



# AdvaMed

Advanced Medical Technology Association

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

# About AdvaMed



- World's largest medical technology association
  - 1,600+ member companies and subsidiaries
- 



- Members produce 90% of sales in domestic market, 50% of sales in global market
  - 70%+ of member companies have less than \$30 million in annual revenue
- 



- 65 staff with global expertise, bi-partisan backgrounds
- 45 member Board of Directors including 5 from smaller companies

# Comparative Clinical Effectiveness Research: Impact on Industry



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- Facilitate diffusion of valuable products
- Winners and losers
- Overall: Good for industry

# Comparative Effectiveness Research and the Device Industry: Some Cautions



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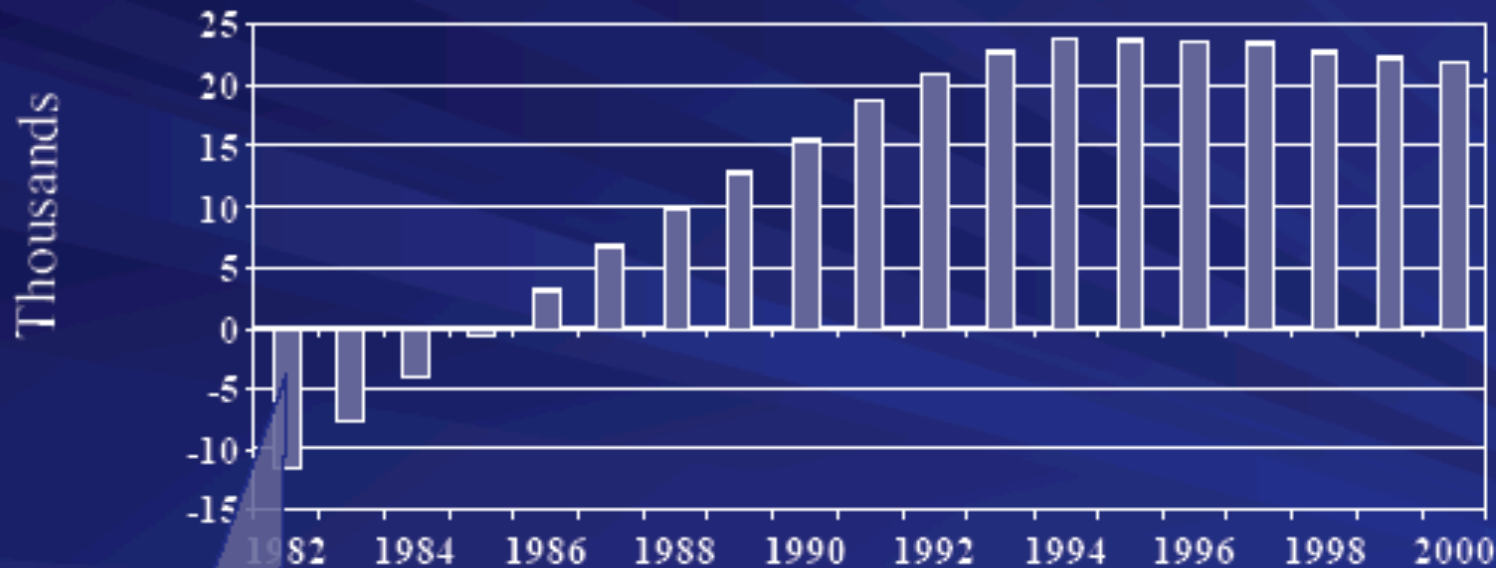
- Time dimension
- Evolving evidence
- Few “slam dunks”

# Angioplasty reduces angina, opens blockages: change in value over time



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Net Benefit per PTCA, New York, 1982-2000

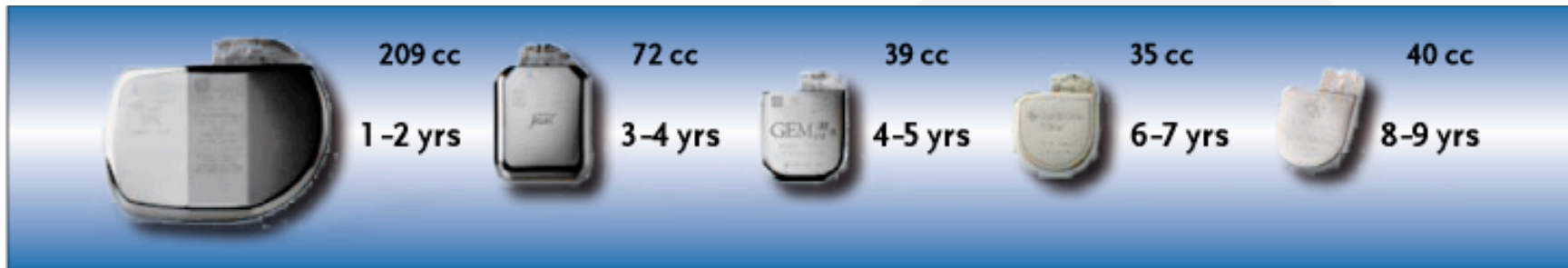


Net benefit  
in 2000 =  
\$21,900

Net cost in  
1982 =  
(\$11,600)

"Technological Development and Medical Productivity: Diffusion of Angioplasty in New York State," Cutler D, Huckman, R; National Bureau of Economic Research, Oct 2002

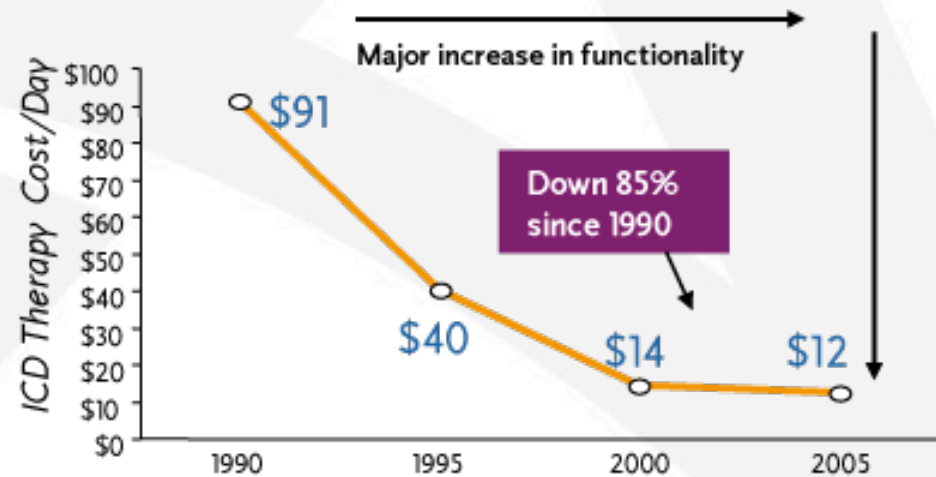
# ICD: Example of pace of innovation



**98% effective**<sup>1</sup>  
**99% reliable**<sup>2</sup>

Cost/day of ICD therapy has decreased:

1. Reduced procedure time (12 to 2 days)
2. Increased battery life (1 to 9 years)
3. Improved device therapy (4x therapies)
4. Better medical outcomes (multi. studies)



<sup>1</sup> Zipes DP. *Circulation*. July 1,1995;92(1):59-65.

<sup>2</sup> Medtronic CRDM Product Performance Report, Second Edition - Issue 55, August, 2006.

# Application of research to coverage and payment



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- Should not be used to deny or reduce payments for safe and effective treatments, *especially* innovative treatments
  - Ignores differences between patients
  - Penalizes evolving treatments
  - Can stifle innovation
- Could be used for
  - Development of quality standards for use in pay for performance systems
  - Professional treatment guidelines
  - Indirectly impact behavior in payment systems that reward quality and efficiency

# Cost Effectiveness: Wrong prescription for industry & patients



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- Flawed methodology
- Denies patients quality care
- Stifles innovation



# Valuing a Human Life through “Quality Adjusted Life Years” (QUALY)



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## Valuing a Life

- Willing to pay for airbags
- Pay differential between risky and safer occupations

## “Quality-Adjusting” a Life

- Respondent rating
- Time trade-off
- “Standard gamble”

# Quality Adjusted Life Years: Theoretical Issues



- Do we really want to make treatment decisions based on a \$ value for human life?
- Subjectivity of estimates: \$30,000-\$200,000+
- Difficulty of translating clinical data to QALYs
  - ⇒ Estimates of QALY from ICDs: \$18,000-\$569,000
- Discriminates against disabled and elderly
- Does not reflect numerous social values: reduction in uncertainty, maintenance of function
- Does not reflect differences in patient preferences, especially of those who are sick or disabled

## The NICE “Model”



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- No coverage for effective but high cost cancer drugs for terminal patients
- No coverage (until recently) for any drugs for MS
- No coverage for one-half of osteoporosis drugs available in U.S.
- No coverage for macular degeneration treatments unless already lost sight in one eye
- No coverage for Alzheimer drugs in early disease stage



- Makes breakthroughs less likely
- Makes progress by cumulative change less likely

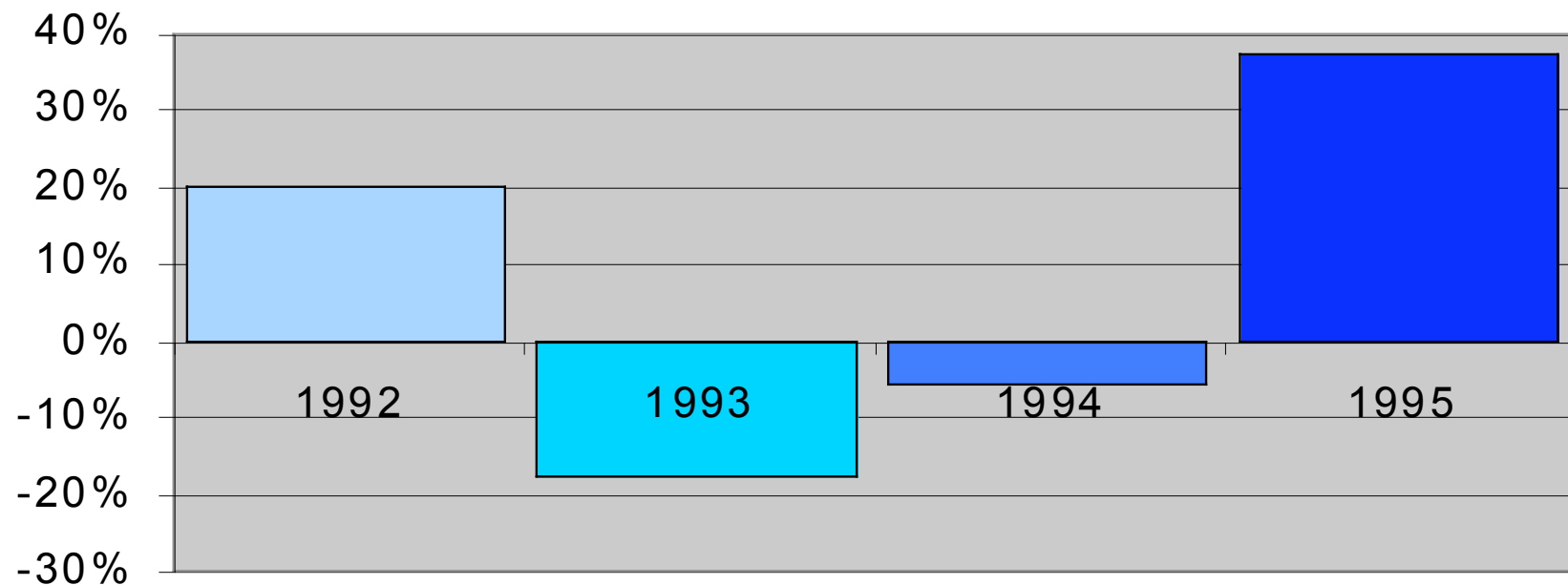


## VC Funded Medical Breakthroughs

- Angioplasty
- Minimally invasive bypass
- Glucose self-monitoring
- Implantable defibrillators
- Joint replacement
- Doppler ultrasound
- Minimally invasive biopsy
- PSA
- MRI
- TPA
- Electro-ablation
- Epogen
- Enbril
- Pulse oximeters

# VC Funding: Sensitivity to Coverage/ Reimbursement

## Change in Number of Life Science Deals <sup>[1]</sup>



[1] See *Fueling Innovation In Medical Devices (And Beyond): Venture Capital IN Health Care*, by D. Clay Ackerly, Ana M. Valverde, Lawrence W. Diener, Kristin L Dossary, and Kevin A Schulman, for additional data indicating close link between reimbursement and venture capital funding.



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