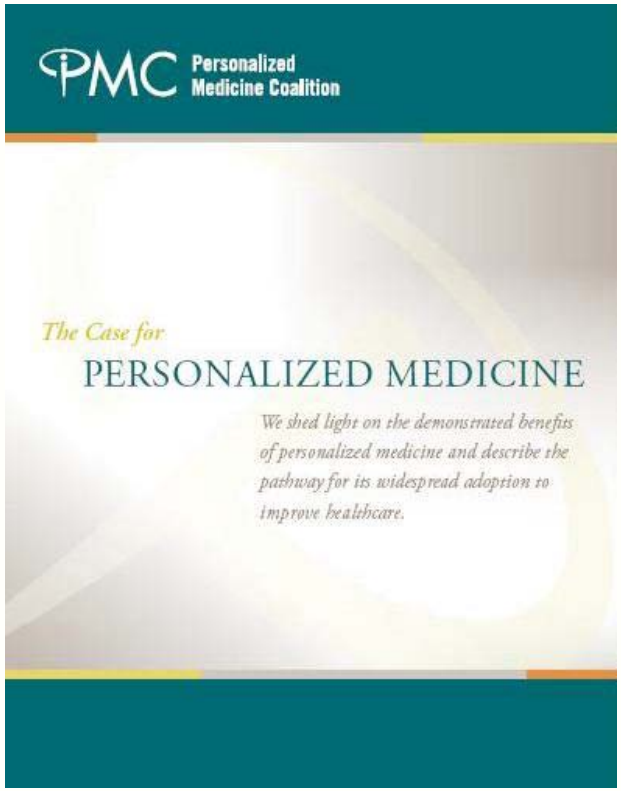
Personalized Medicine Coalition

Personalized Medicine:
The Changing Landscape of Healthcare

International Economic Forum of the Americas
Montreal, Canada
June 10, 2010

Edward Abrahams, Ph.D.
President
Personalized Medicine Coalition

Defining Personalized Medicine



"Personalized medicine refers to the tailoring of medical treatments to the individual characteristics of each patient … Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not."

President's Council of Advisors on Science and Technology (PCAST), *Priorities for Personalized Medicine, September, 2008*

Ancient Precedent

"It's far more important to know what person the disease has than what disease the person has."

Hippocrates (ca. 400 BCE)

Moving from Art to Science

"If it were not for the great variability among individuals, medicine might as well be a science, not an art."

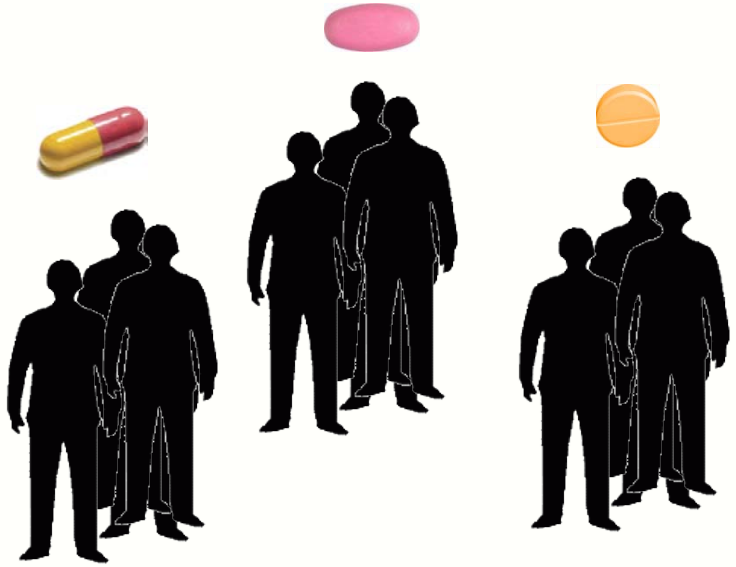
Sir William Osler, Physician (1892)

Defining Personalized Medicine

Current Practice

Trial and error

Personalized Medicine



The **right treatment**
for the **right person**
at the **right time**

What is Driving the Movement to Personalized Medicine?

Consumer Demand for:

Safer, More Effective Drugs

Faster Time to a Cure

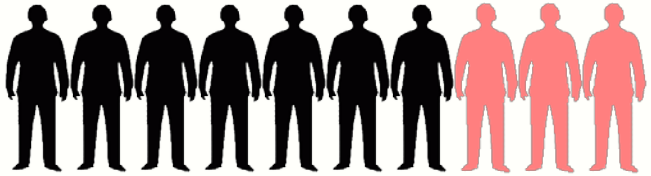
Cost-Effective Healthcare

The Potential Benefits of Personalized Medicine

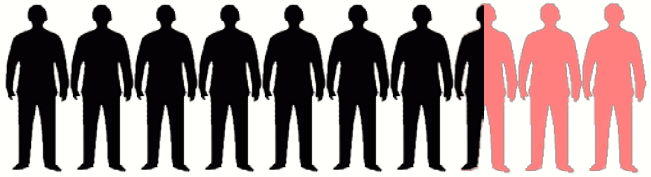
- Shift emphasis in medicine from reaction to prevention
- Select optimal therapies
- Increase safety, reduce adverse drug reactions
- Increase patient compliance
- Reduce the time, cost, and failure rate of clinical trials
- Reduce the overall cost of healthcare

Major Drugs Ineffective for Many

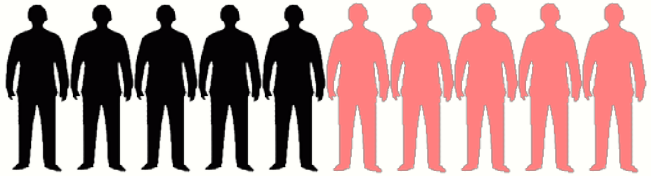
Hypertension Drugs 10-30%
ACE Inhibitors



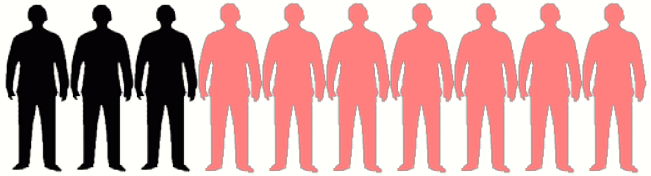
Heart Failure Drugs 15-25%
Beta Blockers



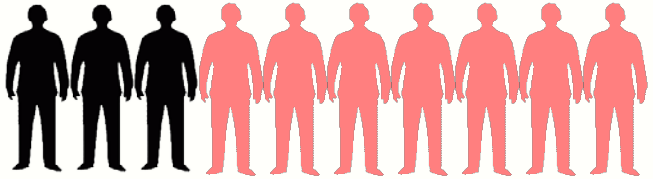
Anti Depressants 20-50%
SSRIs



Cholesterol Drugs 30-70%
Statins



Asthma Drugs 40-70%
Beta-2-agonists



Source: Spear B, Heath-Chiozzi M, Huff J Clinical Trends Molecular Medicine 2001; 7(5):201-4.

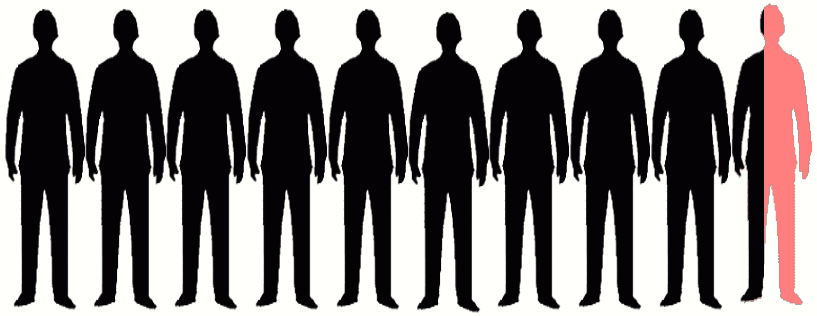
Ineffective Therapies Waste Money

Major Drug	Cost of Ineffectiveness to Healthcare System
Hypertension Drugs Ace Inhibitors	$390 million – $1.2 billion
Heart Failure Drugs Beta Blockers	$345 million – $575 million
Anti Depressants SSRIs	$2.3 billion – $5.8 billion
Cholesterol Drugs Statins	$3.8 billion – $8.8 billion
Asthma Drugs Beta-2-agonists	$560 million – $1.0 billion

Ineffective Therapies Can Cause Harm

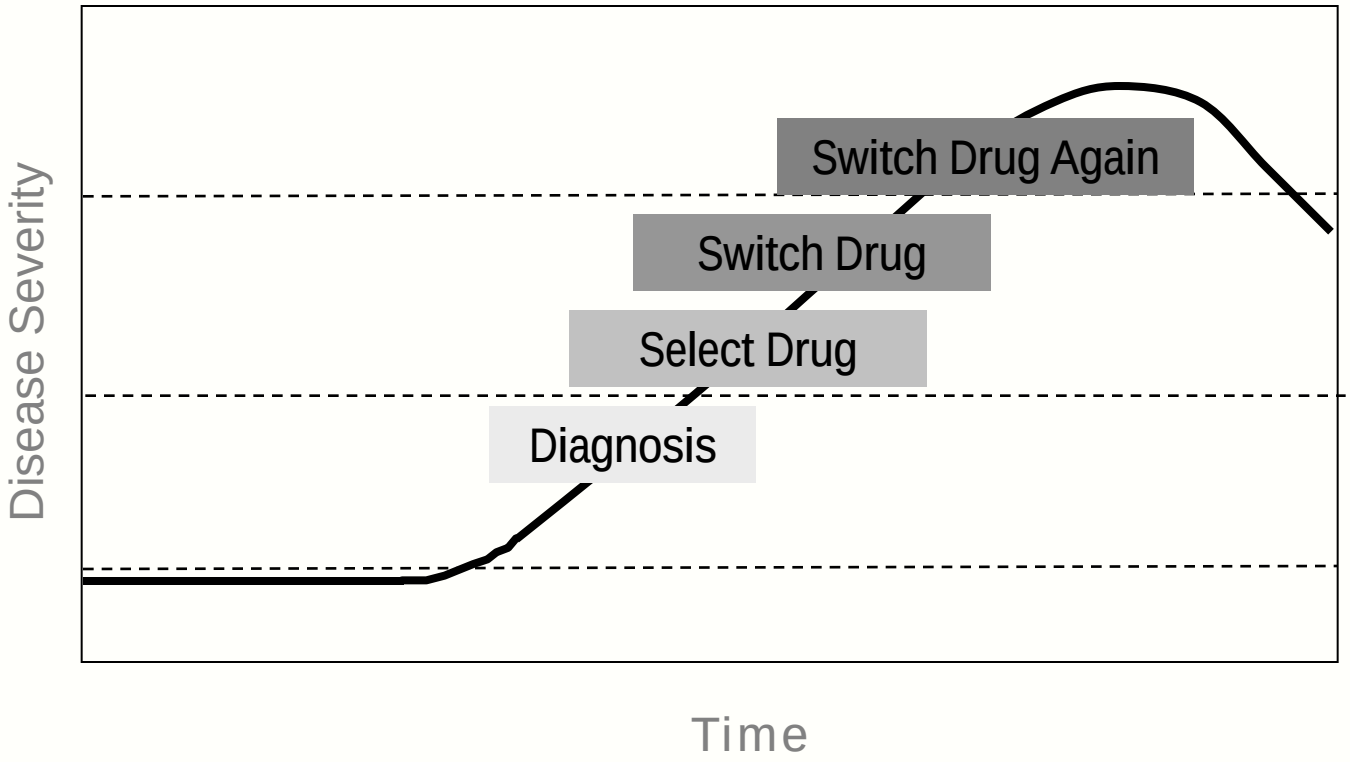
Adverse Events

- Estimated 100,000 deaths per year *(in 1994; Lazarou et al 1998)*
- 6th leading cause of death in the US
- Experienced by approximately 7% of patients (2.2 million) per year
- Medication-related health problems account for an estimated 3% to 7% of hospital admissions *(Pirmohamed M, et al 2004)*
- During their hospital stay, 15% of patients experienced adverse drug reactions *(Davies, et al 2009)*
- Increased patient non-compliance



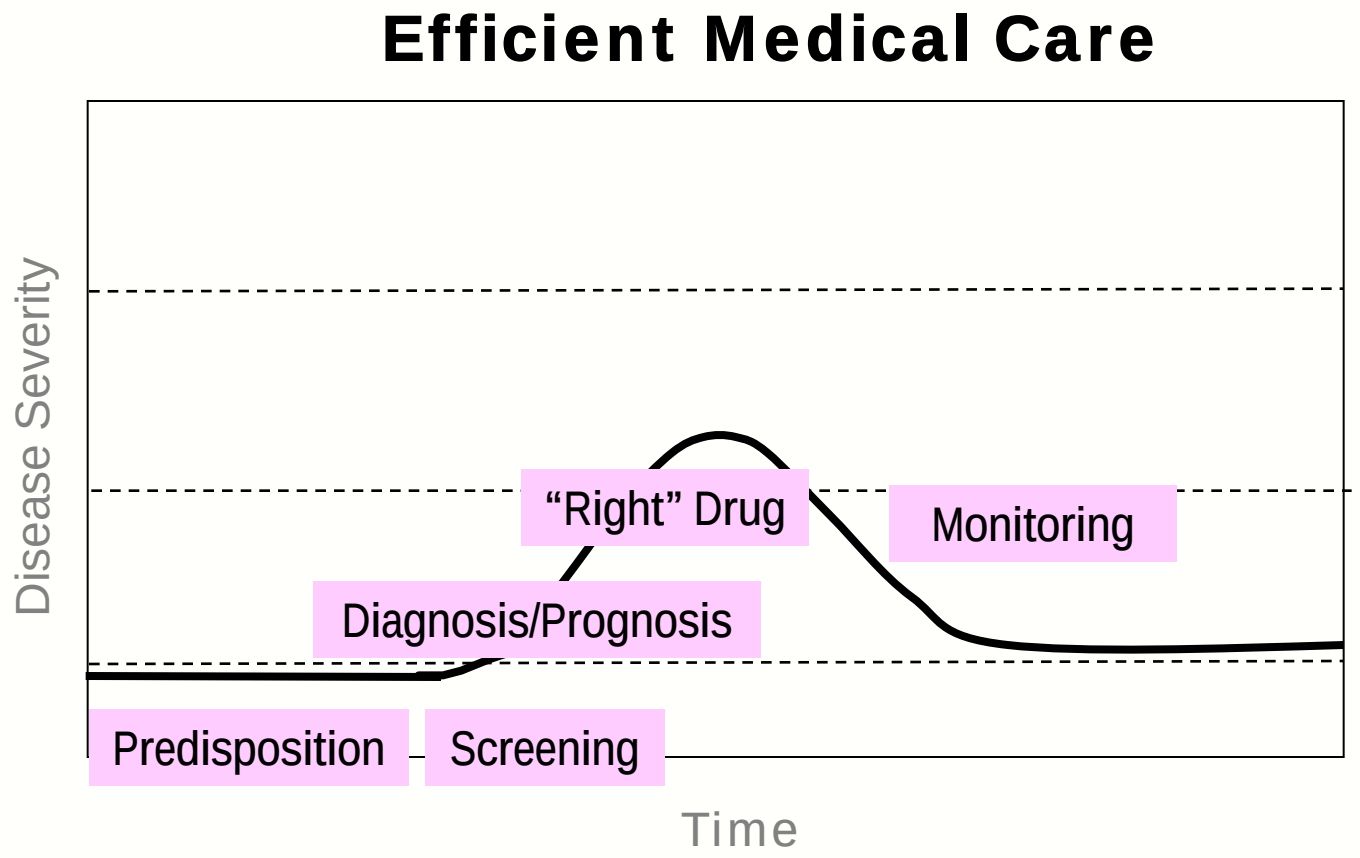
The Old Paradigm: Treatment of Disease

Reactive Medical Care



Diagnose Disease; Treat Symptoms; Costly, Trial and Error Treatment

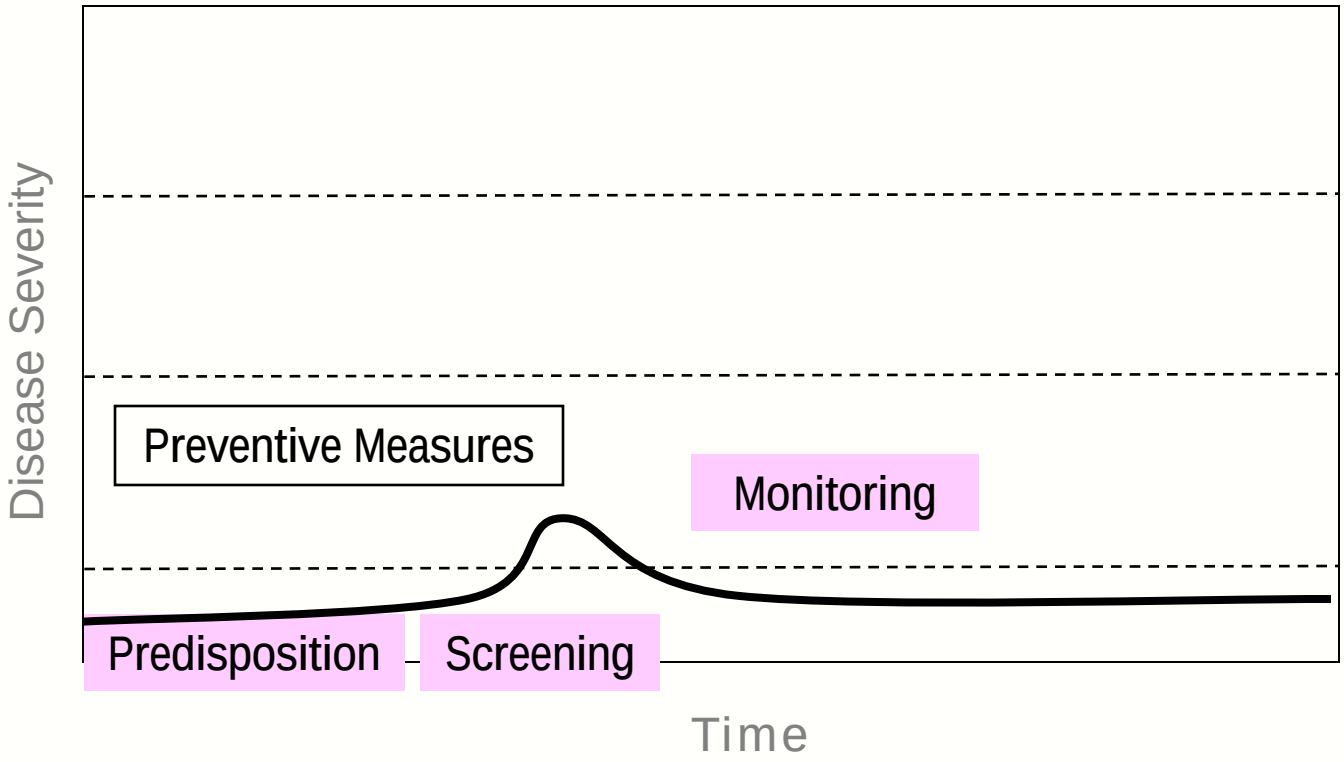
To Effective, Efficient Health Management



Health Management; Molecular Screening; Early Detection; Rapid Effective Treatment; Improved Quality of Care

Personalized Medicine: Moving Healthcare Upstream

Preventive Medical Care



Predisposition Guides Prevention; Treat the Molecular Markers vs. Symptoms and Disease; Healthcare Cost Reduction

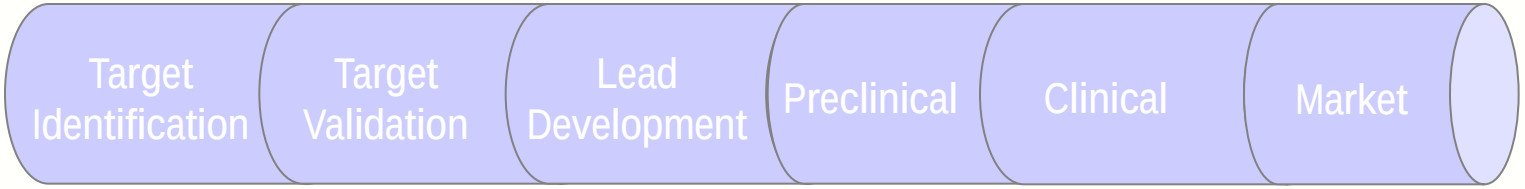
Personalized Medicine In Research & Development

Safer, More Effective Drugs

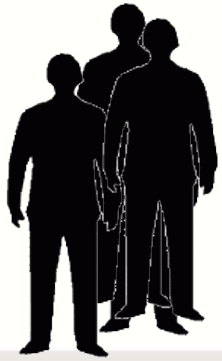
Identify disease targets, speed clinical trials, and advance more drugs that are safe and effective for specific populations

Faster path to disease targets using genetic data

Speed trials by testing on patients selected for likely high response and safety

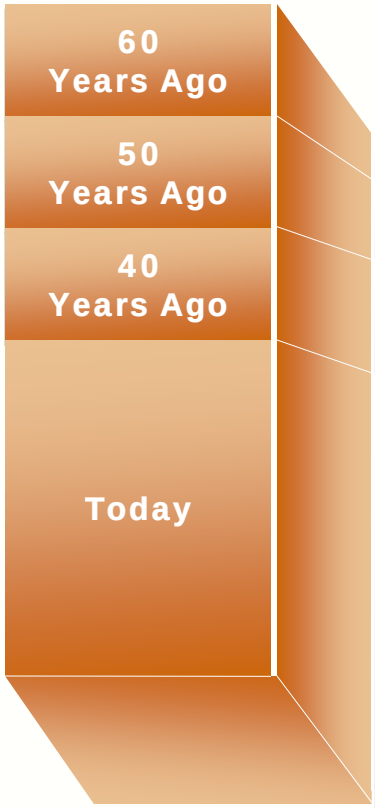


Knowledge of biological pathways and gene variants helps eliminate poor candidates



Target optimal population by combining drug with molecular diagnostic test

Personalized Medicine: Impacts Patient Care



	"Disease of the Blood"	
	Leukemia or Lymphoma	
	Chronic Leukemia Acute Leukemia Preleukemia	Indolent Lymphoma Aggressive Lymphoma
	~38 Leukemia types identified: Acute myeloid leukemia (~12 types) Acute lymphoblastic leukemia (2 types) Acute promyelocytic leukemia (2 types) Acute monocytic leukemia (2 types) Acute erythroid leukemia (2 types) Acute megakaryoblastic leukemia Acute myelomonocytic leukemia (2 types) Chronic myeloid leukemia Chronic myeloproliferative disorders (5 types) Myelodysplastic syndromes (6 types) Mixed myeloproliferative/myelodysplastic syndromes (3 types)	**~51 Lymphomas identified:** Mature B-cell lymphomas (~14 types) Mature T-cell lymphomas (15 types) Plasma cell neoplasm (3 types) Immature (precursor) lymphomas (2 types) Hodgkin's lymphoma (5 types) Immunodeficiency associated lymphomas (~5 types) Other hematolymphoid neoplasms (~7 types)

5 Year Survival

~0%

70%

Ries LAG, Eisner MP, Kosary CL, Hankey BF, Miller BA, Clegg L, Mariotto A, Feuer EJ, Edwards BK (eds). *SEER Cancer Statistics Review, 1975-2002*, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2002/, based on November 2004 SEER data submission, posted to the SEER web site 2005.

Source: Mara G. Aspinall, former President, Genzyme Genetics

Personalized Medicine: In the News

BBC

March 1, 2010

"Gene Test Aid to Cancer Treatment"

The New York Times

March 30, 2010

"Special Report: Fast Machines, Genes And The Future Of Medicine"

nature

April 1, 2010

"Has the Revolution Arrived?"

Francis Collins finds five key lessons for the future of personalized medicine

Bloomberg BusinessWeek

March 16, 2010

"DNA Test May Cut Hospitalizations Caused by Blood Thinner"

THE WALL STREET JOURNAL.

March 22, 2010

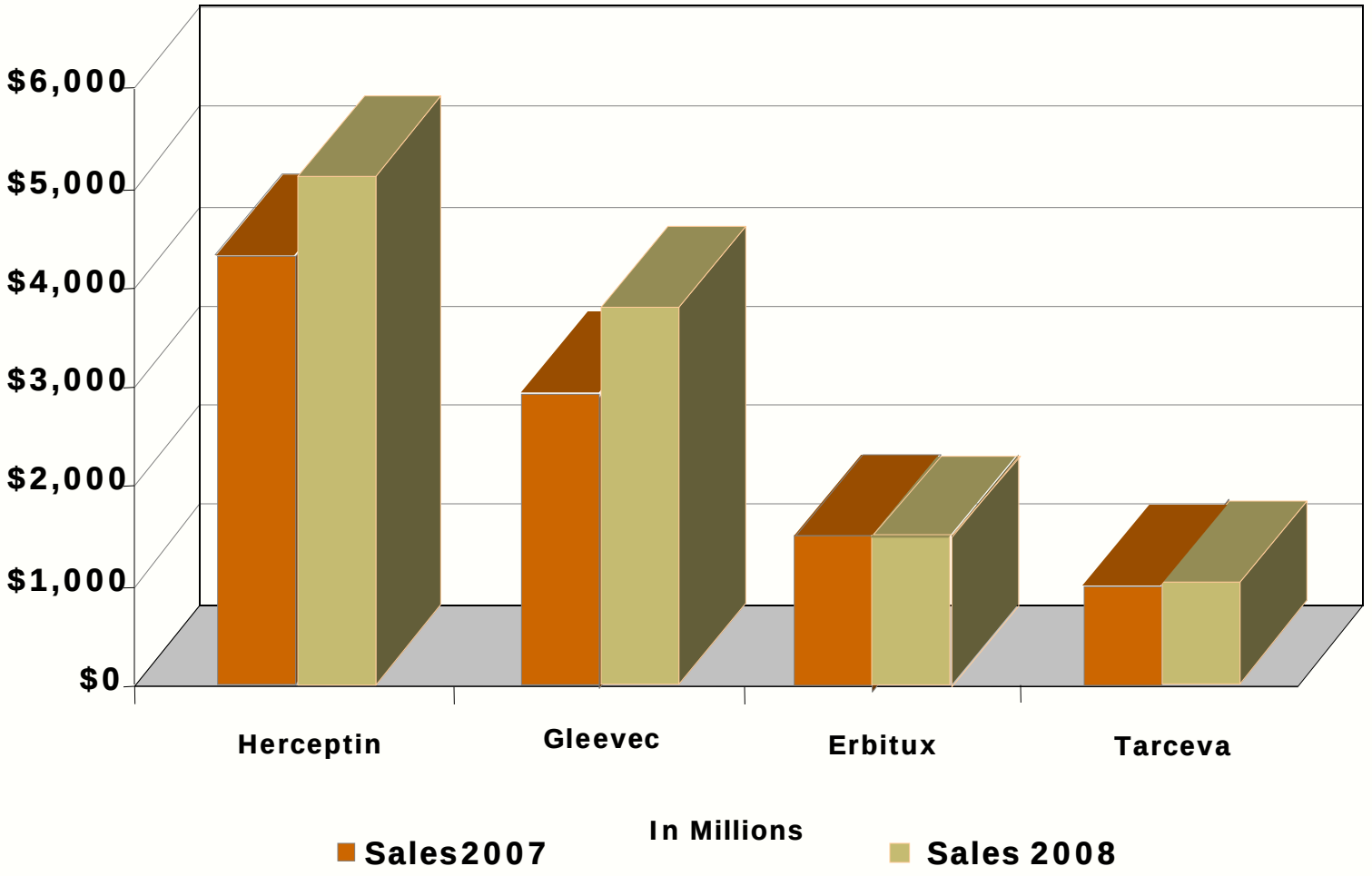
"When Plavix May Not Work"

The Boston Globe

January 25, 2010

"Personalized Prescription: CVS, Medco at vanguard of effort to match patients, drugs by genetic tests"

Marketed Therapeutics with Companion Dx



Source: Company Information

The Blockbuster Model is “Broken”

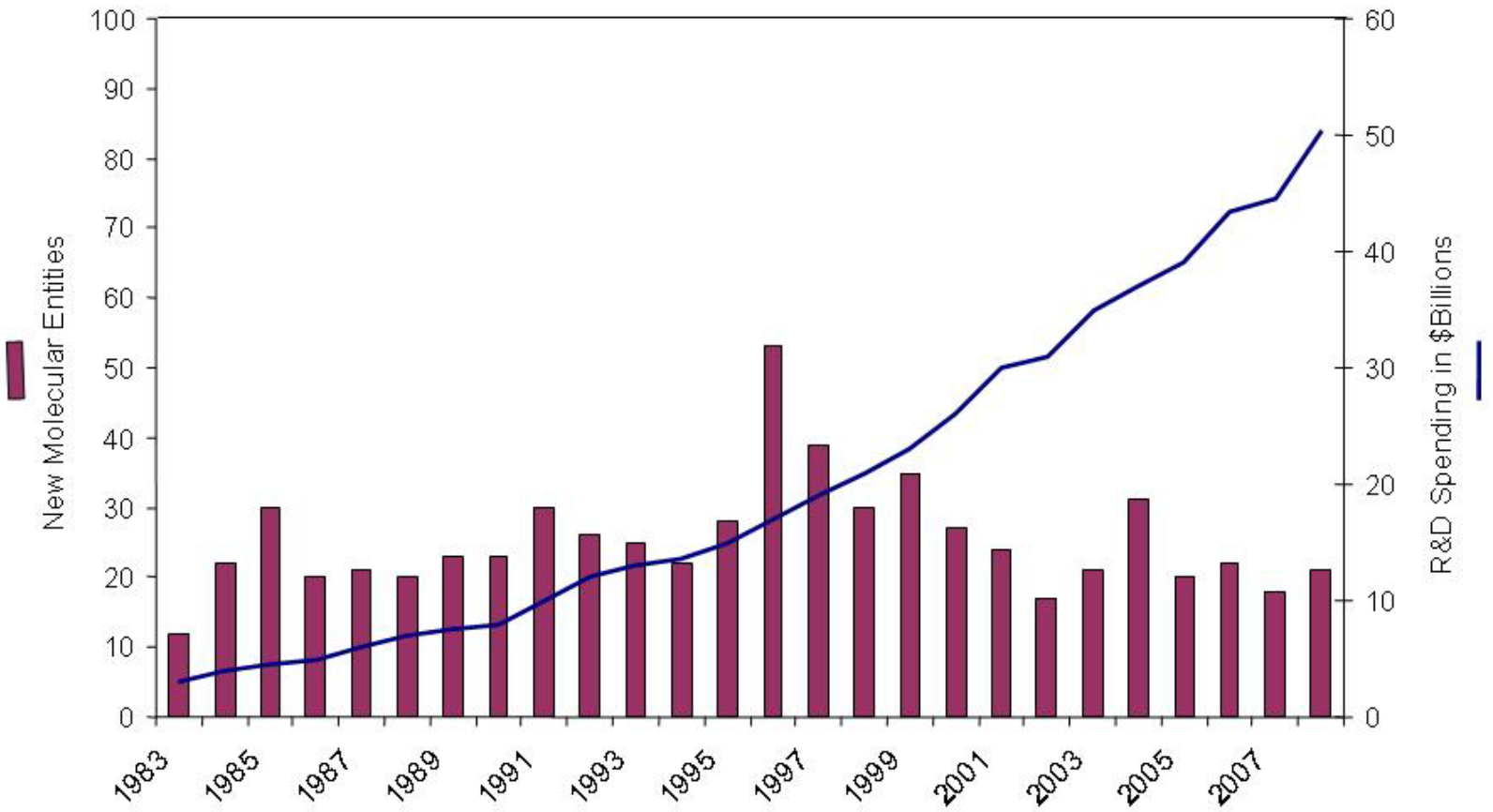
“The power in tailored therapeutics is for us to say more clearly to payers, providers, and patients -- ‘this drug is not for everyone but it is for you.’”

John C. Lechleiter, Ph.D.

Chief Executive Officer

Eli Lilly and Company

Trends in R&D Costs



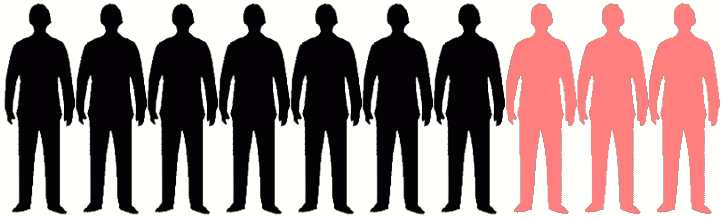
Diagnostics in Personalized Medicine

"Therapeutics is where most of the money was made in the past, and the majors will fight to win that battle. Yet diagnostics is where the most attractive profits will be made in the future."

Clayton M. Christensen
The Innovator's Prescription (2009)

Examples of Personalized Medicine - Herceptin

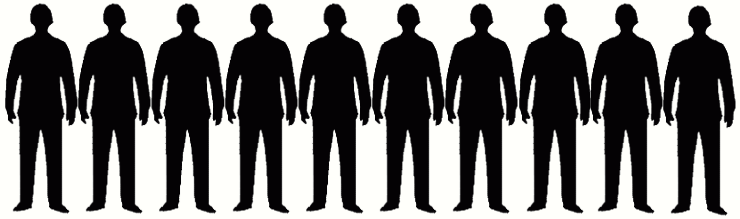
Target treatment…



Some women with metastatic breast cancer have tumors that overexpress the *HER2* gene and have a poorer response to chemotherapy

Herceptin +

- **HercepTest®** } IHC
- **Pathway®** } IHC
- **PathVysion®** } FISH
- **HER2 pharmDx™** } FISH



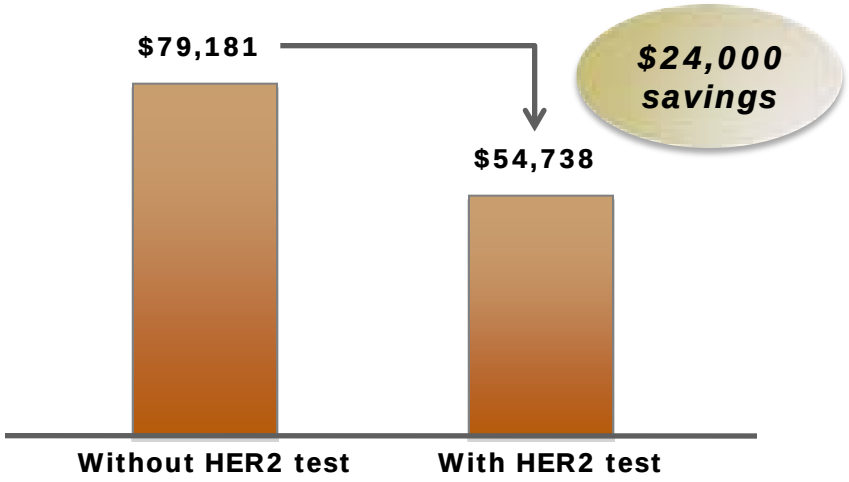
Identifying HER2+ patients with genetic (FISH) or immunological (IHC) tests and targeting with Herceptin improves treatment.

50% reduced risk of recurrence after one year

Examples of Personalized Medicine - Herceptin

Value based on health outcomes and savings

Cost of Herceptin therapy per patient



Reimbursement based on CPT-codes

Price of HER2 testing per patient*

CPT Code	Description	Fee
88368	Morphometric analysis, in situ hybridization (probe #1)	$183
88368	Morphometric analysis, in situ hybridization (probe #2)	$183
Total		**$366**

HER2 test delivers healthcare savings that are ~65x its cost

*As measured by FISH and reimbursed by CMS, Los Angeles, 2007 rates
Source: Elkin et al. *HER-2 Testing and Trastuzumab Therapy for Metastatic Breast Cancer: A Cost-Effectiveness Analysis.* J Clin Oncol (2004) 22: 854-863; Genzyme analysis

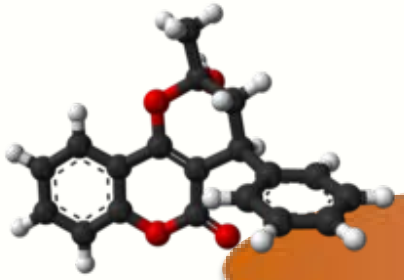
Source: Mara G. Aspinall, former President, Genzyme Genetics

Examples of Personalized Medicine - Warfarin

Adjust dosing…

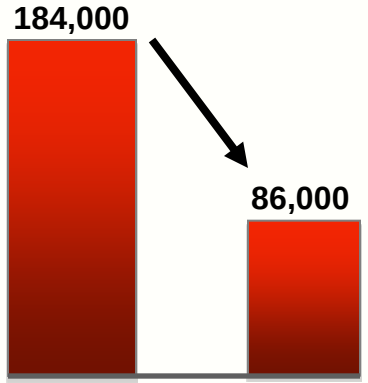
CYP2C9: Mutations can lead to slow metabolism and increased risk of internal bleeding

VKORC1 mutations can make warfarin less effective, increasing the risk of blood clots and stroke

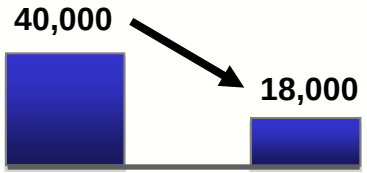


40% of dose variation is attributable to genetics

With genetic testing*…



Bleeding events



Stroke events

*Based on model from: Health Care Savings from Personalized Medicine Using Genetic Testing: The Case of Warfarin AEI-Brookings Joint Center for Regulatory Studies Working Paper 06-23, November 2006

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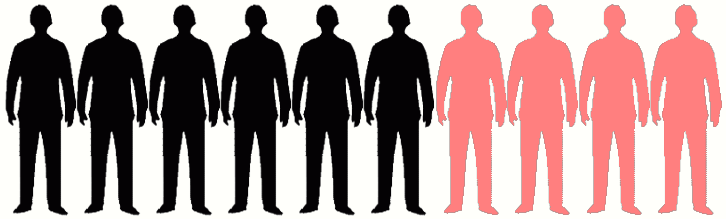
Examples of Personalized Medicine - Erbitux

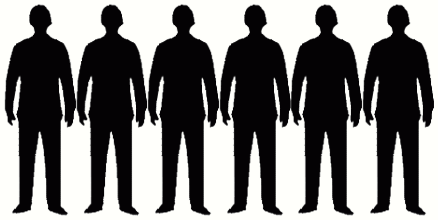
Avoid ineffective therapy…

Erbitux and Vectibix block epidermal growth factor receptors (EGFRs), inhibiting cell growth in tumors



40% of patients with ***metastatic colorectal cancer*** have a mutation in the KRAS gene, rendering Erbitux and Vectibix ineffective.

With a genetic test…

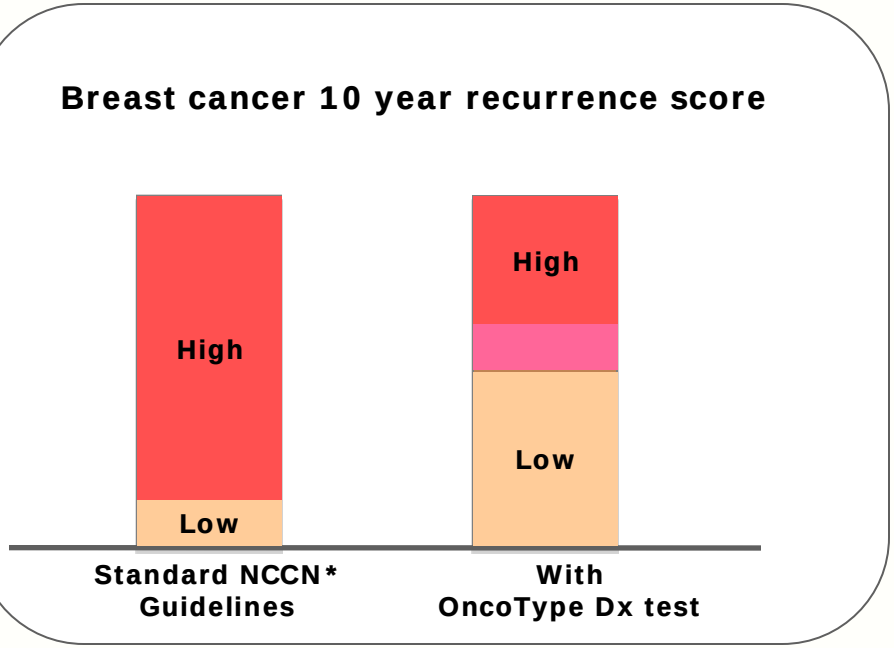


Potential savings of $3580 per patient*

Expensive and ineffective treatment, and potential toxicities can be avoided for these patients

Examples of Personalized Medicine – OncoType Dx

Value based on health outcomes and savings



oncotype DX® Breast Cancer Assay

A 21-gene scan yielding an accurate recurrence score for likelihood that the cancer will return within 10 years

Using OncoType Dx, 45% of patients who would have had to suffer through chemotherapy were able to avoid it safely

Reclassification with OncoType Dx test could deliver net healthcare savings of $2028/patient*

*National Comprehensive Cancer Network

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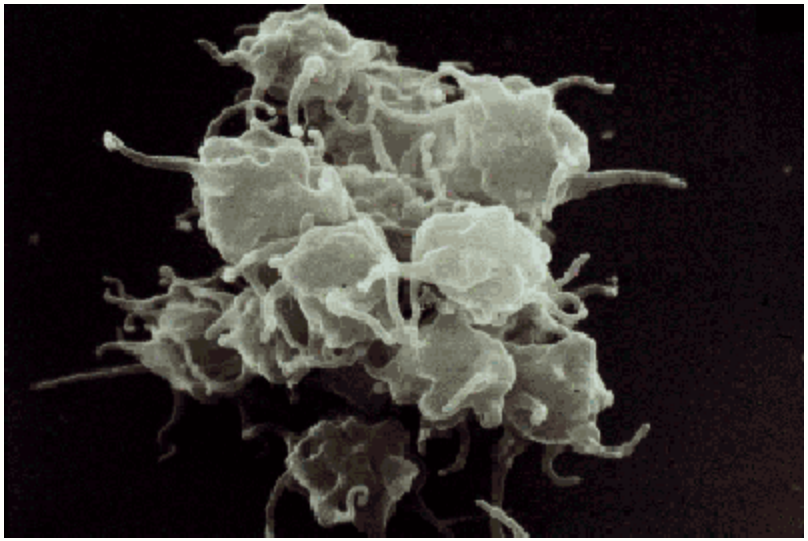
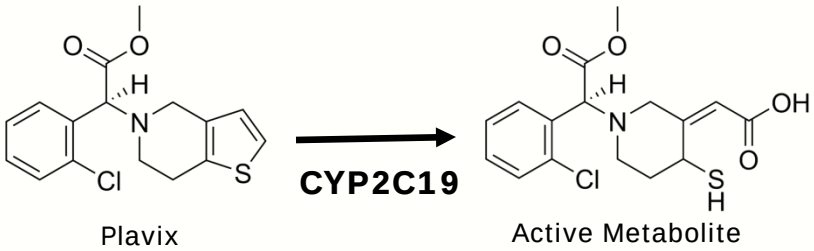
Examples of Personalized Medicine – Plavix



Plavix (clopidogrel) anti-platelet "pro-drug"

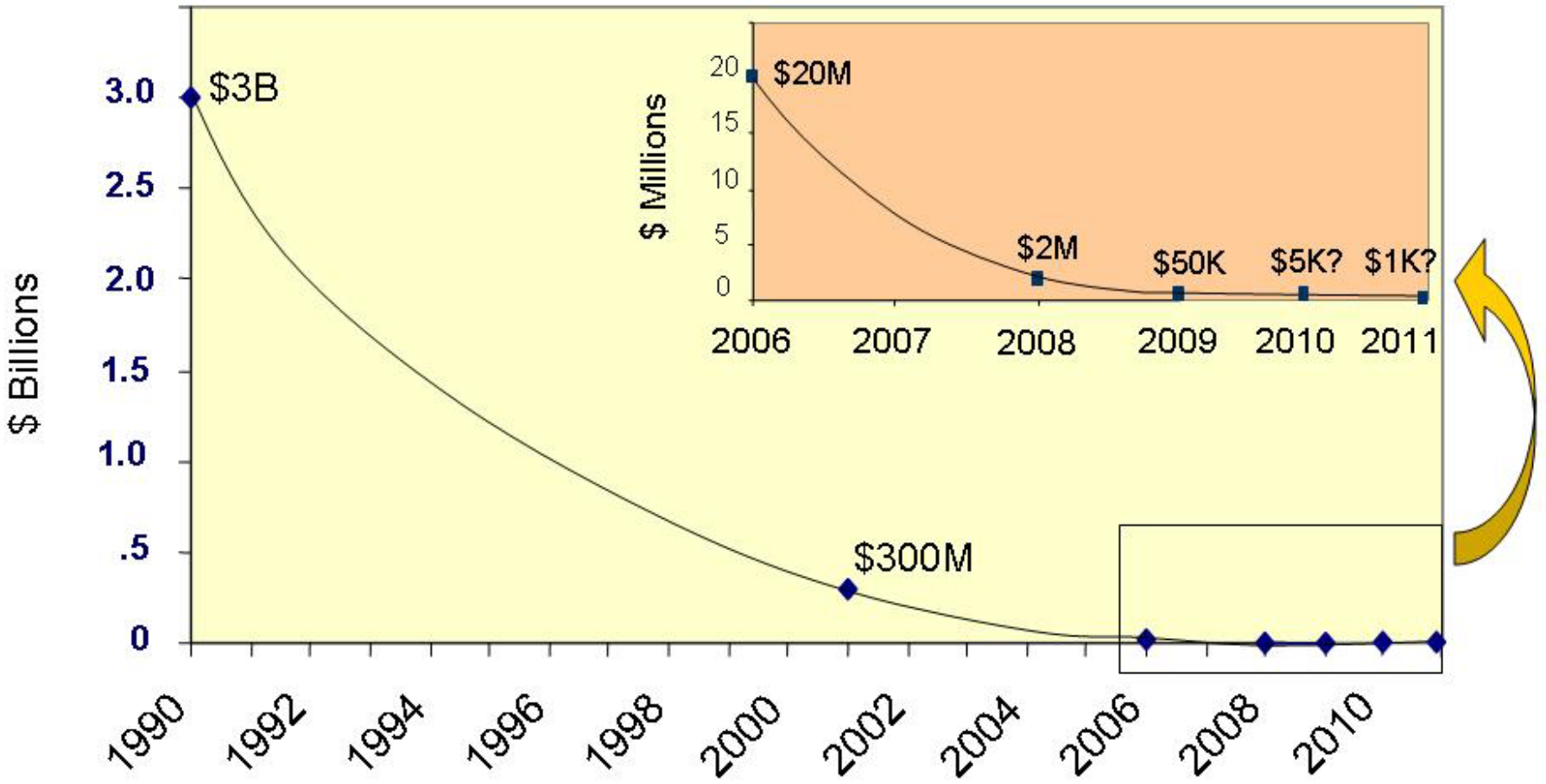


Plavix Active Metabolite

25 million prescriptions in 2007

FDA black box warning (March 12, 2010): 14% of patients have a "slow" variant of cytochrome P450 enzyme CYP2C19 and an increased risk of complications or death (1.5x to 3x). ***Genetic testing is suggested***.

Game Changer?
Declining Cost of Sequencing Genomes



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Personalized Medicine:

How Will It Affect Healthcare?

Changing Role of the Patient

- Greater knowledge of one's genetic risks
- Actionable lifestyle prescription for reducing risk of disease
- Greater control and patient-centered access to medical records
- Treatment decisions will be improved by patient education

Changing Role of the Healthcare Provider

- Physician as manager, rather than repository of medical knowledge
- Greater reliance on HIT for decision support
- Improved care through use of aggregate patient data
- Highly networked, team-based care
- New ethical and legal issues/quandaries

New Business Strategies for Pharma

- Uncertain economics of drug development and commercialization
- Regulatory mandates could disrupt development budgets and market plans
- “Personalization” of drugs will require partnering with diagnostics companies

New Demands On and From Payers

- Greater emphasis on clinical validity and utility of diagnostic tests
- Increased need to demonstrate cost efficiencies
- Proactive strategies to limit reimbursement
- Increased pressure to change paradigm towards preventive medicine

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Personalized Medicine Coalition:

An Agent of Change

Addressing Public Policy Issues

The potential impact of Personalized Medicine is very broad and far-reaching. There are an array of issues facing us:

- Regulation
- Reimbursement
- Comparative effectiveness research
- Physician education and adoption
- R&D incentives
- Intellectual property
- Privacy / Ethics
- Patient education

Personalized Medicine Coalition

The Personalized Medicine Coalition, representing a broad spectrum of academic, industrial, patient, provider, and payer communities, seeks to advance the understanding and adoption of personalized medicine concepts and products for the benefit of patients.

Personalized Medicine Coalition

The Personalized Medicine Coalition

To learn more, visit:

www.PersonalizedMedicineCoalition.org