

BIOETHICS

Do corporate gifts compromise biotech researchers?

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With the news this past April that the US Securities and Exchange Commission (SEC) has begun to crack down on classic insider trading schemes by biomedical researchers, the biotechnology industry has begun to look more closely at relationships between academic researchers and the private sector (*Nature Biotechnology* 16:395, May 1998). In the cases reported by the SEC to date, researchers have apparently owned stock in companies about which they traded inside knowledge or had inside knowledge of fastbreaking developments in the pharmaceutical industry and advised others who owned stock in affected companies.

Thus far, most cases of outright fraud that have surfaced have involved clinical researchers who were either privy to or involved first-hand in, lucrative drug development trials. So far at least, government investigators have settled claims against the perpetrators—with price tags well into six figures—without publicly forcing them to admit guilt.

There is also mounting evidence that a far subtler, and perhaps more pervasive, pattern of misconduct may be arising as a result of discourse between researchers and pharmaceutical companies. Indeed, it appears that the prevalence of gifts bestowed on top academic researchers by corporations now threaten to overturn traditional assumptions about free scientific inquiry, the independence of academic researchers and, in some instances, the quality and availability of research results.

Those are the tentative conclusions of a Harvard University–University of Minnesota study entitled "Looking a Gift Horse in the Mouth: Corporate Gifts Supporting Life Sciences Research," published in the April 1 issue of the Journal of the American Medical Association.

The possible distortions created by corporate research gifts are obviously a far cry from the lure of quick riches involved in insider trading deals. The gifts at issue here are not endowments or large-scale academic grants that are circumscribed by stringent, if variable, university policies. Rather, they are those increasingly commonplace gifts bestowed upon research scientists, often prominent in their fields, that may include everything from biomaterials—cell lines, DNA samples, reagents, etc., to discretionary funds, research equipment, or trips to professional meetings that often do not register on the radar of university technology transfer or ethics policies.

The "Gift Horse" study sketches in broad strokes the shape of the problem at the 50 top

research universities that received most funding from the National Institutes of Health in 1993. Its authors suggest that the time has come for universities to examine such practices, especially regarding the implicit quid pro quos involved on behalf of corporate donors. These can—and apparently often do—include lengthy pre-publication preview by companies of academic research, ownership rights of patentable results, as well as a host of lesser restrictions.

The JAMA report is a clear warning that researchers who take money or resources from the private sector in exchange for restrictions on publication or ownership rights may well be on a collision course with their universities and the scientific community. Both have a stake in the free, timely flow of research data and in the disposition of patents that may result.

The study found, for example, that of the 43% of researchers who received gifts, 66% considered those gifts important to their research. Between 66% and 75% of respondents considered receiving biomaterials, discretionary funds, or research equipment "essential," "very important," or "important" to their work. Of those, almost a third reported that sponsoring companies insisted on pre-publication review of their research and 19% believed the donor corporation expected ownership of all patentable results.

One of the most intriguing aspects of the study is just how productive corporate gifts are for both the recipients and companies that engage in the practice. Faculty researchers who receive such gifts tend to be "significantly more productive," publish "significantly more articles," and engage in "significantly more hours of student contact," the study contends. Whether applying for patents, getting a new product on the market or starting a new company, those "who received research-related gifts were significantly more commercially productive," than those that did not, conclude the authors.

As they readily acknowledge, the study raises more questions than it answers. What exactly are corporations trying to achieve with research-related gifts? What do they want in return? How extensively are researchers in compliance with those expectations? What are the effects of such gifts on researchers' attitudes toward sharing scientific data? Answers to these questions will have to await further study.

Still, the danger is that corporate gift-giving to academic researchers may be used as a means of bypassing existing institutional safeguards relating to management of research grants and contracts. Such gifts, to hear researchers tell it, already represent a significant contribution to the advancement of scientific knowledge and its commercial applications. Left unmonitored, they may also represent a sore temptation to redirect resources or withhold research data that is no more in the best interest of good science than it is in the interests of good business.

The study presents a troubling picture of high-tech, research-intensive sectors like pharmaceutical biotechnology, where basic researchers and clinical researchers alike are privy to information with tremendous financial implications, whether they hold stocks or corporate gifts with strings attached. Though many universities and university hospitals have strict guidelines-requiring, for example, that researchers linked with companies place their stock into escrow accounts for a period of time after commercializationothers are less assiduous. Even those with broad disclosure rules have no way of knowing whether faculty employees are playing by the rules, much less receiving nonmonetary corporate gifts.

The best hope for the future, short of uniform academic rules governing privatesector gift-giving, may well be planned increases in the levels of government biomedical funding at major funding agencies such as the National Institutions for Health. David Blumenthal of the Harvard Medical School, the "Gift Horse" study's lead author, says the demand for biomedical research in the past 10 years has far outstripped the supply of research funding, leaving an opening the industry has willingly filled. He believes that the best way to manage the problem is for the federal government to make adequate enough resources available to enable academic researchers to deal with industry from a position of strength, rather than desperation.

Blumenthal believes that most academic researchers would prefer prestigious government research grants anyway. As for the corporate gift-givers, he says, "It is in industry's best interest to preserve the goose that lays the golden egg." Industry has a stake in respecting academic prerogatives. In short, strong universities that do not brook compromise on basic principles such as shared research data, timely publication of research results, and free scientific inquiry will lead to a stronger biotechnology industry. ///