

Conflict of Interest and Humans: a Dangerous Equation?

by Joyce Freedman

The San Jose Mercury News (San Jose, California) has run a series of articles of late regarding financial conflict of interest and what they label as a dangerous equation at medical institutions. These articles have been critical of the lax enforcement of the conflict of interest regulations by the federal agencies, in particular the National Institutes of Health (NIH). The author of the article queried Edward Greg Koski, the former director of DHHS' Office of Human Research Protections, about the agency's laissez-faire attitude toward enforcement of their conflict of interest regulations. Koski responded that... "It is largely a 'don't ask don't tell' scenario." The Mercury News questioned why the federal agencies leave the monitoring of these complex rules to the institutions that also manage agency funds; in particular, at medical institutions conducting studies using human subjects?

Paul Jacobs, the journalist who produced the series of articles, compared a financial conflict of interest for a faculty member in information technology with one in the medical arena. His take away message is that a conflict of interest in a field in which the worst case scenario is someone getting rich from publicly funded research cannot pretend to be in the same league as a tragedy involving human subjects when a financial conflict results in a loss of objectivity.

Stanford's President John L. Hennessy thinks that universities are doing an appropriate job of monitoring conflicts of interests. In response to the possibility of too much oversight by the agencies regarding the conflict of interest regulations, Hennessy states, "I'm deathly afraid ... you kill the goose that laid the golden egg. You break that process of transferring new technologies from research environment to products. It already takes too long in the medical arena because we have such a focus on safety and risk avoidance. Imagine it taking a lot longer. I view that as a tragedy for all the people who have a disease that technology could help... The golden egg here is that technology that actually gets out there and saves lives."

In addition to the Mercury News articles, there have been scholarly journal articles about conflict of interest at academic medical centers. Troyen A. Brennan, MD, JD, MPH et al. published an article in the *Journal of the American Medical Association (JAMA)* (January 2006) entitled "Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers." The abstract starts off stating that "Conflict of interest between physicians' commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products pose challenges to the principles of medical professionals. These conflicts occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's role are or will be compromised." A November 2000, *New England Journal of Medicine* article, authored by Bernard Lo, MD et al. looked at "Conflict-of-Interest Policies for Investigators in Clinical Trials." The background for this piece was the concern that financial conflicts of interest on the part of investigators conducting clinical trials may compromise the well-being of research subjects. The conclusion was "...that university scientists who conduct clinical research should be held to a higher standard than researchers employed by commercial organizations...and that financial conflict of interests restrictions should apply to all members of a research team and their immediate families, not just to the investigators with responsibility for the clinical decisions."

JAMA has recently updated its conflict of interest policy for publication in its journal. JAMA's update policy requires complete disclosure of all relevant financial relationships and potential

financial conflicts of interest. Regardless of amount or value, a disclosure must be made in the acknowledgement section of the author's article.

Both the *New York Times* and the *San Francisco Chronicle* recently ran articles about the relationships between medical practitioners and the pharmaceutical industry. Although not specifically on point about financial conflicts of interest in academe, the features point out that "free lunches" from pharma can "curry favor" and influence the decision-making of the recipient. The *San Francisco Chronicle* reports that "A 2003 study in the *American Journal of Bioethics* found that when a person accepts a gift, no matter how small, 'the obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behavior.'"

Those of us who work at public institutions in the State of California have been dealing with two sets of conflict of interest regulations and laws; the federal regulations from the NIH and National Science Foundation (NSF) and the State's Fair Political Practices Act. The State law requires that faculty receiving research funding from private-sector sponsors disclose all financial ties with the sponsor (including those of their spouses, domestic partners and dependent children). The law is not aimed exclusively at biomedical research, but it does require that we take a closer look at financial relationships between a for-profit sponsor and an individual faculty researcher.

University of California-San Francisco (UCSF) operates under three separate conflict of interest reviews for studies involving human subjects and has one of the strictest conflict of interest policies in the nation. We follow the federal guidelines for NIH and NSF, we follow the State laws for private funding, and we have a financial conflict of interest review for all human-subject protocols. For industry-sponsored research and for human-subject protocols our tolerance for financial conflicts is zero when human subjects are involved.

The first and most important role of medical schools remains the training of physicians and scientists, and of course, providing high-level patient care. Today's academic medical institutions are also looked to as the leaders for determining the causes of diseases and developing the treatments for such. Current expectations are that medical institutions work collaboratively with the pharmaceutical industry to get discoveries quickly out to the bedside.

The issues posed by the above are two-fold: do academic medical institutions need to have stricter guidelines for conflict of interest when human lives are at risk? And can those institutions monitor the conflicts of interest without further intervention from the federal government?

Based upon the national dialogue, I say yes to both.

References

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