

# It Is All About The Adoption... More Than a Mantra

David Barone

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[www.bmtadvisors.com](http://www.bmtadvisors.com)

[www.bmtCROgroup.com](http://www.bmtCROgroup.com)

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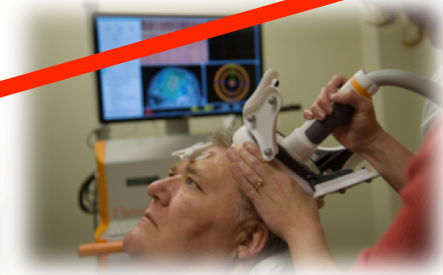
# Medical Device Industry Health Report 2014

- Projected CAGR ~5% through next 10 years
- Top 15 companies control >80% market share
- Leaving >\$60B to all other companies; >\$85B by 2020
- US is still and will remain the most important market
  - Size, innovation, leadership / impact, pricing
  - 12 out of top 20 companies are US; 7 - EU based; 1 – Japan
- Innovation is still strong; 3,000+ 510(k) / year
- M&A: Stronger than ever
  - Deals value are up, but
  - Deals volume are down
  - Large exits: 50% w/ FDA approval; 25% CE; 25% development



# Time-To-Market Is Increasing....

Years

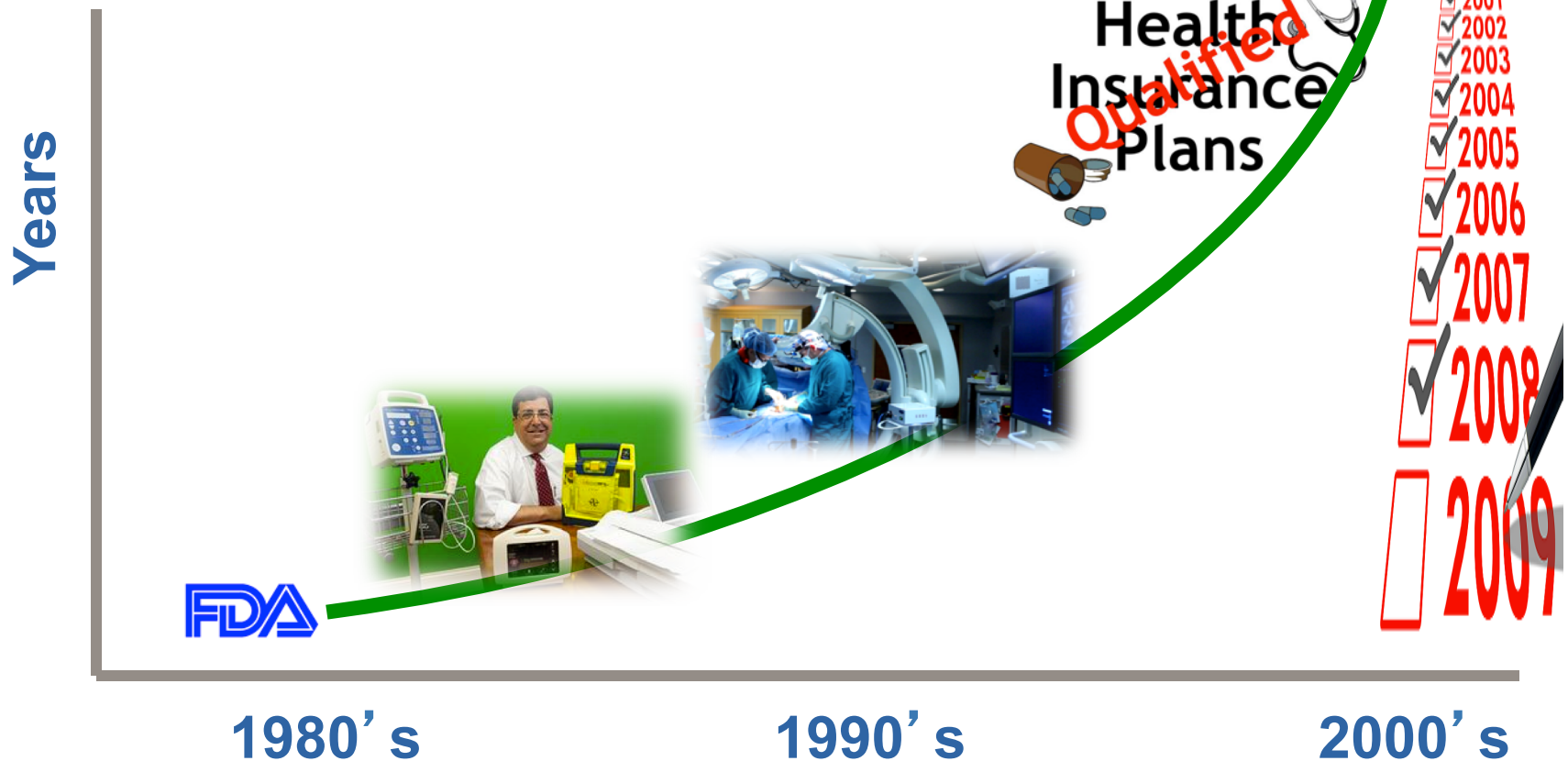


1980' s

1990' s

2000' s

# ...But The Big Story... The Increase In Time-To-Market Acceptance





# Longer Time-To- Adoption Has Considerable Implications

**Delayed revenue**

**Need for additional funds and financing rounds**

**Valuations are negatively impacted**

**Business development initiatives are delayed**

**Increased risk of new competitors**

# What Changed During the Last 20 Years?

Resistance to  
change

Providers are  
vested in current  
technologies and  
practices

Greater competition

Multiple decision  
makers with  
conflicting interests

Changing  
economic  
incentives

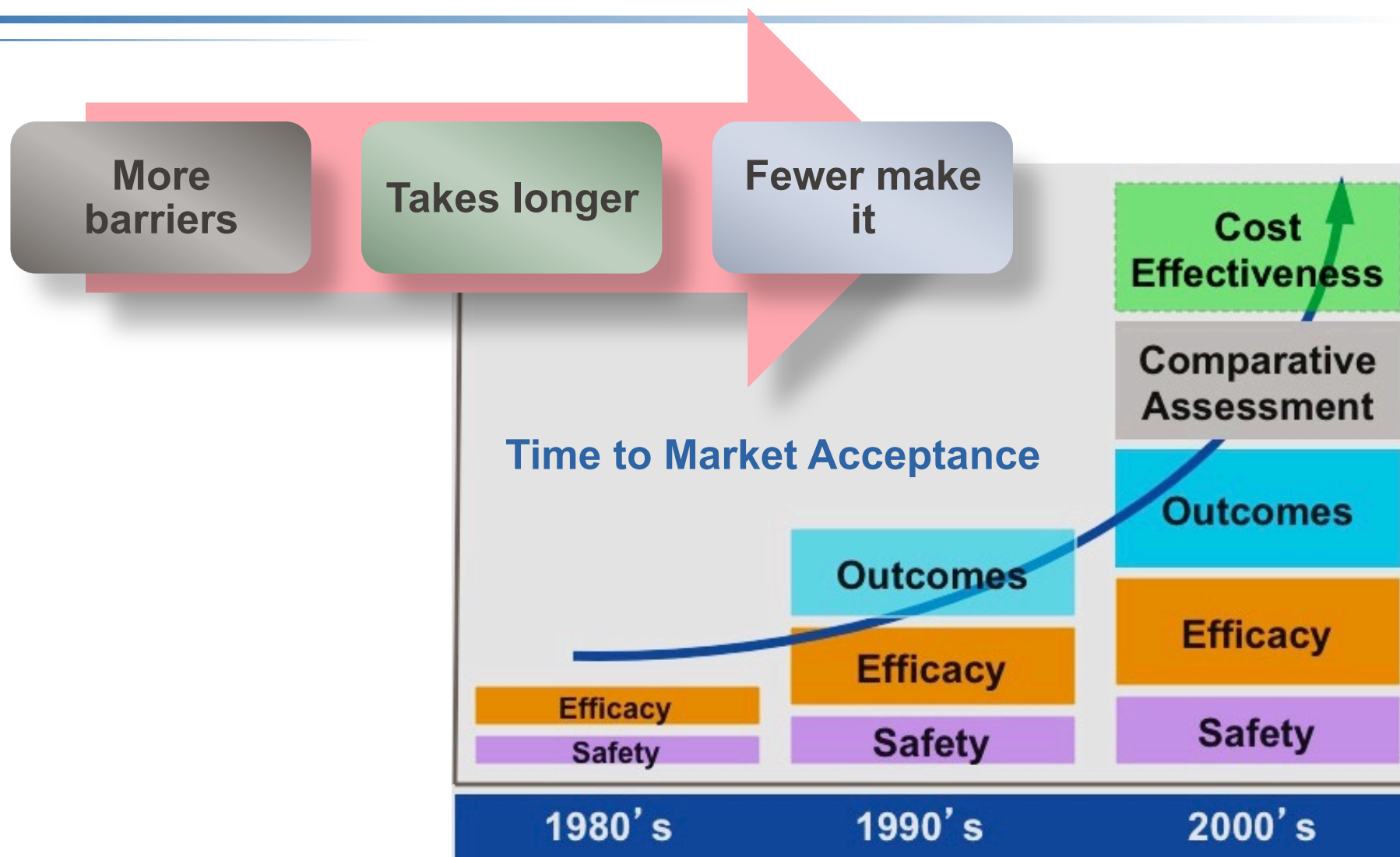
Evidence-based  
medicine... looking  
for more evidence

Slow acceptance  
by payers

Incremental  
features and  
benefits do not  
justify change

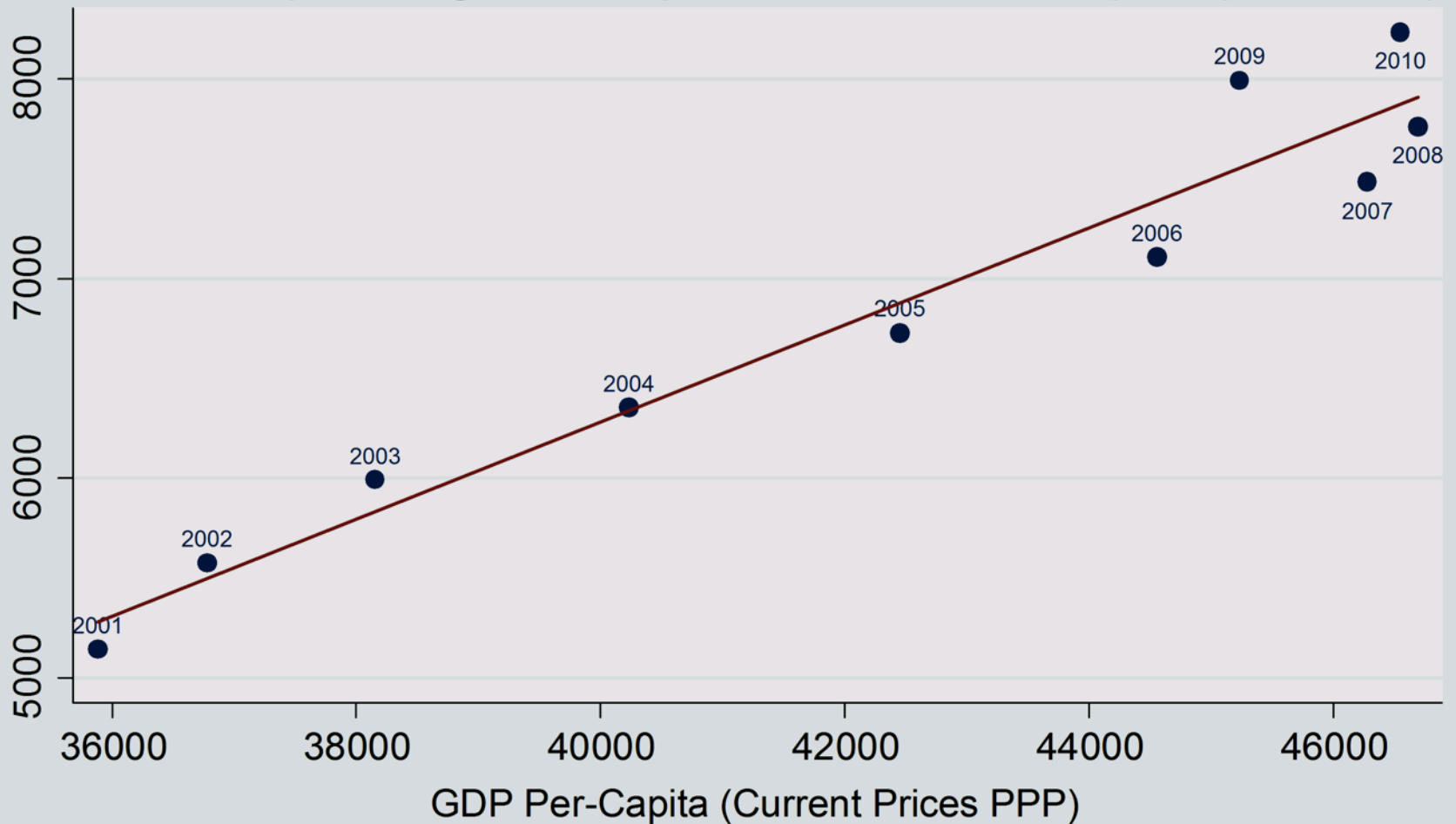
Politics

# While Healthcare Markets Continue to Grow...



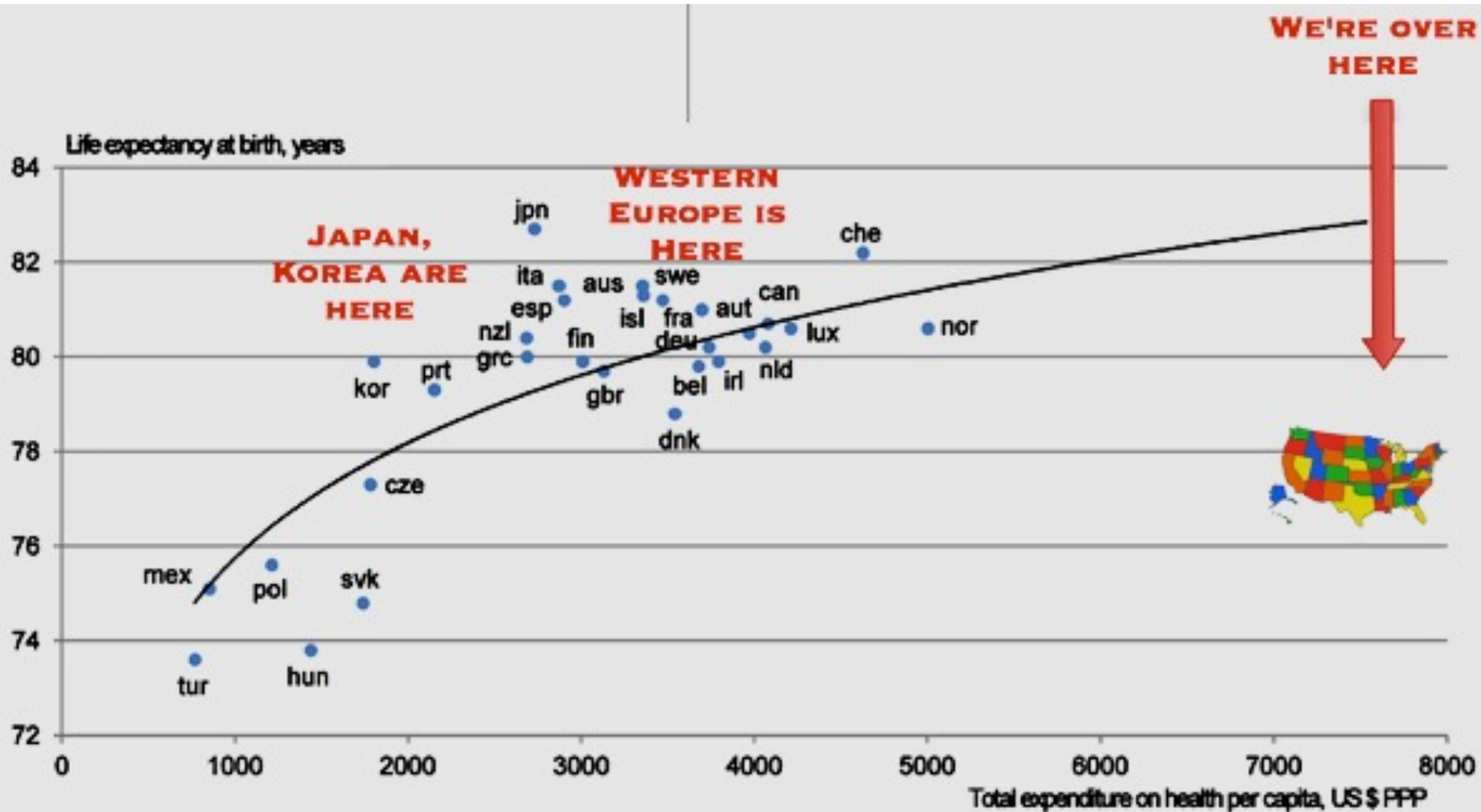
# MORE CHANGES IN STORE...

# Health Spending Per-Capita & GDP Per-Capita (2001-10)



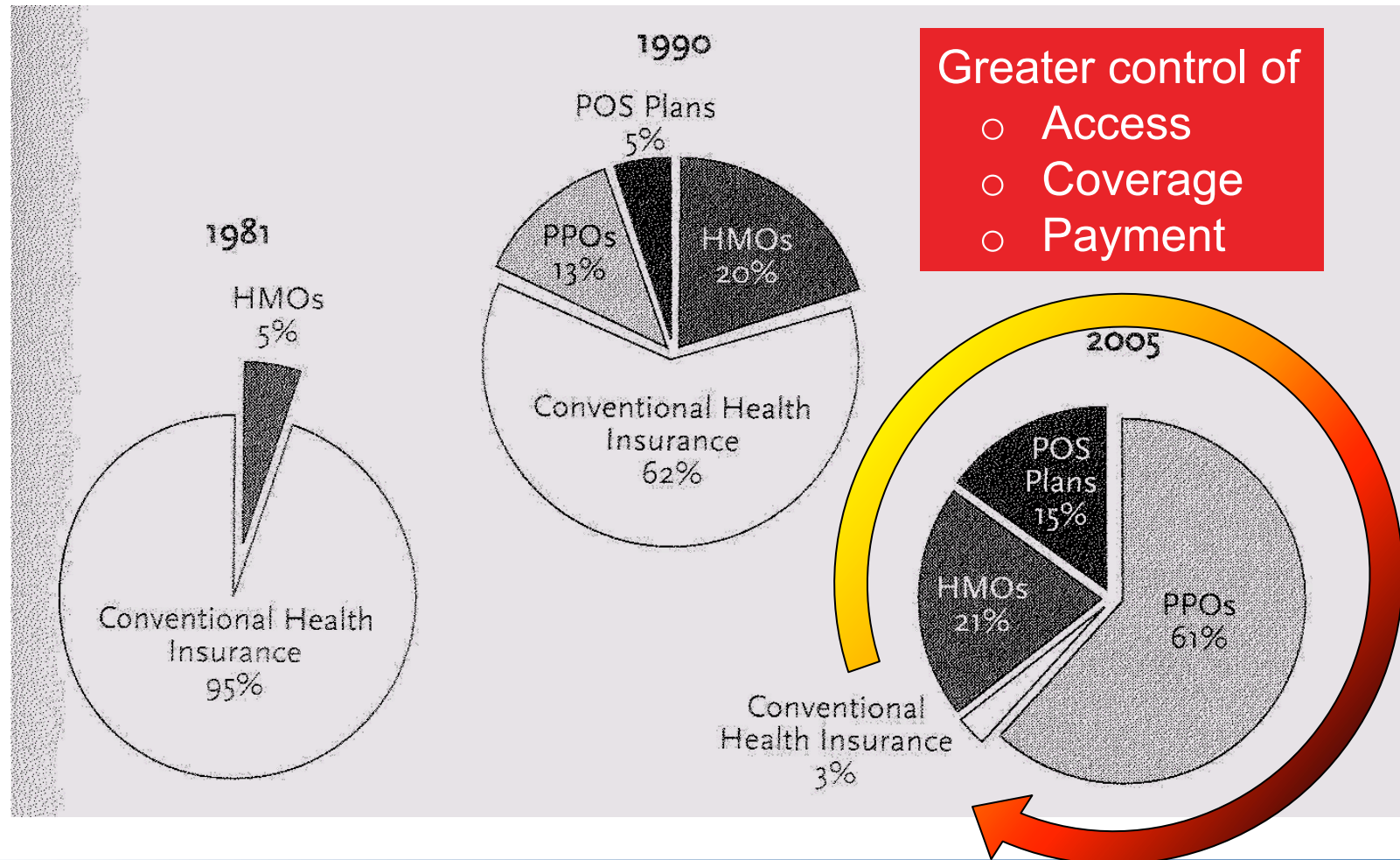
● Per-Capita Health Spending

# Do Outcomes Justify the Cost?





# Payers Required a Change to Managed Care



# But Healthcare Spending Continue to Exceed GDP

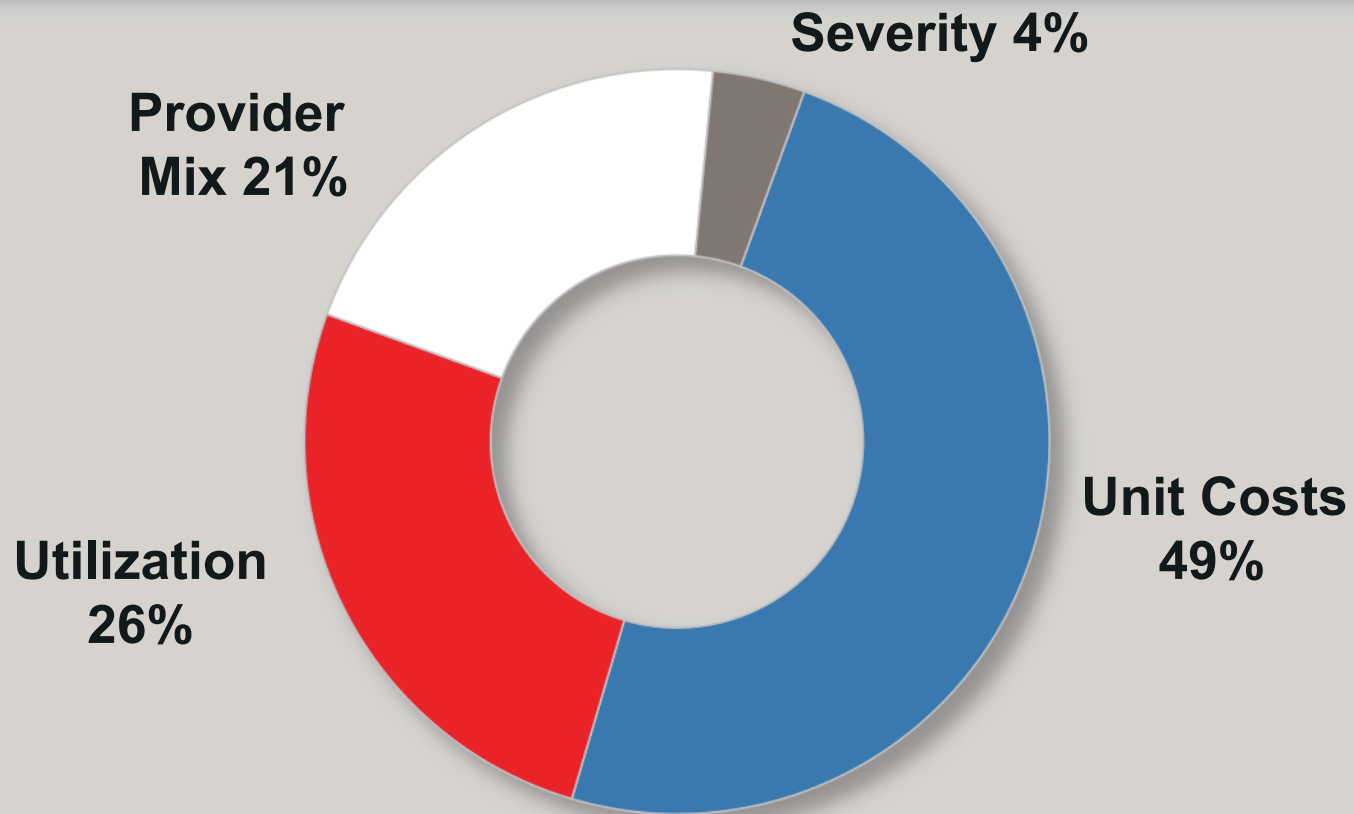
Figure II  
Real Per Capita Growth in GDP and Health Care Spending  
(Trailing 10-year average)



Source: Author's calculations based on Bureau of Economic Analysis data.

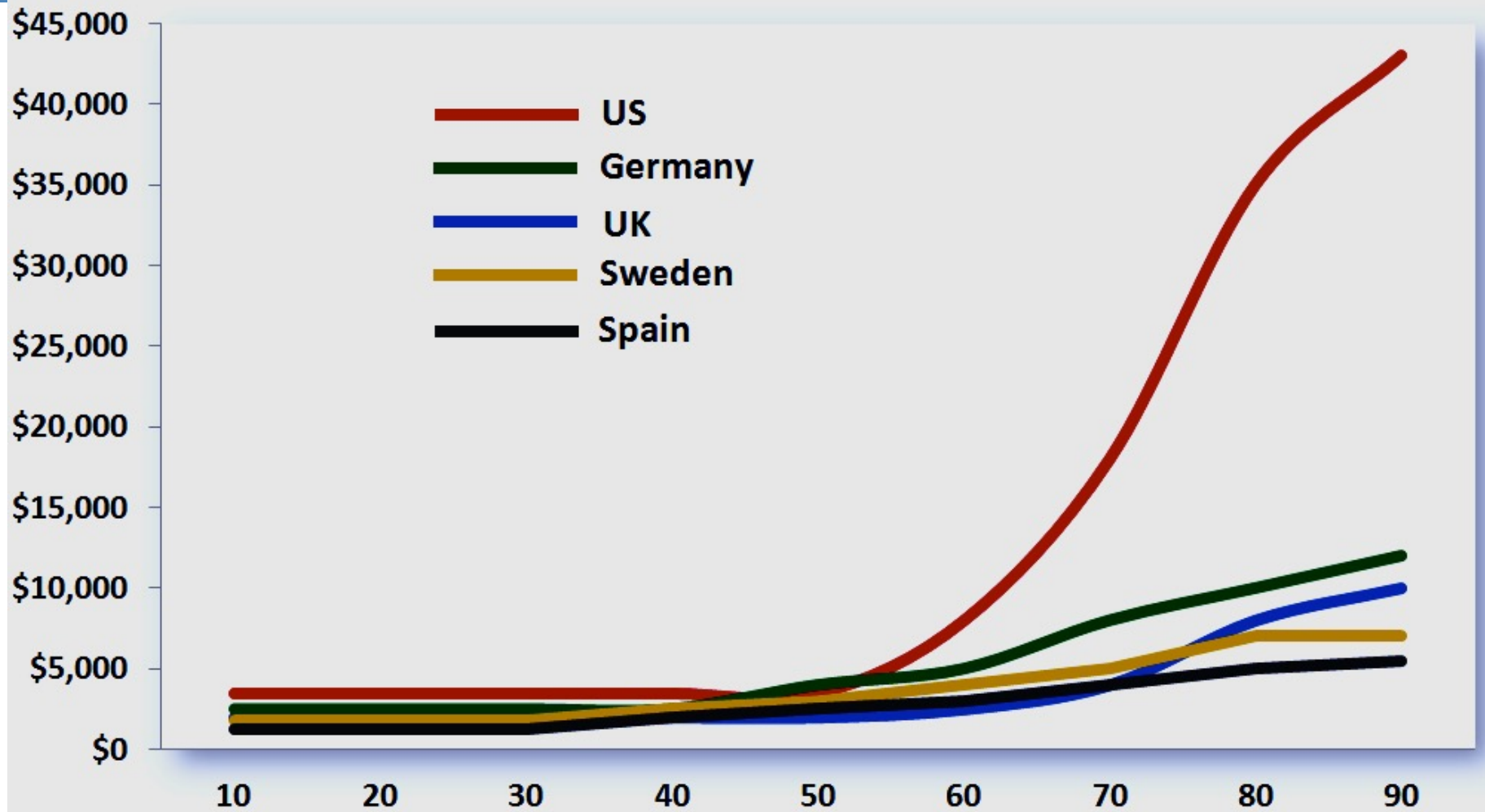


# Cost Drivers



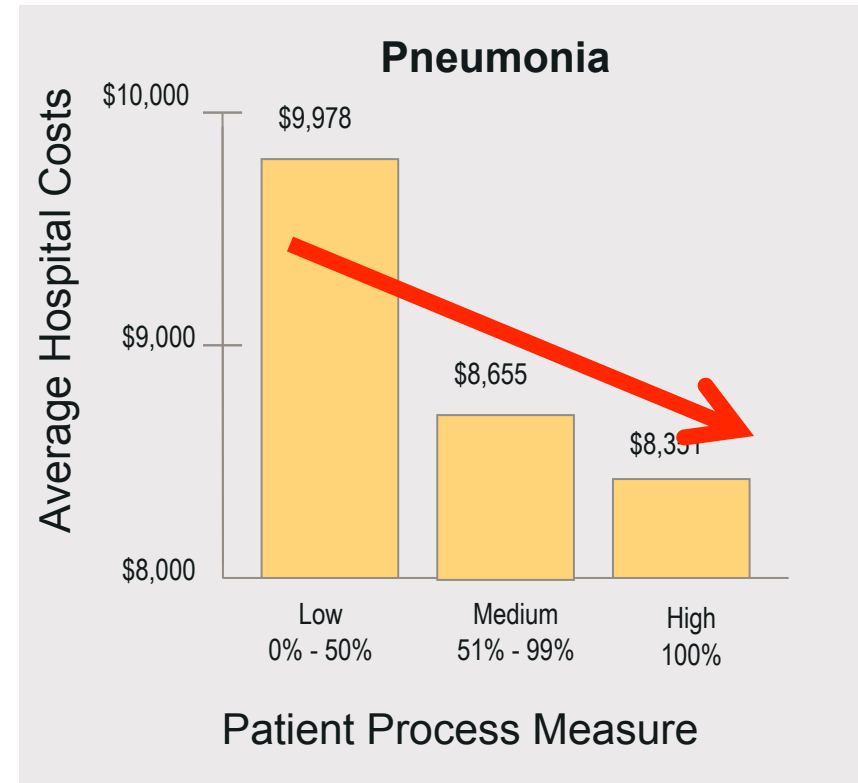
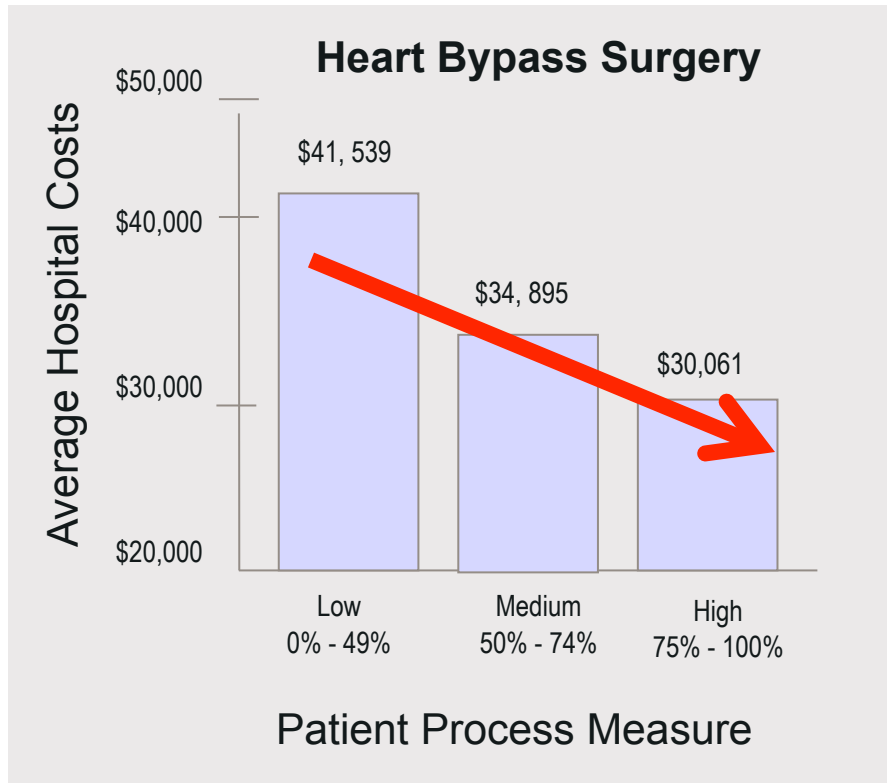
Source: BCBSMA Actuarial & Analytic Services.

## Annual Per Capita Healthcare Costs by Age



# Performance Pays Off

Cost



Quality

# Experts Agree...

Rate reviews cannot fundamentally address the growth of health care costs...



PHOTO: THINKSTOCK

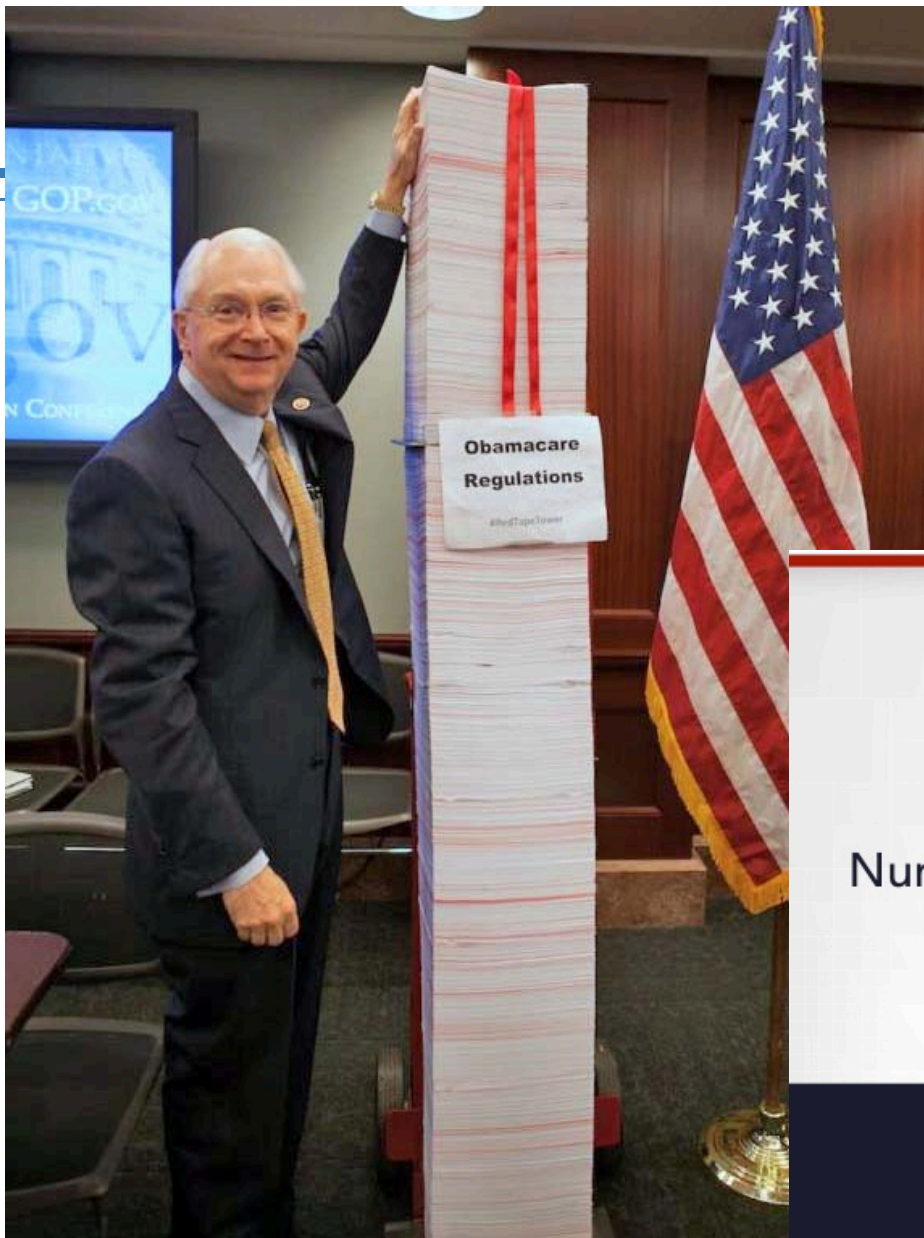
...costs must be addressed through payment reform, delivery system changes, an emphasis on prevention and consumer engagement.

National Association of Insurance Commissioners letter to Congress February 23, 2010

# Patient Protection and Affordable Care Act (2010)







# 10,000+

Number of pages of Obamacare regulations  
(eight times longer than the Bible).

SOURCE: Competitive Enterprise Institute



U.S. CHAMBER OF COMMERCE

# Many Reforms and New Initiatives

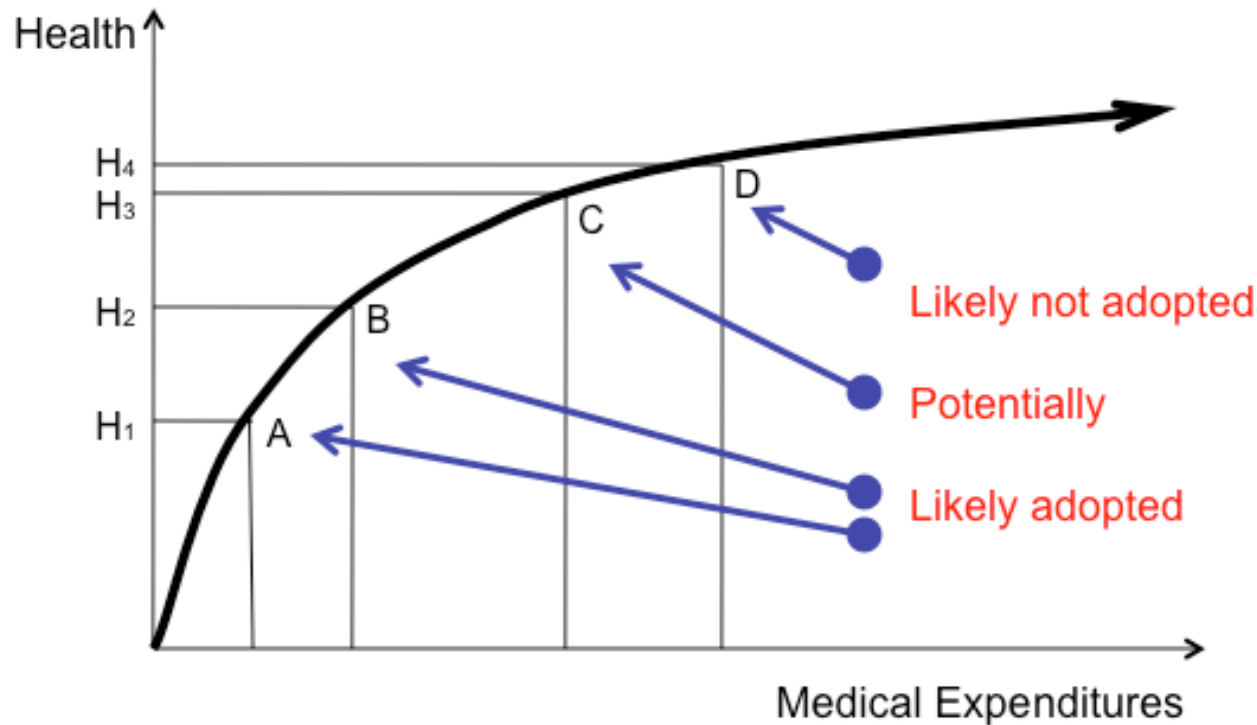
- **Value-Based Purchasing (VBP) Program**
  - reward value and patient outcomes, instead of just volume of services
- **Reduced Payments for Hospital Acquired Conditions** - Stop paying for certain conditions developed while the patient is hospitalized
- **Accountable Care Organizations (ACO)** - shift from fragmented and inconsistent care to coordinated care and measured performance
- **Payment Reforms** - incentivize Quality, not Volume



$$\text{Value} = \frac{\text{Quality (Outcomes, Safety, Service)}}{\text{Cost}}$$

# Value-based purchasing

**Devices pricing will be based on ability to remove costs from the system**





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# Implications to Medical Device Companies

# Time To 'Market Acceptance' is Increasing





# ADOPTION ~~IT'S THE ECONOMY STUPID!~~



# We Have a New Landscape

- |                                       |                                  |
|---------------------------------------|----------------------------------|
| ➤ <b>Volume based incentives</b>      | ➔ <b>Value based / outcomes</b>  |
| ➤ <b>Individual providers</b>         | ➔ <b>Providers consolidation</b> |
| ➤ <b>Fee-for-service</b>              | ➔ <b>Bundled care</b>            |
| ➤ <b>Payers assume financial risk</b> | ➔ <b>Payers &amp; providers</b>  |
| ➤ <b>Site of service hospital</b>     | ➔ <b>Least expensive</b>         |
| ➤ <b>Documenting care</b>             | ➔ <b>Coordination of care</b>    |
| ➤ <b>Brand defines quality</b>        | ➔ <b>Quality defines brand</b>   |
| ➤ <b>Device selected by physician</b> | ➔ <b>System decisions</b>        |

# What Do We Need To Learn Early On?

## Who is the first market?

- Who will be our initial target?
- Check with all the right people, not only MD's

## Benefits

- Improved patient care and/or delivery of care
- How does our solution compare with the current standard-of-care?

## Standard of care

- Guidelines
- What actually happens in the field, why?

## Regulatory

- Need to understand the strategy at the very outset of product development

## Reimbursement

- Cost and effectiveness of existing alternatives
- Availability and level of payments for similar devices
- Codes and payments for professional and institutional services

## Clinical studies

- Roadmap beyond regulatory approval

# How To Spend Early Funds?



- **Find out the barriers**
- **Develop a roadmap**
- **Reduce the primary risks**

## Common mistakes:

- No clear understanding / rationale of first target market, or picking the wrong market
- Using funds to refine prototype designs (beyond proof of concept)
- Under investing in IP
- Staffing up prematurely instead of relying on external experts (typ. Offering broader experience at lower cost than internal hires)
- Rushing to market before addressing market risks

# Transitioning To Sales

- **The old good days - (1) develop, (2) sell – are over**
- Make sure you have a scalable model before hiring sales force, signing national distributors or booking the 30'x30' booth
- **Without the proper evidence your ability to sell and scale are slim**
- First 2 years:
  - Understand your clinical and economic value
  - Is the product ready for prime time
  - What support services are needed?
- **Track meaningful metrics - #1: Repeat purchases**
- Don't jump to the water naked (w/o the skills and funds)



# A Few Myths

- **A great product will sell itself...**  
*sorry, it will not...*
- **We are not good at marketing, so once we get the 510k we will sign the right distributor...** *and you really expect them to do your work?...*
- **We don't have money, we need to be creative...** *cutting corners and still expect to make it?...*



# More Myths...



- **We will do the studies needed to get FDA / CE approvals and the early customers will do the rest...** *we can certainly hope this will be the case, but 'hope' is generally not a good plan...*
- **We do not need Business Plan...** *we really do not know what is our plan...*
- **Once we get money we will do the right staff...** *unfortunately investors want you to do the right staff before they give you the money ...*

