COI Stories in the Press
Hypothetical Scenario

Have you ever imagined a world with no hypothetical situations?
Drug Interactions

Financial Ties to Industry Cloud Major Depression Study
At Issue: Whether It's Safe For Pregnant Women To Stay on Medication
JAMA Asks Authors to Explain
By DAVID ARMSTRONG
Taking antidepressants during pregnancy
Mass General, UCLA, Emory

Drug Interactions
Stopping meds increases relapse

Good news for drug makers

Financial Ties to Industry

Cloud Major Depression Study

At Issue: Whether It’s Safe For Pregnant
Women To Stay on Medication

JAMA Asks Authors to Explain

None of the financial ties were reported

Failed to disclose >60 financial relationships
Financial Ties to Industry

Research was funded by NIH.
“... it didn’t seem relevant” to disclose Industry “tends to pick experts…”
“We are not talking about megabucks.”
“Your attention on the disclosures is obscuring the findings and doing a huge disservice to women and their families who are now, more than ever, confused.”
Medical Journal Accountability

“It sounds to me like they’re being sloppy.”

Dr. Jerome Kassirer
Former Editor, NEJM
Medical Journal Accountability

“I’m not God and I’m not the FBI.”

Dr. Catherine DeAngelis
Editor, JAMA
Medical Journal Accountability

“I don’t give lie detector tests.”

Dr. Catherine DeAngelis
Editor, JAMA
Update on JAMA's Conflict of Interest Policy
July 12, 2006

“… err on the side of full disclosure…”

“All such disclosures should be listed in the Acknowledgment section…”

“…all relevant financial interests and relationships or financial conflicts within the past 5 years and for the foreseeable future…”
Update on JAMA's Conflict of Interest Policy
July 12, 2006

“…employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending…”

“…JAMA requires complete disclosure… regardless of amount or value.”

“If authors are uncertain… they should contact the editorial office.”
The New York Times

Charities Tied to Doctors Get Drug Industry Gifts
By REED ABELSON, NY Times
June 28, 2006

round the country, doctors in private
ass evident were some of the financial in-

These industry-run charities pay large outlays to doctors who then use or recommend a specific drug or device, companies could be violating the law..."
Charities Tied to Doctors Get Drug Industry Gifts
REED ABELSON, NY Times
June 28, 2006
MHF is a non-profit research and education foundation dedicated to improving the prevention and management of cardiovascular and related diseases through research, education, and community leadership.

Since 1988, Midwest Heart Foundation has conducted over 260 clinical trials in all areas of cardiology.
• Healthcare professionals are experiencing the safe, effective, and predictable removal of excess salt and water...
• In 2004 CHF gave MHF $180,000 donation.
• MHF physician is paid consultant to CHF.
• MHF received millions of dollars from pharmaceutical and medical device companies over several years.
• Foundation created to prevent potential COI.
• DOJ subpoena for marketing – Scios.
Doctor-run Charities

• Legitimate research & education
• Real or apparent COI
• “Relationship funding”
• Flow of $$$ to for-profit medical groups
• Cover business expenses & salaries
• Must benefit the public not doctors or companies
Doctor-run Charities

• Unknown # – off the radar screen
• Attracting sizable donations
• “Teaching other doctors how to use Stryker products”
• Used to defray the cost of a fellowship
• CME of physicians in for-profit practice
• Must benefit the public not doctors or companies
Doctor-run Charities

“… concerned about end-runs around the system.”

-Patrick L. Meehan, US Attorney
Delicate Operation
How a Famed Hospital Invests In Device It Uses and Promotes
Cleveland Clinic Set Up Fund That Has Stock in Maker Of Heart-Surgery System
Dr. Cosgrove's Multiple Roles
By DAVID ARMSTRONG
Staff Reporter of THE WALL STREET JOURNAL
December 12, 2005; Page A1
Cleveland Clinic Strips Topol of Post Cardiologist Loses Position As Provost, Academic Chief, But Retains Chairman Role

By DAVID ARMSTRONG
Staff Reporter of THE WALL STREET JOURNAL

December 13, 2005; Page D6
Conflicts Review Is Sought by CEO Of Cleveland Clinic
By DAVID ARMSTRONG
Staff Reporter of THE WALL STREET JOURNAL
December 15, 2005; Page A6
Cleveland Clinic Had Ties to Maker Of Faulted Device
By DAVID ARMSTRONG
Staff Reporter of THE WALL STREET JOURNAL
December 16, 2005; Page A3
Cleveland Clinic COI

The AtriCure Device
Cleveland Clinic COI

• Atrial fibrillation
• >1,200 patients since 2002
• “The AtriCure Procedure”
• Publications & presentations
• Leading advocates
• Off-label use
• At least 4 patient deaths
Cleveland Clinic COI

• Helped found venture partnership
• Ownership of 4.1% equity ($7MM)
• Dr. Toby Cosgrove (CEO of CCF) on AtriCure’s Board of Directors
• Personally invested
• Managing Director
• Entitled to royalties
• MDs paid consultants at CCF
Cleveland Clinic COI

- Venture fund has 2 other companies doing clinical trials at CC
- Spring 2004 – COI Committee
- Ties are questioned (Topol)
- Dec 2005 – Cosgrove demotes Topol
- Topol off COI Committee
- Topol off Board of Governors
Cleveland Clinic COI

• Patients/subjects not informed
• CCF reworked the ICF
• CCF imposed consulting limits
• Cosgrove: AtriCure works and is safe
• Little long-term data
• FDA rejected AtriCure’s application three times
• FDA not notified about deaths
Cleveland Clinic COI

- CCF investments in other companies testing at the Clinic
- COI first raised at IRB
- New ICF says CCF would probably benefit financially
- Non-research pts not informed
Cleveland Clinic COI

“I have not received one penny…”
-Dr. Toby Cosgrove

“He hasn’t received anything yet…but when and if…he will donate it to the Clinic”
-CCF Spokeswoman
Cleveland Clinic COI

HHS requirement... to manage, reduce or eliminate conflicts

“How they do so is left largely to them.”

David Armstrong, The WSJ
Bright Line
COI Continuum
COI Continuum

Risk

Permissive

Restrictive
Hypothetical Scenario

- Dr Samantha Slideruler
- Bioengineering center grant
- Upcoming site visit
- Two reviewers with “hidden agenda”
Dr. Gary Grudge

- Rancor State University
- Upset of colleague’s move
- Vowed to “kill the grants”
- Concerned about vindictiveness
Dr. Ulrich Ubertech

- Inventor of the *Uberlaser*
- Direct relevance to project in grant
- Published: *Why the Uberlaser is the only worthwhile laser technology of this century*
- Project uses a different technology
- Intellectual COI
COI Concerns Raised

• Contacted SRA
• Telephone conversation
• SRA is unconcerned
• Absence of COI already certified
• Professionals – dispassionate
• Grudge story is hearsay
• All scientists are opinionated
Questions

• Do Drs. Grudge or Ubertech have a COI?
• Should Dr. Slideruler pursue formally?
• How should SRA approach each?
• If you were either Dr. Grudge or Dr. Ubertech – would you disclose a possible COI?
Postscript

- Dr. Ubertech is commercializing the *Uberlaser* technology
- He is majority owner of the company
- The company existed prior to the publication of his article
- The article contained no disclosure
This week's headlines...
August 10, 2006
• NIH Site Visits Checking Conflict-of-Interest Implementation
• Going to Dean's Office Has 'Profound Impact'
• Summit Will Address Institutional-Industry Partnerships
• 'Finders Fees' Part of 'Commercialization of Research'
Coming Soon!
NEWS FROM THE DIRECTOR OF OER: NIH’s Partnership with the Extramural Community—Reporting Conflict of Interest

Dear Extramural Community:

• Site visits began last fall (12)
• Valuable insights
• Working to address problems
• Public sharing of observations
COI – Summary

- Variable interpretation
- Interest of the press
- Increased government scrutiny
- Risk losing public’s trust
Thank You

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