
What HIT Policy Changes Will Mean for MedTech

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AdvaMed Facts

- **Founded in 1974 as the Health Industry Manufacturers Association (HIMA)**
- **Now grown to 1,200 + member companies and subsidiaries (devices, diagnostics, HIS)**
- **Members manufacture 90% of sales in domestic market, 50% global market**
- **\$16 million budget, 60 staff with global expertise**
- **45 - member Board of Directors**

Our Goals

- Rapid approval by FDA
- Adequate payment
- Speedy coverage determinations here and abroad
- Access to international markets

IT in Medical Technologies: Some Examples

- Smart IV pumps
- Bar-coded medication administration
- Computerized physician order entry
- Remote physiological monitoring for health disease
- Remote monitoring of device performance
- Digital imaging
- Lab test management and communication

**MT Is at the front end of the HI
System**

Today's Presentation

- ***Major Policy Issues***
 - ⌚ ***Incentives for use of HIT***
 - ⌚ ***Standards and Interoperability***
 - ⌚ ***FDA Regulation***
- ***Recent Progress***
- ***Proving the Value***

Reimbursement

- *CMS Demonstration Projects - New Opportunities*
 - 🔦 Doctor's Office Quality Information Technology (DOQ-IT)
 - 🔦 Pay for Performance
 - 🔦 Chronic Care Improvement Program
- *AHRQ Grants*

Standards and Interoperability

- *CMS Demonstration Projects - New Opportunities*
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FDA Regulation

- *Software Regulation*
 - 💡 Clarify the regulatory status of software in devices
 - 💡 Issues of software patches
 - 💡 Level of regulatory requirements
- *AHRQ Grants*

***Medicare Modernization Act of
2003***

Major Reimbursement Reforms Hold Real Promise

- ***Medicare Modernization Act***, 14 provisions impacting Medical Technology, valued at over \$1 billion
 - 💡 New technology DRGs and add-on payments
 - 💡 National Coverage deadlines
 - 💡 Clinical trial coverage for breakthrough technologies
 - 💡 Maintenance of the local coverage system
 - 💡 Chronic care improvement demo
 - 💡 Council for technology and Innovation

FDA Reform & Implementation

FDA Product Approval Accelerating

- ***Medical Devices User Fee and Modernization Act of 2002***
 - 💡 Stemmed the staffing and resource decline in CDRH
 - 💡 Clear performance goals
 - 💡 Office of Combination Products
 - 💡 Regulation of reuse of single use devices
 - 💡 Third party inspections

BUT,

Implementation Remains



So, What does it all Mean?

Expect!

- *E-Health*
- Shifting to consumer driven health care, Health Savings Accounts (HSAs)

BUT

- Continued drive to cut, cut, cut healthcare spending!!!
- Evidence and Health Technology Assessment

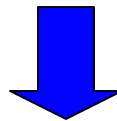


The Challenge

Will the Health Care System Reward Innovation?

- Health care cost pressure
- Government deficits
- New prescription drug coverage creating new fiscal strain

What is the solution to this long term challenge?

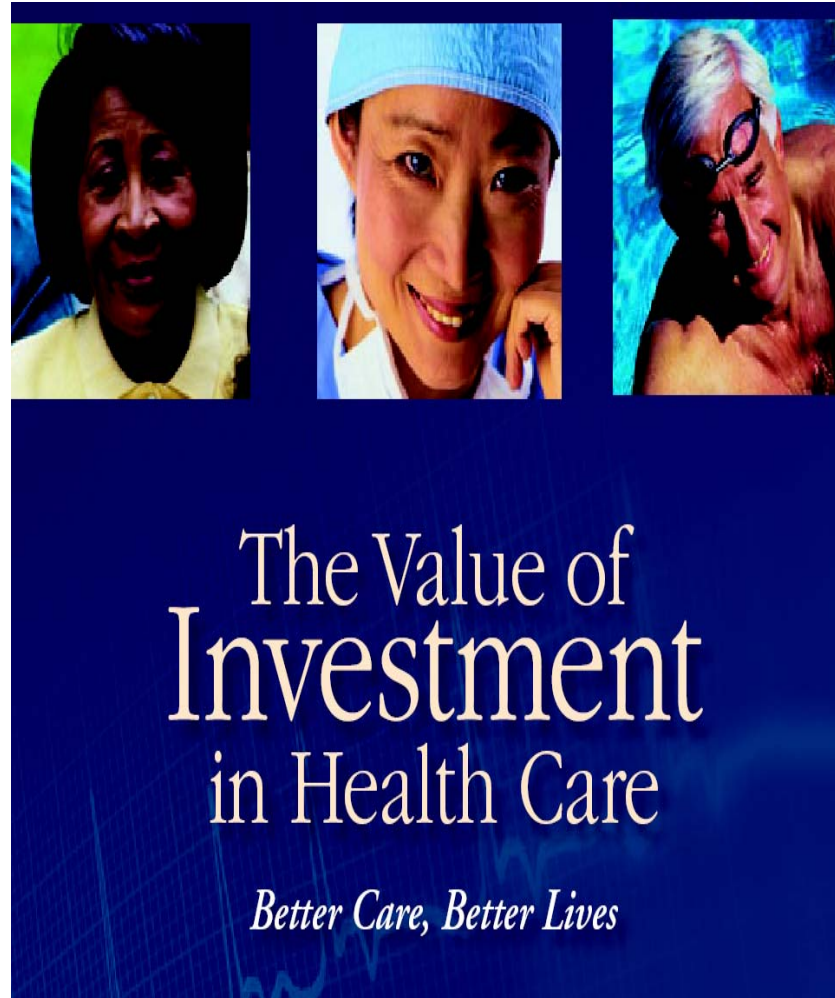


Recognize the Value of Innovation and need for Investment

Important Coalition, Important Report

The Value Group:

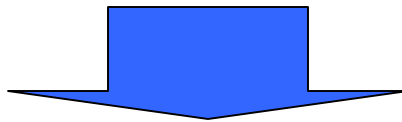
- AdvaMed
- American College of Cardiology
- American Hospital Association
- Federation of American Hospitals
- Healthcare Leadership Council
- National Pharmaceutical Council
- PhRMA



Overall Value of Innovation, Findings:

Since 1980, per capita expenses are up \$2,254, but:

- Overall death rate is down 16%
- Life expectancy from birth is up by 3.2 years
- Disability rates are down 25% for people over 65*
- 56% fewer days are spent in the hospital



*Health gains of \$2.40 to \$3.00
per dollar invested*

*Value of this improvement not quantified.

Value of Innovation

**Where would we be in 2000
without innovations since 1980?**

**\$2254 per
capita
in
savings**

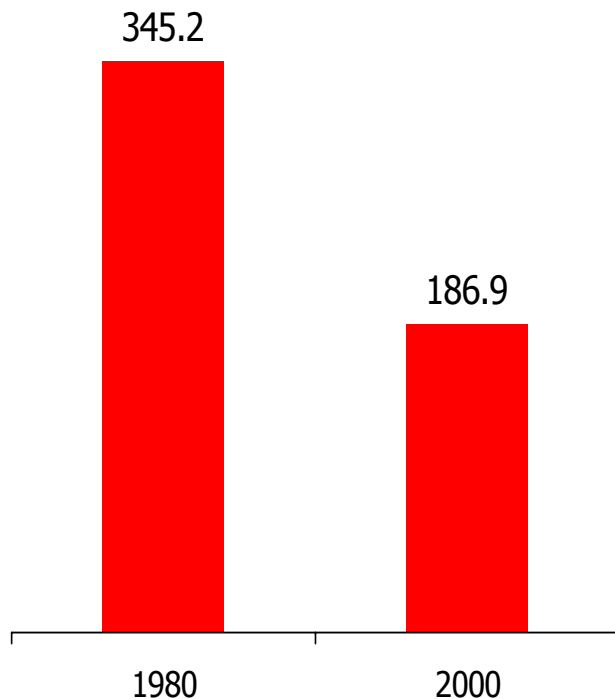
**470,000
more
deaths**

**2.3
million
more
disabled
persons**

**206
million
more
days in
hospital**

Heart Attack: Improvement in Outcomes

Death Rate Due to Heart Attack (Age-adjusted, per 100,000)

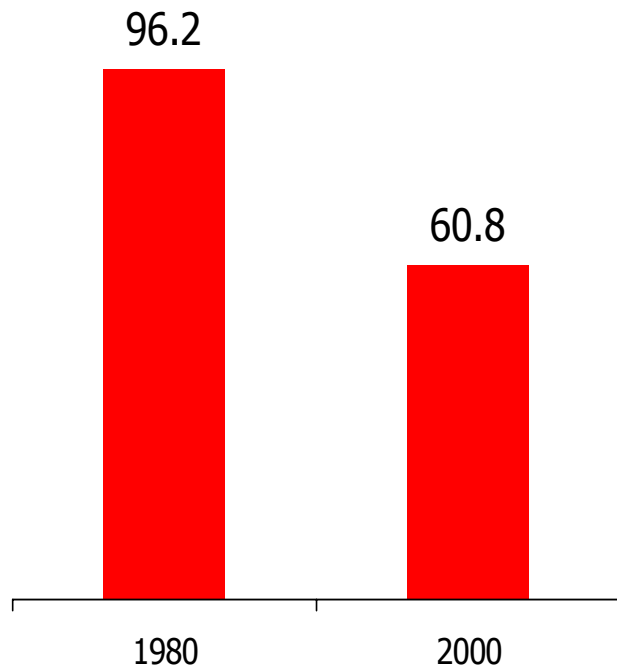


Source: www.cdc.gov/nchs

- Mortality cut nearly in half
- Death within 30 days cut from 1 in 4 to 1 in 8
- \$1.10 back in value for every \$1 spent in Medicare

Stroke: Improvement in Outcomes

Death Rate Due to Stroke (Age-adjusted, per 100,000)

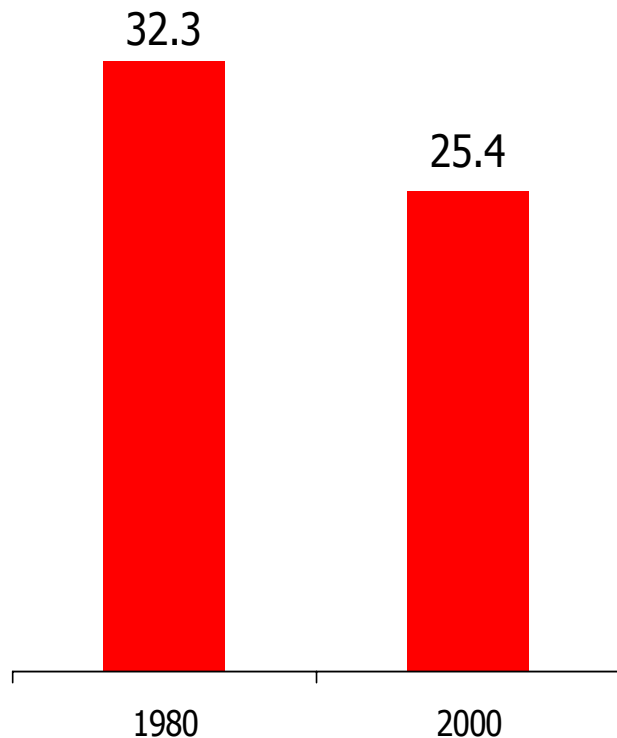


Source: www.cdc.gov/nchs

- Mortality cut by 37 percent
- Faster diagnosis
- Stroke-related disability after 3 months reduced by up to 30 percent with rt-PA
- \$1.55 back in value for every \$1 spent in Medicare

Breast Cancer: Improvement in Outcomes

Death Rate Due to Breast Cancer (Age-adjusted, per 100,000)



- Mortality cut by 21 percent
- Five-year overall survival rates increased from 76.9% to 86.6%
- Risk of developing metastatic disease declined from 40% to 15%
- \$4.80 back in value for every \$1 spent in Medicare

Meeting the Challenge

- **Policies that encourage investment in HIT**
- **Regulatory resourcing and reforms**
- **Standards and Interoperability**
- **Communicate the value of your technologies**

Thank You