

How Should Changes in Healthcare Markets Affect Your Business Plan?

March 20, 2017

David Barone, Principal

BOSTON | GERMANY | ISRAEL

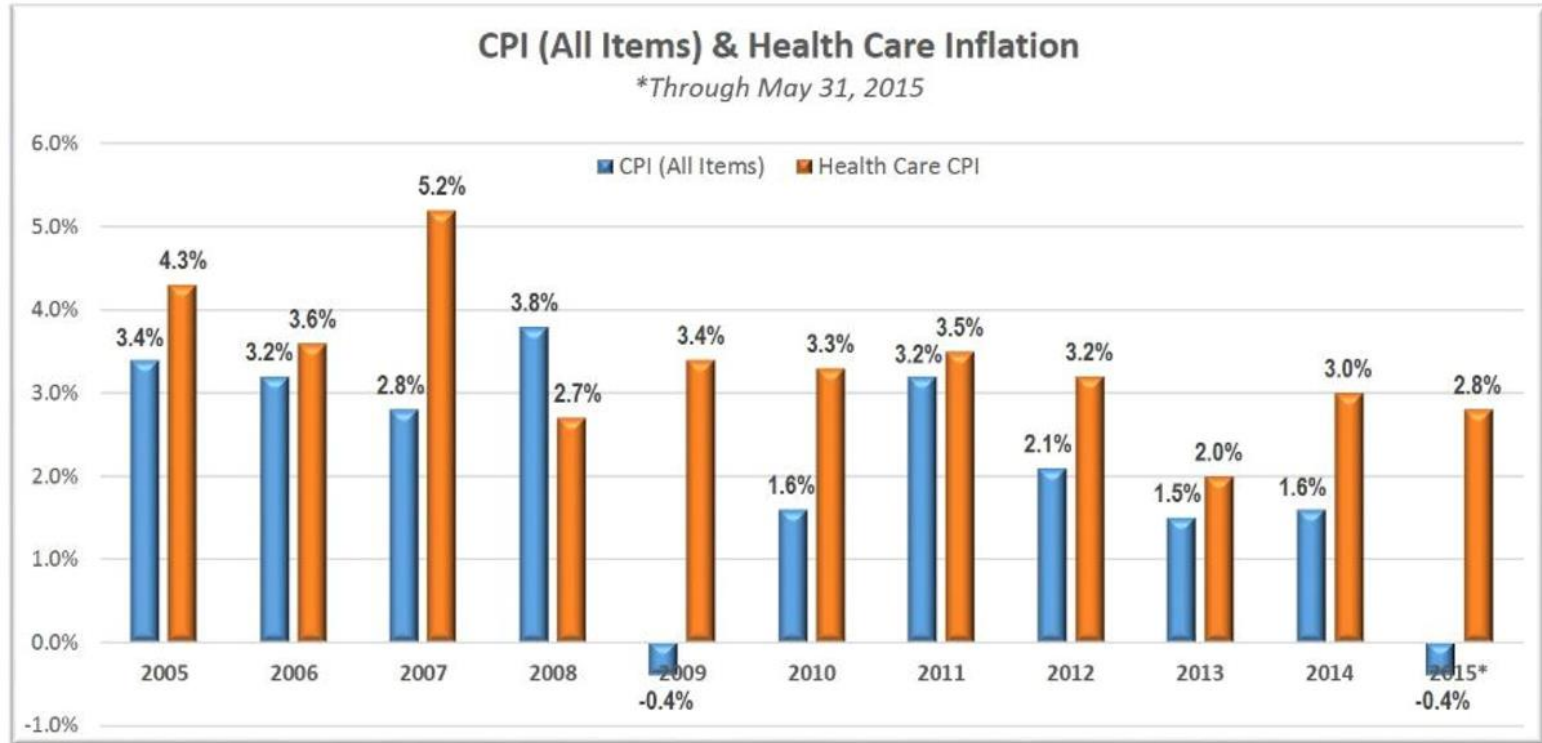
www.bmtadvisors.com www.bmtCROgroup.com

Medical Device Industry - 2017 Report Card

- Projected CAGR next 10 years ~5%
- U.S. will remain the most important market
 - Size, innovation, leadership / impact, pricing
 - U.S. – home of 12 out of top 20 companies; EU - 7; Japan – 1
- Innovation is still strong
 - 3,000 – 3,500 FDA approvals / year
 - >200,000 health apps (but 90%<5,000 users)
- Continuing M&A; start-ups & small companies are the primary source of innovation pipeline
 - ~25% of transactions - acquired company is still in the development stage
 - ~75% approved products / started commercialization
- Emergence of disruptive technologies

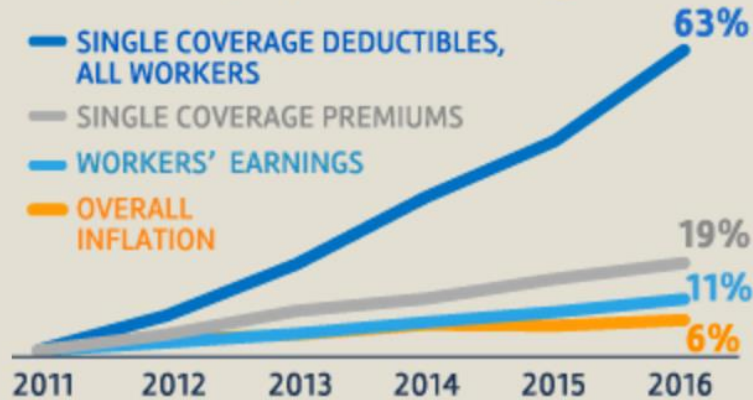


Cost is #1 Issue



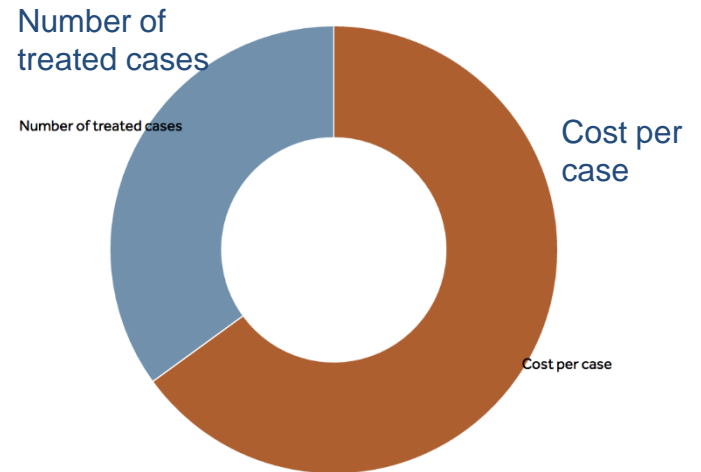
Premiums Rise Modestly, but Deductibles Climb More Quickly

Cumulative Increases in Premiums, Deductibles, Inflation and Wages

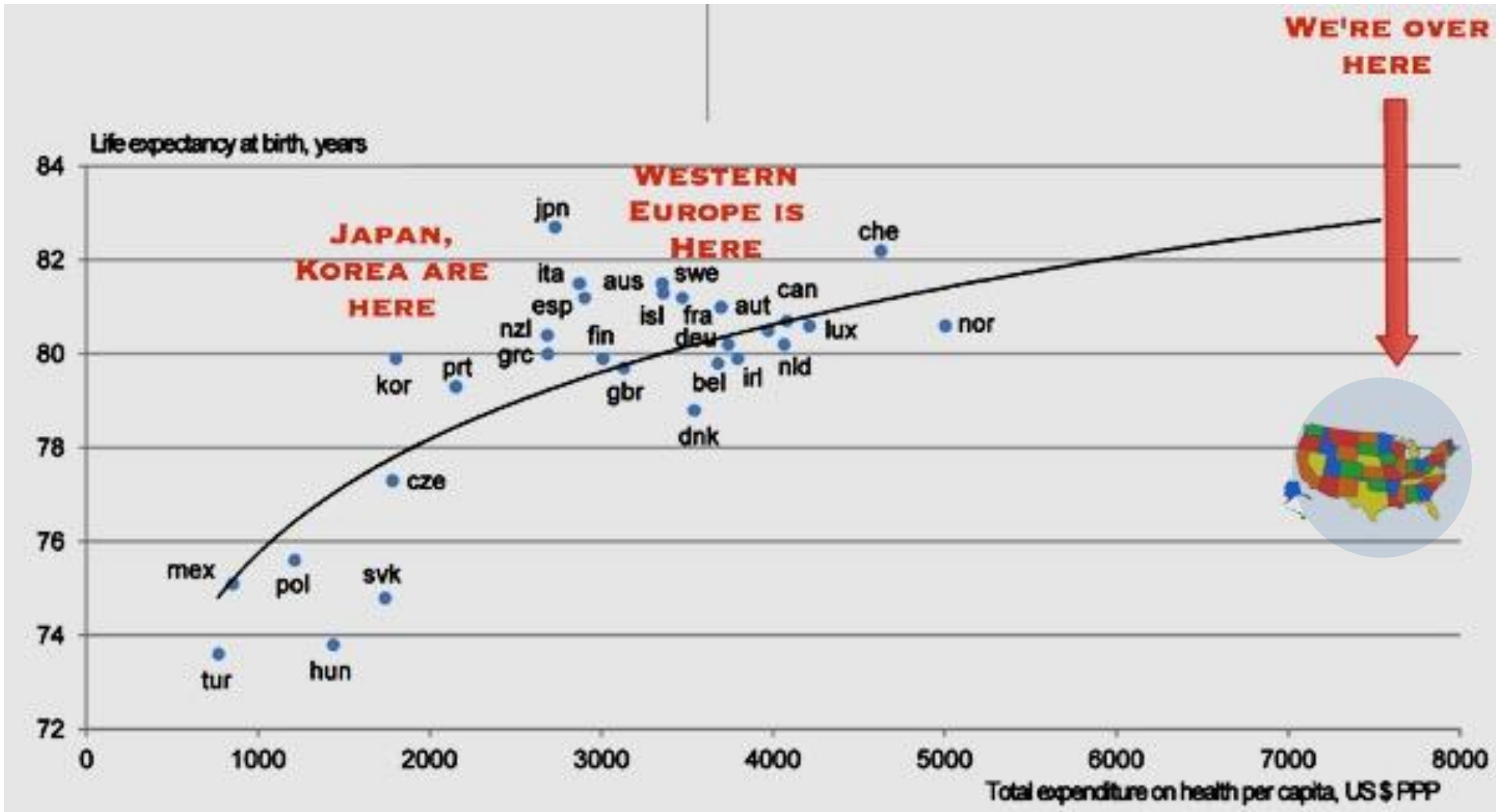


Increases in prices and service intensity have driven most of spending growth

Percent change from previous year for price indexes and real expenditures on medical services by disease, 2001 - 2012

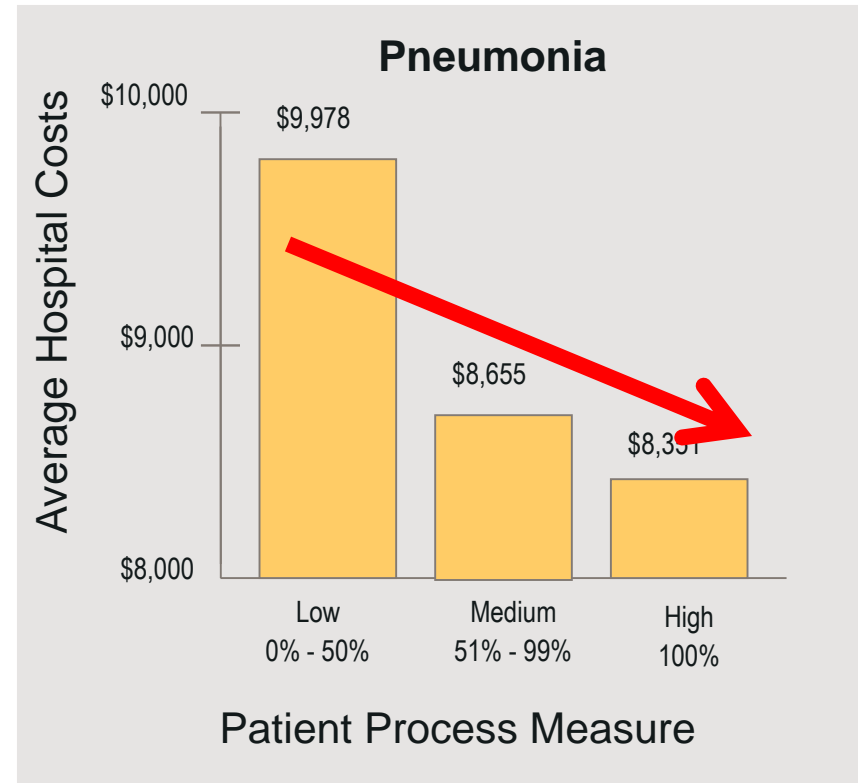
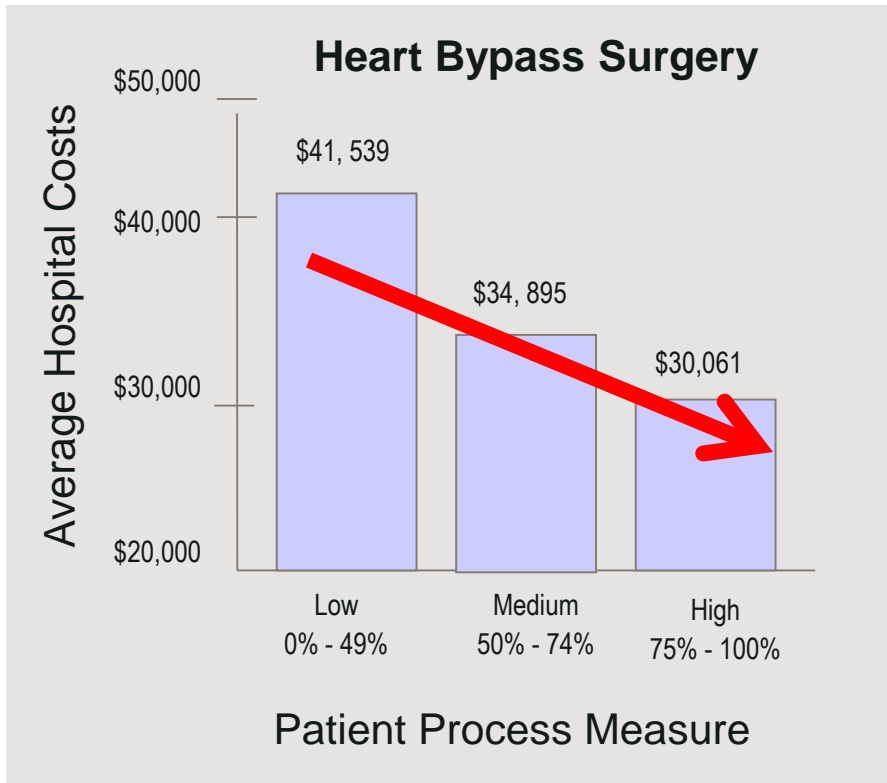


The Higher Costs Do Not Provide Better Health



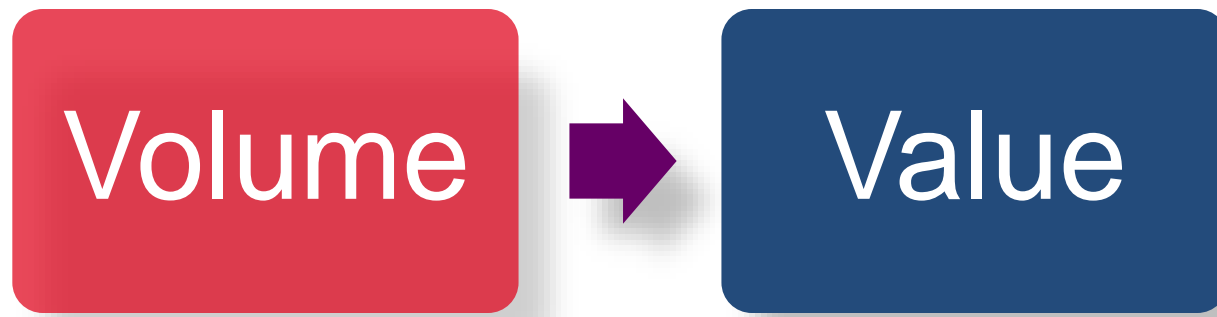
Performance Pays Off

Cost



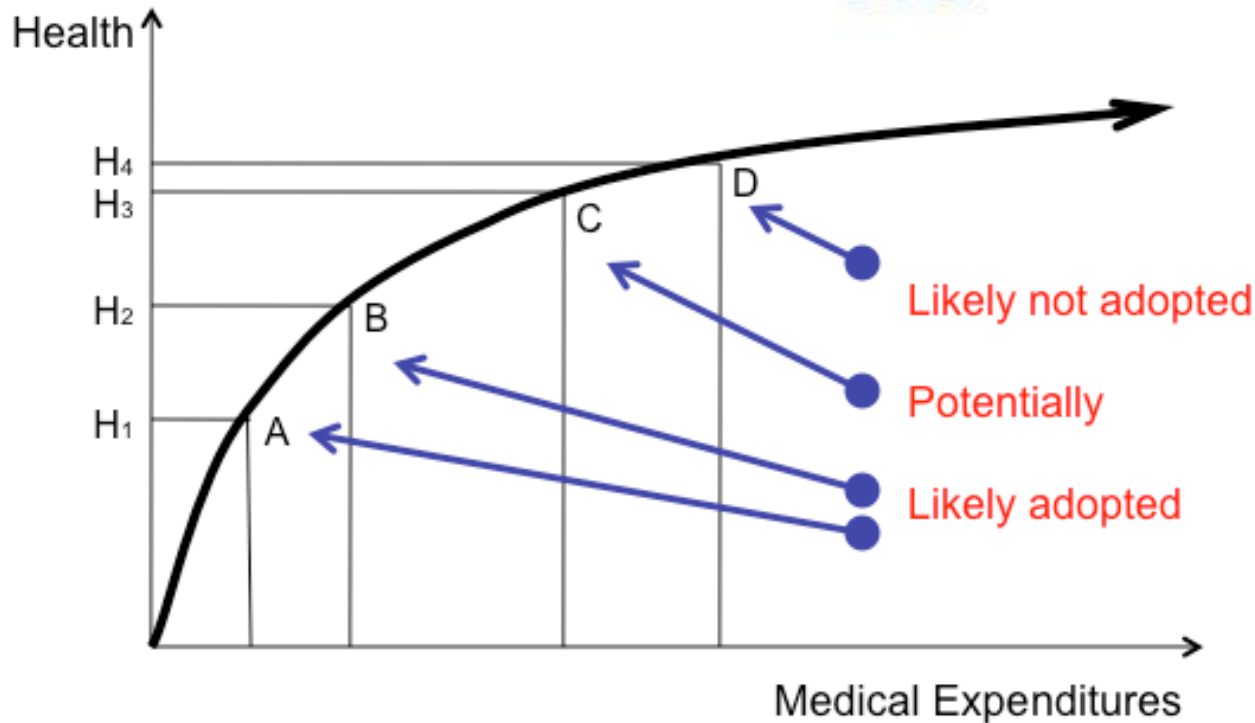
Quality

Change is Underway



Value-Based Purchasing

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



Adoption of new devices, drugs, and diagnostic will be increasingly based on ability of the product / procedure to lower costs

Affordable Care Act (2010) -



Broadly implemented but premium cost increases and limited access to 'exchanges' need to be addressed.

“Repeal and Replace?” Maybe, not for sure...



American Health Care Act (2017)

- Insurance reforms
- Personal mandate
- Role of states vs. federal government
- Limit growth of Medicaid

Current status

- Many details unknown; changes still being made
- CBO projections:
 - Increase in un-insured
 - Long-term cost saving (Medicaid, lower premiums)
- Plan - gradual implementation
- Multiple objections; not clear the AHCA can gain enough votes in congress
- **AHCA addresses covered benefits, but no changes to most payment reforms, other ACA initiatives**

ACA - 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; pay-for-performance (value)

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

- **Since 2012 – hospital Medicare readmissions declined by 200,000.**

- **VBP (2015):**
 - **1,714 hospitals - Medicare payments boosted**
 - **1,375 hospitals - Medicare payments reduced**

- **By 2018 - 90% of all payments will be linked to quality or value**
- **50% of Medicare payments will move to alternative payment models like ACOs and bundled payment programs.**

- **Within 5 years fee-for service will decrease from 56% to 32% of services.**

Pricing - Risk Sharing; Money Back Guarantee?

“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.

We Have a New Landscape

Volume based incentives → Value based / outcomes

Fee-for-service → Bundled care

Payers assume financial risk → Payers & providers share risk

Devices selected by physician → System decisions

Medical Technologies - 4G

- G1: 60's -70's First solutions; the birth of the biomed industry
- G2: 80's - 90's Significant improvements in technology and clinical practices; the emergence of the big players; rapid adoption
- G3: 90's - 10's Start-ups driving innovation; sophisticated solutions; most - incremental evolutions; more barriers to adoption
- G4: 10's → Shift to 'value'; disruptive technologies and care models

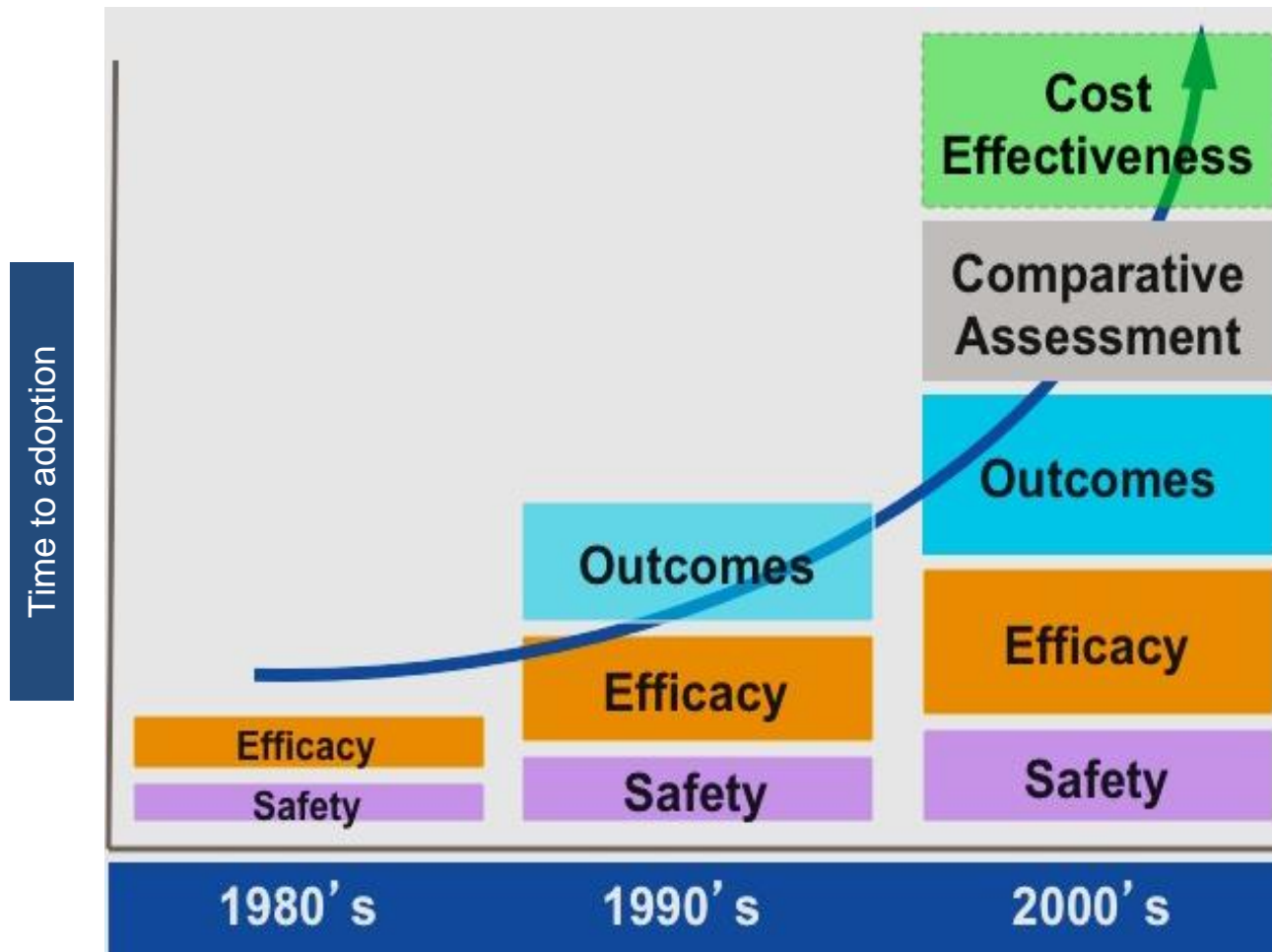
The Era of Digital Health?

- Innovation will disrupt all medical and diagnostic services that rely heavily on physical facilities and staff.
- Point-of-care is expanding into the home
 - Monitoring medical conditions and diseases
 - Detecting early symptoms and the onset of new diseases
 - Remote access - telemedicine; estimates - 85% of medical consultation do not need to be in person.
 - 2016: >50% of all interactions with Kaiser physicians were virtual (>1M / month)
- Digital health and mobile technologies connect 'lifestyle & wellness' apps with medical conditions
 - Sedentary lifestyle exacerbates a heart condition
 - Social-media patterns may point to increase risk of depression
- 2016: 36 FDA approved connected health apps
- Digital health start-up funding (U.S.) increased from \$1.5B in 2010 to ~\$6B in 2016.

Will Digital Health Disrupt Healthcare?

- Risks to drug companies
 - Detecting drugs that do not work
 - New services that might involve taking no drugs at all.
 - Onduo (JV Google / Verily Life Sciences - Sanofi): help diabetics and pre-diabetics make better decisions on their lifestyle habits.
 - Drugs will be sold based on patient outcomes
- Reducing non-compliance can save ~\$300B / year
 - Receiving payments when patients take their drug on time
 - Paying for delivering weight loss rather than for the pills
 - Pay-for-performance models (complicated; not proven, yet)
- Implementing 'disruption' requires adjustments in regulatory and reimbursement frameworks.

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



Longer Time-To- Adoption Has Considerable Implications

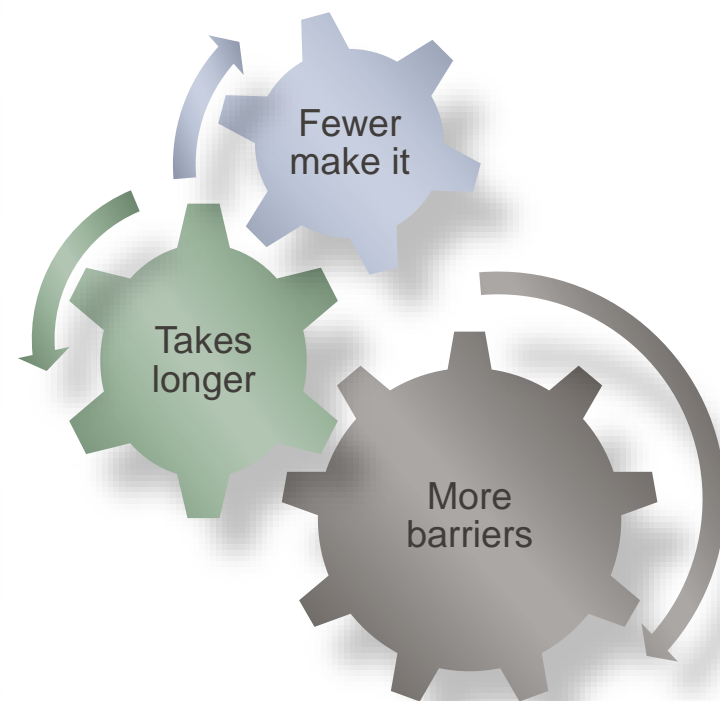
Delayed revenue

Need for additional funds and financing rounds

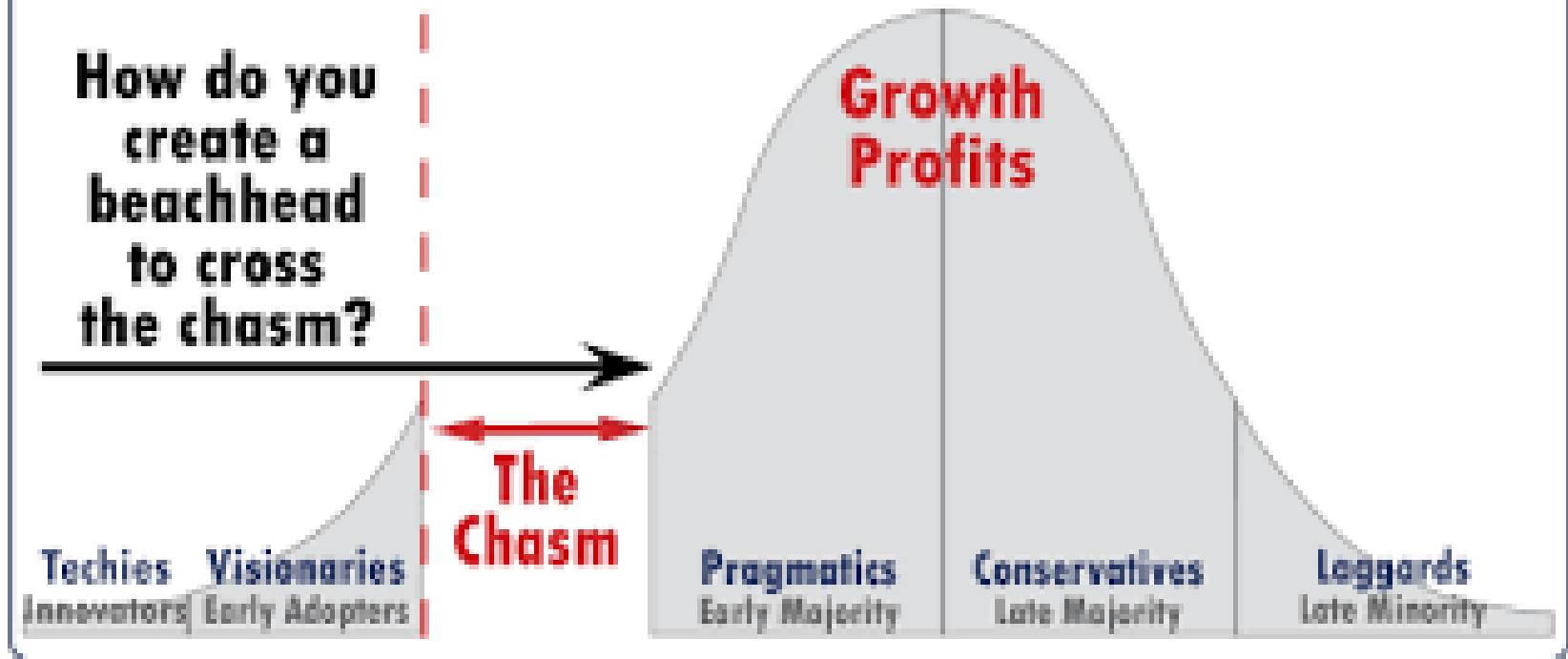
Valuations are negatively impacted

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

When Are We Ready to Launch Sales?



Adoption of new technologies require manufacturers to

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

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...**
- **We do not need a Business Plan...**
- **We don't have money, we need to be creative...**
- **Once we get money we will do the right things...**



