# Getting Your Products Reimbursed by Private Payers

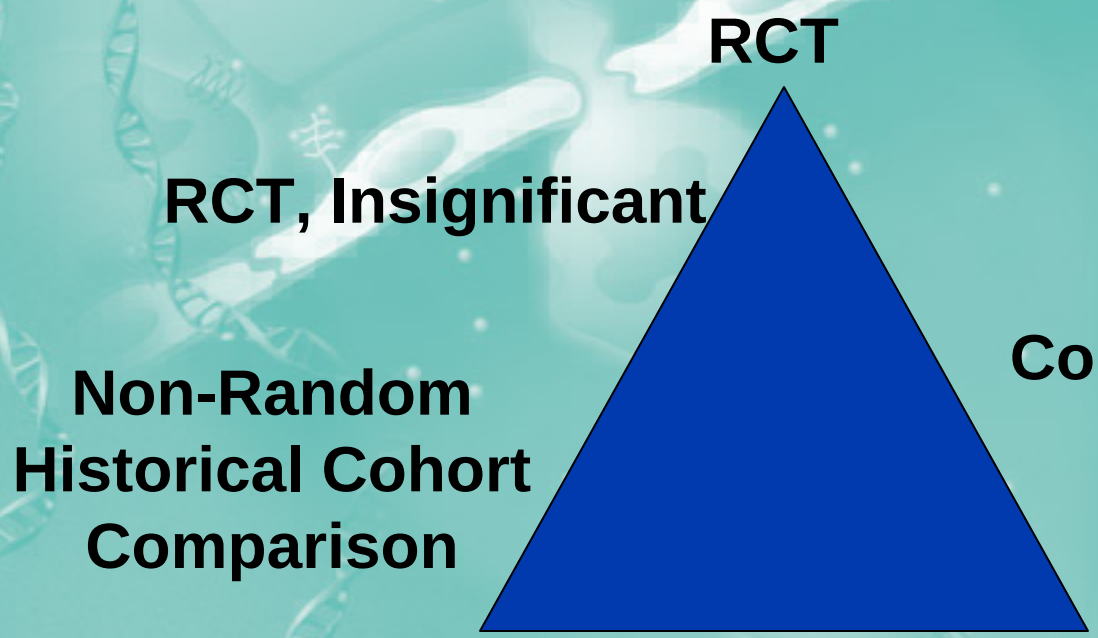
Jeffrey Bush
Director, Corporate Reimbursement
Becton, Dickinson and Company (BD)

BD
Helping all people live healthy lives

# *What Outcomes Do Payers Expect?*

- Payers Require Medical Evidence that a Given New Technology Brings Value to Members & Ideally to the Bottom Line
  - Stronger Evidence = More Enthusiastic Payer
  - Greater Savings = More Enthusiastic Payer
    - Sooner Savings Can Be Realized = Enthusiastic Payer
  - Randomized Control Trial (RCT) Demonstrating Value/Savings is Consensus Gold Standard
    - Most Medical Device Trials Are Not RCT's
    - FDA Challenges with RCT's for Medical Devices

# Be Prepared to Defend Your Choice of Evidence Collection




From criteria proposed by Cook et al, Rules of evidence Chest 1992 ; 305S-311S

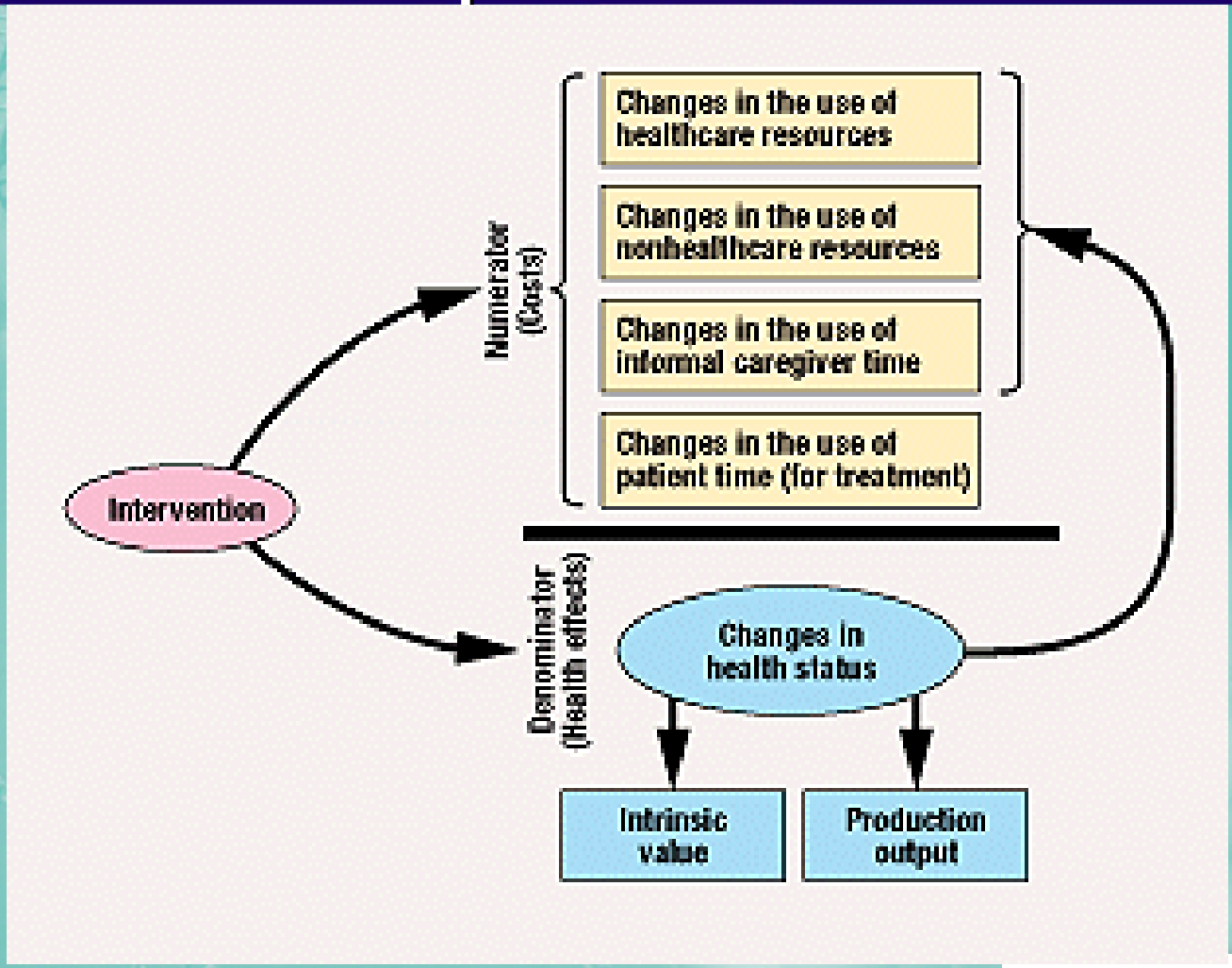
# Medical Devices & Evidence

- Examples of Devices that have provided high level of evidence
  - Standard Stents
  - Drug Eluting Stents
  - ICD's
  - Biventricular Pacemakers (MIRACLE trial)

# *Device Outcomes Examples*

- RCT's & Modeled Outcomes
  - Examples of Device Based Outcomes Studies
    - MIRACLE Trial for CRT
    - RAVEL, SIRIUS, C-SIRIUS & E-SIRIUS for DES
    - D.K. Owens et al, *Cost-Effectiveness of Implantable Cardioverter Defibrillators*, NEJM, Oct 6, 2005.
    - Stents - Numerous

# Understand Payer Evidence Expectations




From Bryan Luce & Ann Elixhauser, "Documenting the Value of a Medical Device," Medical Device & Diagnostic Insustry, January, 1999.

BD

Helping all people live healthy lives

# *Consider Outcomes Alternatives*

- Outcomes Modeling
  - PC Based Modeling of Cost-Benefit
    - E.g., Markov Simulations
  - Comparative Effectiveness
    - CPLYS/CPQALYS Savings Estimates
  - Require Variable Input
    - Must Collect Some Data (Clin Trial or Other)

# Drug Eluting Stent Example

(JAMC • 1er FÉVR. 2005; 172 (3))

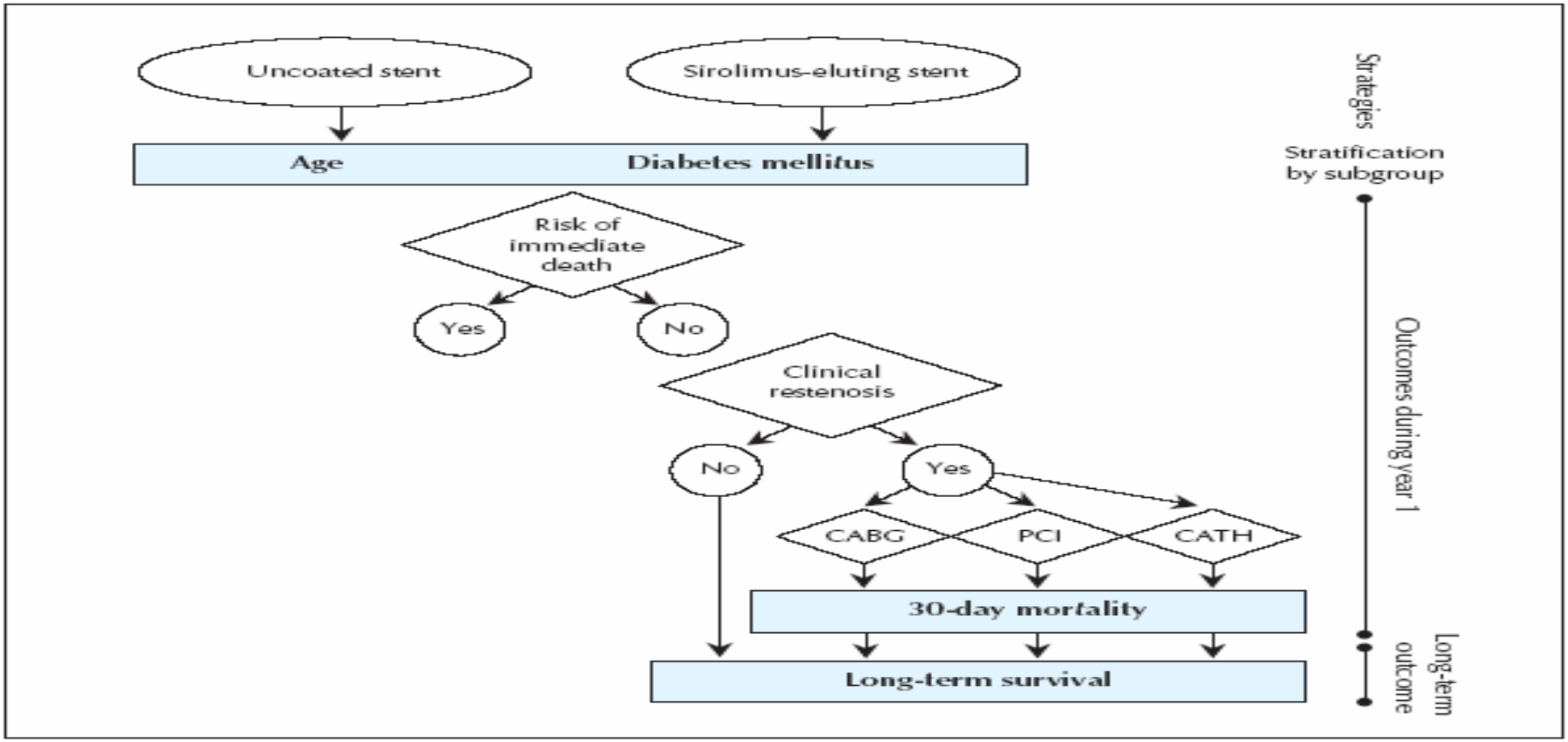



**Fig. 1: Markov model, showing cost and clinical outcomes after percutaneous coronary intervention (PCI) with stenting in 6-month intervals.** After initial PCI, patients are at risk of clinical restenosis over the first year. During this year, they may progress through 5 discrete health states: 1) alive with no clinical restenosis (i.e., event-free), 2) clinical restenosis as determined by the need for a subsequent coronary artery bypass graft (CABG), 3) clinical restenosis as determined by the need for repeat PCI, 4) repeat catheterization with no subsequent revascularization procedure (defined as no PCI or CABG in the ensuing 3 months) and 5) death. Restenosis is considered to occur only in the first year after initial PCI.[1] Thereafter, patients have an ongoing long-term risk of death. CATH = catheterization.

# QALY Assessment of Stenting

**TABLE 5. Cost-Effectiveness of Stenting and Abciximab in the CADILLAC Trial Under Alternate Assumptions Regarding 1-Year Mortality**

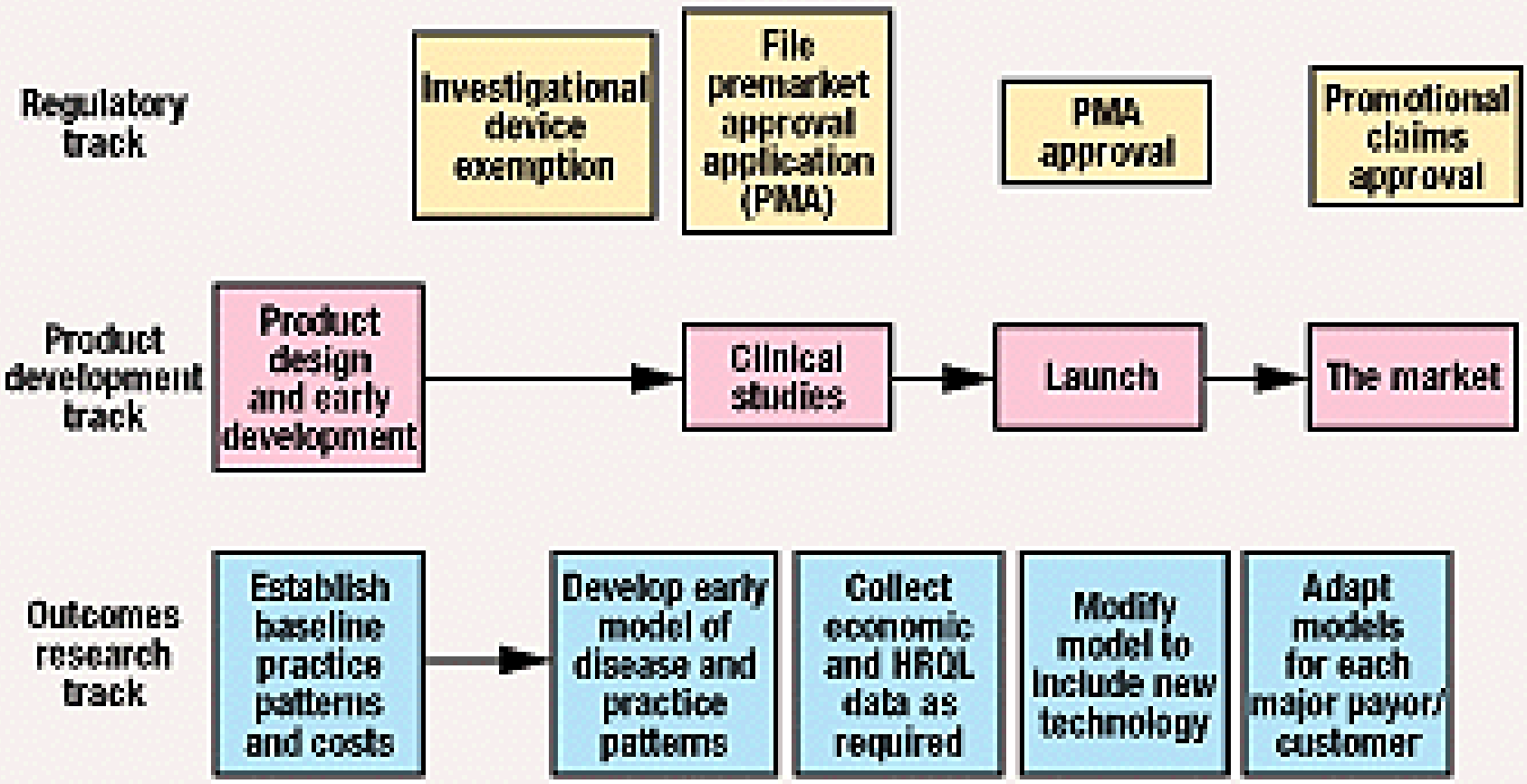
| Scenario | Δ Cost (95% CI),* US $ | Δ QALYs (95% CI)* | C/E Ratio ($/QALY) | % <$50 000 per QALY* | % Dominant* | % Dominated* |
|---|---|---|---|---|---|---|
| Stent vs PTCA | | | | | | |
| Primary analysis | 169 (−821 to 1177) | 0.015 (0.011 to 0.019) | 11 237 | 86.4 | 38.2 | 0.0 |
| With mortality differences | 242 (−961 to 1368) | 0.034 (−0.164 to 0.247) | 7067 | 60.2 | 22.5 | 24.7 |
| Abciximab vs no abciximab | | | | | | |
| Primary analysis | 1244 (289 to 2288) | −0.002 (−0.006 to 0.002) | Dominated | 0.1 | 0.1 | 75.8 |
| With mortality differences | 1468 (205 to 2385) | 0.058 (−0.130 to 0.266) | 25 136 | 64.0 | 1.0 | 26.5 |

*Percentages and CIs are based on 1000 bootstrap simulations of trial results.

# Communicate With Tech Assessors

- Blue Cross & Blue Shield TEC – TA for Association Members & Others
- Hayes – TA for Customers
- ECRI – TA for Customers
- Aetna – Internal TA Group
- United HealthCare – Internal TA's
- Kaiser – Some Internal TA's

# Design Trials With Outcomes Data Collection in Mind




From Bryan Luce & Ann Elixhauser, "Documenting the Value of a Medical Device," Medical Device & Diagnostic Insustry, January, 1999.

# *DON'T!!!!!*

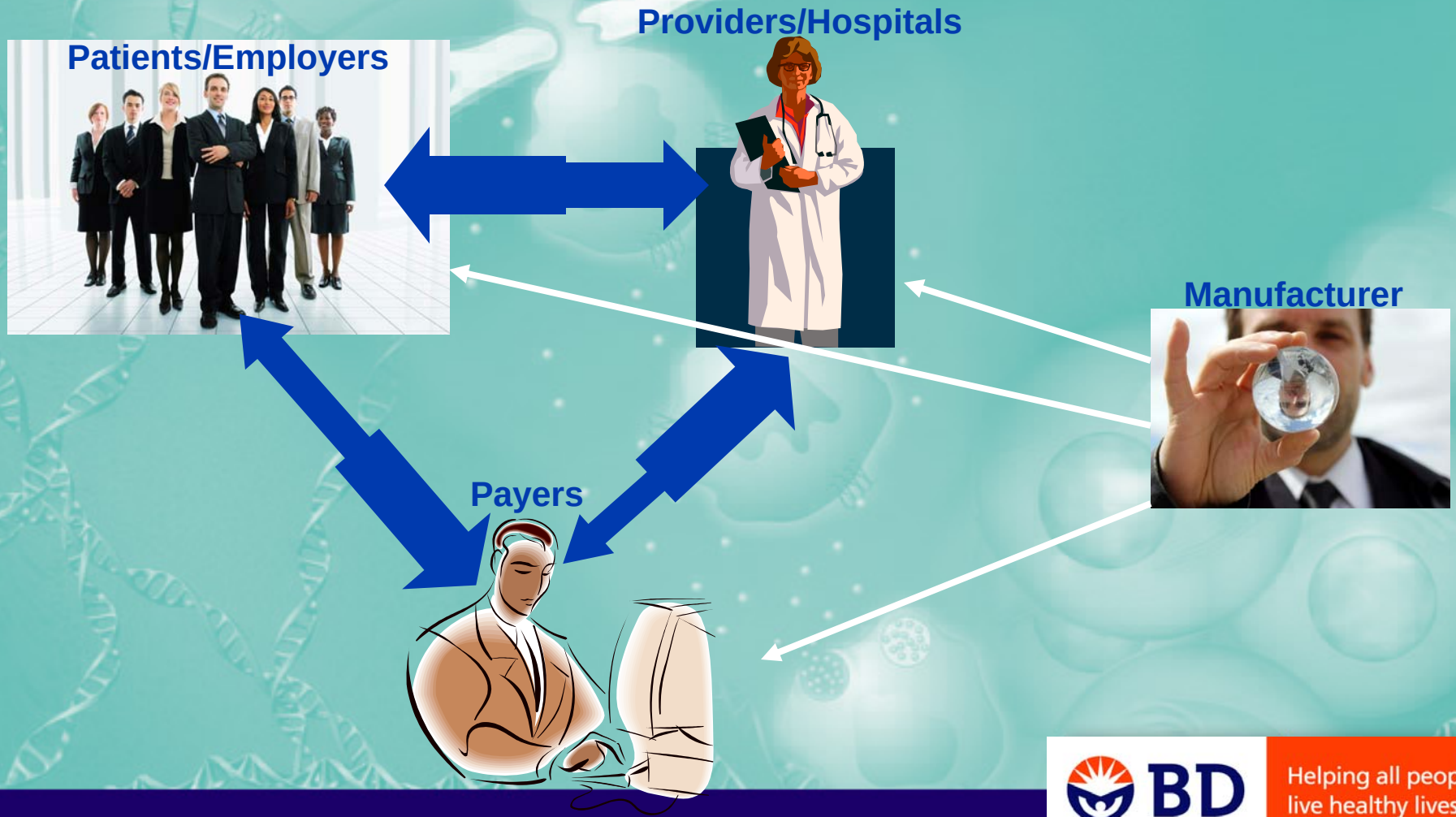
- ***Expect Payers to Embrace Your Product If You Can't Prove What's In It for Them***

# Next Steps

- ✓Worked with Payers/Tech Assessors
- ✓Collected Your Evidence
- ✓Developed Economic Modeling
- ✓Prepared Your Best Case
- NOW WHAT?

# Next Steps

- Strategic Plan Development




BD Helping all people live healthy lives

# Next Steps

- Have a Plan to Reach All Relevant Stakeholders
- Medicare Precedent is Often Important, if Established
- Peer Payer Implementation Creates Competitive Disadvantage
- Reliance on Good Evidence Alone Naïve
- Influence Payers from Multiple Angles
  - Develop Provider and Patient Champions

# Case Example

- Liquid based cytology and Aetna
  - Despite strong study data, Aetna refused coverage
  - Advocacy campaign leveraged upon senior medical directors and executives
    - Provider & Patient Focused
  - Overriding internal opposition, Aetna reversed coverage decision

# THANK YOU!!!!

BD

Helping all people live healthy lives

# Stent RCT's

Table 1: Results of RCTs of PTCA vs Stents

| Trial<br>N of patients | Immediate clinical results: stent v PTCA | Immediate angiographic results: stent v PTCA | Longer term clinical results: stent v PTCA | Longer term angiographic results for stent v PTCA | Comments |
|---|---|---|---|---|---|
| ***BENESTENT***[4-8]<br>516 | Increased bleeding, vascular complications, LOS | Increased MLD.<br>Decreased % stenosis | Increased event free survival at 12 mths.<br>Decreased risk of PTCA and of any event 7 and 12 mths. | Increased reference diameter.<br>Decreased restenosis rate and % stenosis at 7 mths. | Clearly reported. Includes subgroup follow up of exercise testing showing no difference between stent and PTCA groups. |
| ***STRESS***[9-14]<br>316 | No significant differences | Increased MLD.<br>Decreased % stenosis | No significant differences | Increased MLD.<br>Decreased restenosis rate and %stenosis at 7 mths | Target vessel revascularization result p=0.06 taken to be statistically significant by trial authors but not in this review. |
| ***Switzerland***[15]<br>84 | Increased vascular complications, LOS | Increased MLD.<br>Decreased % stenosis | No significant differences | No significant difference restenosis rate, % stenosis, MLD | Different stent which is more radio-opaque so borderline restenosis more difficult to judge |
| ***Italy***[16]<br>120 | Increased vascular complications, LOS | Increased MLD.<br>Decreased % stenosis | Increased event free survival | Increased MLD.<br>Decreased restenosis rate , % stenosis. | Some clinical results have to be inferred from text as presentation of results not clear |
| ***BENESTENT II***[17]<br>823 | No significant differences | Increased MLD.<br>Decreased % stenosis | Increased event free survival<br>Decreased repeat PTCA | Increased MLD.<br>Decreased % stenosis | Cost effectiveness data – stents more effective and more costly. Subgroup follow up of angiographic and clinical or clinical only - clinical follow up only have increased rate rpt PTCA. |
| ***SICCO***[18] | Increased | Increased MLD. | Increased angina free | Increased MLD. | Some clinical results have to |

# More Stent RCT's

| | | | | | |
|---|---|---|---|---|---|
| 117 | bleeding at puncture site, LOS | Decreased % stenosis | survival | Decreased restenosis rate , % stenosis. | be inferred from text as presentation unclear. |
| ***GISSOC***[19] 110 | See longer term results | Increased MLD Decreased % stenosis | Increased LOS. Decreased TVA, recurrent ischaemia | Increased MLD. Decreased restenosis rate, reocclusion rate, % stenosis. | Does not state how occlusions were found at >30 days duration. |
| ***Britain***[20] 60 | No significant differences | Increased MLD. Decreased % stenosis | No significant differences | Increased MLD. Decreased reocclusion rate. | Some clinical results have to be inferred from text as presentation unclear. |
| ***GRAMI***[21] 104 | Increased TIMI flow, event free survival. Decreased recurrent ischaemia | Decreased % stenosis | Increased event free survival | Not given | Angiographic restenosis rates at follow up not reported |
| ***FRESCO***[22] 150 | Decreased recurrent ischaemia, repeat PTCA | Increased MLD Decreased restenosis | Decreased repeat PTCA, recurrent ischaemia | Increased MLD. Decreased restenosis rate. | Also includes results for non-randomised comparison group who had non-optimal PTCA result. |
| ***Holland***[23] 227 | No significant differences | Increased MLD. Decreased % stenosis | Increased event free survival. Decreased re-current MI, repeat PTCA. | Not given | Anticoagulation therapy changed during trial from Warfarin to Ticlopidine |