



## **Cost-Effectiveness Methods, Analysis, & Challenges for Medical Technology Companies**

Offices of Sidley Austin  
Washington, DC  
June 30 – July 1, 2009

### **Tuesday, June 30<sup>th</sup>**

**8:30 – 9:00**

**REGISTRATION AND CONTINENTAL BREAKFAST**

**9:00 – 9:05**

**Welcome**

*Thomas Maeder, Executive Director, MTLI, AdvaMed*

**9:05 – 10:00**

**Evidence and Health Technology Assessment – Terms, Concepts, and Landscape**

*Parashar Patel, Vice President, Health Economics & Reimbursement, Boston Scientific*

- What is the body of evidence surrounding any medical technology?
- What are the roles of evidence in product clearance/approval, coverage & payment, and clinical adoption?
- What are the types of health economic and health technology assessment data?
- What are cost-effectiveness and comparative effectiveness and how are they used?
- Where does health economic data typically come from?
- What have medical device companies done in these areas?
- Caveats and pitfalls, methodological and other

**10:00 – 10:45**

**Breakout Exercise on Cost-Effectiveness Analysis**

*Gregory de Lissovoy, Senior Research Scientist, Vice President of Health Technology, United BioSource*

- Participants break into small groups to work through an illustrative case study of cost-effectiveness analysis and comparison of several alternative therapeutic approaches. No prior experience is required.

- 10:45 – 12:00**      **Methods of Cost-Effectiveness Analysis**  
*John Hernandez, Vice President, Neuromodulation, Health Economics & Reimbursement, Boston Scientific*
- Types of analysis and their applications
  - Cost Savings Analysis
  - Cost Effectiveness Analysis
  - Cost Benefit Analysis
  - Cost Utility Analysis
- 12:00 – 1:00**      **LUNCH**
- 1:00 – 1:45**      **Cost-Effectiveness in Different Product Types and Therapeutic Categories**  
*Liesl Cooper, Vice President, Global Healthcare Economics, Policy & Reimbursement, Medical Devices, Covidien*
- Study designs revisited – different measures and endpoints
  - Different product categories or therapeutic applications that illustrate the challenges of choosing the right objectives, study endpoints, and data sources
  - The right study for the right purpose
- 1:45 – 2:30**      **Case Study: The Drug-Eluting Stent**  
*Speaker TBA*
- 2:30 – 3:15**      **Case Study: Deep Brain Stimulation**  
*Bonnie Handke, Senior Director, Neuromodulation Reimbursement, Medtronic*
- 3:15 – 3:30**      **BREAK**
- 3:30 – 4:30**      **Policies and Cost-Effectiveness Around the World**  
*Speaker TBA*
- What criteria are used and how are they applied in key countries?
  - The NICE example
  - Can companies develop global strategies for generating and using cost-effectiveness information?
  - Are data from one country useable in others?
  - Examples of successes and less optimal results
  - Where is the global trend likely to go, and what should we anticipate domestically?
- 4:30 – 5:15**      **Case Study: Using Cost-Effectiveness Data in a Coverage Decision**  
*William Sarraille, Partner, Sidley Austin*
- How the U.S. Task Force for Preventive Services approaches cost-effectiveness, and the process of securing a positive recommendation for Medicare coverage of a screening test
- 5:15 – 5:30**      **Closing Remarks for the Day**

## ADJOURNMENT

**5:30 – 6:30**

**RECEPTION**

**Wednesday, July 1<sup>st</sup>**

**8:00 – 8:30**

**REGISTRATION AND CONTINENTAL BREAKFAST**

**8:30 – 9:30**

### **Internal Resources**

*Richard Toselli, Worldwide Vice President of Clinical Evidence & External Relations, DePuy Spine, a J&J Company*

- Do you need a health economics team? How do you know?
- What is your business strategy? What products do you make, what are your clinical areas, what is your pipeline?
- Defining objectives and outputs
- Maximizing limited resources: buy or build?
- What is the desired skill mix?

**9:30 – 10:30**

### **Panel Discussion: Strategic, Tactical, and Business Considerations**

*Thomas F. Goss, Vice President, Boston Healthcare Associates*

- Anticipating long-term data needs and designing studies and trials that anticipate multiple uses (regulatory approval, coverage and reimbursement)
- Opportunities and risks of designing studies to meet multiple purposes
- Monitoring a changing environment and designing studies that anticipate higher evidence standards
- Integrating value assessment and demonstration into clinical development
- Evaluating the time, cost, and return on additional evidence development

**10:30 – 10:45**

**BREAK**

**10:45 – 11:30**

### **Case Study: Percutaneous Heart Assist**

*Andrew Greenfield, VP, Healthcare Solutions  
Abiomed, Inc.*

**11:30 – 12:15**

### **Opportunities and Risks of Cost-Effectiveness Data**

*Liesl Cooper, Vice President, Global Healthcare Economics, Policy & Reimbursement, Medical Devices, Covidien*

- Internal uses during product development, evaluation, positioning, pricing, etc.
- External uses of data with public and private payers and providers
- Different meanings of “cost” and “effectiveness” to different stakeholders

**12:15 – 1:00**                      **Closing Discussion**

**1:00**                                **ADJOURNMENT**

***Important Notice***

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