

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

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Conflicts Panel II

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**History of Medical Device Breakthroughs:
Triumph of Passion & Persistence**

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

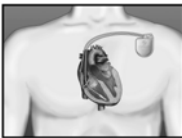
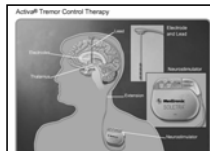
Each of these breakthroughs was highly controversial and was received cynically in its nascent period.

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



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



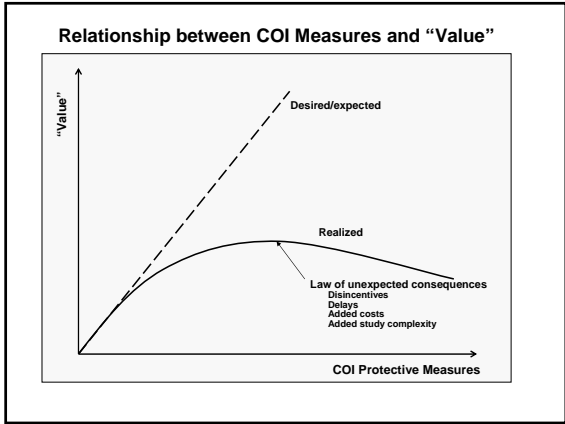
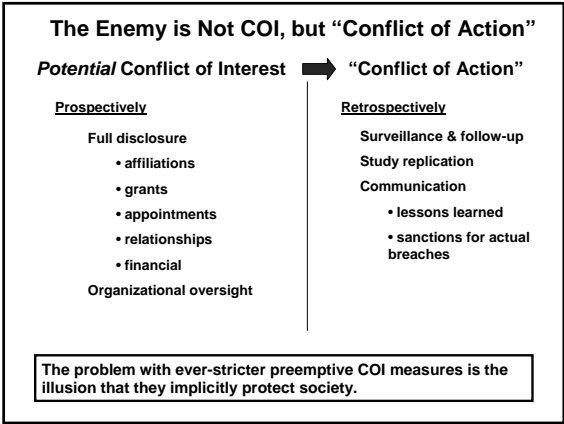
**Medical Devices Are Different Than Drugs:
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- Difficult to blind
- Randomization and crossover trials raise ethical concerns
- Clearer, more definitive endpoints vs. drugs
- Novel device & novel surgical technique inextricably intertwined
 - Clinician-innovator 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!

Article I, Section 8: 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;.....

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 - Unpatented innovations will not be developed
- Inventor's vision and experience may trump "expert" opinion and conventional wisdom
 - Cynics -- "results too good to be true" "It'll never work!"
- Relatively few patient compliance and reporting issues by virtue of implant, automatic function, and objective outcomes



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.”