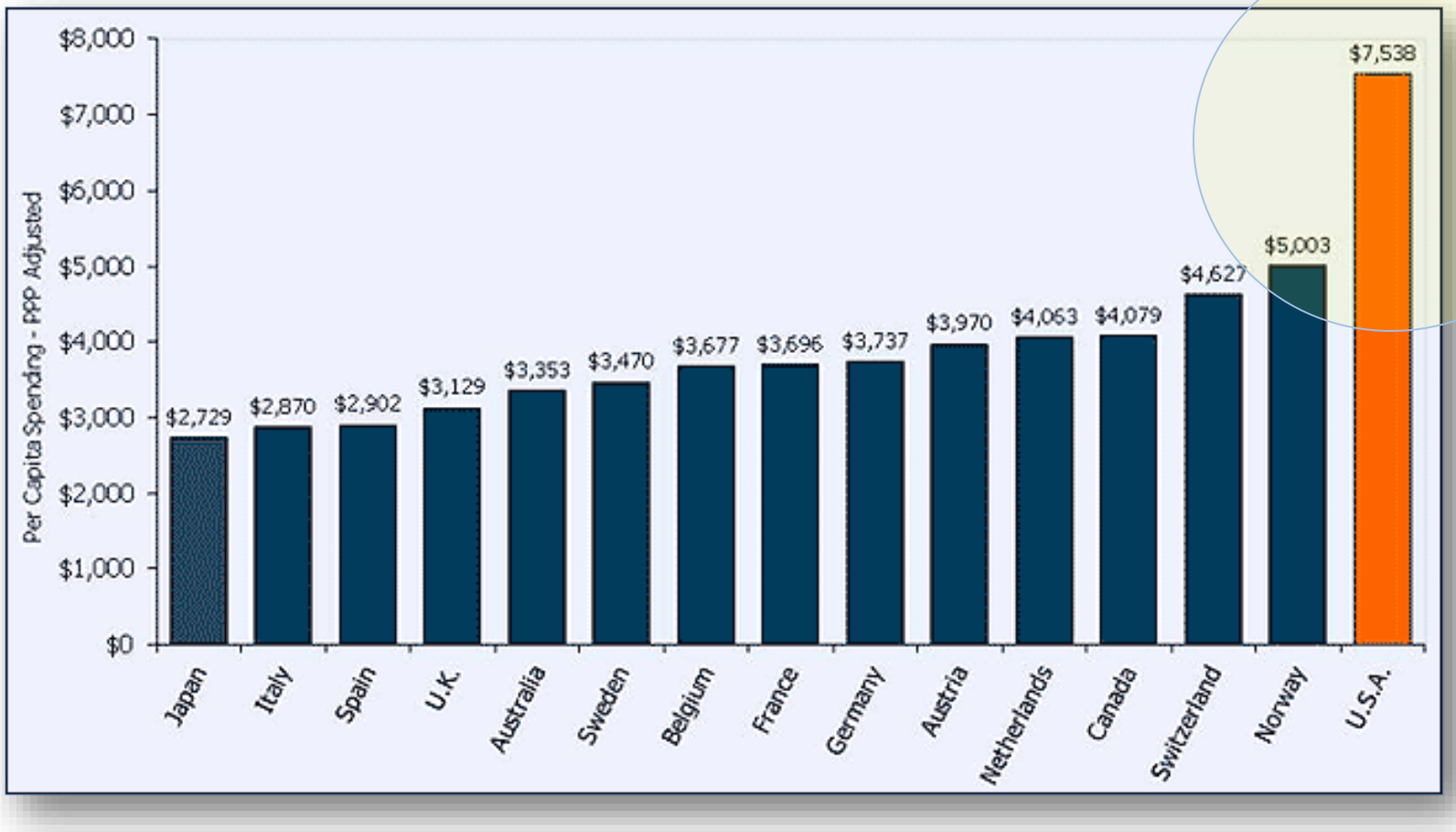
Changes in Reimbursement Environment (US) and Implications for Medical Device Companies

November 2013

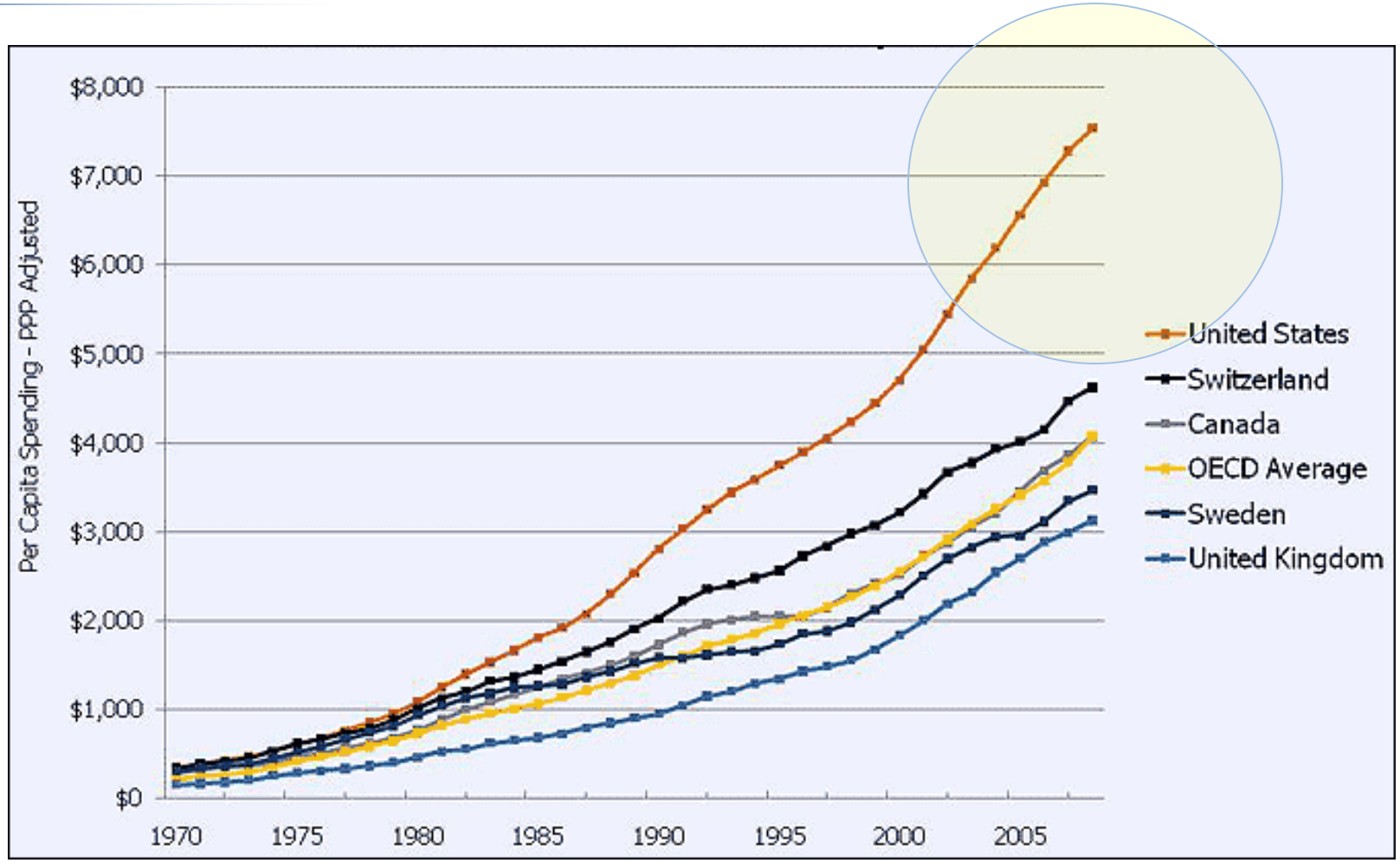
David Barone

US: Highest Health Expenditure per Capita



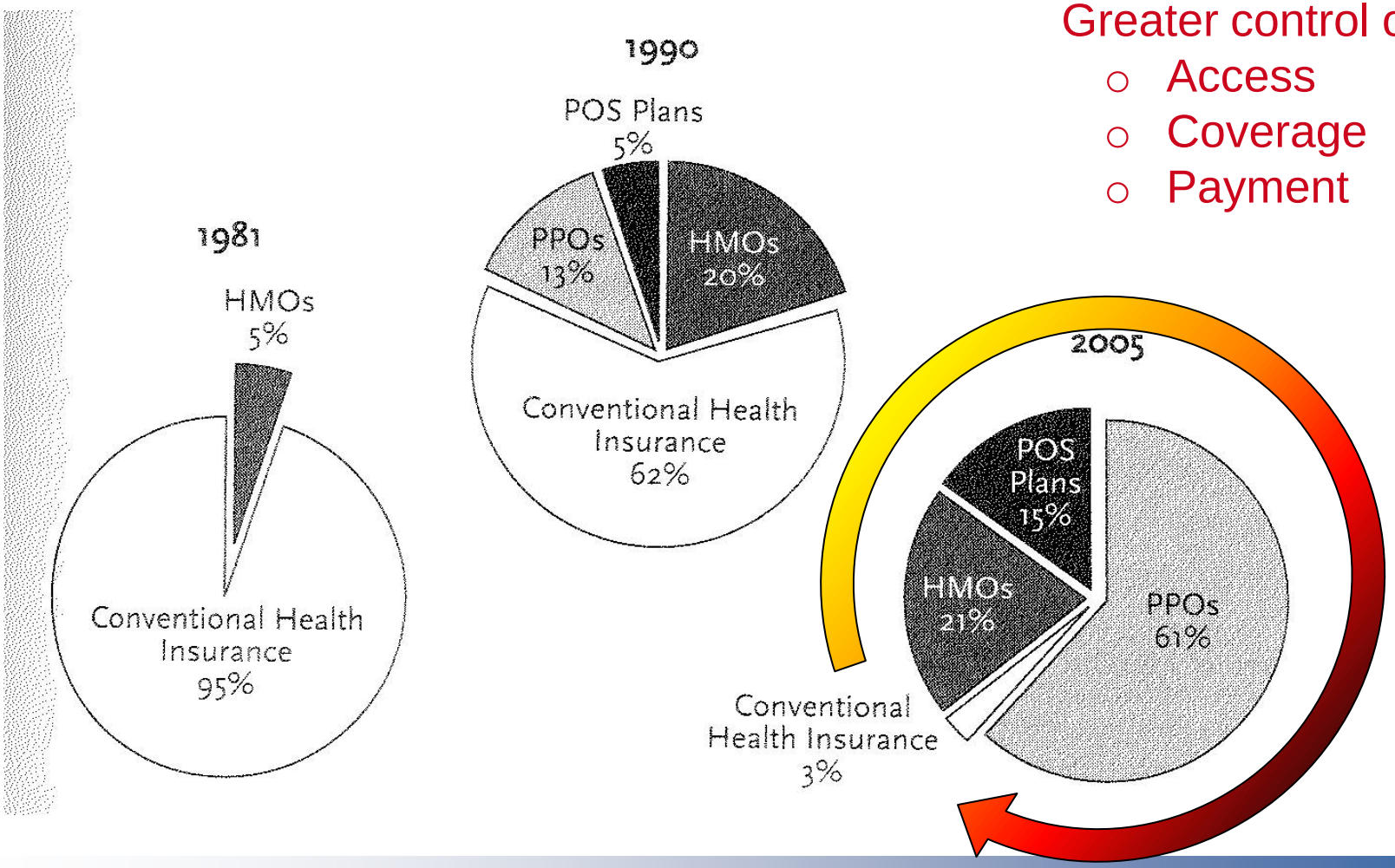
Ref: Kaiser Family Foundation, 2011

Growth in Total Health Expenditure Per Capita



Ref: Kaiser Family Foundation, 2011

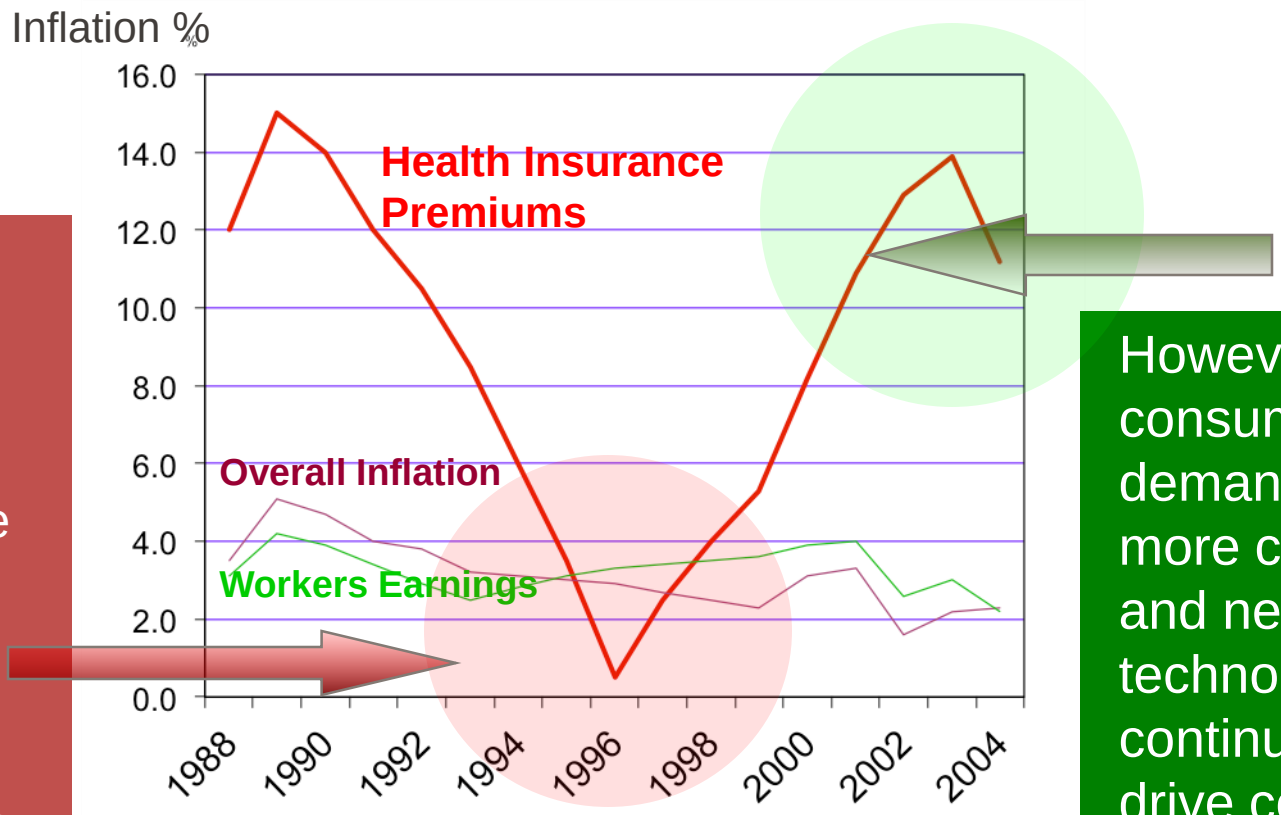
The 90's Market Response → Managed Care



Greater control of

- Access
- Coverage
- Payment

But Medical Costs Continued to Outpace Inflation



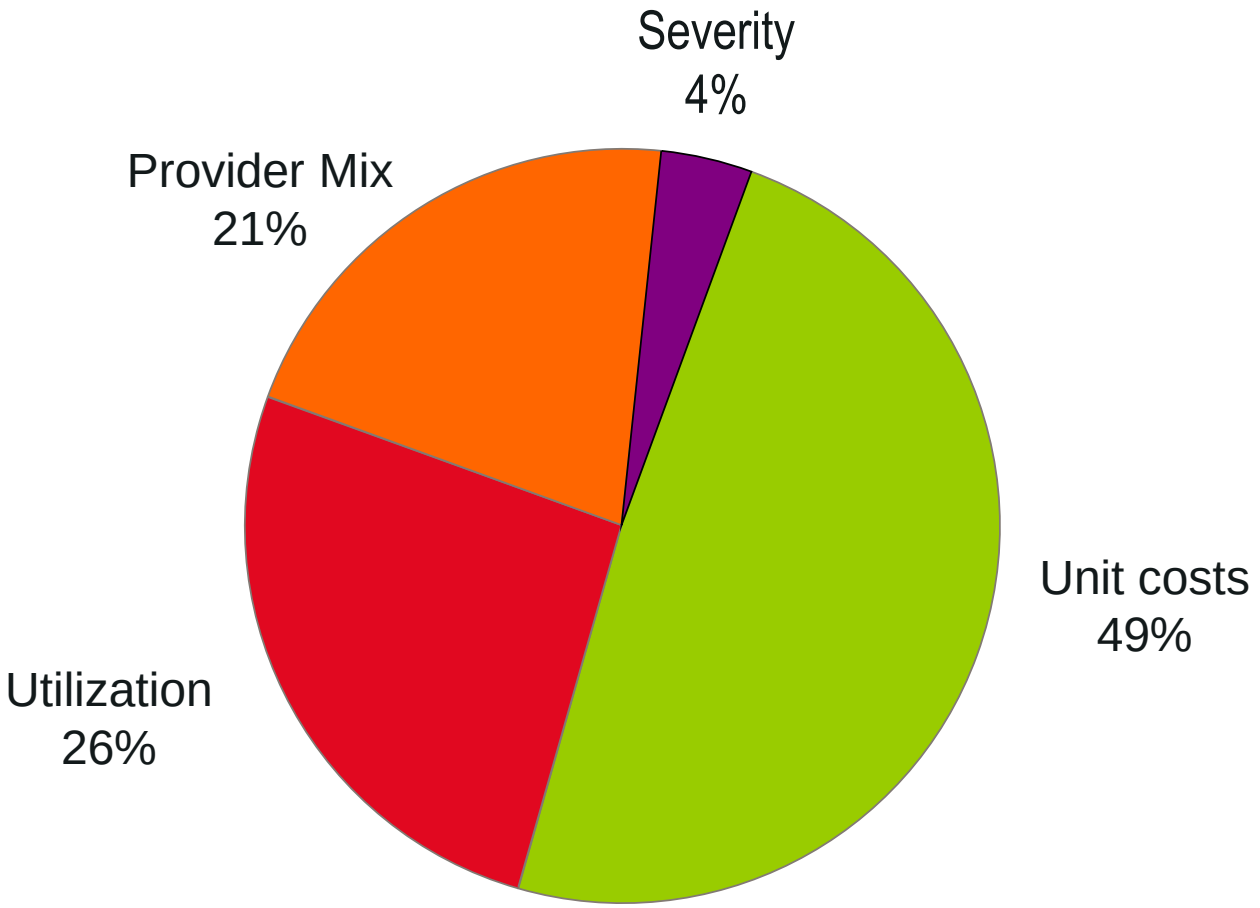
Managed care did work for a while:

- Applying administrative restrictions to curtail utilization
- Negotiating lower fees for services

However, consumer demand for more care and new technology continued to drive costs

Source: National Coalition on Health Care, 2004

Cost Drivers



Source: BCBSMA Actuarial & Analytic Services.

The Boston Globe

Insurers may slash rates to hospitals Some patients might have to switch MDs

By Liz Kowalczyk

Globe Staff / May 24, 2010

Insurers seeking payment changes

By Jennifer Huberdeau, North Adams Transcript

Posted: 05/26/2010 08:15:41 AM EDT

Wednesday May 26, 2010

This is first of a two-part series

New Bedford Standard Times

Blue Cross, Southcoast at loggerheads in contract negotiations

By Dan McDonald, dmcdonald@s-t.com

September 18, 2010

NEW BEDFORD — After seven months of talks, Southcoast Health System, the region's largest employer, and Blue Cross Blue Shield of Massachusetts, the state's largest private health insurance company, are deadlocked in negotiations over reimbursement rates for care rendered to Blue Cross policy holders at Southcoast facilities.

RUNNING A HOSPITAL

This is a blog started by a CEO of a large Boston hospital to share thoughts about hospitals, medicine, and health care issues.

Robin Hood in Reverse

Wednesday, May 12, 2010

Jim Stergios and Amy Lischko from the Pioneer Institute write a well reasoned op-ed article in today's *Boston Globe* about current events in Massachusetts, where the Insurance Commissioner has decided to impose arbitra... a portion of the health care ins... background here.

Pressure to Cut What Doctors Get Paid is Mounting, and There's Not Much to Stop It

By Ken Terry | June 2, 2010

Threats to doctors' incomes are multiplying — and not necessarily in a good way. While physicians are understandably focused on the latest congressional effort to head off a 21 percent cut in **Medicare** reimbursement, they should also pay attention to state regulation of insurance rates. Because if state governments decide to take a hard line on premium increases, the result will translate into lower payments to doctors and hospitals.

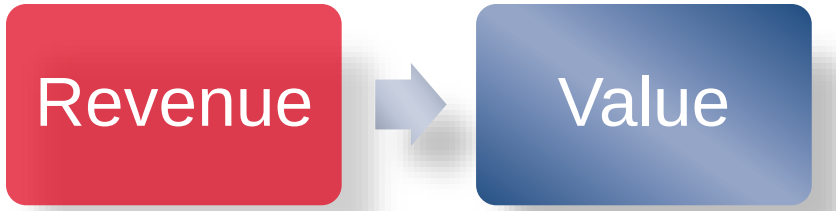
Experts Agree…

Rate reviews can help constraining the growth of costs short term, but they cannot fundamentally address the growth of health care costs…

…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

The Big Paradigm Shift



↑ Revenue = more services x higher service fees

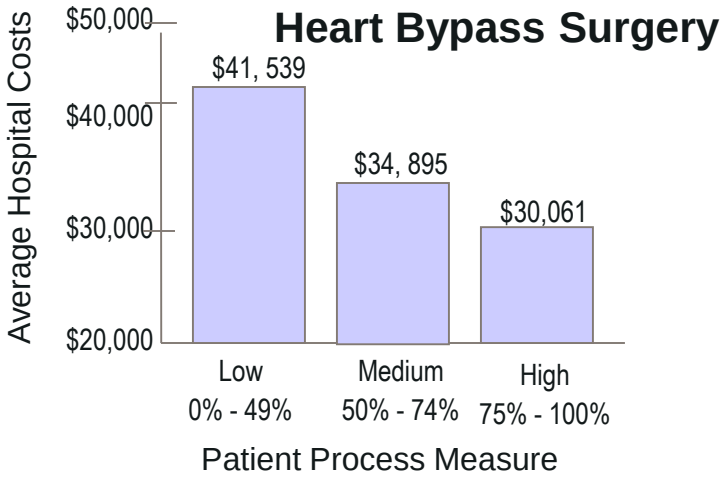
$$\uparrow \text{Value} = \frac{\text{Quality (health outcomes)}}{\text{Cost of Service}}$$

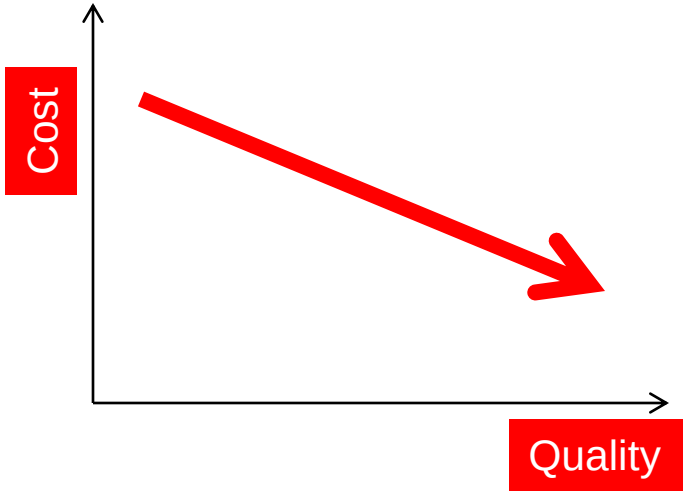
↑ Quality / ↓ Cost = ↑↑ Value

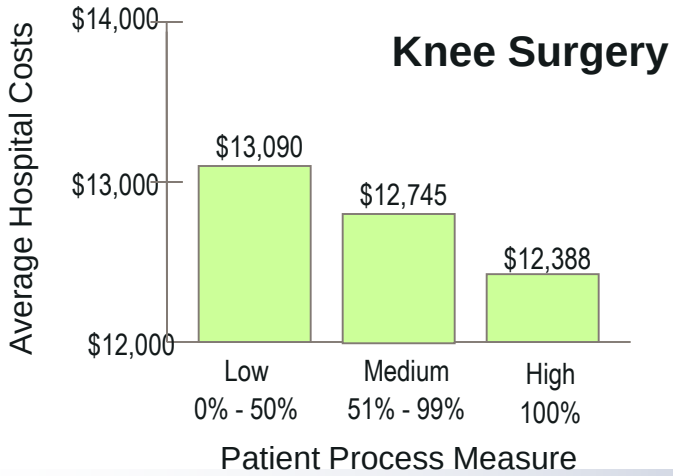
± Quality / ↓ Cost = ↑ Value

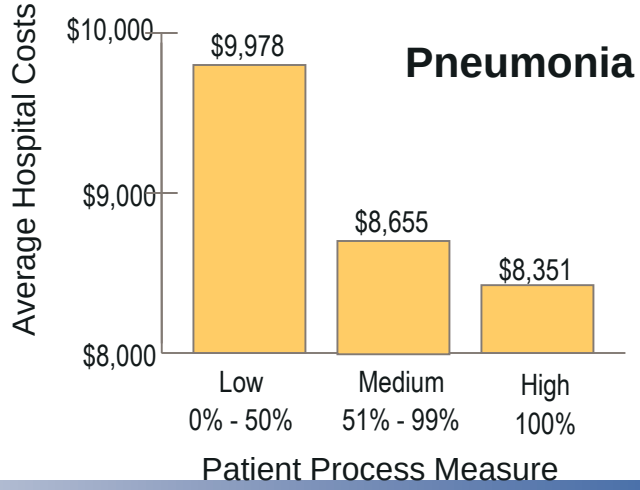
↑ Quality / ± Cost = ↑ Value

Performance Pays Off









Payment Reform: Incentivize Quality, Not Volume

Fee-for-Service

Incentives for:

- Increased volume
- Delivering more costly services

Little or no incentive for:

- Achieving positive results
- Preventive services or other services with low financial margins

Global Payment

Emphasize:

- Quality improvement
- Integration and coordination of care (within acute care episodes and chronic conditions)

Eliminate incentives for:

- Increased volume
- Providing higher-cost services over lower-cost services that are equally effective

Multiple Initiatives

Healthcare Reform Laws

- Emergency medical Treatment (1986)
- Health Insurance Portability and Accountability Act (1996)
- Medicare Prescription Drugs (2003)
- Patient Safety and Quality Improvement Act (2005)
- Health Information Technology for Economic and Clinical Health Act (2009)
- Patient Protection and Affordable Care Act (2010)

Hospitals' Value-Based Purchasing (VBP) Program

- Goal: Pay for care that rewards better value and patient outcomes, instead of just volume of services
- 2004: Requiring hospitals to report Quality Data in order to obtain 'Annual Payment Updates' [www.hospitalcompare. hhs.gov]
- 2012: Starting to pay for performance
- VBP Criteria:
  - 12 Clinical Process of Care Measures (70% weighted value)
  - 8 Patient Experience of Care Dimensions (30% weighted value)
- Future:
  - Changing criteria
  - Expanding to outpatient and ASC (2014)
  - Shifting from 'process' measures to 'outcomes'

Reduced Payments for Hospital Acquired Conditions

- Certain conditions developed while the patient is hospitalized will not justify incremental reimbursement
- Gradual implementation starting 2014
- Plans to add measures

- Foreign object retained after surgery
- Blood incompatibility
- Pressure ulcers (stage III-IV)
- Falls and trauma
- Manifestations of poor glycemic control
- Catheter-associated urinary tract infection
- Vascular catheter-associated infection
- Surgical site infection (CABG, bariatric, orthopedic)
- Deep vein thrombosis (DVT) / air embolism (total knee, hip)

Accountable Care Organizations (ACO)

- **ACO:** A local set of providers accountable for the cost and quality of care delivered to a defined population

- **Objective:** Shift from fragmented and inconsistent care to coordinated care, and from volume-based to value-based payment system

ACO's must:

- Share responsibility for coordinated care.
- Include PCP's
- Provide care across the continuum of care
- Can have flexible structures - specialists, hospitals, pharmacies, post-acute providers, etc.
- Cover min. of 5,000 beneficiaries
- Measure performance

Bundled Payments

- **Objective:** Align incentives and improve patient's care during inpatient and post-discharge recovery
- **Current system:** surgery generates claims from hospital, surgeon, anesthesiology, radiology, pathology, post-discharge providers, etc.
- **New system:** A single 'bundled' payment made to the 'team' of providers involved.

Providers can determine which services will be bundled (4 models):

- Inpatient care + 30/90 days post-discharge; single payment to all providers
- Start at discharge up to (min) 30 days after discharge (include readmission); single payment to all providers
- All services, incl. by physicians, during inpatient; paid to hospital (which pays the physicians)
- Inpatient stay at the general acute care hospital; hospitals and physicians paid separately but can share gains arising from better care coordination

Comparative Effectiveness Research (CER)

Objective: Help clinicians and patients to make care decisions by developing evidence-based information about the effectiveness of treatments relative to other options.

Coordinating Council

- 15 members council overseeing research areas
- >$1 B funding (NIH, AHRQ, HHS, other)

Traditional clinical research: examines effectiveness of one method or product at a time

Comparative effectiveness research: compares 2+ different methods

- Methods: clinical trials, analysis of claims records, computer modeling, review of existing literature, other.
- Example: randomized trial for treatment of osteoarthritis of the knee → surgery had similar outcomes to Rx + PT

Cannot recommend clinical guidelines for payments, coverage or treatment.

Implications to Medical Device Companies

FDA Approval Is Necessary But Not Enough

FDA

Does the product do what it claims - <u>Safety and efficacy</u>

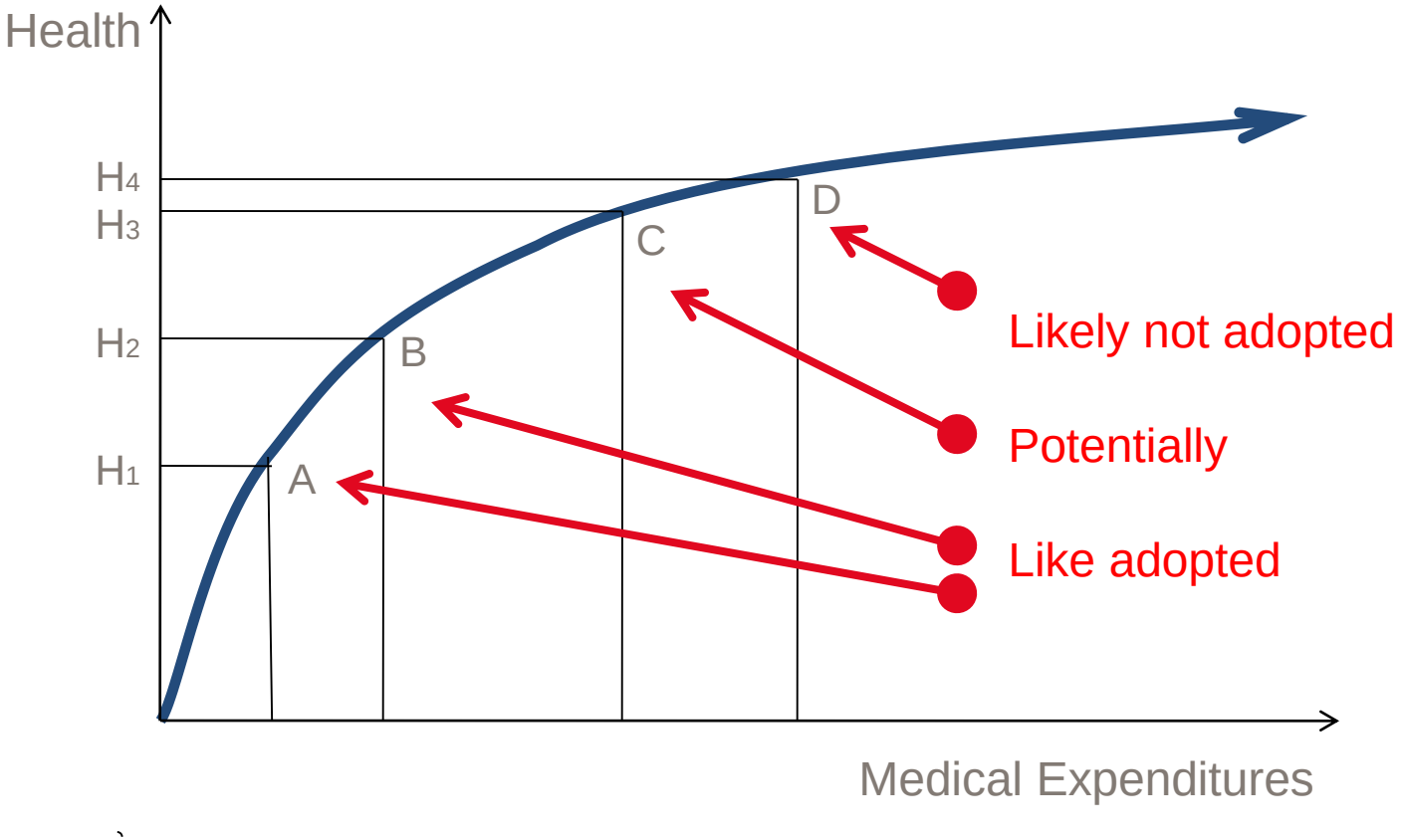
- Short-term or intermediate outcomes
- No cost considerations
- Data generated in controlled setting
- Decision made with minimally required data

Providers & Payers

Does the product / procedure improves outcomes - <u>Reasonable and necessary</u>

- Long term health outcomes
- Cost is often key consideration
- Use in "real world" - non-academic and routine conditions
- Significant evidence is required; professional societies input is important

“Value-based purchasing is on the way”



Ref.: Health Policy Issues, PJ Feldstein, 2007

Effect on Pricing

- Devices pricing will be based on ability to remove costs from the system
  - Stents versus CABG
  - Less invasive procedures, e.g. laparoscopy
  - Diagnostics screening, e.g. hospital acquired infections

- Drug prices will be based on performance and outcome
  - Cholesterol drugs – shift from surrogate endpoints, e.g. LDL, to clinical outcomes, e.g., heart attacks, mortality
  - Diabetes drugs - cardiovascular outcomes
  - Oncology drugs - show overall survival benefits

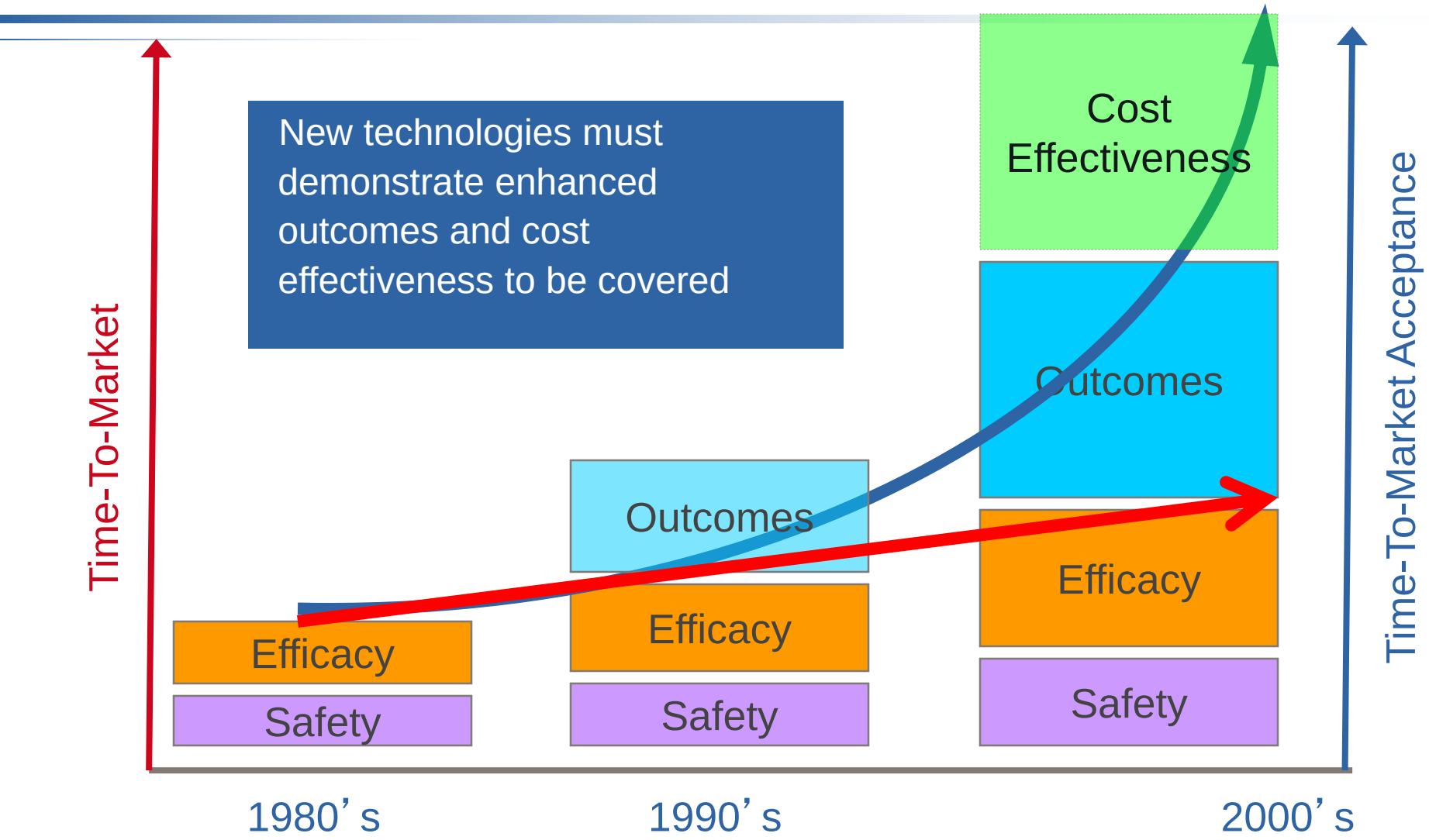
Evidence Based Medicine Is Essential

- Evidence that providers and payers are getting **quality improvements for resources used**
- Systematic and **comprehensive evaluation of the medical and economic implications** of the use of health technology
  - New technology – drugs, biologics, devices, support systems
  - New application of existing technology
- Critical evidence can often be shown only when establishing an installed base
  - May require larger populations and broader demographics
  - Longer outcomes

Not all studies are 'good evidence'

- Studies showing conflicting results
- Evidence of net benefits but the benefits are small
- Evidence that new technology is beneficial but still unclear that the 'new' is better than 'existing'.

Time To 'Market Acceptance' is Increasing



Considerable Implications to MedTech Companies

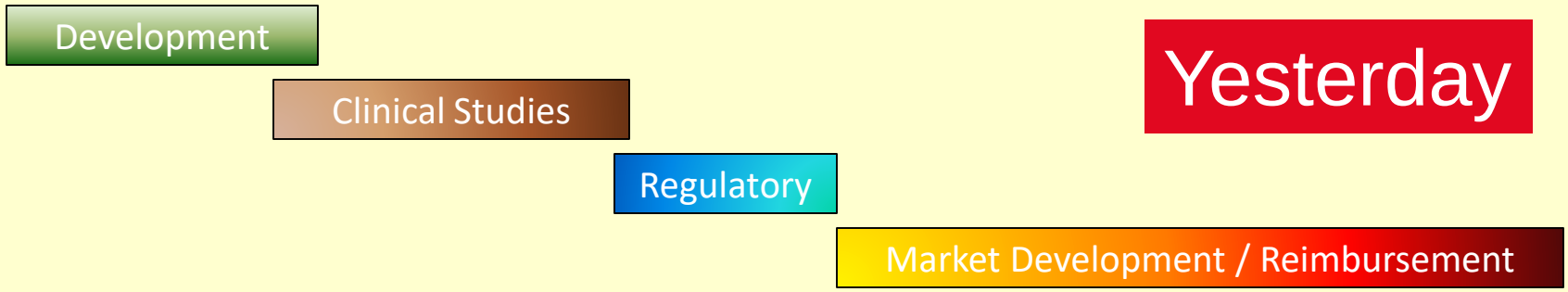
- Delayed revenue
- Need for additional funds and financing rounds
- Valuations are negatively impacted
- Business development initiatives are delayed
- Prospective distributors sit on the sidelines
- Increased risk of new competitors

So What Did We Learn at Boston MedTech Advisors?

Key Lessons

- Need to understand factors leading to clinical / market adoption of the new technology and barriers to adoption
  - Not necessarily same drivers as in the past
  - More barriers than in the past
- To improve likelihood of successful business, assessment of adoption & barriers must be done at all times, starting at the early development, continuing through pre-market and post-launch phases
  - Considering new inputs (e.g., clinical data, market research), competitive developments, changes in regulations, etc.
- Appropriate R&D, regulatory, clinical, reimbursement and marketing plans cannot be developed without such knowledge
- Going to market: Instead of asking '*how quickly can we start selling?*' ask '*are we ready to start selling – and build adoption?*'
- Funding and valuations are predicated on convincing investors about the likelihood of adoption.

If you still work like this, you could run out of money and/or out of time…



The new paradigm