WASH. POST 7/2/06

What's Wrong With Money in Science?

By Thomas Stossel
and David Shaywitz

Dr. Harvey Alter, a scientist at the National Institutes of Health, was co-winner of the 2000 Lasker Award, the U.S. equivalent of the Nobel Prize, for his role in discovering the virus that causes hepatitis C and improving the safety of the U.S. blood supply. Just a few years later, however, Alter made news of a different sort, being castigated in the press for lawfully accepting $34,000 in consulting fees from several private companies between 2001 and 2003 — just one more casualty of the witch hunt against supposed conflicts of interest in scientific and medical research.

There is little hard evidence showing that financial ties between university or government researchers and drug companies create health hazards for consumers. Nevertheless, these links are now widely portrayed as dangerous, corrupting the pursuit of scientific truth and threatening the public. Institutions such as NIH and the Food and Drug Administration have expended considerable effort in the past few years to root out such ties. NIH Director Elias A. Zerhouni referred to such alleged conflicts as a "systemic problem" last year and NIH has since imposed restrictions on employees receiving fees and stock options from the private sector.

Over the past two decades, private biotechnology firms and other drug companies have increasingly played a major role in cutting-edge medical research. These companies have built relationships with many of the best and brightest academic scientists, helping to bring about huge advances in medical treatment, including powerful new hormones and anti-cancer drugs as well as new devices that repair heart damage. But they have also drawn scrutiny from those who believe that, with so much money at stake, corruption must surely be present. Instead of assuming that scientists would want, above all, to protect their reputations and their research, critics have assumed the worst — and have underestimated the positive impact of relationships between university researchers and companies.

Links between researchers and drug companies are widely portrayed as dangerous, corrupting the pursuit of scientific truth and threatening public health.

This issue surfaced recently, and ominously, when the consumer watchdog group Public Citizen investigated the biases and financial conflicts among experts serving on the FDA's drug advisory committees. The FDA uses these committees — staffed by university researchers and other top experts in a field — to evaluate new drugs and make recommendations about their approval. More often than not, the FDA follows those recommendations.

Public Citizen reviewed 221 committee meetings from 2001 to 2004. The study found that although about a third of advisory committee members had ties to drug companies (FDA requires disclosure of such connections), those links had no significant impact on whether particular drugs received approval. In other words, there was no smoking gun.

Even so, the advocacy group concluded that the process is too conflict-ridden to be good for the U.S. consumer. Aiding its cause was the venue in which the study was published: the venerable Journal of the American Medical Association, one of the country's preeminent medical research journals.

Normally, before publishing an article by academic researchers, JAMA requires that the authors disclose any support from industry, which helps keep the system honest. But it then bans even leading experts in their fields from writing editorial commentaries if they have ties to companies that are in any way related to the subject of their article. Further, the editors demand that independent statisticians analyze any paper that has corporate sponsorship, reflecting their bias that any research involving companies is uniquely untrustworthy.

Unfortunately, JAMA's editors applied none of this tough-mindedness to Public Citizen's report. Most egregiously, JAMA did not challenge the authors when they took small, insignificant differences in voting behavior (FDA advisers who consulted with industry were 10 percent more likely to vote for drug approval), and even speculated about what the data would show if a larger study were performed. Had this been an industry-sponsored study, JAMA almost certainly would have expunged such overreaching years on commercial conflicts of interest. In the end, however, JAMA seemed willing to apply a looser standard for a consumer activist group that reflects its ideological viewpoint — corporate sponsorship corrupts research — than it does for top scientists and doctors who receive industry funding.

In fact, the spin was so successful that few newspaper stories about the study emphasized the key finding: An FDA adviser's financial connections to the drug companies had no statistically significant effect on the approval of new drugs.

Medical care available to Americans is immensely better today than when we began our careers in medicine, in large measure because physicians have far superior technology at their disposal. And while much of the knowledge underlying these developments originated in universities, it was biotechnology firms and other companies that transformed this knowledge into the new drugs and devices that have proved so useful to the public. Little of this technology — be it vaccines for hepatitis, heart valves, or new anti-inflammatory drugs for rheumatoid arthritis — was developed by scholars and researchers without supposed conflicts of interest. And none of it came from

Thomas Stossel, a professor at Harvard Medical School, conducts basic research supported by NIH and serves as a consultant to biotechnology and pharmaceutical companies. David Shaywitz is an endocrinologist at Massachusetts General Hospital.

WASH. P. 11/27/06

Scientists Who Serve

The Oct. 30 news story "NIH's New Ethics Rules Lead Some to Ponder Jumping Ship" sounded the alarm that restrictions on outside income may cause the best and the brightest of the National Institutes of Health's researchers to retire or leave for academia, which has more lenient rules on moonlighting.

But NIH Director Elias A. Zerhouni cast doubt on this conclusion in a recent memorandum he sent to NIH staff members. He told the NIH employees that data last year indicate there has "not been a change in the rate of resignations or retirements among NIH scientists over the past several years."

Clearly some researchers at NIH want the extra pay of private consulting on top of a full-time NIH salary, which for some exceeds $150,000. If they leave, they could be replaced by scientists more dedicated to public service.

NED FEDER
Investigator
Project on Government Oversight
Washington

The writer is a former NIH scientist.