The Blind Alley of Financial Conflicts of Interest

By ACSH Staff — December 13, 2004

"Follow the money," Deep Throat warned Woodward and Bernstein as the two reporters were about to break open the Watergate scandal. Generally, this is good advice for anyone seeking to understand what is happening in a complicated business story. But not always. Former New England Journal of Medicine (NEJM) editor-in-chief Jerome Kassirer would have us believe that contemporary medical scientific research is so riddled with financial conflicts of interests as to be all but worthless. His assessment of the current National Institutes of Health (NIH) cholesterol guidelines, which appeared in a Washington Post op-ed, "Why Should We Swallow What These Studies Say?" (Aug. 1), and is amplified in a new book bashing the pharmaceutical industry, On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health, seriously misreads the nature of these relationships and is blind to other, potentially graver conflicts. Even worse, his draconian solution could harm the public by compromising the quality and reliability of future scientific research.

As Kassirer tells the story, the physicians who helped draw up the tough new cholesterol recommendations for the NIH's National Cholesterol Education Program, and those who reviewed those findings, should have recused themselves from the proceedings because they had received research grants, speaking honoraria, or consulting fees from the manufacturers of a class of drugs known as "statins." These drugs are remarkably powerful in lowering levels of cholesterol. They also are remarkably profitable for their makers.

Did this "conflicted panel of scientists" somehow "color [its] analysis" to adopt tough new guidelines, thereby encouraging community physicians to prescribe new statins more aggressively than necessary? Even though there is no evidence of bias, Kassirer presumes malfeasance, arguing that the use of such obviously compromised experts is hardly "the best way of getting an unadulterated assessment of clinical data."

Disclosure of the nature of these relationships is not enough, he insists, for it does not tell us whether the evidence actually is compromised. "Disclosure covers up the question of bias with a patina of honesty," Kassirer says. The only solution is to find researchers without ties to industry, or failing that, with as few financial conflicts as possible. Physicians should be encouraged to reject all such monetary incentives, for only those who are fully independent of industry will ever achieve a level of disinterestedness sufficient to advise the public.

Is Kassirer correct that such conflicts are a petri dish of dishonesty? I would suggest not. One reason these physicians were selected for the NIH panel in the first place is that they have deep scientific knowledge and practical clinical experience in the use of these drugs. This expertise is in part a result of their long-standing consultative relationship with industry. Who is better suited to developing cholesterol treatment guidelines than the very physicians who helped evaluate the
therapies in the first place? Certainly not a doctor who has only a passing familiarity with statins or a medical journal editor. I know that if I ever required a sensitive surgical procedure, I would prefer to use the surgeon most experienced in the technology, even if he had "soiled his hands" by accepting remuneration from the manufacturer to help develop and test the special instrument used in that procedure. My guess is Kassirer would head directly to that same surgeon.

**Other Types of Bias**

Moreover, there are other potential biases and sources of self-interest, sources to which Kassirer appears blind. As a proponent of big government, he naturally supports a research environment in which independent NIH scientists and academics such as himself conduct the studies, analyze the findings, and report the conclusions. In this way, he argues, public health would most effectively be maintained.

However, as public choice theorists have pointed out, the government is a special interest group no different from any other. Thus, it is subject to its own nest of potential biases and conflicts. NIH researchers and university professors are likely to support those projects and agendas that grant them more money, power, and prestige, and ignore those that compromise those interests. Former medical journal editors who write books about how the pharmaceutical industry buys off its scientific investigators, particularly those with titles as impressive as Kassirer's, stand to benefit from a jump in book sales to an anxious, health-conscious public. Self-interest is hard-wired into our genetic make-up, the evolutionary psychologists have written, and attempting to regulate it out of existence is as hopeless an enterprise as trying to ban Monday mornings. Nevertheless, it is not inherently corrupting, as Kassirer would have us believe.

Does the government act disinterestedly in matters of public health? The silicone breast implant controversy boldly highlights how unacknowledged self-interest can compromise administrative decision-making. As Marcia Angell demonstrates in her illuminating study of the case, *Science on Trial*, the Food and Drug Administration (FDA), which was responsible for ensuring the safety of the devices, was battered for several years by public pressure from concerned women, vocal feminist and consumer-interest groups, and a hungry plaintiff's bar anxious to sink its teeth into a lucrative class-action and multi-litigant banquet. Hearings were held in which many gave emotional testimony and few provided any serious critical review. Fearing that his agency might be weakened if it were seen as caving in to industry, FDA Commissioner David Kessler decided to ban the implants, despite the absence of any credible scientific evidence that they caused autoimmune and connective tissue disease. In making this judgment, the agency was acting not like an objective regulatory authority, but as a self-interested political body, with its guard up and ears keenly attuned to the social landscape.

The aftershock of this ill-advised decision demonstrates how the public is harmed when even the best-intentioned government officials succumb to outside influences. The leading implant manufacturer, Dow Corning, went bankrupt as a consequence of multiple class-action lawsuits. Countless women who had already undergone implantation surgery were subjected to a second unnecessary procedure to remove the devices. Others who still wanted breast implants for cosmetic or medical reasons were denied that choice. Since then, one epidemiological study after another has confirmed the safety of silicone breast implants. Yet the FDA's ban remains in effect
today. Like any other public body caught in the harsh glare of the media's spotlight and worried about its reputation, the agency appears to have assumed the worst about implants and then covered its collective behind.

"Conflict" May Be Unavoidable

For Kassirer, the mere appearance of a conflict is sufficient to indict the suspects. By this reasoning, every individual should consult at least two doctors for every visit: one to diagnose, another to treat. After all, is there not the same inherent conflict in deciding what is wrong with the patient and prescribing potentially expensive care? In fact, the presumption that medicine was so conflicted led to the sorry state of health care delivery today. Our irrational system is riddled with a lack of real choice, countless financial distortions, and few incentives to control costs at the point of delivery -- in large part because faceless government bureaucrats, stingy insurance underwriters, and impersonal managed care gatekeepers make medical decisions, while doctors act like assembly line workers, treating patients by formula. While it would be foolish to deny that some serious abuses occurred under traditional fee-for-service arrangements, managed care, which tends to subsidize "first-dollar" rather than more expensive catastrophic coverage, has neither reduced costs nor improved the overall quality of care. Since 2000, health care costs have jumped an average of nearly 9% a year. Few are satisfied with the workings of this dysfunctional medical-health complex.

To be sure, Kassirer is correct that professional societies such as the American Heart Association and medical journals such as the NEJM should be on the alert to ensure that treatment guidelines and drug research remains free of bias. The best way to accomplish this end is to continue to demand full disclosure of all potential conflicts, be they financial, scientific, or political, and then evaluate them. But before challenging the integrity of those scientists who choose to work closely with industry simply because they might somehow profit from the enterprise, we should listen to what these voices of experience have to tell us.

Sometimes if you "follow the money" you find a crook. But blind adherence to this dictum more often will dampen innovation, eliminate valuable and essential sources of funding, and create even more flawed institutions than those presumably in need of repair.

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