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The Implications of Comparative Effectiveness Research for Medical Device & Diagnostics Manufacturers

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BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

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About AdvaMed

AdvaMed
Advanced Medical Technology Association

- 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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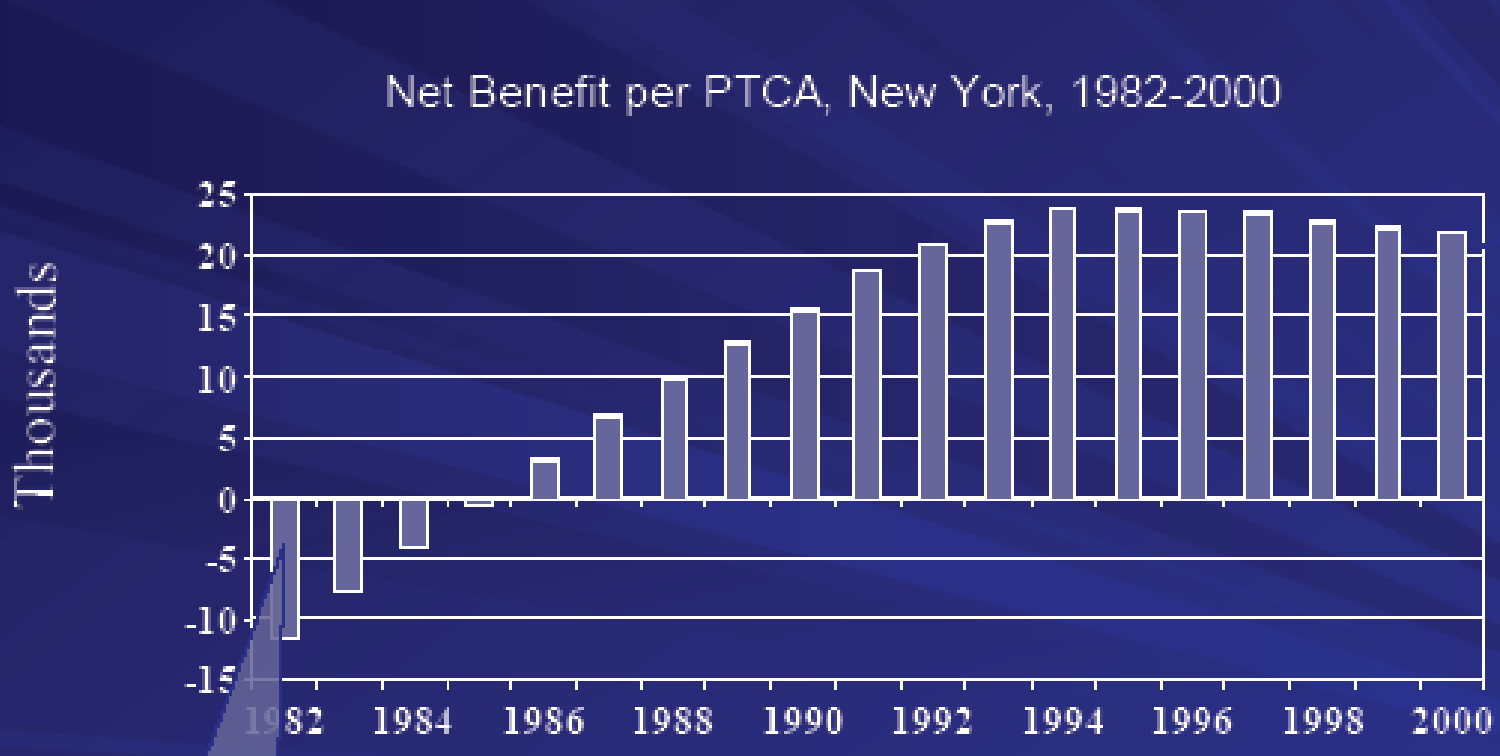

"Technological Development and Medical Productivity: Diffusion of Angioplasty in New York State," Cutler D, Huckman, R; National Bureau of Economic Research, Oct 2002

ICD:
Example of pace of innovation

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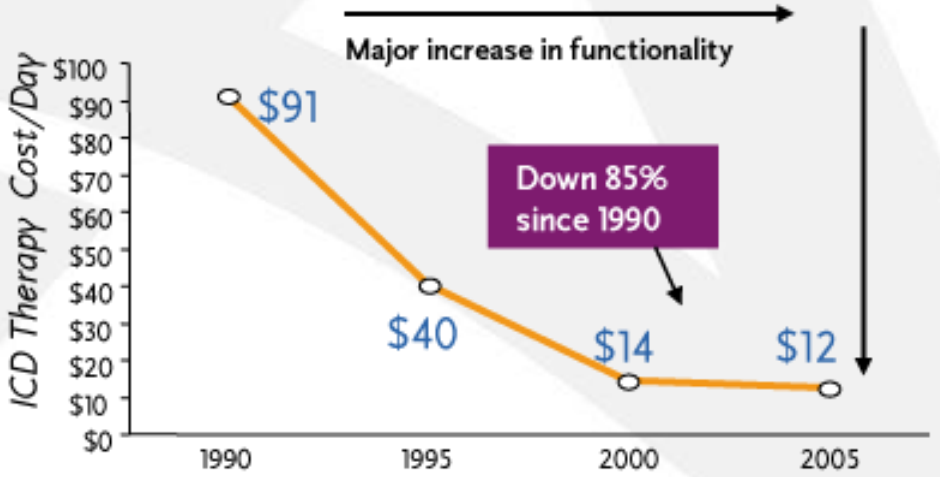
98% effective [1]

99% reliable [2]



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)

[1] Zipes DP. *Circulation.* July 1,1995;92(1):59-65.
[2] 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" (QALY)

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Valuing a Life

"Quality-Adjusting" a Life

Quality Adjusted Life Years: Theoretical Issues

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- Appropriate for broad policy decisions affecting individual treatment?
- Subjectivity of estimates
- Translating clinical data to QALYs
- Discrimination against disabled and elderly
- How to reflect numerous social values: reduction in uncertainty, maintenance of function
- 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

Cost Effectiveness and Innovation

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

Venture Capital Funding: Critical to Innovation

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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

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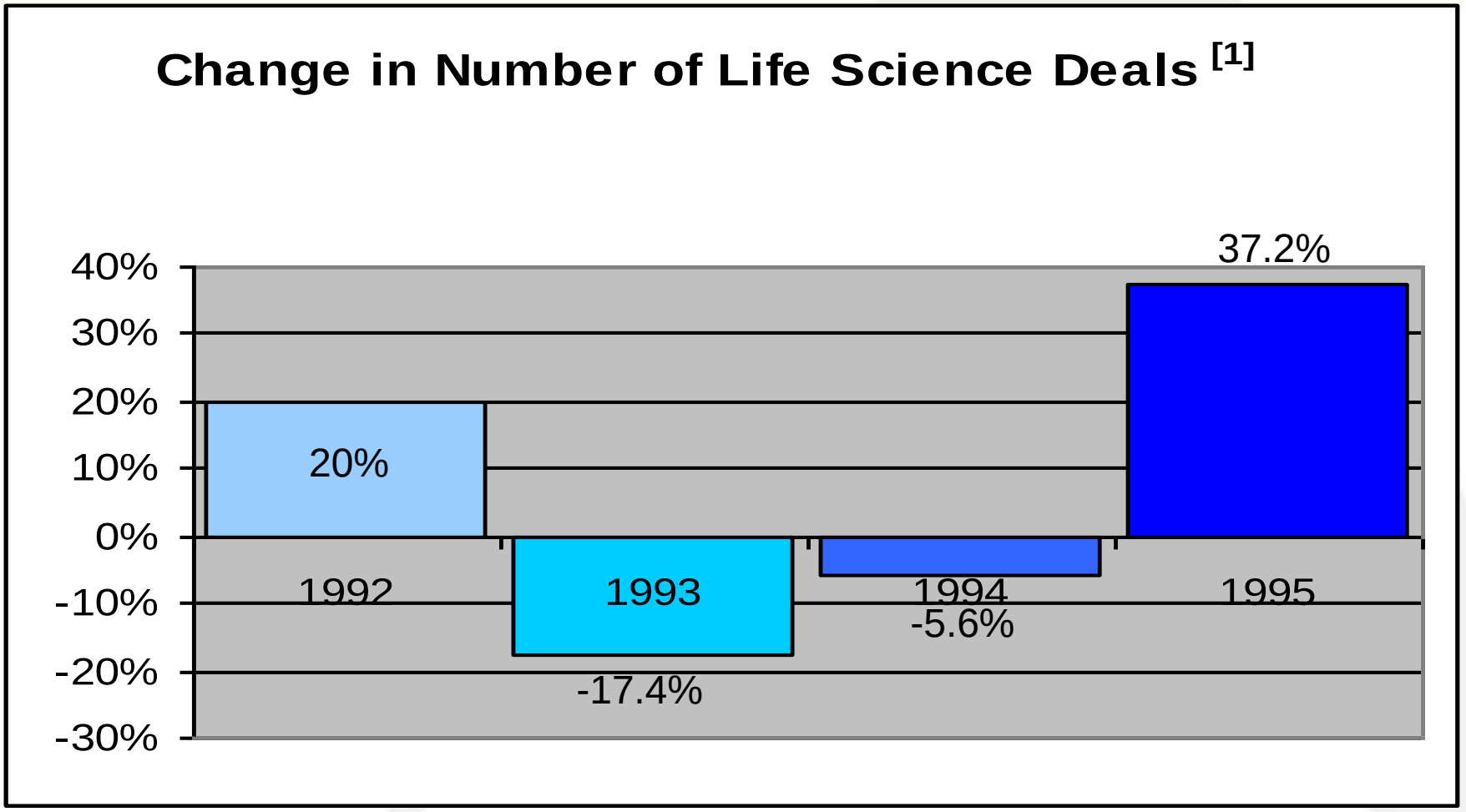

[1] See *Fueling Innovation In Medical Devices (And Beyond): Venture Capital IN Health Care*, by D. Clay Ackerly, Ana M. Valverde, Lawrence W. Diener, Kristin L Dossary, and Kevin A Schulman, for additional data indicating close link between reimbursement and venture capital funding.

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