

Conflicts of interest

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Why?

Why?

- Because of the potential for abuse, having a financial interest that conflicts with the patient's interest is a problem, even if the physician has good intentions, never exploits the conflict, and does not harm anyone.
 - Financial interests cloud judgment.
 - Health professionals are in a special position of trust.
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Laws

- Stark
 - Antikickback
 - State conflict of interest laws (for state or public university workforce)
 - Lots of case law
 - In California, this is one way of blowing past the MICRA limits
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Physicians' oaths

- I will use my power to help the sick to the best of my ability and judgment. (Hippocratic Oath) ca 400 BC
 - ... may neither avarice nor miserliness, nor thirst for glory or for a great reputation engage my mind; for the enemies of truth and philanthropy could easily deceive me and make me forgetful of my lofty aim of doing good to Thy children. (Oath of Maimonides) ca 1200
 - The health of my patient will be my first consideration. (Declaration of Geneva) 1948–2006
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Fiduciary duty

- An obligation to act in the best interest of another party.
 - Latin *fīdūciārius*, from *fīdūcia*, trust.
 - Faith: duty of fulfilling one's trust.
 - Fidelity
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Fiduciary duty

- “... patients, often lacking sophisticated knowledge about health care, enter relationships with health professionals expecting that their interests will outweigh the interests of the doctor and expecting that appropriate health care will be offered and provided.”
 - “The patient is entitled to expect that the doctor will place the patient’s interests above those of the doctor herself...”
 - 42 Mercer L. Rev. 989 1990-1991
 - Moore vs Regents University of California
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Features of fiduciary relationships

- Fiduciaries provide services to the entrustors
 - Fiduciaries must have power over the entrustor to be effective
 - Sole purpose of the relationship is to serve the entrustor
 - Entrustor finds it difficult to assess the quality of the fiduciary’s performance as fiduciary has expertise entrustor lacks
 - Cost of monitoring use of power high
 - Have two doctors in the room?
 - Alternative controls on fiduciary too weak
 - Physicians can have financial investments in treatments
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A fiduciary relationship is special

- Held to a higher standard of behavior than in the usual relationship
 - Fiduciary duties
 - Loyalty
 - must not put their personal interests before the duty
 - Care
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Trust me, I'm a doctor



How to analyze potential conflicts of interest

What constitutes an interest?

- Financial
 - Investments
 - Income
 - Gifts
 - Etc.
 - Non-financial
 - Fame
 - Getting tenure
 - Research support
 - Etc.
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How far through the family tree?

- First degree relatives?
 - More distant relatives?
 - Domestic partners?
 - Household members?
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Is the interest material?

- Is there a threshold?
 - A \$1 investment in Merck is probably not a material interest
 - Need to set some bounds, unless you say that any interest, no matter how small, is material
 - One way of determining a bound
 - How much money would it take to sway an evil person?
 - Remember—trying to take away even an appearance of a conflict, so worst-case scenario analysis probably best fit
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Problem with non-financial interests

- How do you set a materiality threshold?
 - We're not mind-readers
 - Generally, non-financial interests are ignored in conflict of interest policies
 - But you should still worry about them
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Is the person involved in the decision?

- No harm no foul—financial interests, when not connected to any decision-making, don't matter
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Is the decision important enough to care about conflicts?

- Patient care: yes
 - \$1000 purchase: probably not
 - Again, a threshold decision
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How do you fix the problem?

- Disclosure
 - To protect the institution
 - This does not help patients
 - Divestiture
 - Recusal
 - Second line of review
 - E.g., second opinion
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Vendor relationships

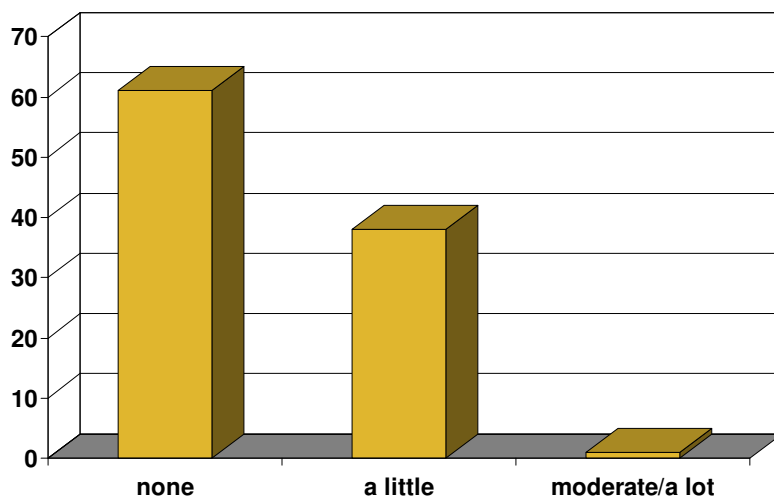
Conflict vs. vendor relationships

- Conflict – person has potential to “double-deal”
 - Vendor issues—social effects of relationships—no thought of self-gain
 - Effect of vendor relationships probably more pervasive than conflicts
 - Target of marketing
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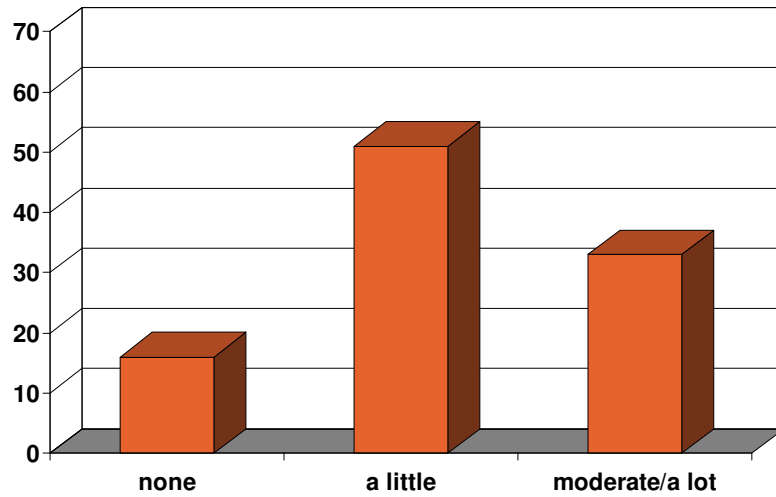
This is not a small issue!

- Marketing \$12-15B/year
- \$8,000 to \$15,000 per physician
- Typical pharmaceutical company
 - Marketing 33% of expenses
- N Engl J Med 351;18 p 1885

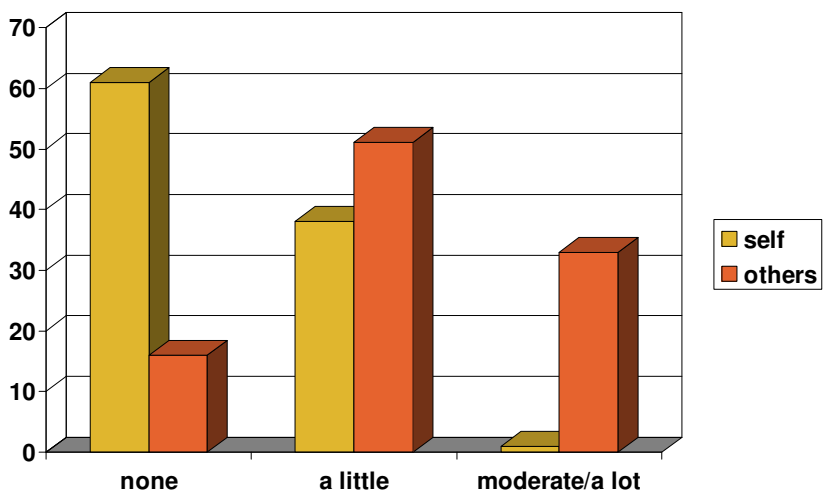
How much do pharma reps influence your prescribing practices?



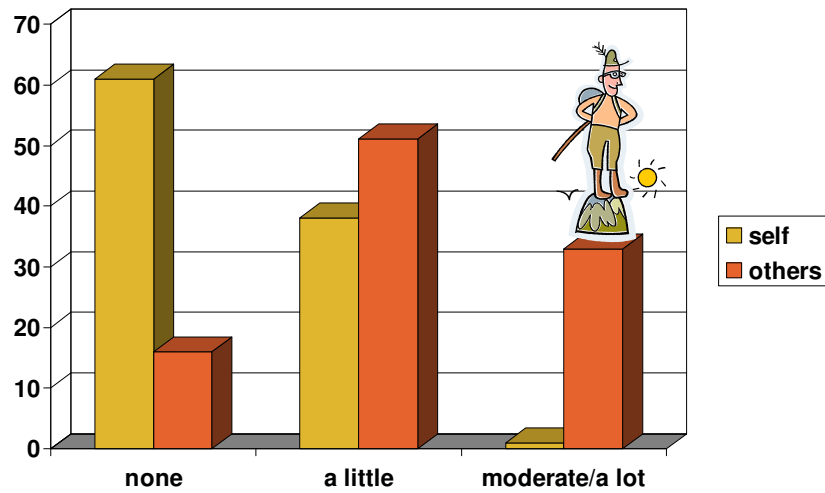
How much do pharma reps influence other doctors' prescribing practices?



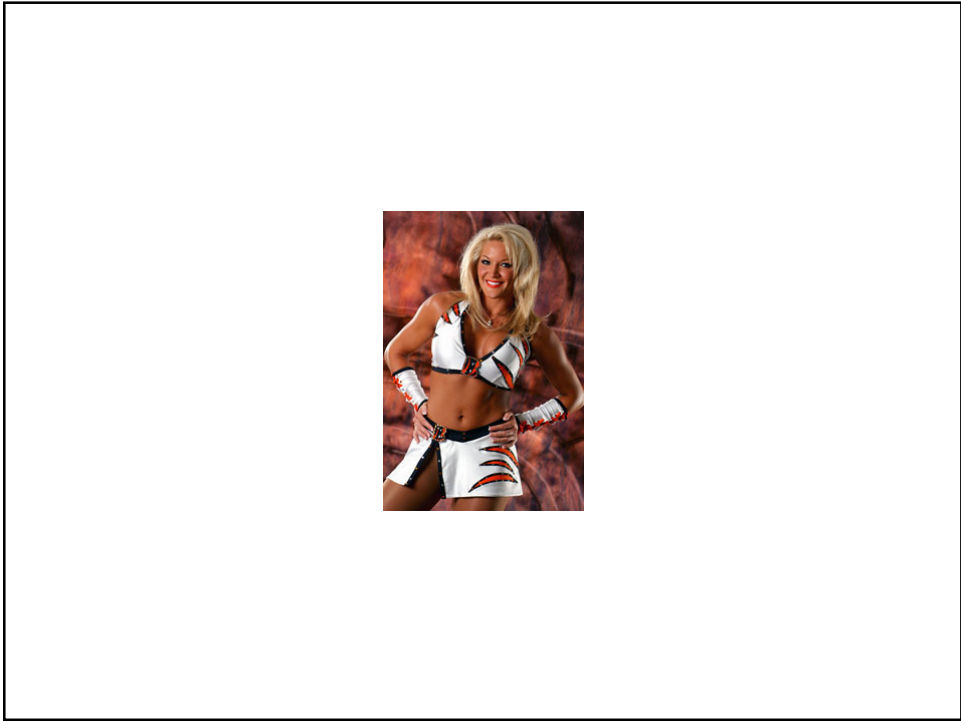
A bit of dissonance?



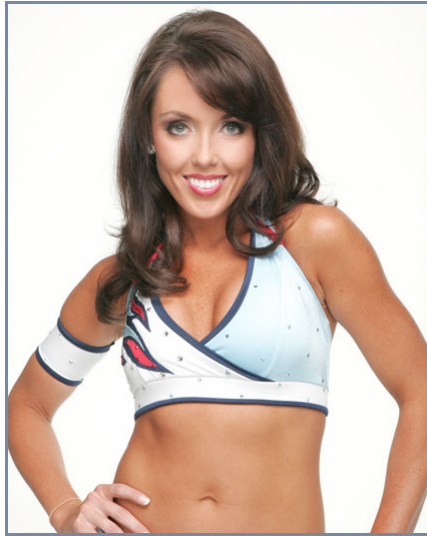
A bit of dissonance?



What two things do these people have in common?



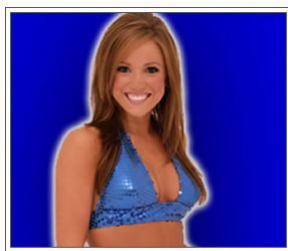
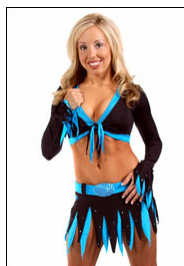












“ Cerissa smiled when I asked her to have my baby. ”





Miss Illinois, 2007



Web site ad

- Are you interested in making yourself available to an exciting career in medical sales? Do you have the experience of performing in front of thousands of people and representing your institution to students, faculty and alumni? Contact your Spirited Sales solution to take the next step!
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Cheerleaders as Pharma reps?

- “Gimme an Rx! Cheerleaders Pep Up Drug Sales”
– NY Times, 11/28/2005
 - “Obviously, people hired for the work have to be extroverts, a good conversationalist, a pleasant person to talk to; but that has nothing to do with looks, it’s the personality.” – Bristol-Myers Squibb spokesman
 - <http://www.spiritedsales.com/>
 - “Former Varsity staff are currently excelling in the pharma and medical industry as national sales trainers, regional and district managers, marketing executives and top performing reps for dozens of companies.”
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How do gifts work?

- Bias is unintentional
 - Even well-intentioned people succumb
 - Bias is unconscious
 - Telling people to avoid bias doesn't work
 - This is not people "being bad"
 - A social science perspective on gifts to physicians from industry
 - JAMA 7/9/2003: Vol 290 No 2 P 252
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Key point with gifts

- "Policies that make sense if bias is interpreted as a matter of deliberate choice (e.g., limiting gift size, educational initiatives, and mandatory disclosure of interests) are unlikely to be effective if bias is in fact unintentional and unconscious."
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What are gifts?

- Anything of value you get without providing an item or service of similar or greater value in exchange
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What are gifts?



The challenge

- “The task of convincing physicians, who are selected for their ability to reason, that they are not reliably reasonable is not simple.”
 - The Scientific Basis of Influence and Reciprocity: A Symposium; AAMC June 12, 2007
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