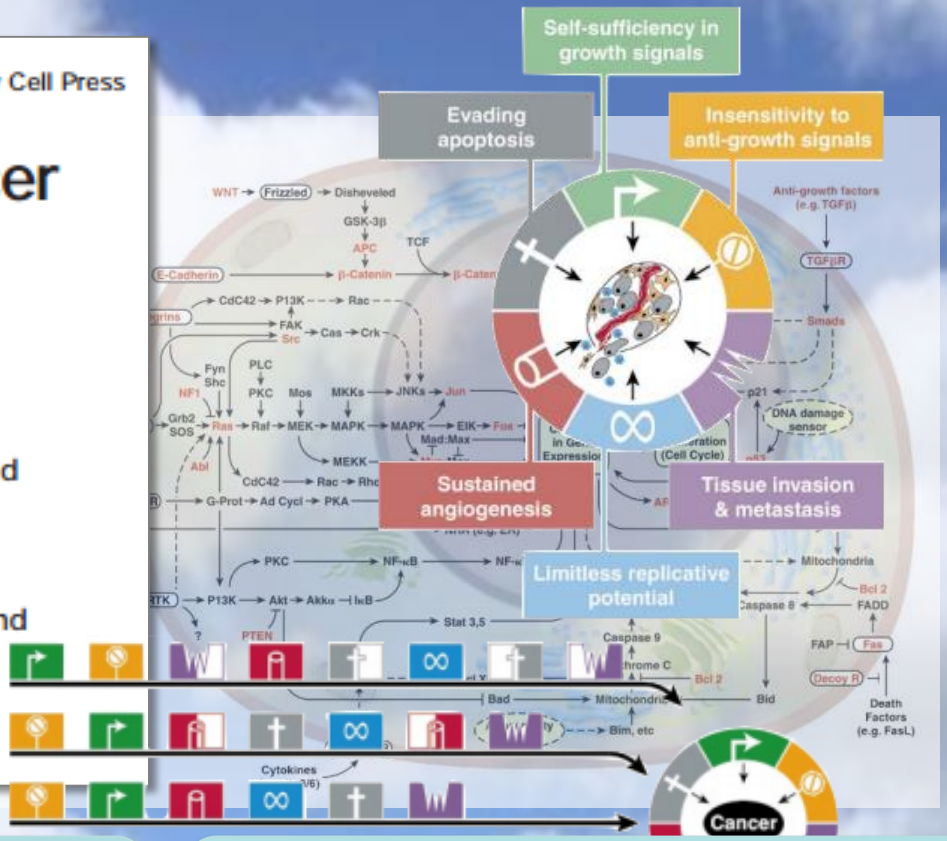
Biologics – *I can't imagine the world of medicine without precision targeted therapies*

The possibility at the millennium, 2000

Cell, Vol. 100, 57–70, January 7, 2000, Copyright ©2000 by Cell Press

The Hallmarks of Cancer

Douglas Hanahan* and Robert A. Weinberg†
*Department of Biochemistry and Biophysics and Hormone Research Institute
University of California at San Francisco
San Francisco, California 94143
†Whitehead Institute for Biomedical Research and Department of Biology
Massachusetts Institute of Technology
Cambridge, Massachusetts 02142



the complexity of 200 different cancers may be explained by a few unregulated pathways

And so the diversity of cancer might be treated by a limited panel of concurrent targeted precision therapies

Ref [1] Hanahan D, Weinberg RA (January 2000). "The Hallmarks of Cancer". Cell 100 (1): 57–70

Where are we now?

I am sorry to report that you have breast cancer

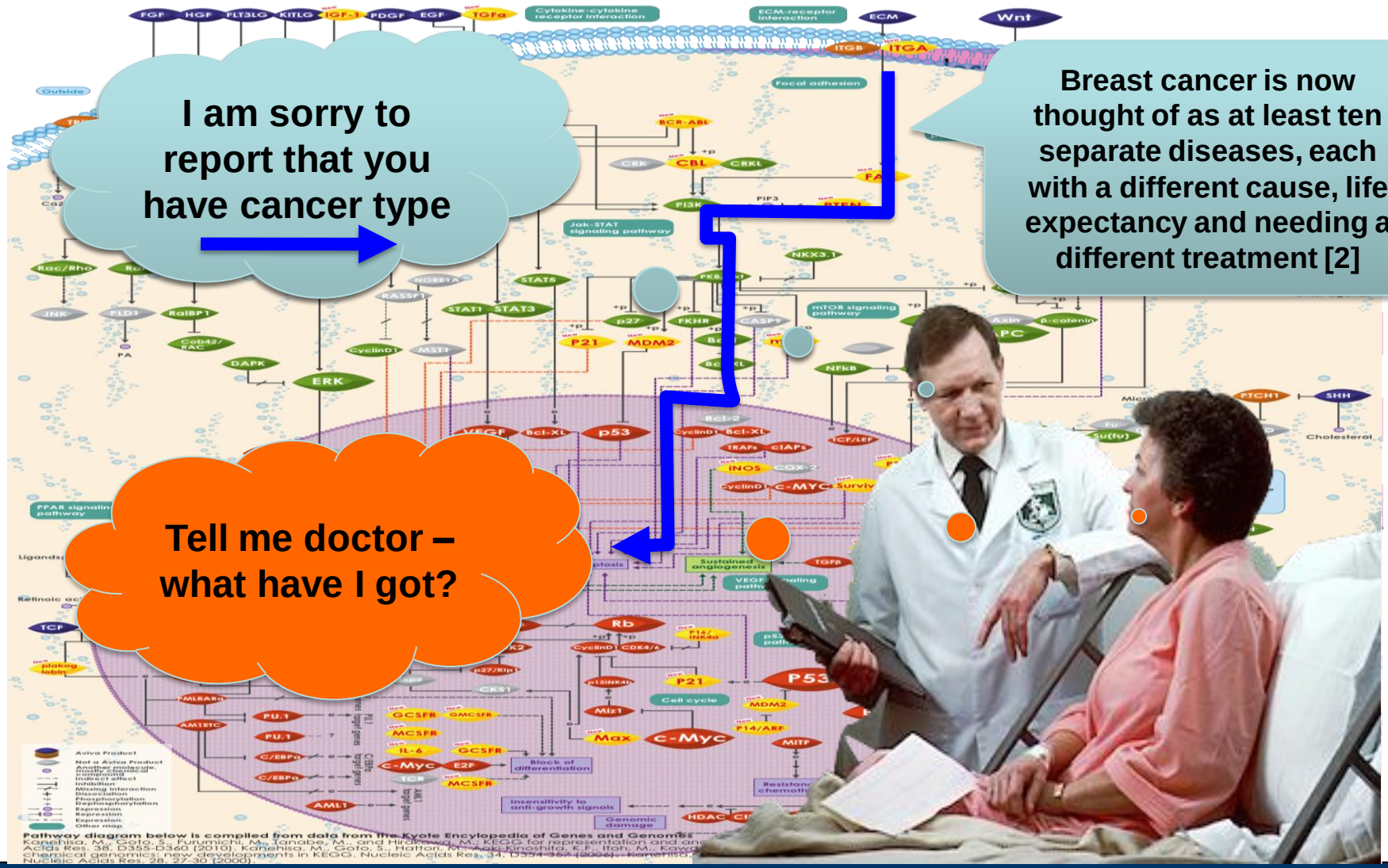
Tell me doctor – what have I got?

Anatomic diagnosis

Malignant Neoplasm of Female Breast
ICD-10-CM (Category C50)
Nipple and areola – *right, left, unspecified*
Central portion – *right, left, unspecified*
Upper-inner quadrant – *right, left, unspecified*
Lower-inner quadrant – *right, left, unspecified*
Upper-outer quadrant – *right, left, unspecified*
Lower-outer quadrant – *right, left, unspecified*
Axillary tail – *right, left, unspecified*
Overlapping
Unspecified

Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September 15, 2015

Where are we soon?



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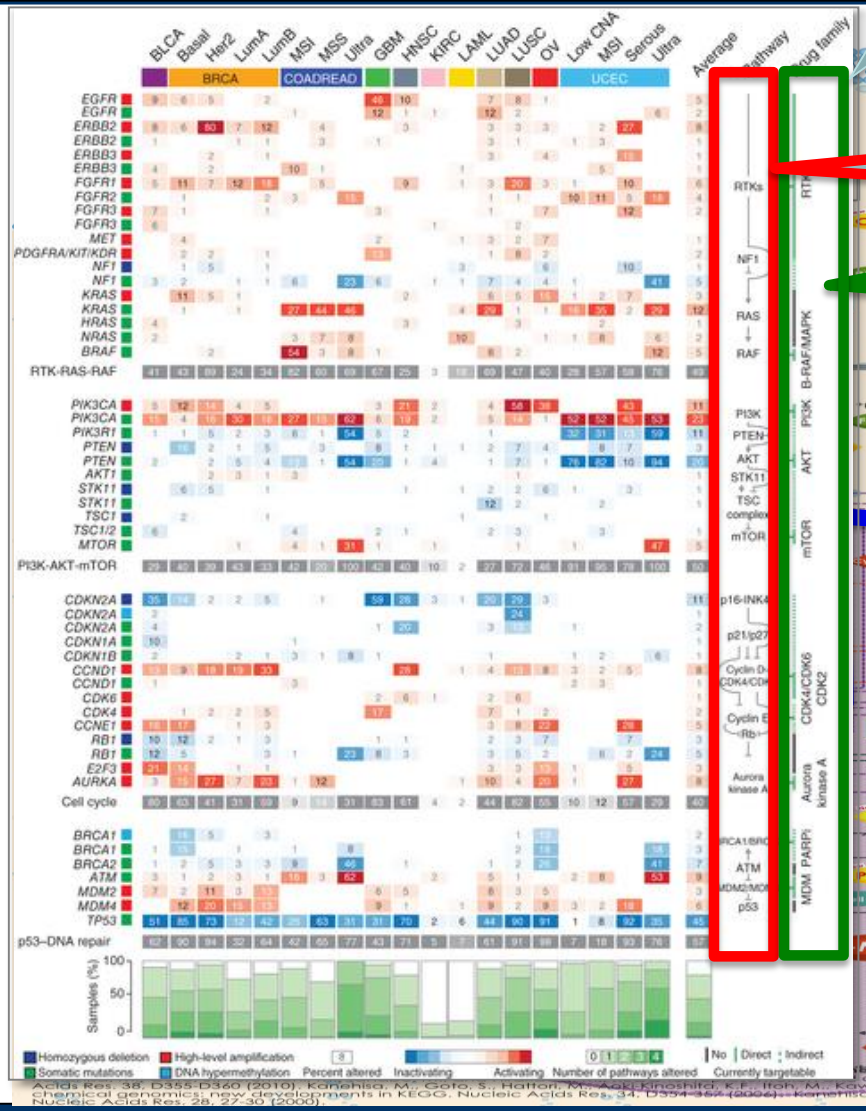
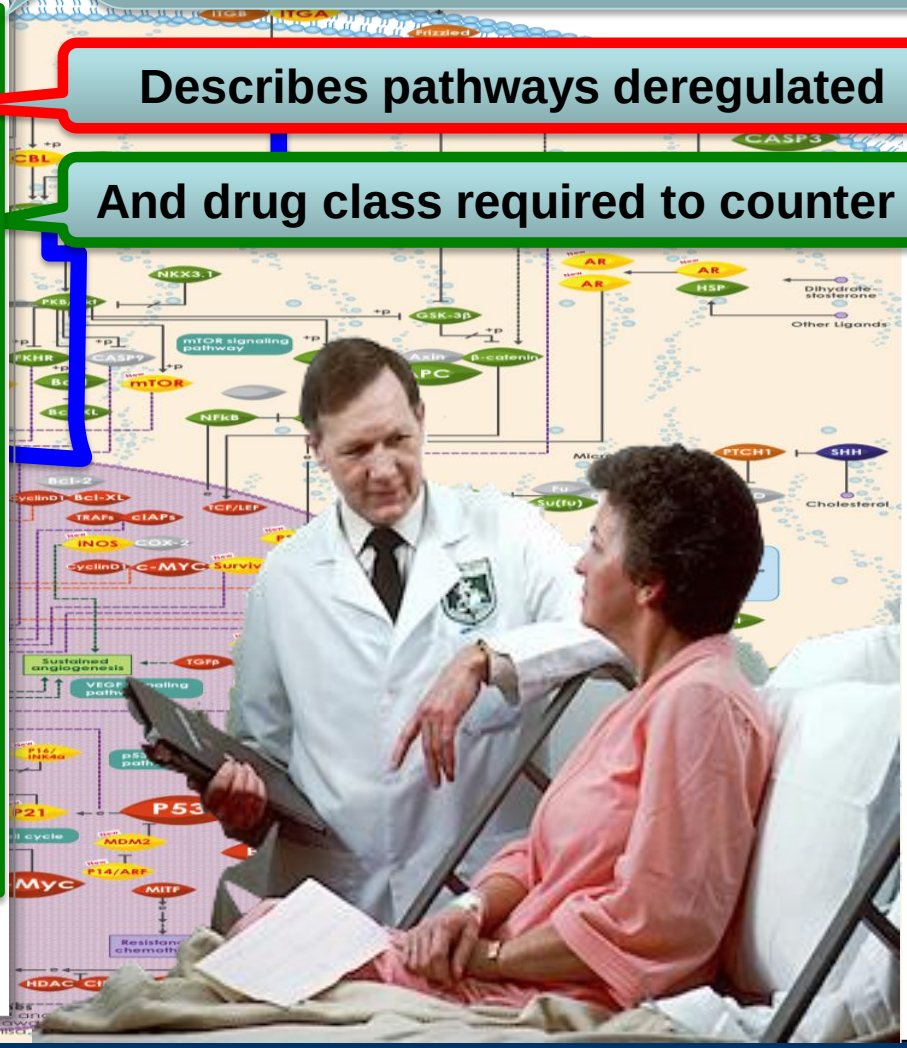
Where are we heading?

The Cancer Genome Atlas is a working Map of functional and actionable alterations across different tumour types [4]

Describes pathways deregulated

And drug class required to counter it





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Where are we heading?

2016: Targeting two deregulated pathways with lapatinib and trastuzumab - Tumours can be gone in as short as 11 days! [5]

Describes pathways deregulated

And drug class required to counter it

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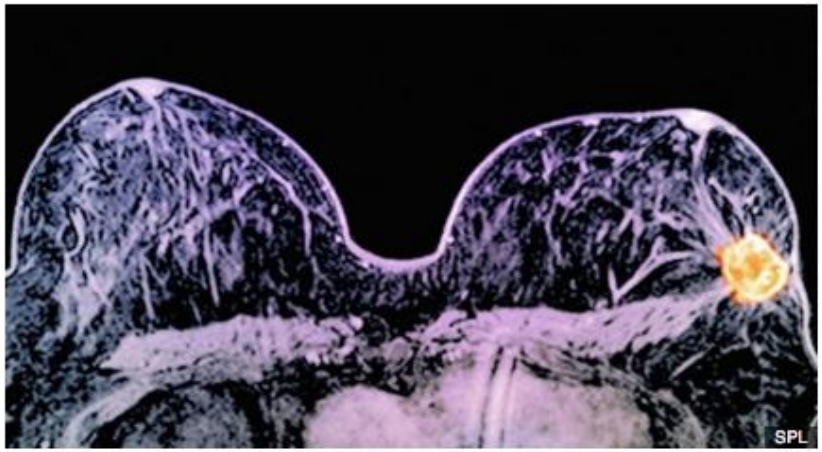
Health

Tumours shrunk 'dramatically' in 11 days

By James Gallagher
Health editor, BBC News website

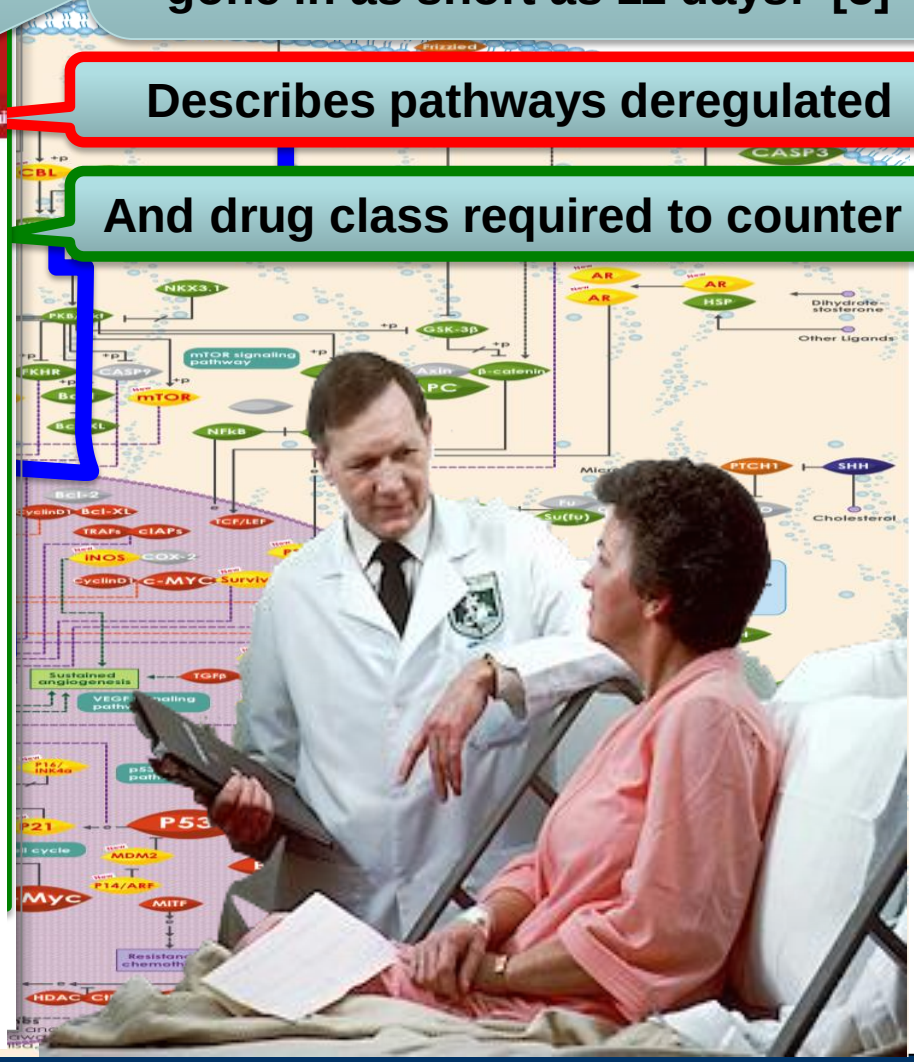
10 March 2016 | Health



A pair of drugs can dramatically shrink and eliminate some breast cancers in just 11 days, UK doctors have shown.

They said the "surprise" findings, reported at the European Breast Cancer Conference, could mean some women no longer need chemotherapy.

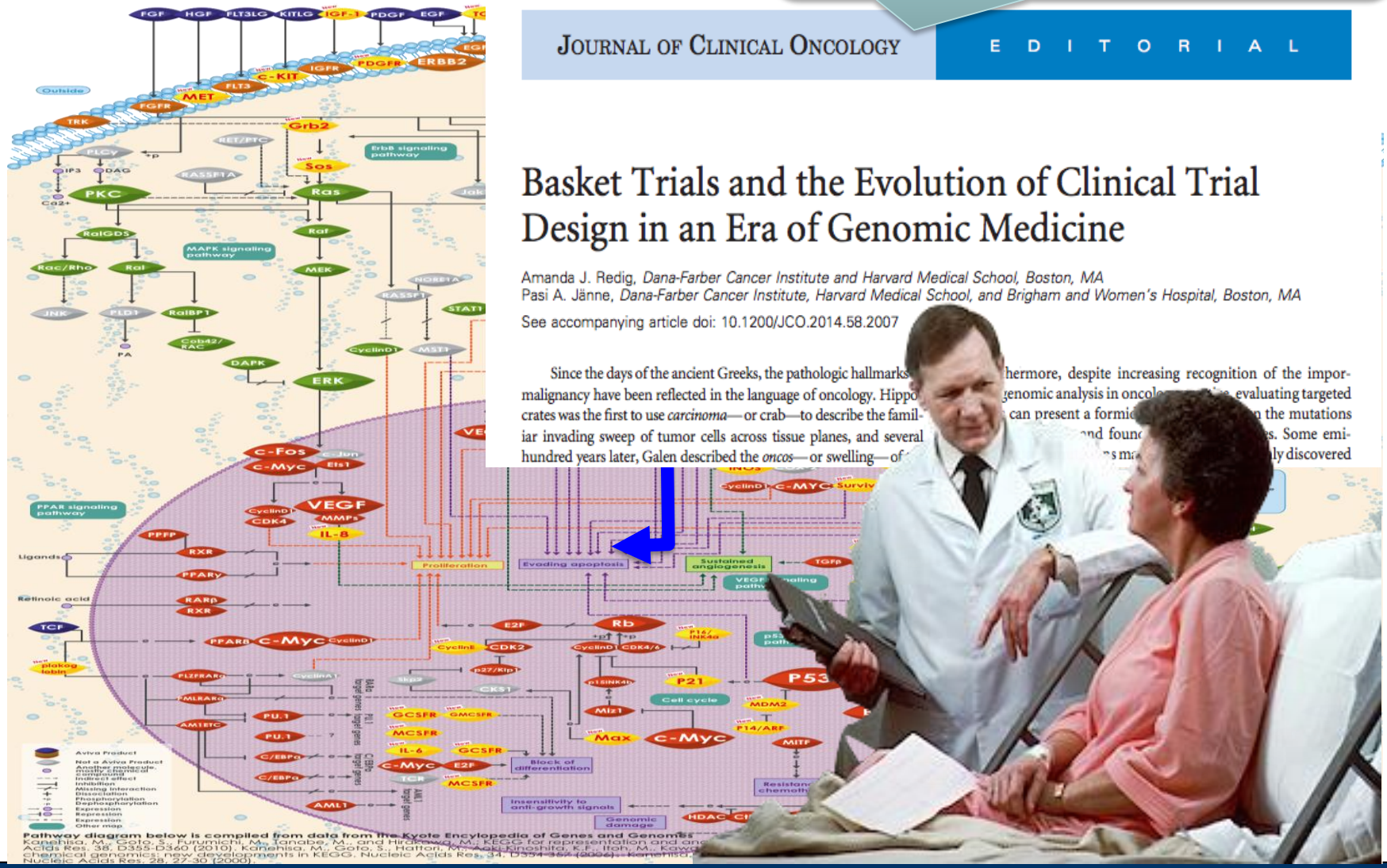
Nucleic Acids Res. 28, 27-30 (2000)



Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September 15, 2015. [3] Sharma, P et al. Immune Checkpoint Targeting in Cancer Therapy: Toward Combination Strategies with Curative Potential. Cell 2015;161(2):205–214 [4] Giovanni Ciriello G et al. Emerging landscape of

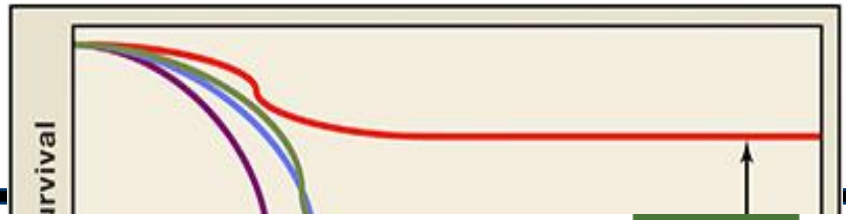
Where are we heading?

"Basket trials" now mean we will treat cancers by genomic diagnosis, not anatomic site [4]



Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September 15, 2015. [3] Sharma, P et al. Immune Checkpoint Targeting in Cancer Therapy: Toward Combination Strategies with Curative Potential. Cell 2015;161(2):205–214 [4] Redig, AJ et al. Basket Trials and the Evolution of Clinical Trial Design in an Era of Genomic Medicine. JCO February 9, 2015

Where are we heading?



With 3 key steps deregulated – we need 3 concurrent cancer therapies

How should we treat it?

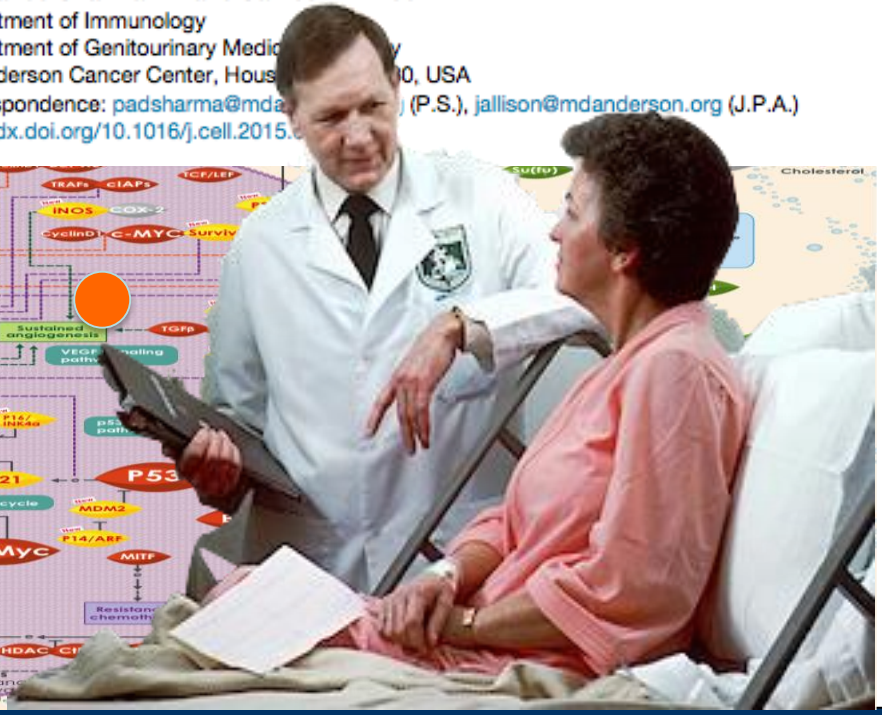
Leading Edge

Review

Cell

Immune Checkpoint Targeting in Cancer Therapy: Toward Combination Strategies with Curative Potential

Padmanee Sharma[1,2,*] and James P. Allison[1,*]
[1]Department of Immunology
[2]Department of Genitourinary Medic
MD Anderson Cancer Center, Hous 0, USA
*Correspondence: padsharma@mda (P.S.), jallison@mdanderson.org (J.P.A.)
http://dx.doi.org/10.1016/j.cell.2015.



Pathway diagram below is compiled from data from the Kyoto Encyclopedia of Genes and Genomes:

Ref: Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] Pathways in cancer. Avivasysbio.com. URL: http://www.avivasysbio.com/media/pdf/etc/Aviva_Pathway_Cancer.pdf. Accessed September

Where are we heading?

With 3 key steps deregulated – we need 3 concurrent cancer therapies

Will my health insurance cover that?

the average cost per month for a branded oncology drug in the U.S. is now approximately $10,000 [2]

$10,000 x 3 x 12 = $360,000 a year

Ref [1] Image modified from https://upload.wikimedia.org/wikipedia/commons/d/d5/Oncology_doctor_consults_with_patient.jpg [2] IMS Health Study: Cancer Drug Innovation Surges As Cost Growth Moderates. URL: http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=19b381d71adc5410VgnVCM100000076192ca2RCRD&vgnextchannel=5ec1e590cb4dc310Vg

2015 was another record year for drug innovation

STICKER SHOCK

New drugs for cancer and rare diseases came with hefty list prices

DRUG NAME	INDICATION	ANNUAL PRICE
Kanuma	LAL deficiency	$310,000
Strensiq	Juvenile-onset hypophosphatasia	$285,000
Orkambi	Cystic fibrosis	$259,000
Uptravi	Pulmonary arterial hypertension	$160,000–170,000
Tagrisso	Lung cancer	$153,000[a]
Alecensa	ALK-positive lung cancer	$150,000[a]
Empliciti	Multiple myeloma	$140,000[b]
Portrazza	Lung cancer	$137,000[a]
Farydak	Multiple myeloma	$119,000[a]
Ibrance	Metastatic breast cancer	$118,200
Ninlaro	Multiple myeloma	$113,000[a]
Darzalex	Multiple myeloma	$110,000

a Based on announced monthly or four-week pricing. **b** For first year of treatment.
NOTE: Blue indicates a cancer drug; yellow indicates a rare drug treatment.
SOURCES: Companies, patient groups

8 cancer drugs approved in 2015 had a six-figure price [1]

The median wage in the US per person is $26,695 [2]

Ref: [1] Lisa M. Jarvis. The Year In New Drugs. Chemical and Engineering News, 2016;94(5):12-17. URL: http://cen.acs.org/articles/94/i5/Year-New-Drugs.html. Accessed Fab 5, 2016 [2] How much do Americans earn? What is the average US income. MyBudget 360. URL: www.mybudget360.com/how-much-do-americans-earn-what-is-the-averag…. Accessed Fab 5, 2016

Where are we heading?

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

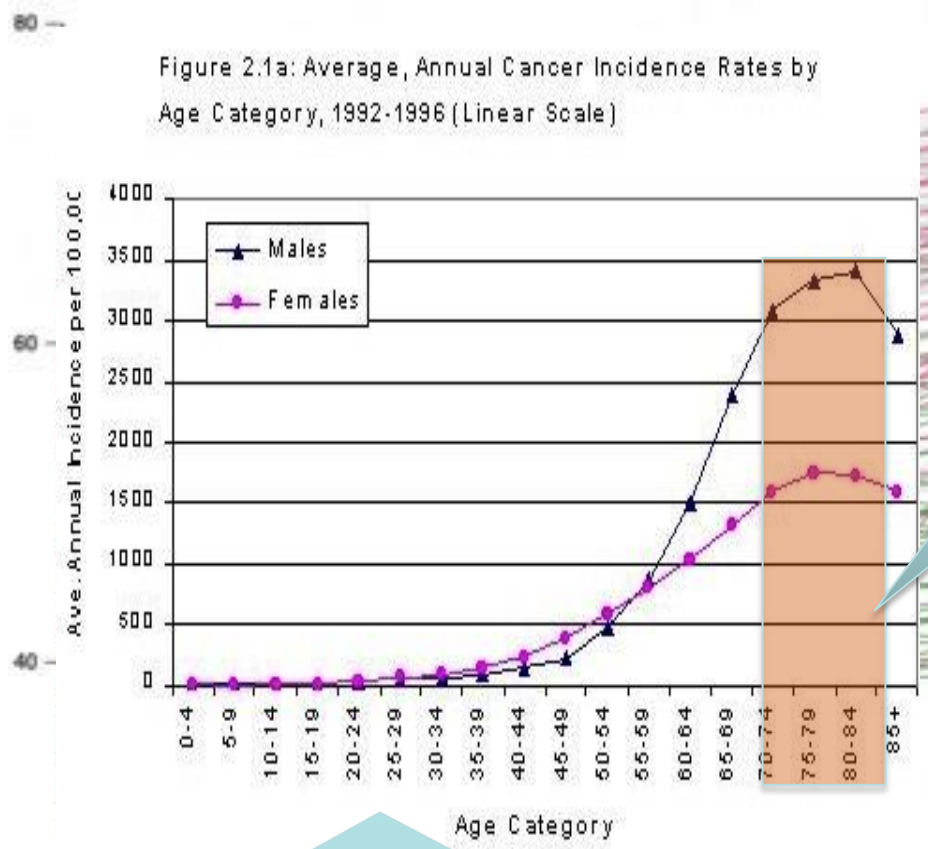
Two years ago, the U.S. Food and Drug Administration took a step that some thought would never occur—it approved the sipuleucel-T (Provenge) vaccine for late-stage prostate cancer. The move came after a protracted episode involving allegations of conflicts of interest among a pair of FDA advisory committee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

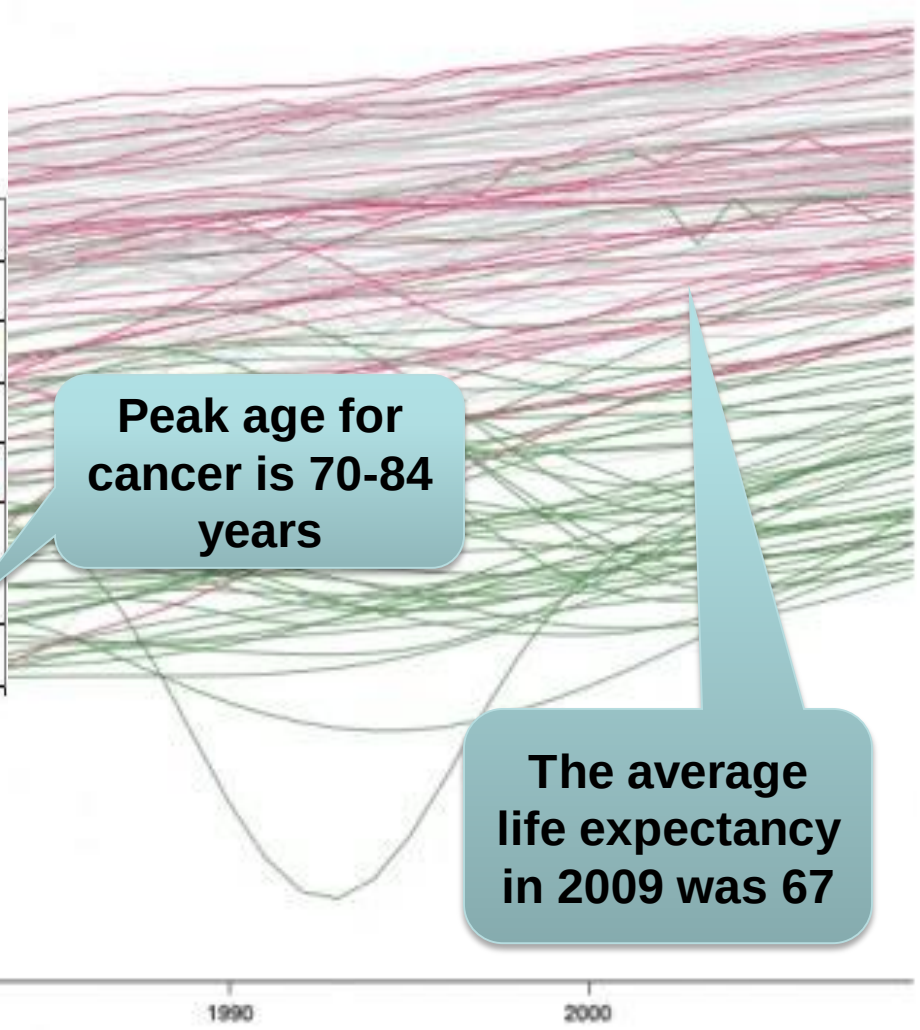
tending a life by 4.1 months is worth the price of Provenge. It has also prompted larger questions about the underlying technology and the need to develop more vaccines.

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

Ref: Silverman E. *Biotechnol Healthc.* 2012;9(4):13-16.

But we have a problem: more cancer to treat





Peak age for cancer is 70-84 years

The average life expectancy in 2009 was 67

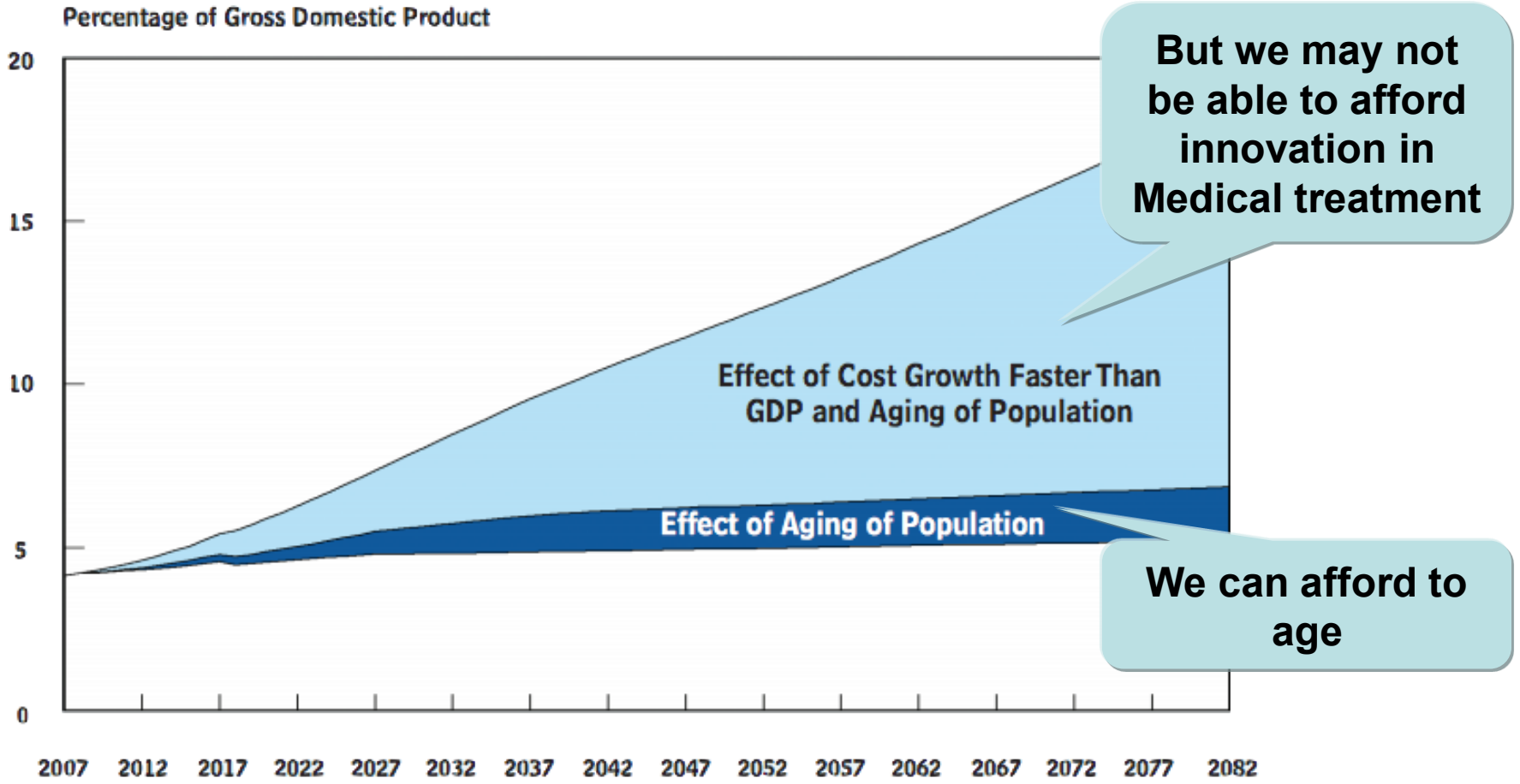
Relationship of cancer incidence with age

http://flowingdata.com/2011/10/13/life-expectancy-changes/.

Myasoedova E. Is the incidence of rheumatoid arthritis rising?: results from Olmsted County, Minnesota, 1955-2007. Arthritis Rheum. 2010 Jun;62(6):1576-82. doi: 10.1002/art.27425.

Planning for the Future: What Will Happen to Costs?

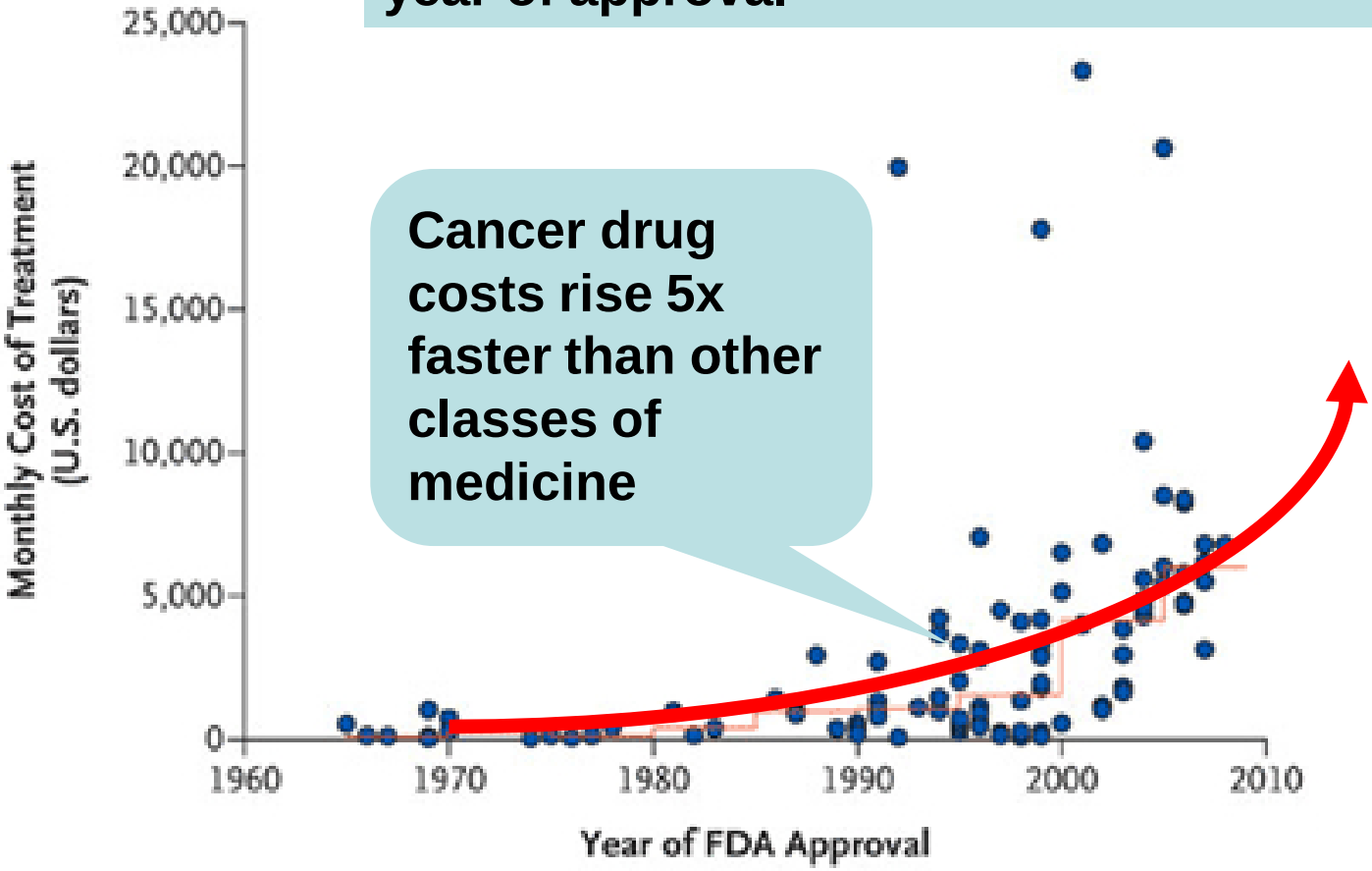
What is the driver for increased spending: Aging populations or medical treatment?



US Congressional Budget Office. The Long-Term Outlook for Health Care Spending. CBO publication/41646, November 13, 2007. http://www.cbo.gov/sites/default/files/11-13-lt-health.pdf. Accessed 10 June 2015

But we have a problem: treatment costs are rising

Monthly cost of new cancer drugs by year of approval



Cancer drug costs rise 5x faster than other classes of medicine

[1] Bach P. Limits on Medicare's ability to control rising spending on cancer drugs NEJM. 2009 Feb 7 [2] Beasley D. Analysis: Drug costs become bigger issue in cancer care. Reuters Fri Jun 15, 2012 12:20am EDT. URL: http://www.reuters.com/article/2012/06/15/us-cancer-cost-idUSBRE85E05B20120615. Accessed Jan 27, 2015 [3] Kantarjian H. High cost of cancer drugs goes beyond the price. Modern Healthcare. April 4, 2015. http://www.modernhealthcare.com/article/20150404/MAGAZINE/304049978. Accessed Sept 26, 2015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LATE NEWS

WALL STREET ★★

WALL ST. IN PANIC AS STOCKS CRASH

Attempt Made to Kill Italy's Crown Prince

ASSASSIN CAUGHT IN BRUSSELS MOB; PRINCE UNHURT

Hollywood Fire Destroys Films Worth Millions

ATTEMPT MADE ON LIFE

FEAR 52 PERISHED IN LAKE MICHIGAN FERRY IS MISSING

PIECE OF PLANE LIKE DITEMAN'S IS FOUND AT SEA

High Duty Group Gave $700,000 to Coolidge Drive

FOR MORE LIBERTITS

STOCKS CRASH IN RUSH TO SELL; BILLIONS LOST

CARNEGIE CHARGE OF PAID ATHLETES ROUSES COLLEGES

HOOVER'S TRAIN HALTED BY AUTO PLACED ON RAILS

WARDER SOUGHT TO KEEP SEA TRIP SECRET, AID SAYS

SOMERS NAMED AS HEAD OF NEW EXCHANGE BANK

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.

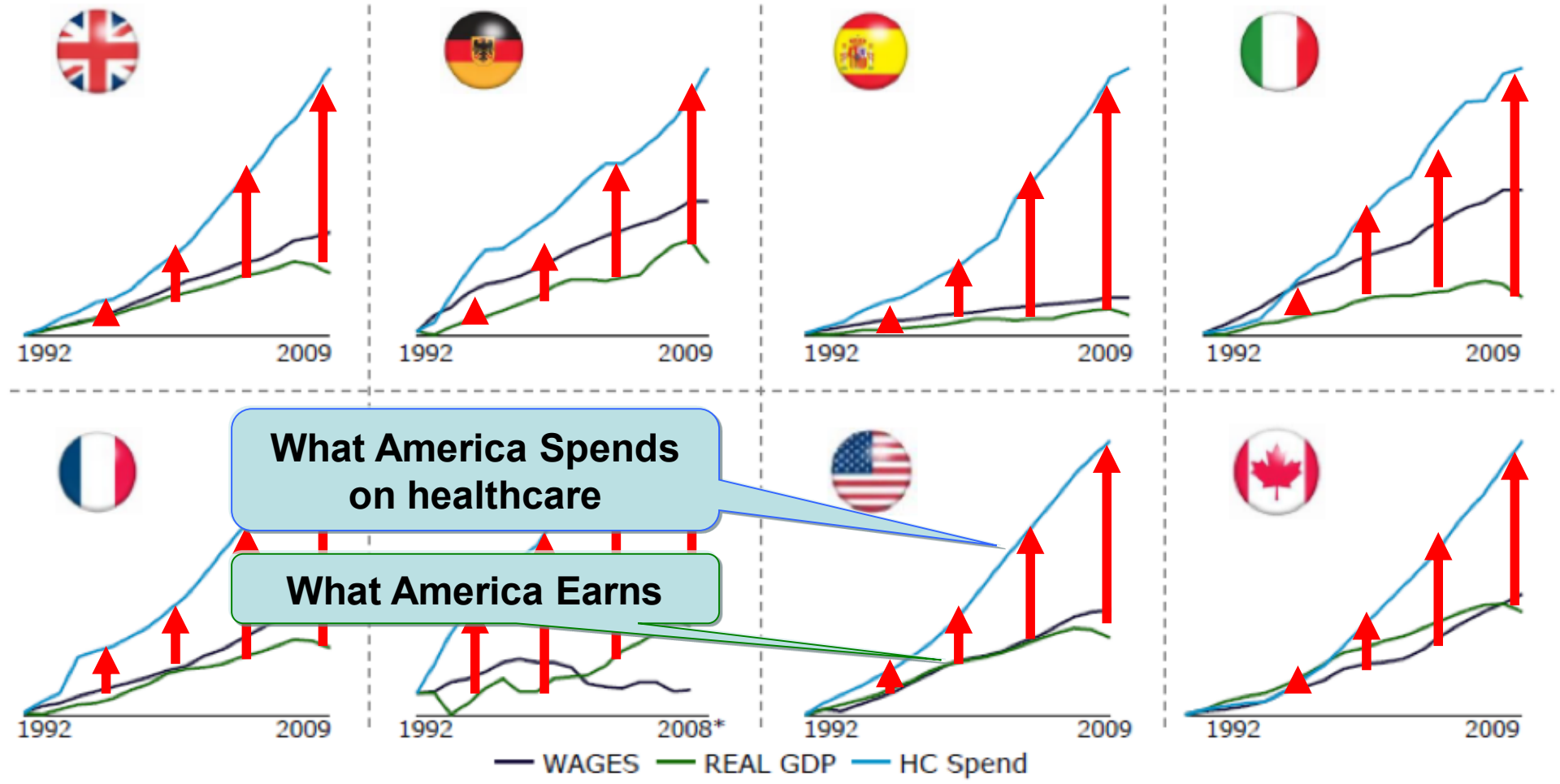
A forbes.com conversation with Robert Langreth, Avik Roy, David Whelan, Matthew Herper--and our audience.

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.

Langreth R. Will Health Costs Bankrupt America?. Forbes. http://www.forbes.com/forbes/2011/0314/health-care-recession-expenditure-bankrupt-america.html. Callahan D. Health care costs and medical technology. http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/health%20care%20costs%20chapter.pdf. Accessed May 7th, 2014

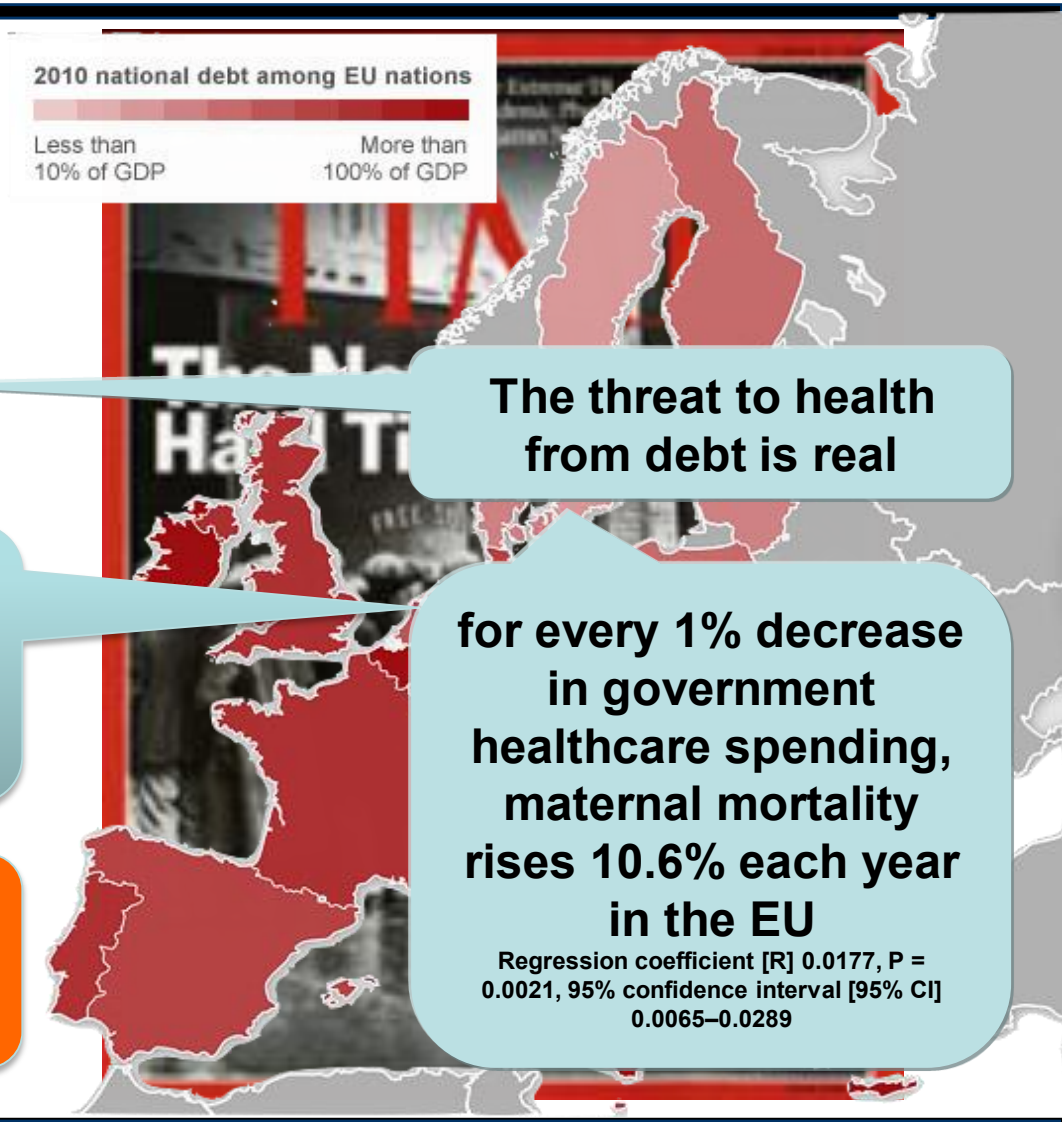
Medical Cost Inflation puts health services at jeopardy



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

We live in difficult times

- To maintain essential services, such as health and education
- The world has borrowed money and created significant debt



The threat to health from debt is real

Even when our current financial crisis is over we will have to repay debt leaving little spare for increased spending

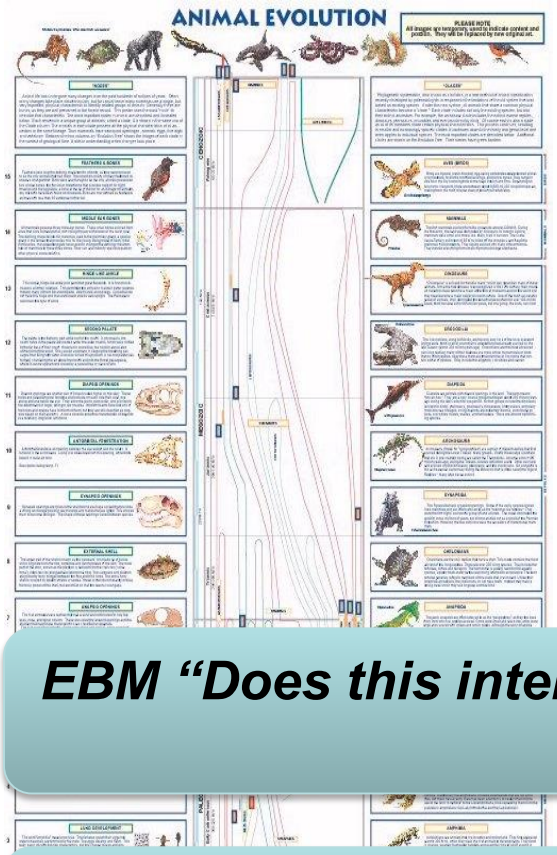
Yet we need an "innovation fund" to enable our patients to access better care

for every 1% decrease in government healthcare spending, maternal mortality rises 10.6% each year in the EU

Regression coefficient [R] 0.0177, P = 0.0021, 95% confidence interval [95% CI] 0.0065–0.0289

Ref: [1] Front Cover, TIME 13th October, 2008 [2] 2010 National Debt among EU nations - from The European debt crisis. CNN Money. URL = http://money.cnn.com/news/storysupplement/economy/euro_debt/images/map.jpg. Accessed July 5, 201e [3] Maruthappu M, Ng KYB, Williams C, Atun R, Agrawal P, Zeltner T. The association between government healthcare spending and maternal mortality in the European Union, 1981–2010: a retrospective study. BJOG 2014; DOI:

The Evolution of Medical Decision Making:



- Pre-EBM - Evidence Based Medicine
  - Focus on a novel mechanism of action? Tumour control, PFS
- EBM - Evidence Based Medicine
  - Focus on efficacy OS & QOL
- VBM - Value Based Medicine
  - Focus on effectiveness and "value" to stakeholders

EBM "Does this intervention make you live significantly longer or live better?"

VBM "Is this worth doing compared with other things we could do with the same resource?"

Huber B et al. Oncology Drug Development and Value-based Medicine. http://www.quintiles.com/library/white-papers/oncology-drug-development-and-value-based-medicine.pdf. Accessed June 27, 2014

by 2018, biologics worth $68 billion in annual sales will lose patent protection

Even with only 20% discount, this should give the world a $14 Billion health innovation fund

30% gets us $21 Billlion

40% pays back $28 Bilion

DEFINITION of 'Blockbuster Drug'

a drug that generates annual sales of at least $1 billion

VBM "Is this worth doing compared with other things we could do with the same resource?"

The WHO has made it very clear

- ***The leading cause of inefficiency in healthcare is underuse of generics and paying more than necessary for medicines [1]***
- ***A Biosimilar is similar in terms of quality, safety, and efficacy to an already licensed reference biotherapeutic product [2]***
- ***To use a more expensive version of a drug is "irrational, inappropriate, improper, incorrect" [3]***

Ref: [1] WHO. World health report 2010.Chapter 4: More health for the money. www.who.int/whr/2010/10_chap04_en.pdf. Accessed 10 June 2015. **[2] World Health Organization. Expert Committee on Biological Standardization. Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs). 23 October 2009. http://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22APRIL2010.pdf. Accessed 10 June 2015. [3] WHO World Medicines Report, 2011 .**

"The only drug that works is a drug that we can afford to give"

There are 196 countries in the world

Just 7 countries in the world buy 75% of all biologic drugs

The unmet need for cheaper biologics is significant

"The only drug that works is a drug that we can afford to give"

We have a common interest between patients, physicians, pharmacists, pharma' and payers in the success of biosimilars

There are 196 countries in the world

Just 7 countries in the world buy 75% of all biologic drugs

The unmet need for cheaper biologics is significant

Biosimilars offer a reward to world health that will be substantial

Biosimilars – why are they so important?

Biosimilars – I can't imagine the world of medicine without them

Biosimilars – I can't imagine the world of medicine without them