

VALUE IS THE NEW MANTRA

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BOSTON | GERMANY | ISRAEL

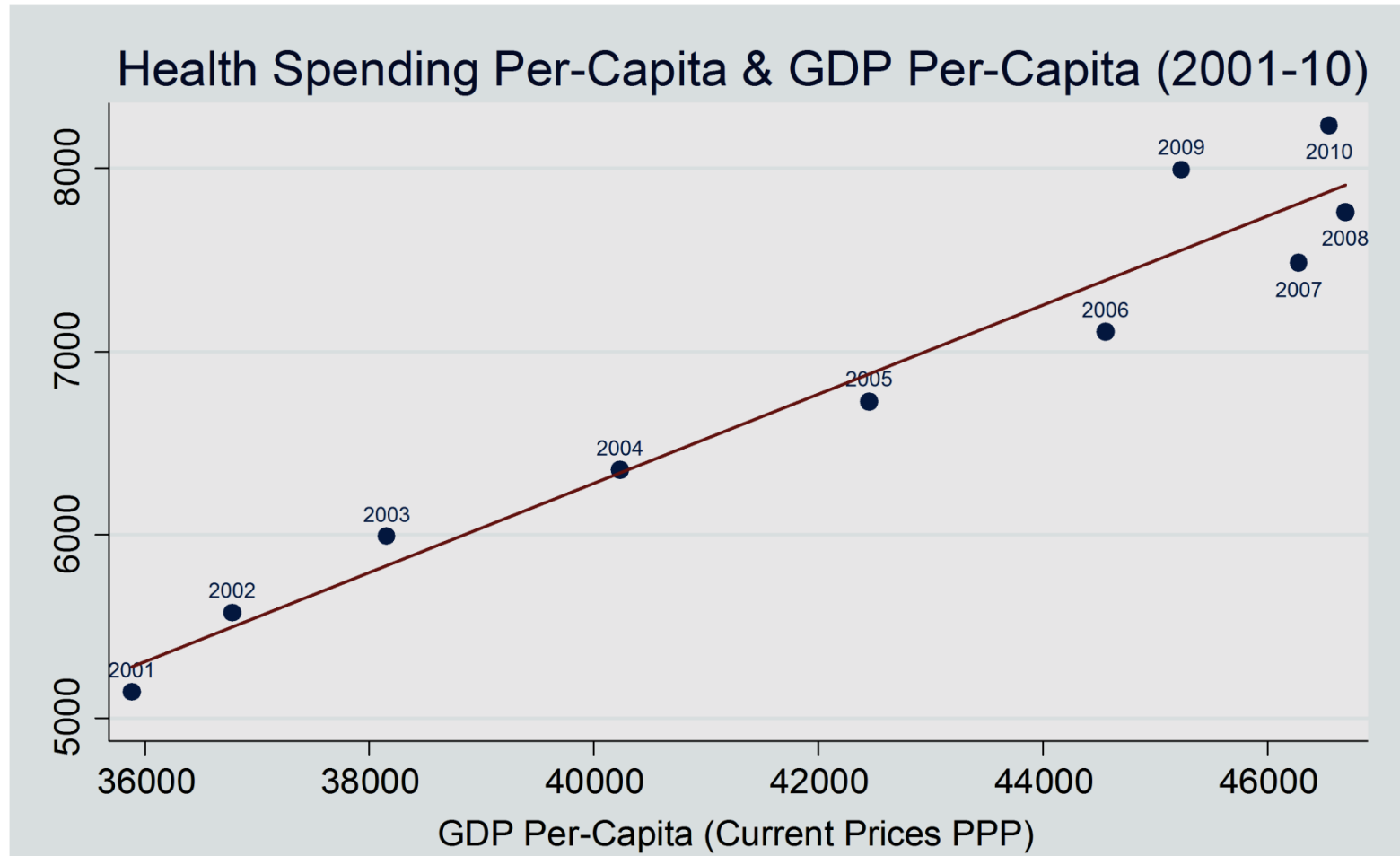
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Medical Device Industry - 2015

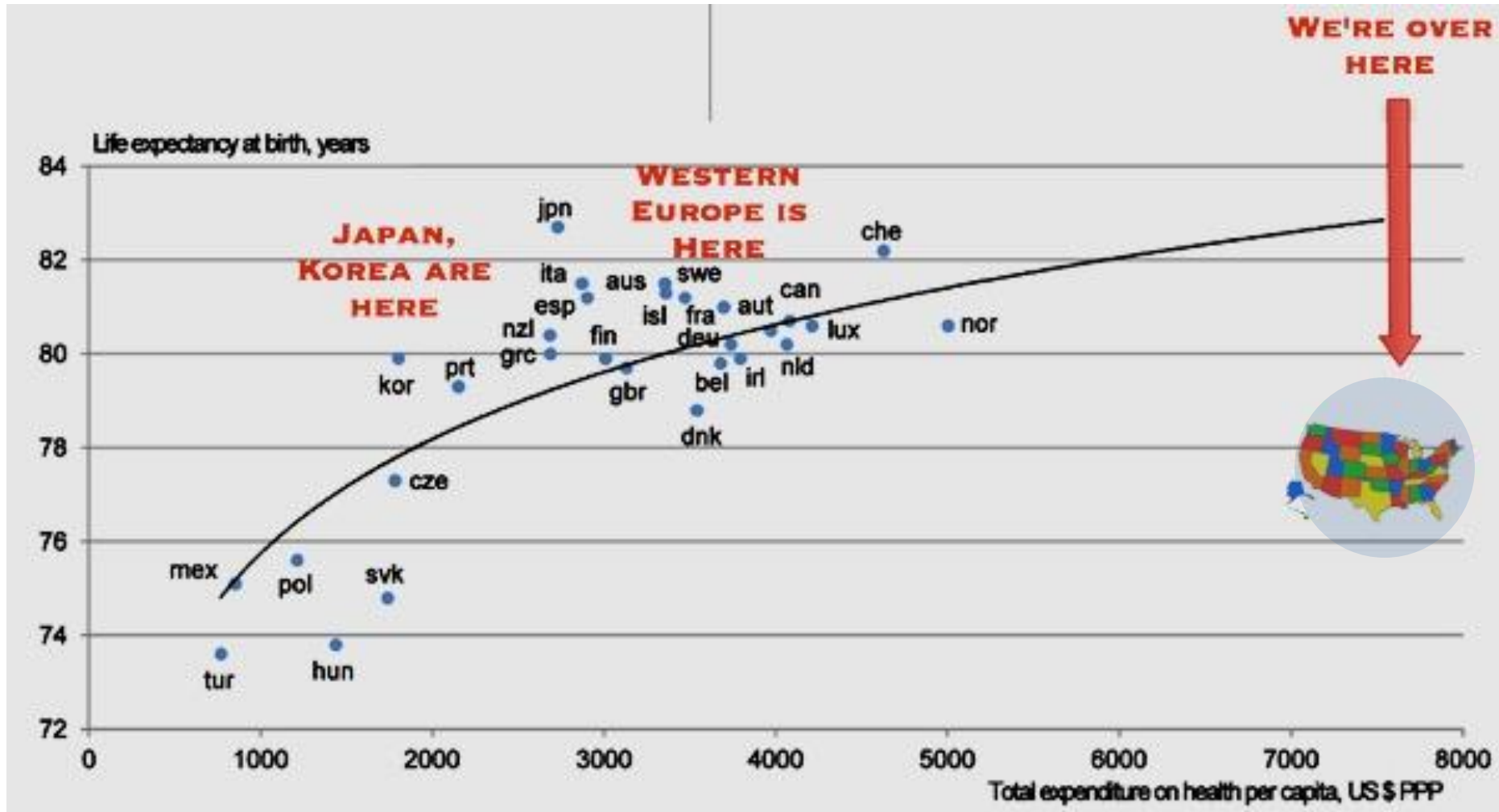
- Projected CAGR next 10 years ~5%
- US will remain the most important market
 - Size, innovation, leadership / impact, pricing
 - US – home of 12 out of top 20 companies; EU - 7; Japan – 1
- Innovation is still strong
 - 3,000 – 3,500 FDA approvals / year
 - >150,000 health apps (but 90%<5,000 users)
- Continuing M&A
 - Start-ups / small companies are the primary innovation pipelines
 - >50% w/ FDA approval
 - ~25% CE
 - ~25% development stage



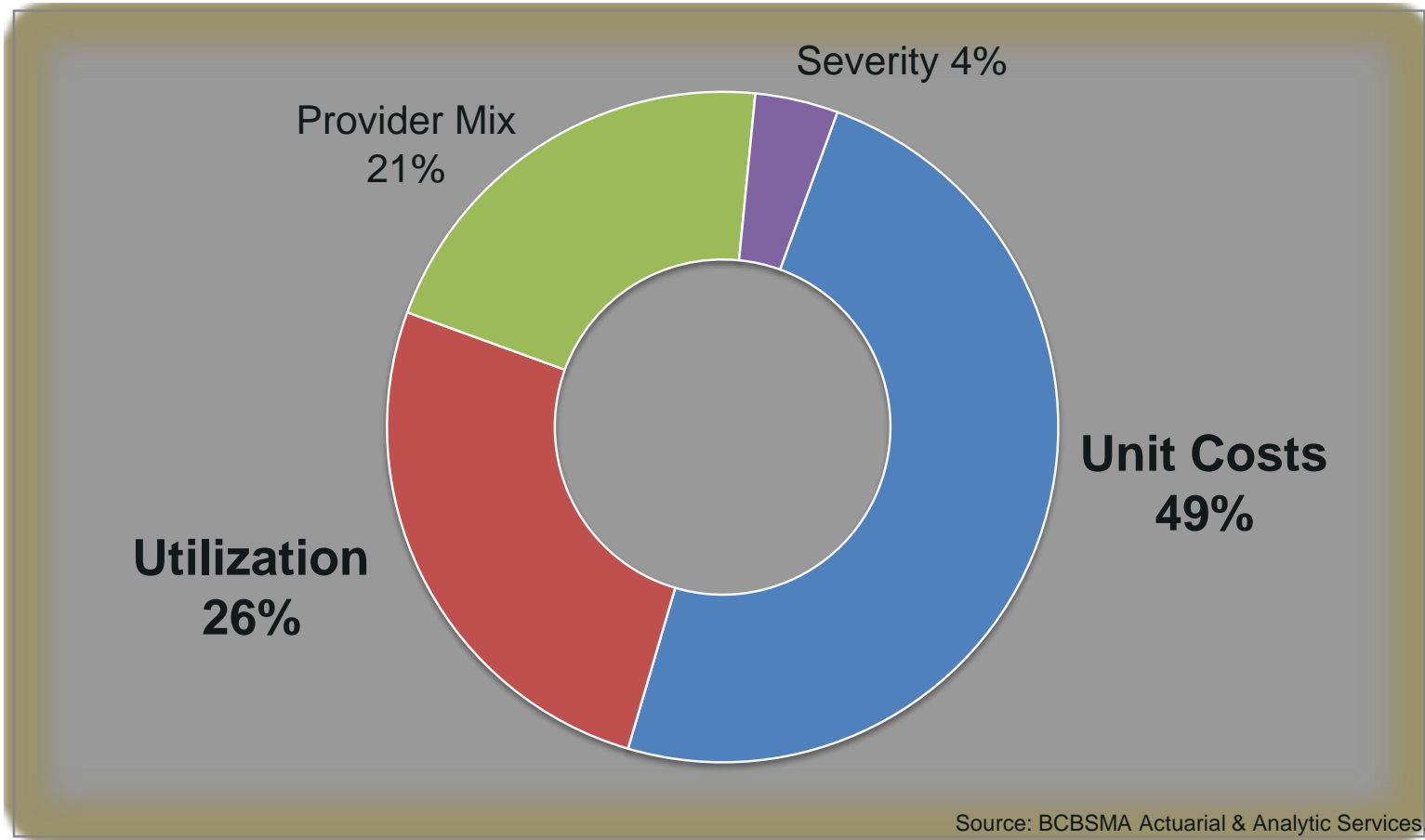
In the US Healthcare Expenses Keep Rising



But Higher Costs Do Not Provide Better Health

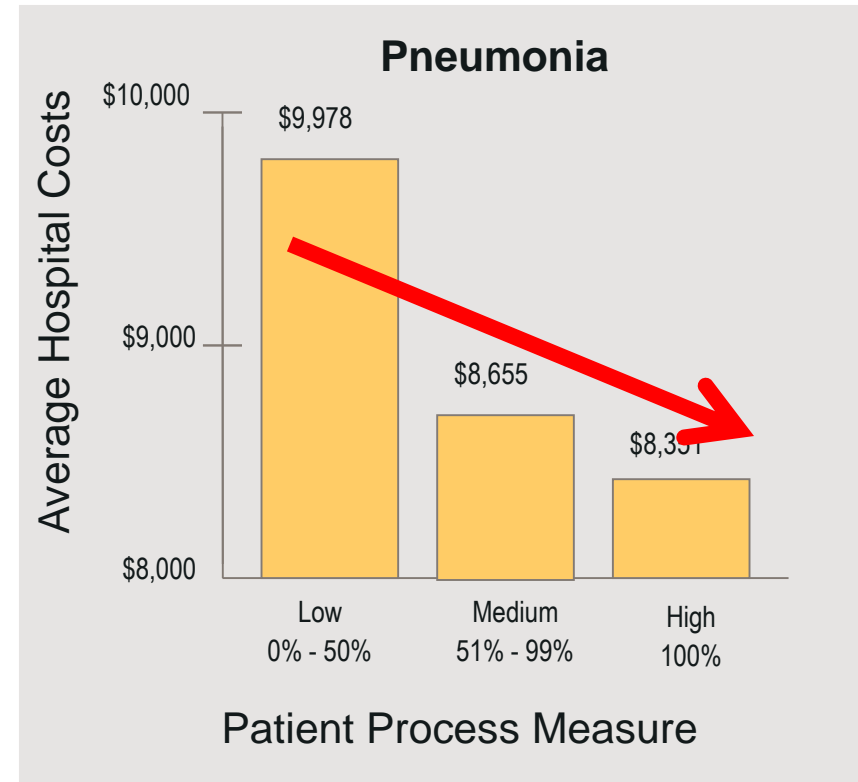
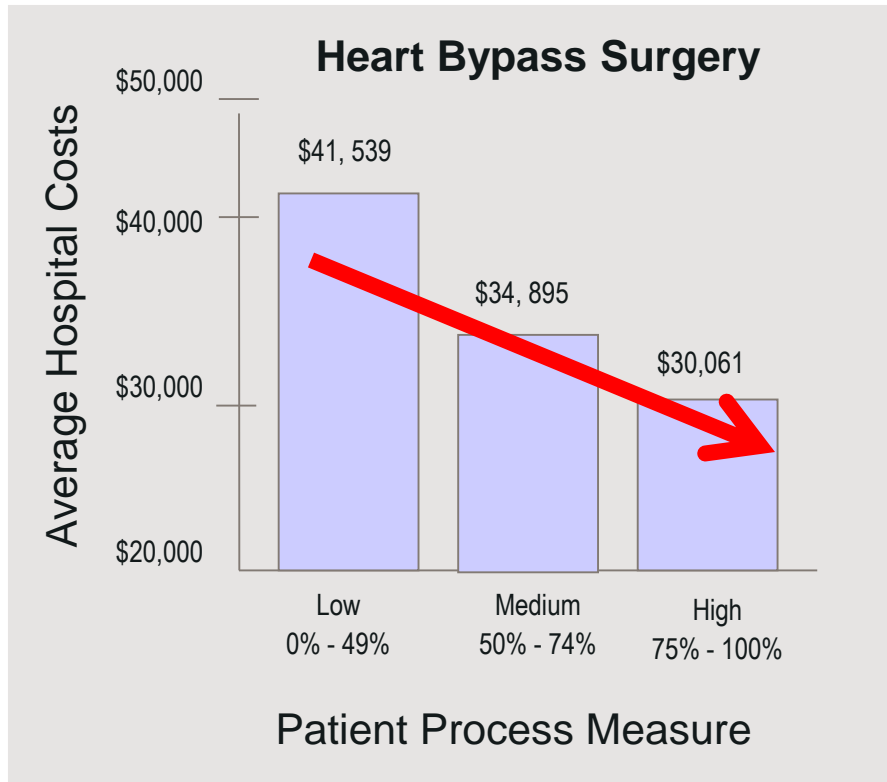


Cost Drivers



Performance Pays Off

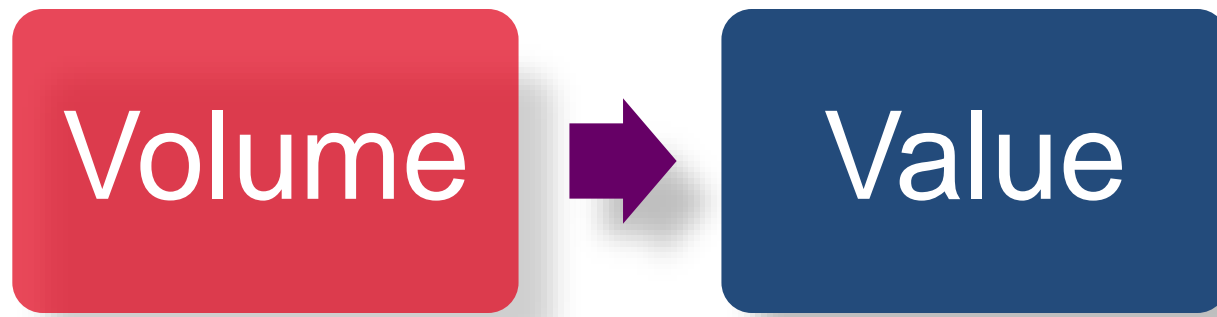
Cost



Quality

Patient Protection and Affordable Care Act (2010)





Many Reforms and Initiatives

- **Accountable Care Organizations (ACO)** - shift from fragmented and inconsistent care to coordinated care and measured performance

- **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

- **Hospitals Readmission Reduction Program** – reduce payments to acute care hospitals with excess readmission

- **Payment Reforms** - incentivize Quality, not Volume

We Have a New Landscape

Volume based incentives → Value based / outcomes

Fee-for-service → Bundled care

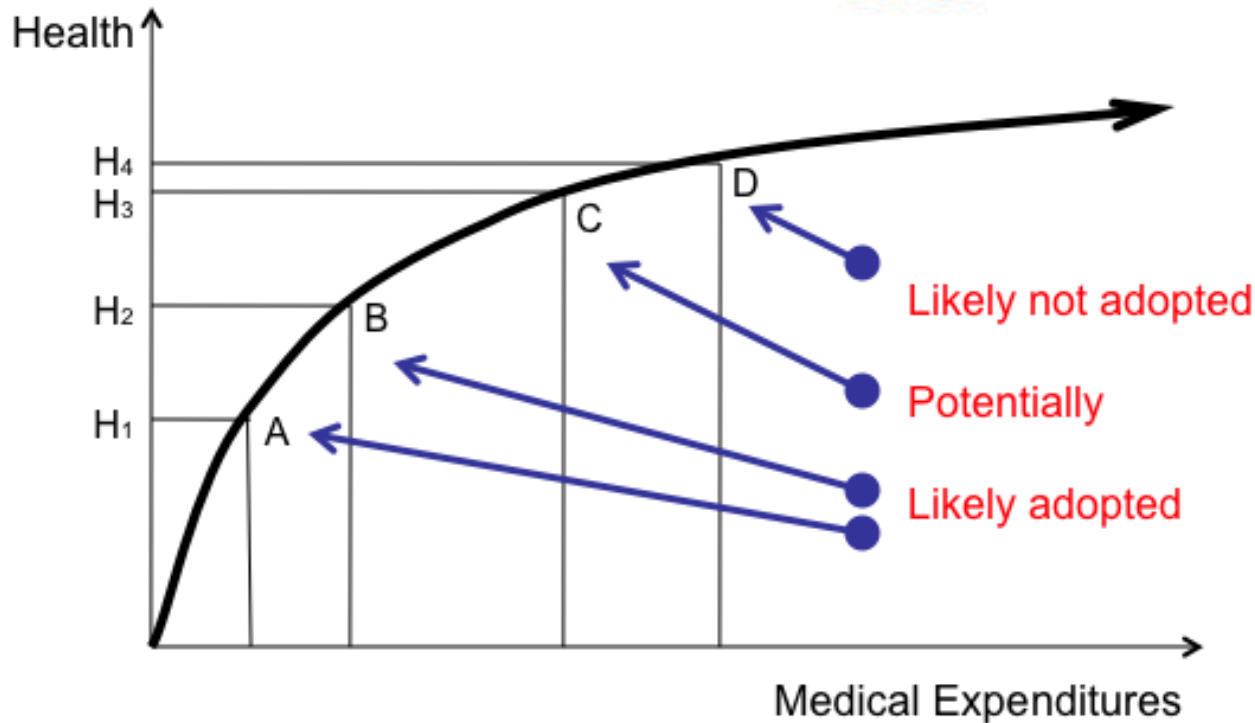
Payers assume financial risk → Payers & providers

Brand defines quality → Quality defines brand

Devices selected by physician → System decisions

Value-Based Purchasing

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



Devices, Drugs, and Diagnostic pricing will be based on ability to remove costs from the system

The Shift From 'Doing More' to 'Doing Better' Is Happening

- By 2018 50% of Medicare payments will move to alternative payment models like ACOs and bundled payment programs.

- By 2018 90% of all payments will be linked to quality or value
- Within 5 years fee-for service will decrease from 56% to 32%

- VBP (2015):
 - 1,714 hospitals will have their Medicare payments boosted (1,251 in 2014)
 - 1,375 hospitals will have their Medicare payments reduced

- 2012 – hospital Medicare readmissions declined by 150,000

What's Next? Money Back Guarantee?

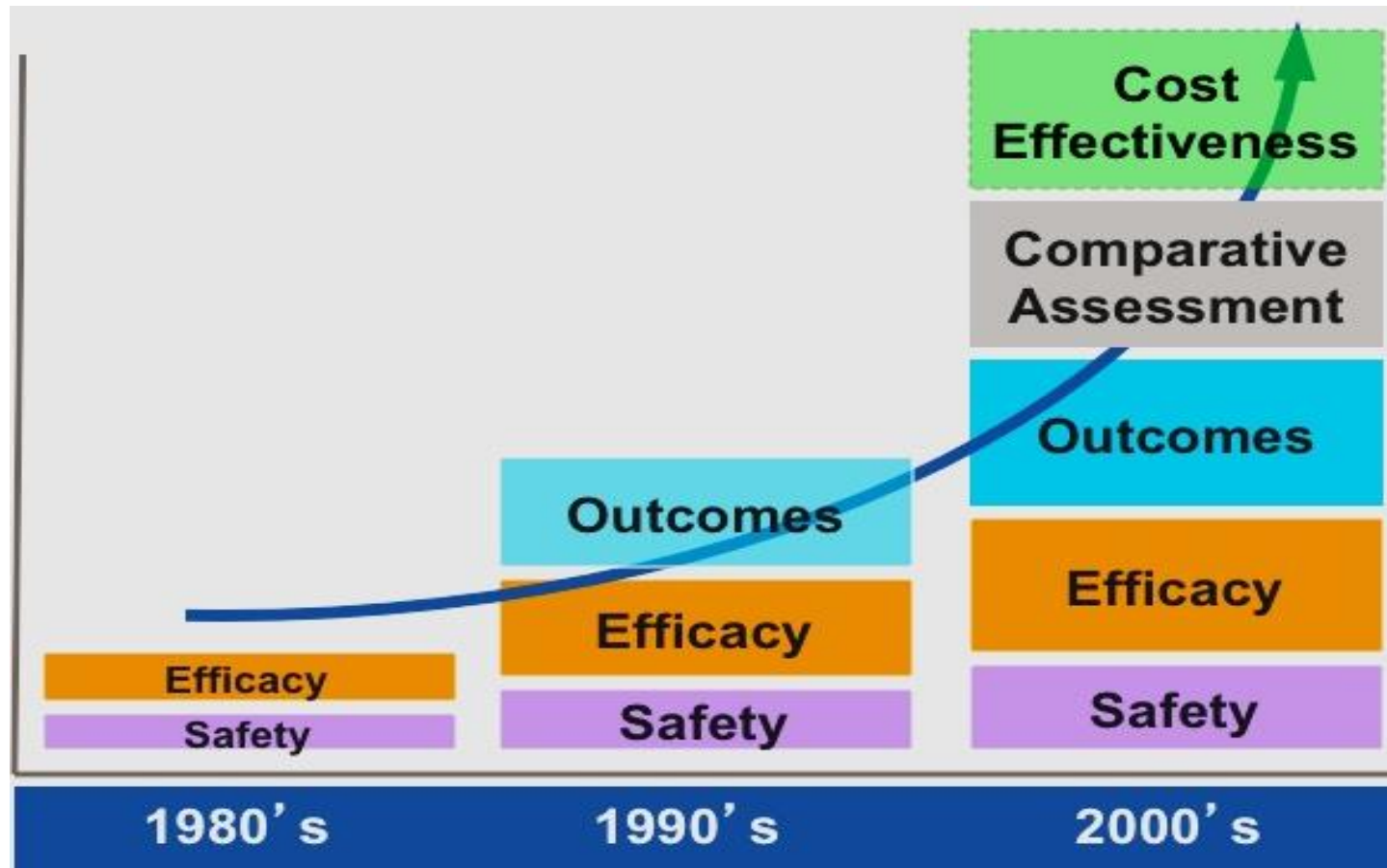
Changes in reimbursement models are rippling out to manufacturers of drugs and devices

“It is inevitable that drug and device makers’ reimbursement will eventually be tied to results.

If that’s the way the hospitals and doctors are going to be paid, then the people they do business with have to be prepared to get paid that way as well”

- Humana – 13 risk-sharing agreements with pharma companies (cancer, MS, diabetes, etc.)
- UnitedHealth – pay-for-performance deals for a new \$1,000 /pill hepatitis C drug
- ICU Medical promises that its connectors for central-line catheters will reduce occlusions. Pay hospitals back if they don’t.
- St. Jude will refund 45% of a cardiac resynchronization device cost if patients require corrective surgery.

While Healthcare Markets Expand, Time to Clinical Adoption Continues to Increase



What's going on?

Resistance to change

Greater competition

**Providers are vested
in current
technologies and
practices**

**Multiple decision
makers with
conflicting interests**

**Changing economic
incentives**

**Evidence-based
medicine... looking
for more data**

**Slow acceptance by
payers**

**Incremental features
not justifying change**

Politics

Longer Time-To- Adoption Has Considerable Implications

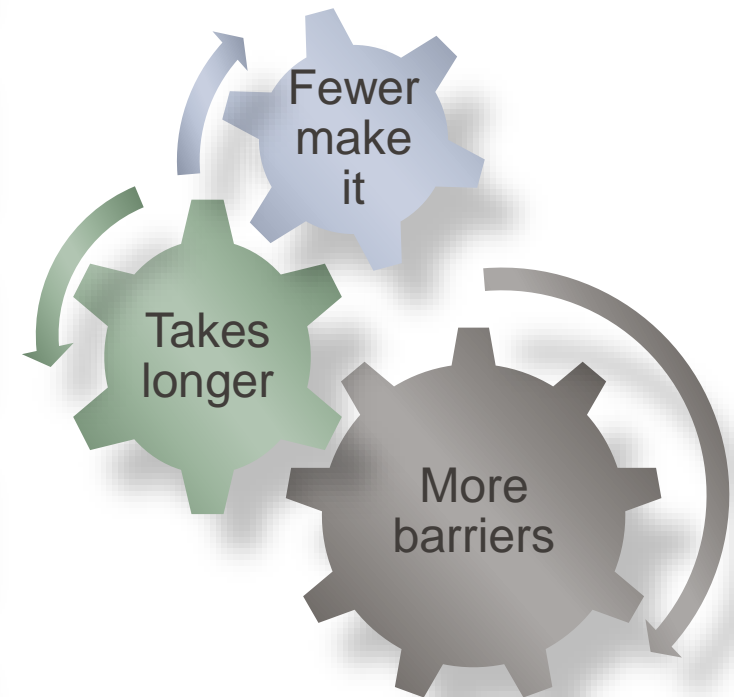
Delayed revenue

Need for additional funds and financing rounds

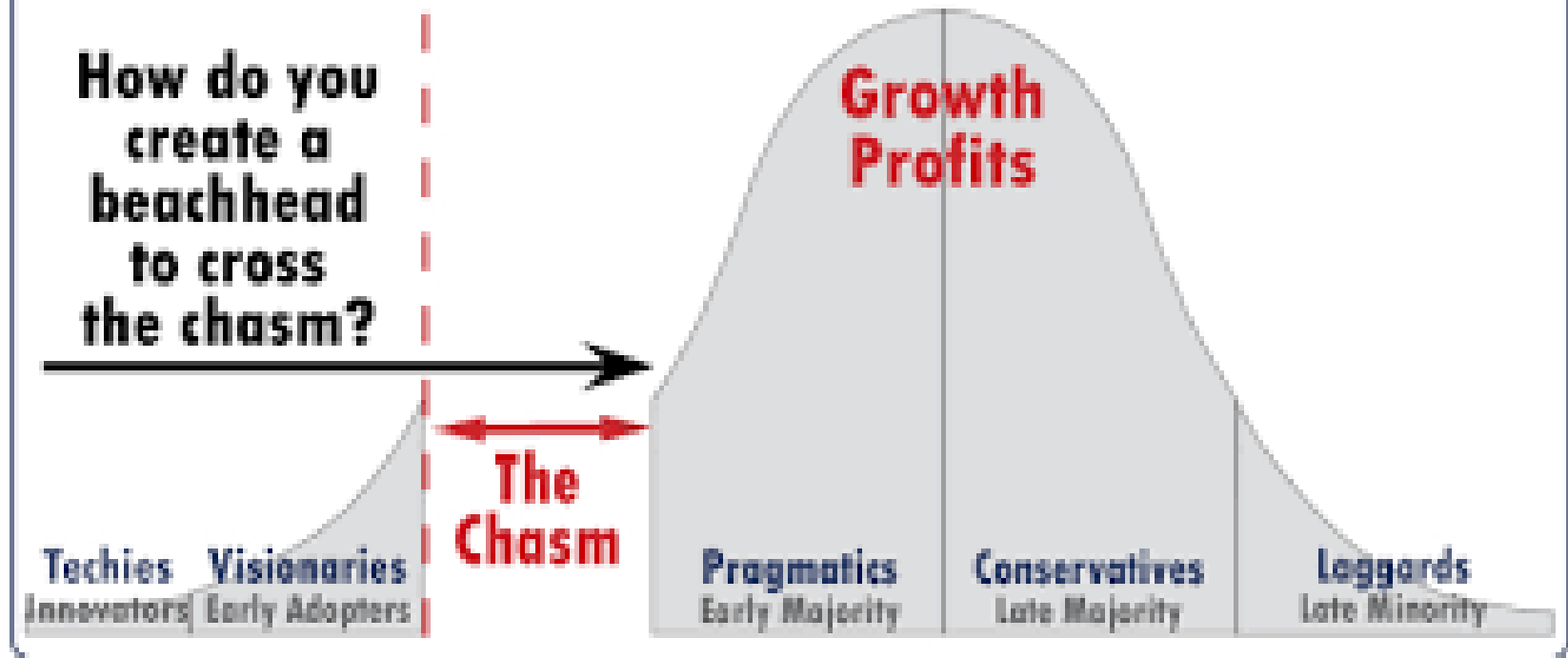
Valuations are negatively impacted

Business development initiatives are delayed

Increased risk of new competitors



Moore's Technology Adoption Life Cycle



Source: "Crossing the Chasm", Geoffrey Moore, Collins Business Essentials, 2004





novocure™

- Clinical Efficacy
- Clinical Pathways
- Pricing / Reimbursement
- Operating Model



When Are We Ready to Launch Sales?



Adoption of new technologies will require manufacturers to

- ✓ Ensure that the new device or drug is well integrated with workflow practices
- ✓ Demonstrate the value of the new products for healthcare providers and insurers
- ✓ How much money does the new drug / device save compared with other treatment options?
- ✓ Understand and demonstrate how much value a new device adds in terms of patient outcomes, and how does this compare with other alternatives?

Beware of the Myths



- We will do the studies needed to get FDA / CE approvals and the early customers will do the rest...
- We are not good at marketing, so once we get the 510k / CE we will sign the right distributor...
- A great product will sell itself...
- We do not need a Business Plan...
- Once we get money we will do the right things...
- We don't have money, we need to be creative...

