

“Doing Double Duty”

Collecting Data for FDA and CMS in the Same Study



**Medical Device Regulatory
& Compliance Congress
March 30, 2006**

**Donald P. Conway, MD, MBA
Director Healthcare Initiatives
Tuck School of Business at Dartmouth**

VIEW FROM 30,000 FEET

- Increase Utilization of Healthcare Services/Products
- Constrained Budgets
- Increased Scrutiny of Healthcare Costs

DIFFERENCES IN PERSPECTIVE

- FDA – Safety, Efficacy
- CMS – Efficiency, Cost Effectiveness
- Manufacturers – Timely Coverage and Adequate Reimbursement

PERSPECTIVE: MANUFACTURERS

Goal: To secure coverage and adequate reimbursement in a timely manner

ASAP

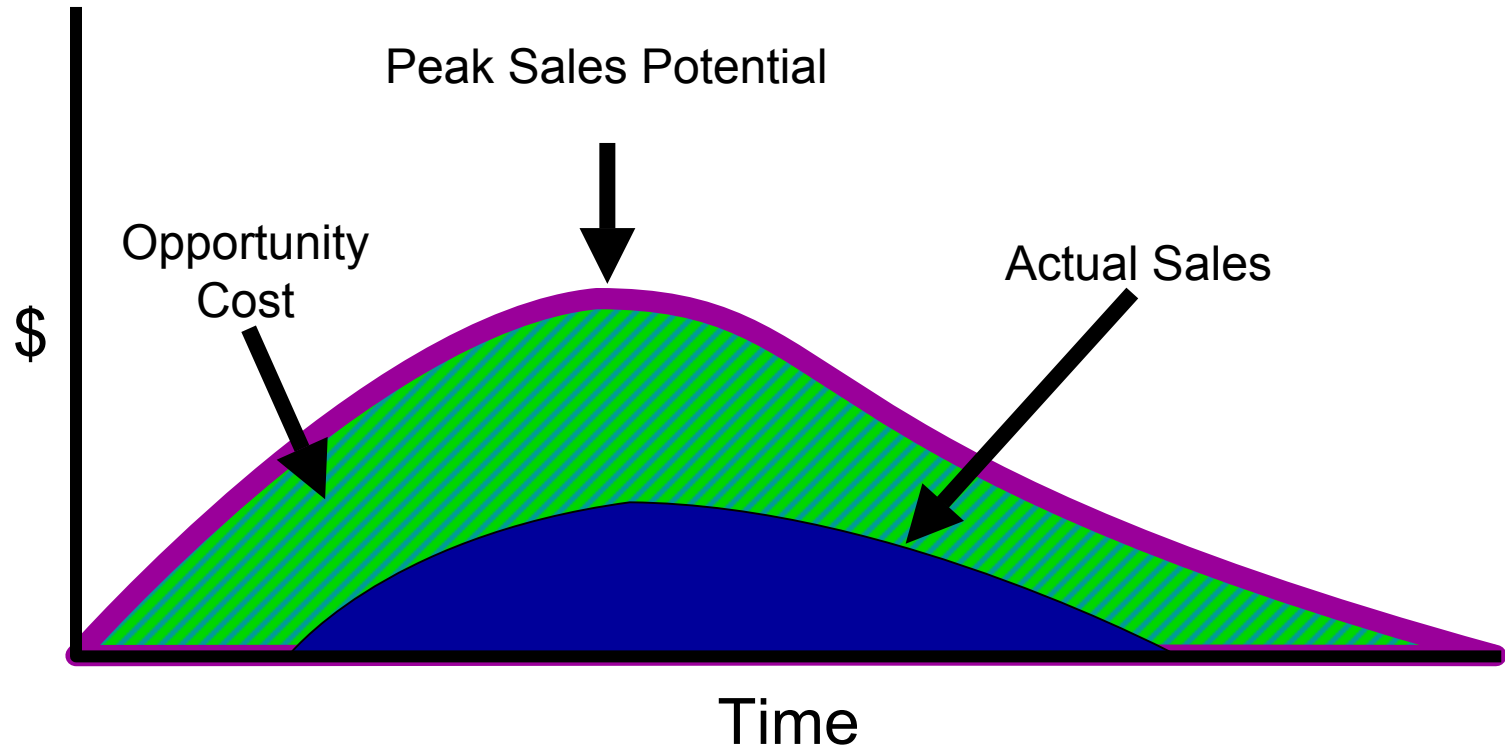
BUSINESS CASE “For Doing Double Duty”

Having the right data
In the right subpopulation
With appropriate power
At the right time.

COST OF NOT OBTAINING COVERAGE

- Additional Trial required
- Opportunity Cost-lost sales
- Competition even more entrenched
- Practice patterns established
- Never realizing true sales potential

DEMONSTRATING VALUE



WHAT MANUFACTURERS CAN DO

- Model Reimbursement landscape
- Incorporate economic “Value Proposition” in the Target Product Profile.

Reimbursement systems are complex mechanisms.

“Understanding reimbursement is absolutely critical. It is one of the key factors we evaluate in every market opportunity.

If precedent for reimbursement exists we look at the level of reimbursement and determine what can be done to upgrade it.

Creating a new reimbursement scheme is a significant undertaking. Reimbursement battles can go on for years post-approval. They can be the major obstacle to ramping up sales.

It is essential that we understand a product’s reimbursement mechanism up front”.

Ross Jaffee, MD, MBA

Versant Ventures

WHAT Manufacturers CAN DO

- Anticipate CMS and Private Payers views
- Dialogue early and often
- Anticipate which competitive technologies will be disrupted
- Anticipate competitors response

WHAT Manufacturers CAN DO

- Ensure pivotal trials include an adequate representation of Medicare eligible patients
- Capture economic endpoints in pivotal trials both Direct and Indirect Costs
- Model global economic impact from these endpoints

WHAT Manufacturers CAN DO

- Ongoing collection of patient level data via open label follow-up
- Establish a Patient Registry to obtain patient level data – economic and patient reported outcomes

PAYER COMMUNITY (CMS AND PRIVATE)

- CMS sets precedent – Not Always
- Demand effectiveness data/NIH
- Comparative clinical effectiveness
- Pay for Performance
- Demand Cost/Effectiveness data
- Increasingly Important role AHRQ

PAYER COMMUNITY

- An Eye to Other Healthcare Systems
- National Institute of Clinical Excellence (NICE)
www.nice.org.uk
- PBAC - Australia
- Provincial authorities - Canada
- County councils – Sweden



Questions / Answers