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# Trends in Personalized Medicine



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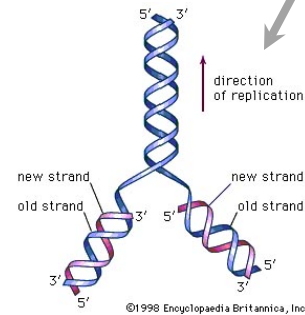
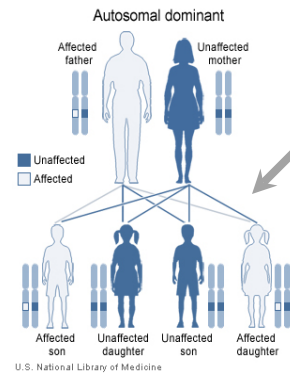
# Time Magazine – January 18, 2010



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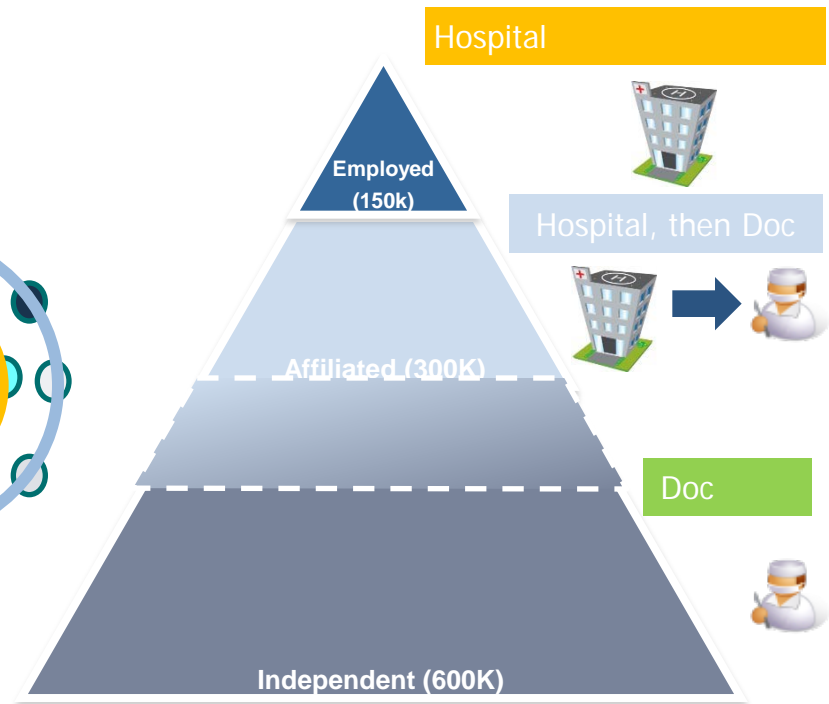
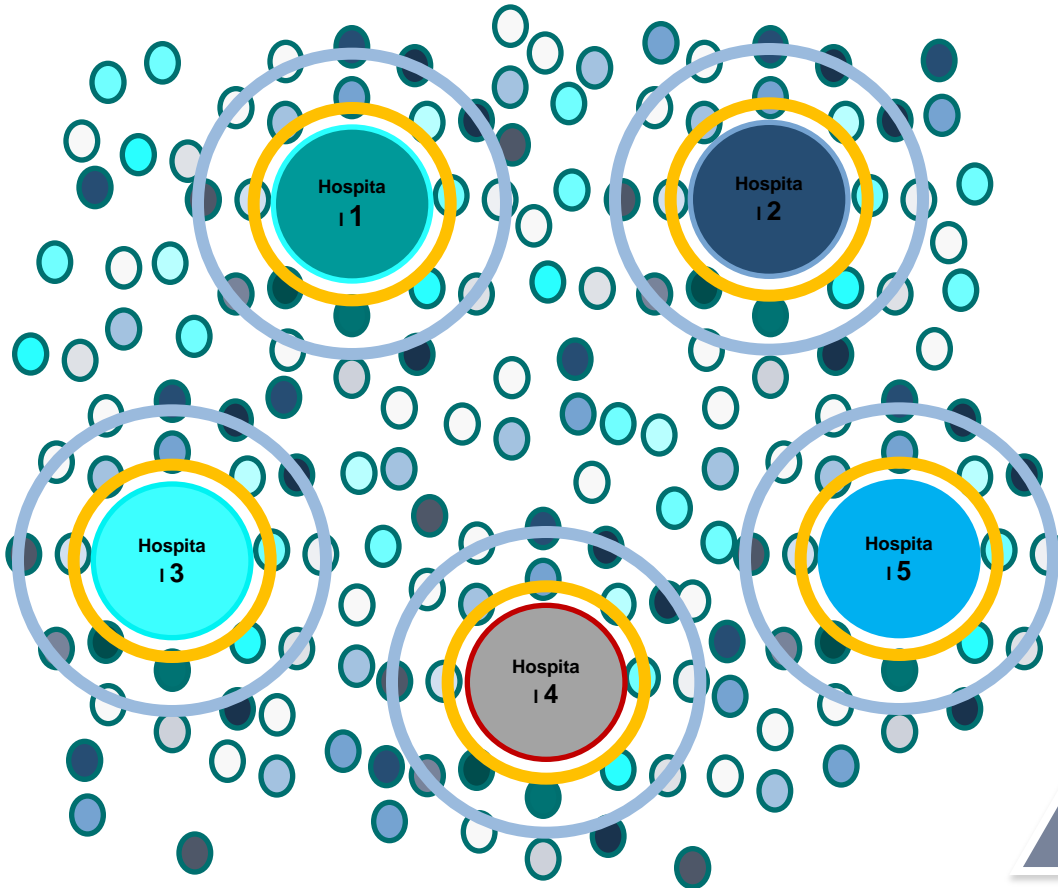
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# US Healthcare System -

10,000+ hospitals, 750,000+ physicians - *Employed (150K) Independent (300 Affiliated, 300 Unaffiliated)*

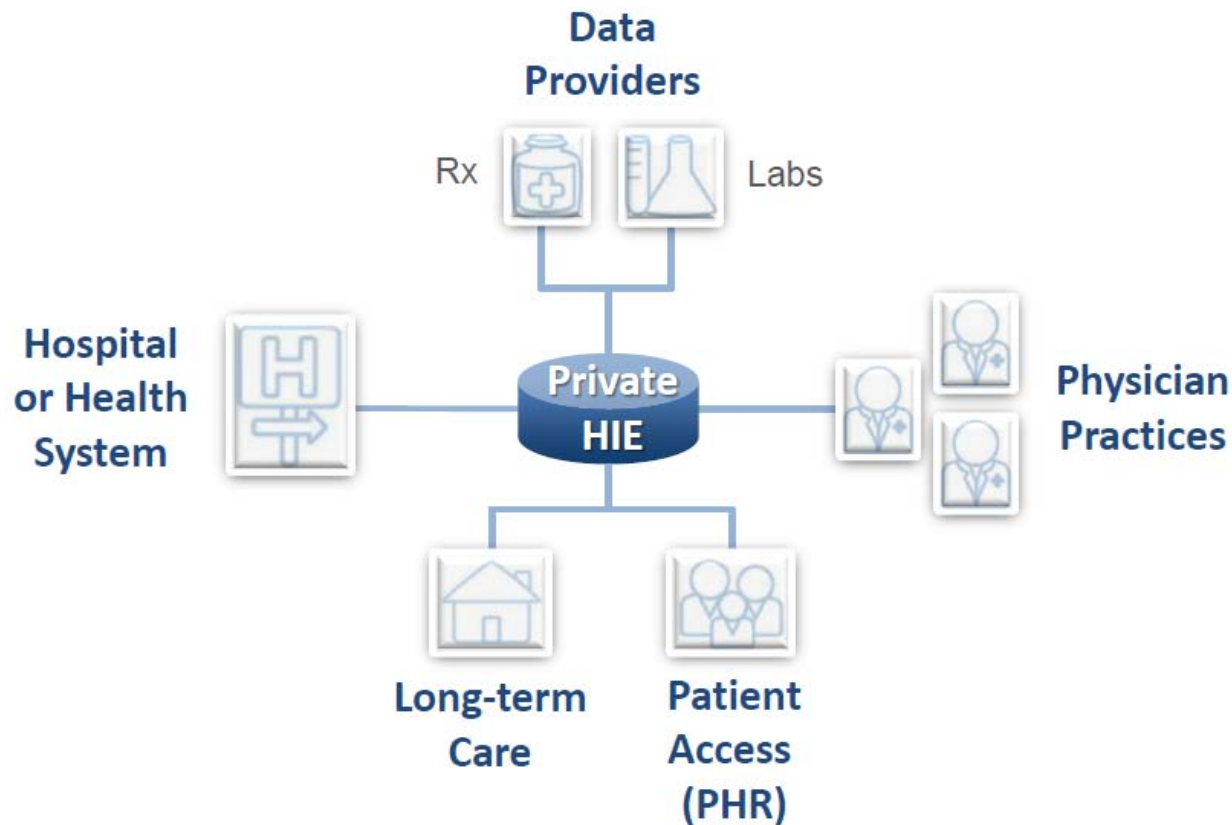


# Private Exchanges - Single Stakeholder

Primary goals of a private HIE: **physician attraction** and **ARRA readiness**

**Governance and Project Management Office**

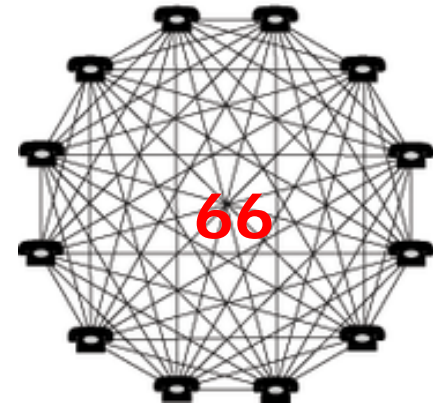
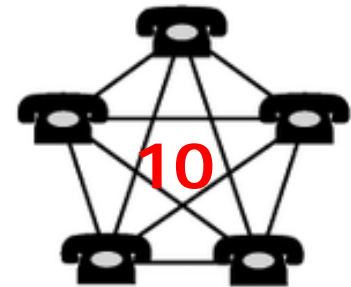
**Design, Deployment, Hosting and Helpdesk Support**



# Metcalfe's Law

Metcalfe's law characterizes many of the network effects of [communication technologies and networks](#) such as the Internet, social networking, and the World Wide Web.

It is related to the fact that the [number of unique connections](#) in a network of a number of nodes ( $n$ ) can be expressed mathematically as the triangular number  $n(n - 1)/2$ , which is proportional to  $n^2$  asymptotically.



# SINGLE Molecule

# 21NGTE WOJENIE

**AB** Applied Biosystems



15 yrs

AFFYMETRIX®



10 yrs

illumina®



5 yrs



# Single Molecule

1 Tb - 30 Mins, HG = \$20k

2yrs: 10 Tb - 30 Mins, HG = \$1k

1. Prepare gDNA Library  
Duration: 3 hr hands-on (6 hrs total)

2. Generate Clusters  
Duration: < 10 min hands on (4 hrs total)

- ▶ Phosphorylate & add A-overhang
- ▶ Ligate adapters
- ▶ Purify library

- ▶ Attach single manifold to flowcell
- ▶ Press Start

Sequencing by Synthesis

Post-Run Data

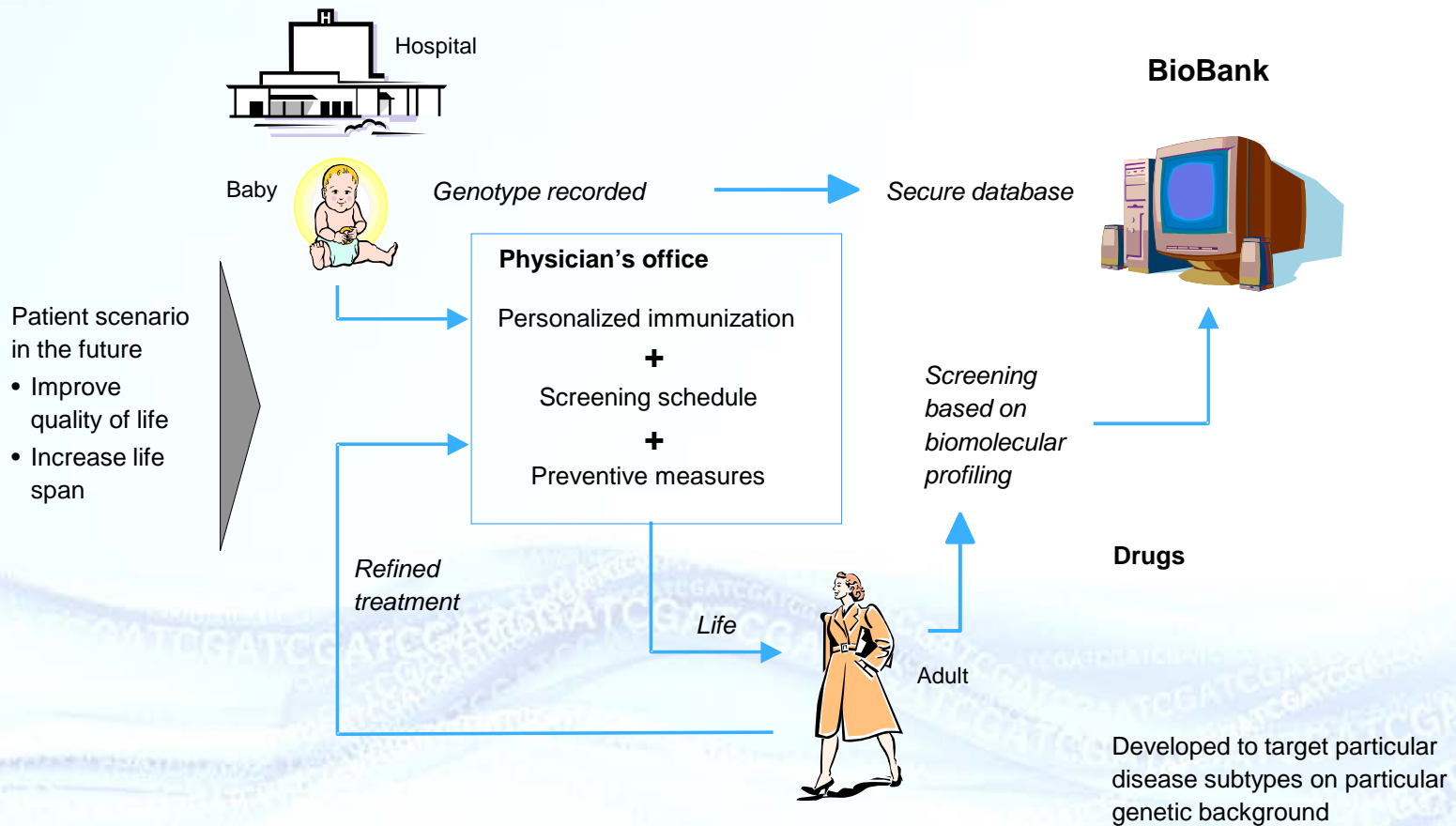
- ▶ Place reagents into the Genome Analyzer
- ▶ Place flow cell into Genome Analyzer
- ▶ Start run
- ▶ Image processing, real-time analysis, base calling

- ▶ Alignment
- ▶ Variant analysis
- ▶ Summary reporting

illumina®



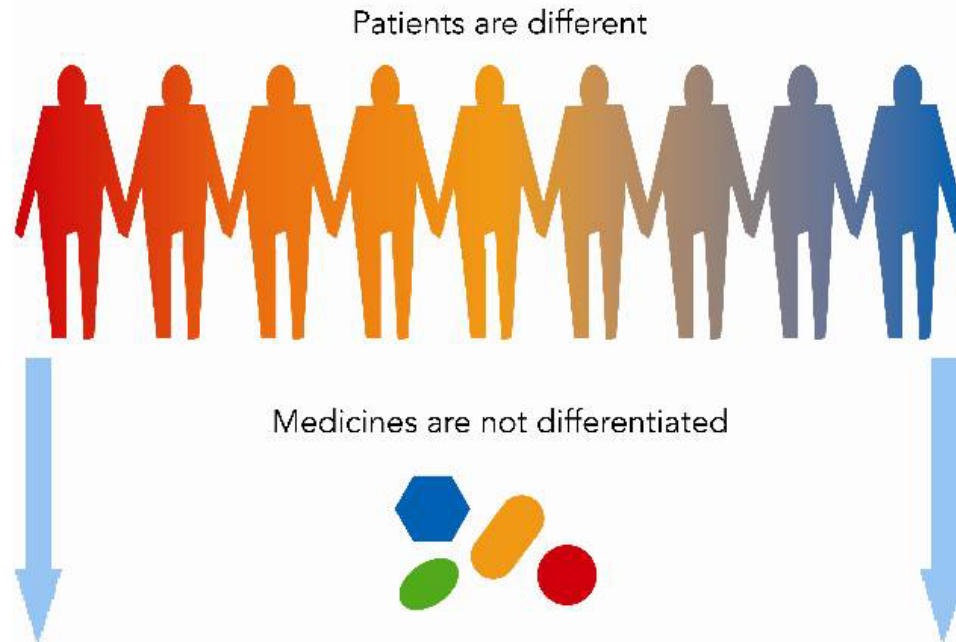
# Patient Centric LifeCare



Source: *Science*, Vol. 207, 17 March 2000



# Today's medicine challenge: One size doesn't fit all

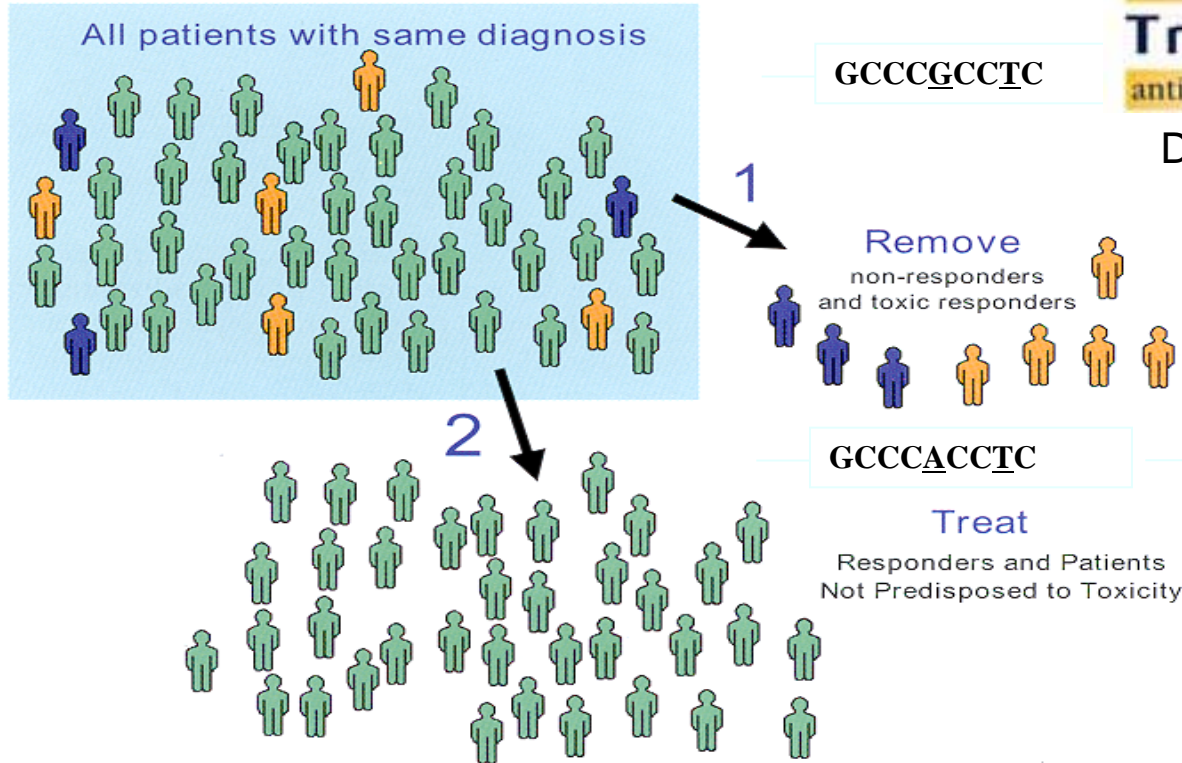


~ 30% of patients do not benefit from medicines<sup>1</sup>  
(100,000 deaths and 2.2 million nonfatal events from ADR in the US in 1994)

<sup>1</sup>JAMA 1998, 279: 1200

Source: Bayer HealthCare Diagnostics and Burrill & Company

# Large patient networks will enable targeted treatments



**Herceptin<sup>®</sup>**  
**Trastuzumab**  
anti-HER<sup>2</sup> monoclonal antibody  
Diagnostics/Biomarkers



Drug Metabolism

Governments and academic medical centers building 'biobank' repositories of samples and information.

# What is at stake?

## Top Global 15 Products

	2008 rank (US\$)	2008 Sales (US\$ MN)	% Growth 2008 (LC\$)	2007 Sales (US\$ MN)	% Growth 2007 (LC\$)	2006 Sales (US\$ MN)	% Growth 2006 (LC\$)	2005 Sales (US\$ MN)	% Growth 2005 (LC\$)	2004 Sales (US\$ MN)
Global Market	0	\$ 724,465	4.4	\$ 673,043	6.2	\$ 612,013	6.6	\$ 572,659	7.2	\$ 530,909
LIPITOR	1	\$ 13,655	(0.9)	\$ 13,526	(3.0)	\$ 13,582	4.2	\$ 12,990	5.9	\$ 12,188
PLAVIX	2	\$ 8,634	16.9	\$ 7,300	21.8	\$ 5,793	(3.6)	\$ 5,969	15.9	\$ 5,127
NEXIUM	3	\$ 7,842	7.8	\$ 7,193	5.5	\$ 6,678	17.0	\$ 5,691	16.7	\$ 4,866
SERETIDE	4	\$ 7,703	7.0	\$ 7,138	9.7	\$ 6,300	10.1	\$ 5,684	19.0	\$ 4,752
ENBREL	5	\$ 5,703	5.6	\$ 5,292	16.6	\$ 4,414	17.0	\$ 3,771	41.2	\$ 2,671
SEROQUEL	6	\$ 5,404	14.9	\$ 4,651	16.1	\$ 3,930	18.1	\$ 3,321	28.0	\$ 2,589
ZYPREXA	7	\$ 5,023	(1.8)	\$ 5,024	2.1	\$ 4,769	(0.1)	\$ 4,762	(6.0)	\$ 5,055
REMICADE	8	\$ 4,935	14.0	\$ 4,233	15.4	\$ 3,585	19.6	\$ 2,996	17.3	\$ 2,554
SINGULAIR	9	\$ 4,673	3.1	\$ 4,465	14.8	\$ 3,829	17.7	\$ 3,248	15.9	\$ 2,794
LOVENOX	10	\$ 4,435	8.9	\$ 3,991	12.1	\$ 3,435	12.5	\$ 3,038	14.2	\$ 2,650
MABTHERA	11	\$ 4,321	12.9	\$ 3,734	12.9	\$ 3,208	17.7	\$ 2,719	23.5	\$ 2,198
TAKEPRON	12	\$ 4,321	(3.6)	\$ 4,405	(2.3)	\$ 4,502	(1.7)	\$ 4,603	2.3	\$ 4,517
EFFEXOR	13	\$ 4,263	3.4	\$ 4,076	0.2	\$ 3,982	3.1	\$ 3,844	1.2	\$ 3,784
HUMIRA	14	\$ 4,075	39.5	\$ 2,858	41.4	\$ 1,944	49.6	\$ 1,289	71.0	\$ 757
AVASTIN	15	\$ 4,016	37.4	\$ 2,867	41.2	\$ 1,995	99.3	\$ 1,000	280.3	\$ 265

[http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/Global\\_Top\\_15\\_Products.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Global_Top_15_Products.pdf)

Note: Lipitor loses patent exclusivity in 2011 – Generic Drugs will be available



# HIPAA & Unintended Consequences

## Living With the BRCA Gene: One Family's Story

Generations of the Price family have been affected by a mutation in the BRCA1 gene that significantly raises the risk of breast and ovarian cancer. A parent who carries the defective gene has a 50 percent chance of passing it on to his or her children. In 2002, Christie Veale became the first family member to have DNA testing that revealed she carried the defective gene. Since then, many of her relatives followed, they have made



How can family members of a deceased individual obtain the deceased individual's protected health information that is relevant to their own health care?

Answer:

**Second**, a covered entity must treat a deceased individual's legally authorized executor or administrator, or a person who is otherwise legally authorized to act on the behalf of the deceased individual or his estate, as a personal representative with respect to protected health information relevant to such representation.

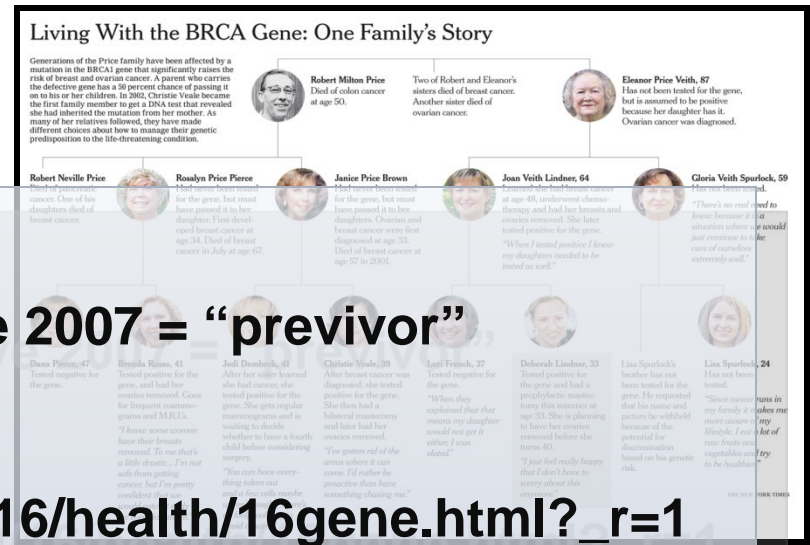
Therefore, if it is within the scope of such personal representative's authority under other law, the Rule permits the personal representative to obtain the information or provide the appropriate authorization for its disclosure.

# Previvor - Cancer Free at 33, but Weighing a Mastectomy



## Personalized Medicine - Biomarkers

- Family History of Cancer Breast/Ovarian/Colon
- Mother recovering from Chemotherapy
- Asymptomatic for pre-cancerous cells
- Positive for BRAC-1



## Diagnostic Monitoring

- Mammography
- Breast Ultrasound
- Ovarian Ultrasound w/CA-128 Blood Test

Search NYTimes Archive 2007 = "previvor"

[http://www.nytimes.com/2007/09/16/health/16gene.html?\\_r=1](http://www.nytimes.com/2007/09/16/health/16gene.html?_r=1)

- Prophylactic Mastectomy
- Tamoxifen

Source: NY Time, Sep 16, 2007



# Getting the Right Statin

20 mg atorvastatin calcium tablets



Novartis CEO  
Daniel Vasella

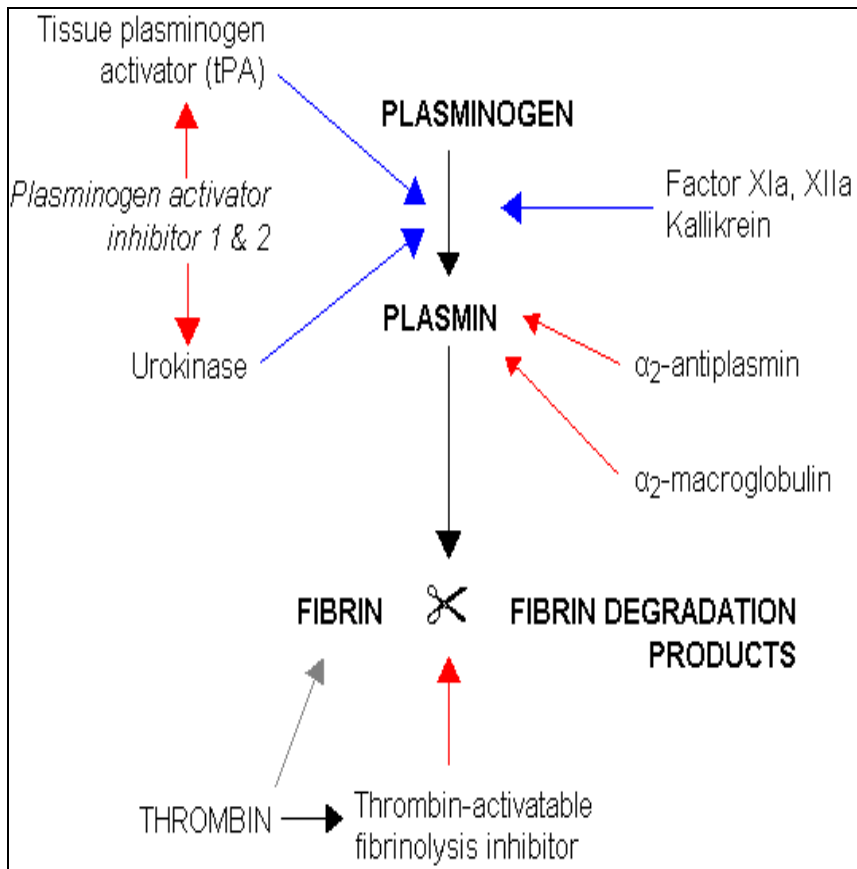
## Diagnosed: High Cholesterol

He tried Lescol twice, but it didn't agree with him.

"I have side effects on our own lipid-lowering drug," he told the Health Blog

"I don't have them on Lipitor, so I take Lipitor. It's funny but it's true."

# Fertility and Genetic Tests



## Basic Medicine

- 40 Yr Female
- Healthy
- No family history of fertility problems
- **Several Miscarriages**
- Full workup (Slightly High FSH)
- Specialties have no definitive answers
- 3 IVF end in Miscarriage

## Personalized Medicine in Action

- New Blood test for Key genetic markers (was included as an after thought)
- Tested Positive for PAI - 1 (Plasminogen activator inhibitor-1)
- Lovenox (Blood thinner) used to counteract natural mechanism





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**Thank You**

