ISCTM 4th Annual Scientific Meeting

Two-Tiered Publication Standards
Dinner Debate

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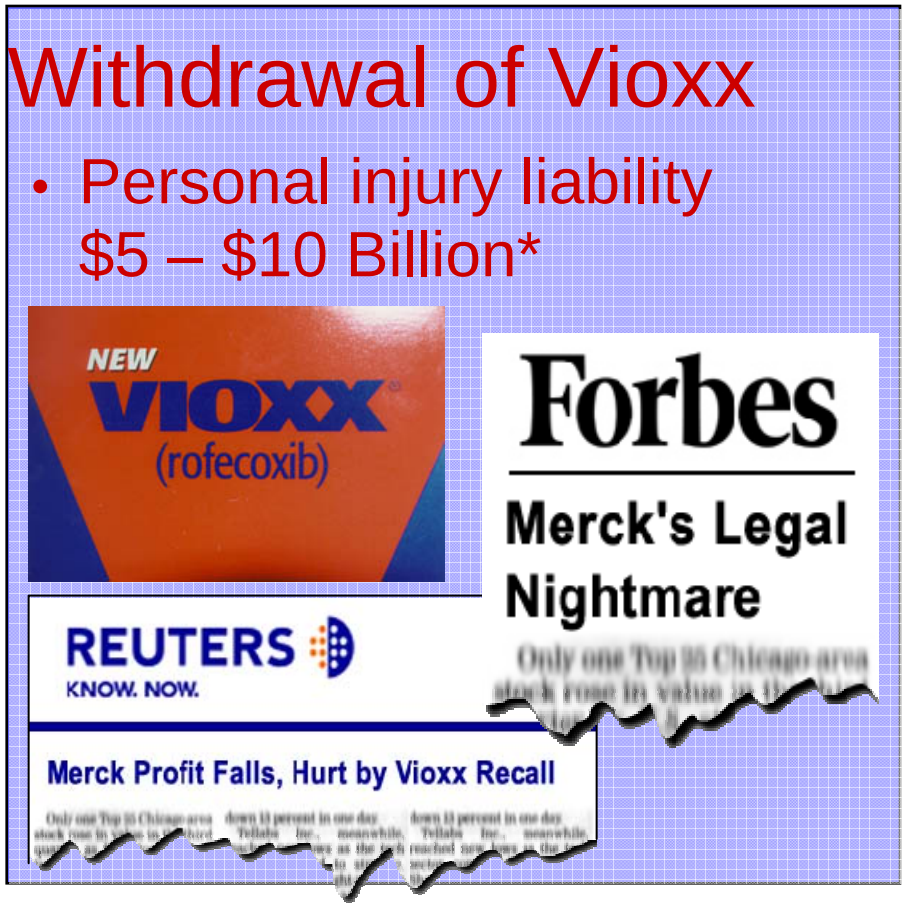
Lilly
Answers That Matter.


SIDE
EFFECTS

Public Confidence in Medical Data Shaken
- Plenty of "blame" to go around



- Industry
  - lack of transparency, kick-backs, Vioxx, Vytorin, Avandia, etc.
- FDA
  - SSRIs and suicide, Vioxx, whistle blowers, etc
- Academia
  - Korean cloning fraud, Lancet NSAID fabrication, conflict of interest, etc

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Two-Tiered Publication Standards for Academic and Industry Authors: *Are They Necessary?*

- **Short Answer: *No***
- **Long Answer: *Increase expectations and requirements for all journal article submissions needed***
  - **Powerful potential conflicts of interest exists for both industry (e.g., sales) and academic (e.g., promotion, notoriety, grant funding, ego) authors**
  - **Managing COI for everybody is important**

Areas of Concern

- **Conflict of interest**
- ***Cherry Picking* (selective data reporting)**
- ***File Drawer Phenomena* (failure to disclose negative studies)**
- **Fraud, data fabrication**
- **Ghost authoring**

Addressing Academic-Industry COI: *Four Key Elements*

- **Transparency**
  - *"Sunshine is the best disinfectant."*
    - Louis Brandeis, Supreme Court, 1914
  - Necessary but not sufficient

- **Codes of Conduct and Policies**
  - *"Rules of the road"* – federal, state, AAMC, university, industry codes
  - Must be strong, specific, enforceable, and have *"teeth"*

- **Compliance measures**
  - Auditing, penalties for noncompliance

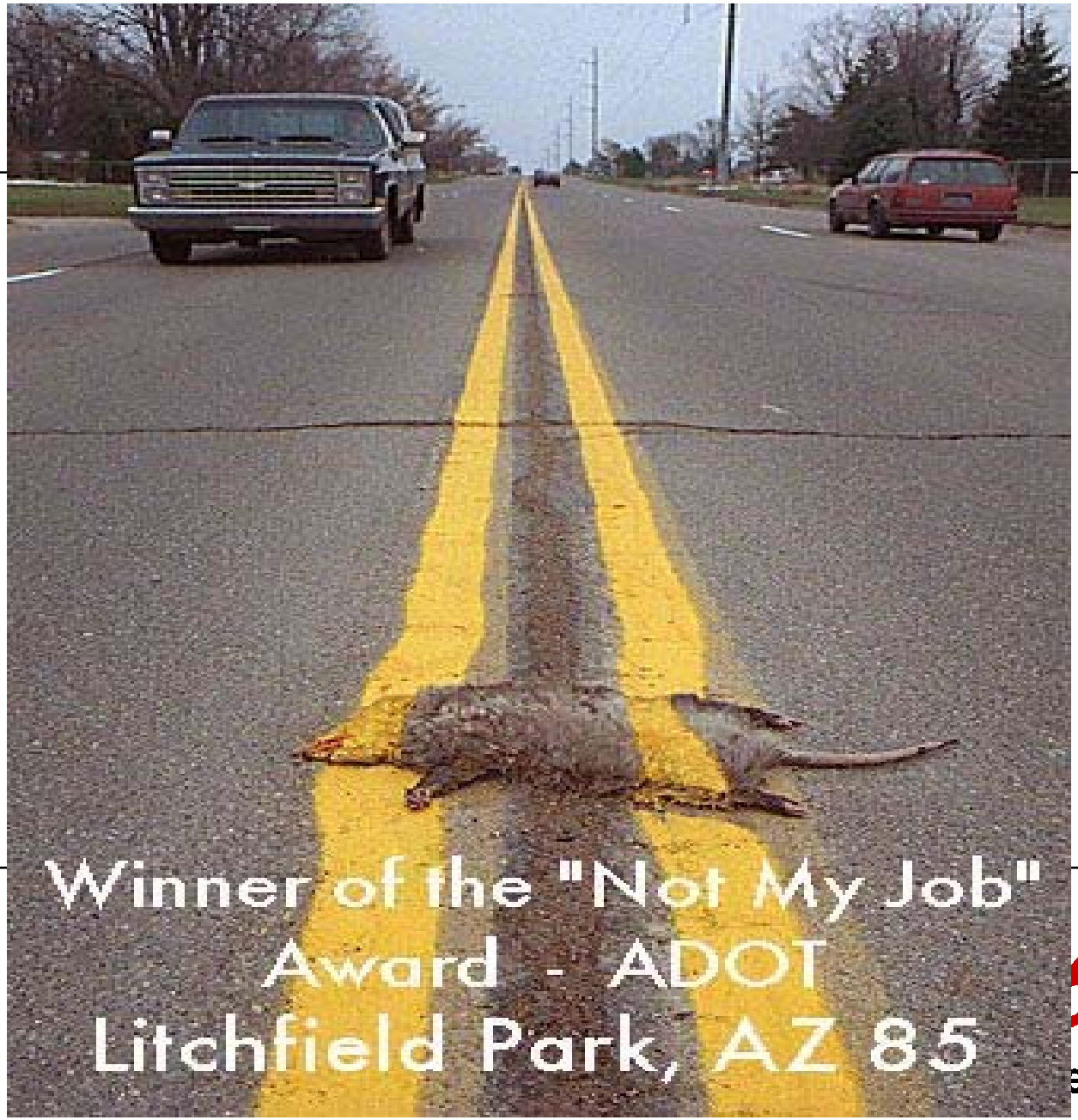
- **Cultural change**
  - Both academia **and** industry must be accountable for behavioral change
    - *"It takes two to tango"*

Enhancing Publication Requirements: Additional considerations

- Provide study protocol, protocol amendments and statistical analytic plan with each submitted manuscript
- Register all trials on *clintrials.gov*
- Provide access to study data and analytic programs with each submitted manuscript
- Disclose journal reviewer's comments
- External audit for compliance

Lilly's Publication Policy

- Publish all clinical trial data (Phase I may be exempt if no relevant safety/efficacy findings)
- Register clinical trials on *Lillytrials.com* and *Clintrials.gov*
- Adhere to ICMJE policy - www.//*ICMJE.org* (updated October 2004)
- No payments for time spent on manuscript preparation, authorships
- No ghost, reverse ghost or guest authorships
- Offer study protocol with every clinical trial submitted for journal publication
- Rigorous quality reviews of all data sets – must stand up to internal and FDA audits
- Marketing not involved in any phase of manuscript preparation


Winner of the "Not My Job"
Award - ADOT
Litchfield Park, AZ 85