Physician-Industry Relationships: Promoting Professional Integrity and Medical Progress

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Looking Back and Looking Ahead:

Medical Professionalism: Does it have to be
- Revived?
- Invented?

The So-Called Good Old Days
- A profession that was all male, white, upper-middle class.
- Conflict of interest was certainly present: Fee-splitting, direct dispensing, fee-for-service.
- Resistance to organizational change: The bias against group practice; The bias against government intervention.

And Yet: A Distinguished Tradition of Professionalism

- The Hippocratic Oath
- Service to the underprivileged
- A life dedicated to serving patients

From Principle to Practice: Taking Professionalism Seriously

The Fundamental Challenges for Professionalism in the 21st Century:

What does it mean to make professionalism a force for change?
Attributes of Professionalism

- Altruism and commitment to patients’ interests
- Self-regulation
- Maintenance of technical competence
- Civic Engagement

The Challenges to Professionalism

Altruism and Commitment to Patients’ Interests above Financial Interests

- HMO / Hospital / Group Practice / Financial Incentives
- Drug and Device Company Relationships

Conflict of Interest in the Polity and the Society

- Should a loan department officer dine or gift the college student loan administrator to increase referrals?
- Should a lobbying group dine or gift a state legislator or congressman to advance legislation?
- Should a brokerage house dine or gift a mutual fund administrator to attract their stock purchases?
- Should an apparel designer dine or gift the department store purchasing agent to seal the purchase?
- Should a public agency dine or gift a journalist to spin a story?

Most will answer no to the above questions.

Why We Say No: Core Principles

- Commitment to organizational integrity and client welfare.
- Decision-making should be free of personal bias.
- Gifts of any size (even small ones) are influential.
- Disclosure is not a sufficient cure.

Conflict of Interest in Medicine

Is there any reason why physicians and drug and device companies should be allowed to play by different rules?

DIAGNOSING THE PROBLEM
Marketing drugs and devices

Companies are very aggressive in marketing their products, both to the general public and to medical professionals.

Lipitor Advertisement

2002-2003 Viagra Campaign with Rafael Palmeiro

- “I Take Batting Practice (Over 500 Home Runs)”
- “I Take Infield Practice (3 Gold Gloves)”
- “I Take Viagra: Let’s Just Say It Works for Me.”

Drug Companies Advertising to Consumers

Device Company Marketing Expenditures

- Estimated 1.5 billion in trade journal ads targeting physicians
- Direct to Consumer Advertising increased from nearly nothing in 1996 to 50 million in 2005

Sources:
Medical Marketing Blog
Medical Device Product Management: Benchmarking Development, Marketing, and Promotion
Direct to Consumer Device Advertising

Zimmer Gender Knee TV Ad

Financial Relationships Between Industry and Physicians

- Samples
- Food, Gifts
- Speakers’ bureau fees
- Ghostwriting fees
- Funds for conferences and Continuing Medical Education (CME)
- Consulting fees
- Royalties
- Stipends and honoraria
- Research funding

- Physicians most commonly received refreshments from industry (84%) followed by drug samples (76%), admission to CME events (23%), consulting fees (17%), expenses for travel (16%), payment for service on a board (8%), tickets to cultural/sporting events (7%), payments in excess of costs for enrolling patients in clinical trials (3%) and gifts for prescribing (2%).

Headlines: The Facts

Hub surgeons got millions from implant firms

By Elizabeth Conney, Globe Correspondent  |  November 7, 2017

Two Boston orthopedic surgeons each received $6.7 million this year from a maker of joint replacement implants, the largest among doctors who received settlement dollars in a $3.1 billion settlement of a decade-long crisis that alleged five companies paid doctors to use their products.

Dr. Richard Scott and Dr. Thomas Thorne of Brigham and Women’s Hospital were paid services and marketing fees by Biomet and Wright Medical Technologies to promote their implant-surgery devices, according to court documents. The payments by the company were seen by some as evidence that manufacturers were influencing surgeons’ decisions.
Headlines: The Facts

Implant firms pay doctors millions; As joint replacements have increased, so have payments to surgeons. Implant firms’ cash for doctors draws notice


In the past decade, leg- and knee-replacement surgeons have included, aside from billions a year and having a realization above implant industry with profit margins approaching 25 percent.

With so much money in play, competition among artificial hip and knee manufacturers has loosened a system of free, ice- and even digital payments to doctors in various, sometimes direct, and sometimes indirect forms.

Device Industry Response: Device Reps are not Drug Reps

“Known for their athleticism, postage-stamp skirts and persuasive enthusiasm, cheerleaders have many qualities the drug industry looks for in its sales force... Drug companies have found that former cheerleaders are good at persuading doctors.”

“Field representatives, employed by device manufacturers, usually provide technical expertise and on-site support during device implantation”

“Industry representatives are a “factory-trained” service department, which will go to a hospital, doctor’s office, nursing home, or, in some cases, accompany a clinician to a patient’s home”

Industry Response: A Different Kind of Rep

Prior to Implant
- Physician input and consultation
- Appropriately sized device
- Battery life support
- Competent sales support
- Clinical follow-up support
- Technical service
- Customer service
- Product performance
- Reliability, Sterility

During Implant
- Smooth implantation
- Competent sales support
- Product support
- Clinical follow-up support
- Technical service
- Product performance
- Reliability, Sterility

After Implant
- Competent sales support
- Technical service
- Product performance
- Reliability, Sterility


The Rise of Transparency

In light of the media attention and growing awareness of conflict of interest, there is a new commitment to transparency.


Taking Stakes in the Outcome

Company Disclosure Data: Biomet - July 7, 2008

Changing the Rules at Academic Medical Centers

- No one wants to demonize industry. There is too much to learn to improve health care outcomes. That fact acknowledged, how can institutions insure that neither education nor research is biased by gifts and grants?

- How can collaborations continue without the loss of scientific integrity or the sacrifice of patient well being?

Recommendations to Academic Medical Centers for Controlling Conflicts of Interest

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<th>Activity</th>
<th>Regulation</th>
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<td>Gifts, meals directly to physician from industry</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Provision of free samples, other patient-use products</td>
<td>An indirect distribution system</td>
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<td>Speakers' Bureaus and Ghostwriting</td>
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<td>Consulting, speaking honoraria, and research contracts</td>
<td>Transparency; Specify terms of service and be available for public inspection</td>
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<td>Formulary and other purchasing decisions</td>
<td>Decision-makers must be conflict free</td>
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NY Times, 2/12/07

“Gifts bring with them the felt need to reciprocate...We’re not saying you’re being bribed. We’re saying you’re being gifted. Some of it could be raw monetary hustling. But some of it is this psychological - ‘Well, they just sent me out to Las Vegas, their drug is as good as anybody else’s, why not just say thank you.'”

- David J. Rothman

AMCs Leading the Way

- Yale University
- University of Pennsylvania
- Stanford University
- University of Michigan
- University of Washington
- Kaiser Permanente
- UC Davis
- UC System
- University of Arizona
- University of Pittsburgh
- Boston University
Catalysts for Change

- **Leadership**
  - Change was “top down” at many AMCs.

- **Sensitivity to Media Coverage**
  - Fear of institutional embarrassment through scandal.

- **An Opportunity to Exercise Professional Leadership**

Barriers to Change

- Dependency on Industry Funding.

- Ignorance of What Leading AMCs and Societies are Doing.

- Fear of Faculty Resistance

- Complicated Hospital/Educational Structures

Best Practices - Gifts

Policy at University of Wisconsin, Kaiser Permanente, University of Pittsburgh, University of Michigan, Stanford University, University of California, Davis, University of Pennsylvania

- Physicians may not accept any gifts of any value from representatives

Best Practices - Meals

Policy at University of Pittsburgh, University of Wisconsin, Kaiser Permanente, Stanford University, University of Michigan, University of California, Davis, University of Pennsylvania

- Meals provided by industry representatives may not be accepted on campus
- Meals provided by industry representatives off campus are discouraged

Best Practices - Ghostwriting

Policy at University of Pittsburgh

- Personnel cannot be listed as co-authors on papers ghostwritten by Industry representatives.
- Personnel should always be responsible for the content of any papers or talks that they give, including the content of slides.

Looking Ahead

To date, most attention has gone to drugs but that is now changing. It is devices that are increasingly the focus of media, policy, and medical center attention.
Questions to Explore in Device Conflict of Interest

- What policy should govern Academic Medical Center interaction with device reps?
- Can formularies work as well with devices as with drugs?

What are the appropriate disclosure policies?
- Should royalties be differentiated from consulting payments?

Given Disclosure of a Significant Financial Relationship, What policies should guide Academic Medical Centers?
- Restrictions on teaching or research?
- Recusal from purchasing decisions?
- Restrictions on patient care?
- Training guidelines?

What would the new world of medicine look like?
- Decisions by physicians would become more evidence-based.
- Expenditures on drugs and devices would decline.
- Increased use of generic products.
- A decreased reliance on inappropriate agents and procedures.
- A clearer and cleaner divide between marketing and education.
- Increased sensitivity among medical students and house staff to the values of medical professionalism and scientific integrity.
- Greater public respect for the profession
- Reduced likelihood of state and federal regulation