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

Teresa L. Lee, JD, MPH
Vice President
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
• Facilitate diffusion of valuable products

• Winners and losers

• Overall: Good for industry
Comparative Effectiveness Research and the Device Industry: Some Cautions

• Time dimension

• Evolving evidence

• Few “slam dunks”
Angioplasty reduces angina, opens blockages: change in value over time

Net Benefit per PTCA, New York, 1982-2000

Net cost in 1982 = ($11,600)

Net benefit in 2000 = $21,900

ICD: Example of pace of innovation

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)

Application of research to coverage and payment

• 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

- Flawed methodology
- Denies patients quality care
- StIFles innovation
Valuing a Human Life through “Quality Adjusted Life Years” (QALY)

Valuing a Life

“Quality-Adjusting” a Life
Quality Adjusted Life Years: Theoretical Issues

- 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
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

- Makes breakthroughs less likely
- Makes progress by cumulative change less likely
Venture Capital Funding: Critical to Innovation

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

-30%  -20%  -10%  0%  10%  20%  30%  40%
-17.4% -5.6%  37.2%

[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.