Conflicts of Interest: The New Frontier in Healthcare Risk

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Executive Summary

This article will provide insight into the evolution of thought on conflicts of interest in healthcare, and will discuss the significant shift in perceptions, policies and practices over the last several years. It will discuss efforts by academic associations, government, and professional societies to bring about a wholesale change in the attitudes and behavior of physicians and the industry at large. It will discuss actions in Congress that will mandate transparency in payments to physicians, as well as the efforts being undertaken by institutions to require disclosure of potential conflicts, and to manage any that are uncovered. These efforts to uncover and manage conflicts of interest will have a profound effect on the ability of a typical organization to manage risk.

Introduction

As the Director of an Academic Faculty Practice Plan in the mid 1980s, I was well aware of the close and mutually beneficial relationships between faculty members and the medical industry. Pharmaceutical and other companies contributed to medical education, funded clinical trials, and provided free product samples to support the teaching, research and clinical practice missions of the organization. In those days, any suggestion that such relationships were improper, or that they might influence decision making in a way that could conflict with the best interests of patients, was met with indignation and dismissive denial. How things have changed.

Background

A conflict of interest occurs when an individual or organization has a financial or other interest that has the potential to interfere with their professional judgment, objectivity, or ethical responsibilities. Conflicts of interest are difficult, if not impossible, to avoid in medicine. Indeed, fee-for-service medicine, where physicians are paid more for doing more, has inherent conflicts. For most of modern history, however, healthcare practitioners have held positions of such high status and regard that they have benefited from a presumption of good and ethical behavior.

Things began to change in the late 1980s. Astute observers noticed that physician referrals to ancillary facilities would tend to increase if the physician had a financial interest in the facility. In response, Congressman Pete Stark of California introduced legislation, which took effect in January 1992, prohibiting self referrals. Unlike the federal anti-kickback statutes, which were on the books since 1972 and prohibited providers from taking outright bribes, the Stark laws represented a tacit admission that medical decisions could be influenced by financial considerations.

In the early 1990s, concerns began to grow that research funded by the Public Health Service (PHS) could be biased by "conflicting financial interest of those investigators responsible for the research."[1] In 1995, the PHS and the Office of the Secretary of Health and Human Services promulgated the first federal regulations, quite weak in retrospect, requiring investigators to "disclose to an official(s) designated by the institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would *reasonably appear* to be affected by the research proposed for funding by the PHS." (Italics added). The regulations required institutions to create and maintain a written policy on financial conflicts of interest, communicate that policy to investigators, identify and manage potential conflicts, and report that information to the government.

The Gelsinger Case

In 1999, a young man by the name of Jesse Gelsinger died from an immune reaction during a clinical trial at the University of Pennsylvania. While essentially healthy, he suffered from a rare metabolic disorder, and had volunteered for an experiment to test gene therapy for babies with a fatal form of the disease. After his death, his family learned that the principal investigator and treating physician had a financial interest in the success of the therapy being tested. The FDA found "serious deficiencies" in the informed consent process, which, the family claimed, did not include a discussion of potential conflicts of interest.

The Gelsinger case was a wake-up call for Academic Medicine. Even so, when the NIH reiterated concerns about "Financial Conflicts of Interest and Research Objectivity" in a June 5, 2000 memorandum, it did little more than make suggestions to the Institutional

[1] Objectivity In Research NIH Guide, http://grants.nih.gov/grants/guide/notice-files/not95-179.html; July 14, 1995

Review Boards (IRB's) responsible for overseeing research at the nation's medical centers:

"While there is no regulatory requirement for IRB's to consider investigator's financial conflicts of interest," the memorandum stated, "the protection of human subjects requires objectivity..." and "IRB's should refer to their institution's policies and procedures for identifying and managing conflicts of interest."[2]

Without detailed and specific guidance from the government it was left to hundreds of separate institutions and thousands of providers to define, assess and manage their own conflicts of interest.

Attitudes Begin to Change

Two articles published in the Journal of the American Medical Association (JAMA) had an impact on the ongoing discussion about conflicts of interest. The first was published in the January 19, 2000 issue, and was titled "Physicians and the Pharmaceutical Industry/Is a Gift Ever Just a Gift?"[3]. The author analyzed 29 separate studies, which provided data on physician interactions with the pharmaceutical industry and the attitudes toward those physician-pharmaceutical industry interactions. The interactions ranged from industry-sponsored meals and samples, to honoraria, conference travel, and research funding. Both residents and practicing physicians expressed the belief that pharmaceutical representatives prioritize product promotion above patient welfare, yet each group denied that gifts and other perks could affect their behavior.

Regression analysis, however, demonstrated that interactions with pharmaceutical representatives had an impact on "the prescribing practice of residents and physicians in terms of prescribing cost, nonrational prescribing, awareness, preference, and rapid prescribing of new drugs, and decreased prescribing of generic drugs." Furthermore, the study continued, "... receiving a gift and the number of gifts received correlated with the belief that pharmaceutical representatives have no impact on prescribing behavior." So not only did industry contacts influence prescribing behavior, but *gifts made physicians less likely to think they had been influenced!*

The second JAMA article, published in July, 2003, was a commentary offering "A Social Science Perspective on Gifts to Physicians From Industry."[4] This article took on the common belief that while large gifts or significant financial support (conference travel, CME support) might influence behavior, smaller gifts (meals, note pads, even pens) were not likely to do so. The authors used both medical and non-medical social science research to demonstrate that "...by subtly affecting the way the receiver evaluates claims made by the gift giver, small gifts may be surprisingly influential. Furthermore, individuals are generally unaware of the bias, so they do not make efforts to correct for it or to avoid conflicts of interest in the first place."

These articles, and others that preceded and followed them, began to shift the conventional wisdom about the effect of conflicts of interest in medicine. Still, it took several very high profile cases to push the issue into public consciousness, and to the front page of the New York Times.

High Profile Cases

On June 8, 2008 the NY Times published a story about Dr. Joseph Biederman, a prominent Harvard psychiatrist who had failed to report at least $1.6 million in consulting fees from drug makers, while publishing research and giving scholarly talks which may have served to promote drugs from those companies.[5]

In October of 2008, the Times reported that another leading psychiatrist, Dr. Charles Nemeroff, had accepted more than $2.8 million in payments from drug makers over a period of several years, failing to report at least $1.2 million to his employer, Emory University.[6]

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The facts surrounding these cases are beyond the scope of this article, but the publicity surrounding these cases and others that followed have created a sense of urgency on the part of organized medicine, academia, and government to define, identify, and manage conflicts that interfere with the delivery of cost effective, evidence-based medicine. The remainder of this article will discuss efforts being undertaken to eliminate conflicts in medical research, medical education, and clinical practice.

Professional Associations Get Involved

The Association of American Medical Colleges (AAMC) represents all 131 accredited U.S. and 17 accredited Canadian medical schools, approximately 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies.[7] The AAMC has taken a lead role in addressing conflicts of interest in its constituent organizations. In the absence of specific direction from

[2] Financial Conflicts Of Interest And Research Objectivity: Issues For Investigators And Institutional Review Boards; NIH Guide, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html; June 5, 2000
[3] Wazana, A. Physicians and the Pharmaceutical Industry / Is a Gift Ever Just a Gift. JAMA, January 9, 2000
[4] Dana J, Loewenstein G. A Social Science Perspective on Gifts to Physicians from Industry. JAMA, July 9, 2003
[5] Harris G, Carey B. Researchers Fail to Reveal Full Drug Pay. New York Times, June 8, 2008
[6] Harris G. Leading Psychiatrist Failed to Report Drug Income. New York Times, October 4, 2008
[7] www.AAMC.com

the federal government, the AAMC, together with the Association of American Universities, issued recommendations in 2001 and 2002 addressing individual and institutional financial conflicts of interest in research.[8]

In 2006, an Advisory Committee was formed to review and revise those guidelines, and in February 2008, they published their recommendations, describing and urging the adoption of consistent COI policies and advocating quick action on the part of its membership. Recommendations addressed disclosure, analysis, and management of conflicts in clinical research. This was followed in June 2008 by a similar report addressing industry funding of Medical Education.[9] These reports significantly strengthened earlier recommendations, suggesting that member institutions prohibit gifts of any size, ban food provided by industry, restrict industry access to physicians, and distribute free product samples through a central repository.

Dozens of Medical Schools and health systems have taken these recommendations, built on earlier progress, and in very short order transformed the culture of their organizations. Boston University, University of Massachusetts, Yale, University of Pennsylvania, the Universities of Michigan, Wisconsin, Chicago, and the entire University of California system all have strong COI programs in place.[10] Stanford has limited CME funding by drug makers.[11] The Cleveland Clinic decided to publicly report the business relationships that any of its 1,800 staff doctors and scientists have with drug and device makers.[12] Harvard, Columbia, and New York University have all worked to strengthen their COI policies.[13,14]

An interesting player in the conversation about COI has been the American Medical Students Association (AMSA) which ranked all United States Medical Schools on the basis of their conflicts of interest policies. Of approximately 130 schools, only nine earned an "A" and 36 a "B".[15] This gives some indication of the progress that still needs to be made.

State and Federal Legislation

A number of individual states and the federal government are hoping to accelerate that progress by mandating disclosure of payments to physicians from pharmaceutical companies and device manufacturers. Legislators in Massachusetts, Maine and Vermont have passed strict disclosure requirements and more than a dozen other states are discussing such legislation. Senator Charles Grassley of Iowa has been at the forefront of the effort to increase oversight of physician-industry ties. He was responsible for uncovering the Biederman and Nemeroff stories, and shedding light on numerous other questionable relationships through his Senate Committee hearings.

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In January 2009 Grassley introduced the Physician Payments Sunshine Act (S.301) requiring drug, biologic and medical device manufacturers to report certain gifts and payments made to physicians. A record of these payments would be maintained in a national database so medical and academic organizations and the public could see if their physicians had received financial support, or gifts, from industry. The proposed legislation includes fines of up to $10,000 for each "transfer of value" that is not reported, and up to $100,000 for knowingly failing to report.

Industry Efforts

In January 2009, The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents leading pharmaceutical and biotech companies, released the newest version of its voluntary "Code on Interactions with Healthcare Professionals". The code went further than ever before in instructing its member companies to prohibit the giving of gifts, entertainment, even pens and other small promotional items, to physicians. Also in 2009, the industry group AdvaMed, which represents medical device manufacturers, implemented a "Code of Ethics" with similar prohibitions. While some see these industry efforts as a cynical attempt to forestall government intervention, others interpret these guidelines as sincere efforts to be part of the solution to a very real problem.

Conclusion

The most recent organization to weigh in on the topic of conflict of interest was the respected Institute of Medicine (IOM), of the National Academies of Science. In April, 2009 the IOM published a comprehensive analysis titled "Conflict of Interest in Medical Research, Education and Practice."[16] The 392 page report provides sixteen recommendations, some aimed at providers, some at industry and some at government. These recommendations, if enacted, would go a long way toward creating policies and systems to manage conflicts of interest in medicine, enabling physicians, other providers, and the institutions that carry out medical research, education and clinical care to maintain public trust.

In difficult economic times, hospitals, medical schools, and physicians rely on the good will and trust of the public more than ever, as they make the case for resources in the political arena. Organizations that ignore the potential damage that conflicts

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[8] Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research; AAMC, February 2008
[9] Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council; AAMC, June 2008
[10] Rothman D, Chimonas S. New Developments in Managing Physician-Industry Relationships; JAMA, September 3, 2008
[11] Harris G. Stanford to Limit Drug Maker Financing. New York Times, August 26, 2008
[12] Abelson R. Cleveland Clinic Discloses Doctor's Industry Ties. New York Times, December 2, 2008,
[13] Kowalczyk L. Harvard Will Stiffen Rules for Staff at Med School. Boston Globe, February 3, 2009
[14] Staley O. Columbia Tells Researchers They Must Reveal Conflicts. Bloomberg.com, April 9, 2009
[15] AMSA PharmFree Scorecard 2009, http://www.amsascorecard.org/
[16] Conflict of Interest in Medical Research, Education and Practice; Institute of Medicine, April, 2009