Conflicts of Interest Are Here to Stay:  
Implications for the Medical Device Innovation Process

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May 3, 2004, Boston  
Conflicts Panel II

History of Medical Device Breakthroughs:  
Triumph of Passion & Persistence

Some examples:  
- Kidney dialysis  
- Heart valves  
- Cardiac pacemakers  
- Balloon angioplasty  
- Implantable defibrillator

Each of these breakthroughs was highly controversial and was received cynically in its nascent period. Each of the pioneers was highly conflicted, but acted responsibly.

Would these therapeutic breakthroughs, now treatments of choice, have survived today’s well intentioned patient protections?

Medical Devices Are Different Than Drugs:  
Drug models to protect against hidden biases and COI may not be relevant and can impede the medical device innovation process.

- Difficult to blind
  - Physical properties
  - Surgery required

- Randomization and crossover trials raise ethical concerns
  - Sham surgery
  - Results are highly apparent; “on/off” effects

- Clearer, more definitive endpoints vs. drugs

- Novel device & novel surgical technique inextricably intertwined
  - Clinician-innovator very often the inventor
  - Innovator may be best-suited for early implants (learning curve)

- Gov’ts recognize inventor is entitled to property rights
  - Articulated in U.S. Constitution!

- Inventor’s vision and experience may trump “expert” opinion and conventional wisdom

- Relatively few patient compliance and reporting issues by virtue of implant, automatic function, and objective outcomes

... The Congress shall have power ... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries ...
The Enemy is Not COI, but “Conflict of Action”

Potential Conflict of Interest → “Conflict of Action”

Prospectively
- Full disclosure
- affiliations
- grants
- appointments
- relationships
- financial
- Organizational oversight

Retrospectively
- Surveillance & follow-up
- Study replication
- Communication
- lessons learned
- sanctions for actual breaches

The problem with ever-stricter preemptive COI measures is the illusion that they implicitly protect society.

Must distinguish between potential conflict of interest and “conflict of action.”

Relationship between COI Measures and “Value”

The problem with ever-stricter preemptive COI measures is the illusion that they implicitly protect society.