

Assessing Faculty Financial Relationships With Industry

A Case Study

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FINANCIAL TIES BETWEEN ACADEMIC researchers and private industry are currently under intense scrutiny.¹⁻⁴ About \$1.5 billion from industry flows into academic institutions annually,⁵ and 1 study has shown that 28% of surveyed life sciences faculty report funding from private sponsors.⁶ There is growing concern among federal and state agencies and academic institutions that industry sponsorship may influence the outcomes of research and undermine traditionally held academic values of intellectual freedom, open exchange of ideas, and research in the interest of the public good.⁷⁻⁹

Such concerns are not without foundation. Several studies have shown an association between single-source sponsorship of clinical research and publication of results favoring the sponsor's product¹⁰⁻¹²; another study has shown that unfavorable results of economic analyses of oncology drugs are less likely to be reported when the study is funded by a pharmaceutical company.¹³ Faculty researchers receiving research support from industry are also more likely to restrict their communication with colleagues than faculty not receiving industry sponsorship,⁶ and many faculty who receive gifts from corporate sponsors are subject to prepub-

See also pp 2156, 2193, 2203, 2234, 2237.

Context A growing number of academic researchers receive industry funding for clinical and basic research, but little is known about the personal financial relationships of researchers with their industry sponsors.

Objectives To assess the extent to which faculty researchers have personal financial relationships with the sponsors of their research, the nature of those financial relationships, and efforts made at the institutional level to address disclosed financial relationships and perceived conflicts of interest.

Design and Setting Case study of the University of California, San Francisco (UCSF). Data sources included disclosure forms and official documents maintained by the UCSF Office of Research Administration from December 1980 to October 1999, including decisions made by the UCSF Chancellor's Advisory Panel on Relations with Industry.

Main Outcome Measures Number and types of personal financial relationships with external sponsors (positive financial disclosures from all clinical, basic, or social science faculty who were principal investigators), amount of annual income received from sponsors, and decisions and management strategies used by the advisory panel.

Results By 1999, almost 7.6% of faculty investigators reported personal financial ties with sponsors of their research. Throughout the study period, 34% of disclosed relationships involved paid speaking engagements (range, \$250–\$20 000 per year), 33% involved consulting agreements between researcher and sponsor (range, <\$1000–\$120 000 per year), and 32% involved the investigator holding a position on a scientific advisory board or board of directors. Fourteen percent involved equity ownership, and 12% involved multiple relationships. The advisory panel recommended managing perceived conflicts of interest in 26% of the cases, including recommending the sale of stock, refusing additional payment for talks, resigning from a management position, or naming a new principal investigator for a project.

Conclusions Faculty researchers are increasingly involved in financial relationships with their research sponsors. Guidelines for what constitutes a conflict and how the conflict should be managed are needed if researchers are to have consistent standards of behavior among institutions.

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lication review or data use restrictions.^{14,15}

In addition to the effects that corporate sponsorship might have on design, outcome, or publication of results, concern exists that a growing number of faculty researchers also have personal financial relationships with the companies sponsoring their research.^{16,17} In 1996, Krinsky et al¹⁸

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Table 1. Federal, State, and Institutional Guidelines for Disclosure or Management of Financial Interests**Federal Guidelines (1995)¹⁹**

All investigators must disclose all "significant" financial interests that would "reasonably" appear related to the sponsored research. *Significant* is defined as \$10 000 per year in income or 5% equity in a company. The guidelines apply to the investigator, spouse, and dependent children.

State Guidelines (1982)²⁰

Principal investigators who receive more than \$250 from a nongovernmental source must disclose "direct or indirect financial interests" in the sponsor of the research. *Direct or indirect financial interests* are defined as an investment of more than \$1000; a position as director, officer, partner, trustee, employee, or other management position; income from the sponsor, including gifts and consulting income of more than \$250; a loan from the sponsor; or any of the above through a spouse or dependent children.

Institutional Policy on Clinical Trials (1996)²²

Faculty who have, or participate in, a sponsored clinical study shall not concurrently receive any compensation from the sponsor, including honoraria and consulting fees, during the course of the study; have any investment or decision-making relationship, such as service on the board of directors or management committee; or be an officer or employee of the company during the study.

found that 15% of Massachusetts-based lead authors of journal articles had personal financial interests in the company sponsoring the research project. Although there is speculation that these additional financial ties result in an increased potential for conflicts of interest because the researchers stand to benefit personally from the outcome of the study, the extent and nature of these ties remain unknown. Furthermore, although universities are now required by the federal government and many states to assess and manage disclosed conflicts of interest,^{19,20} little is known about how universities implement guidelines and evaluate or manage cases of disclosed financial conflicts.

This case study offers a description of the extent and nature of a university's faculty researchers' personal financial relationships with industry sponsors during the past 20 years and that university's response to such financial disclosures. The aims of this study were to assess (1) the extent to which faculty research-

ers have personal financial relationships with corporate sponsors of their research projects, (2) the nature of those relationships, and (3) the efforts made at the institutional level to address disclosed financial relationships.

METHODS**Data Collection**

Data sources for this study were disclosure forms and official documents maintained by the administrator of the conflict of interest policies in the University of California, San Francisco (UCSF) Office of Research Administration. The university is a major research institution with more than 12 000 faculty and staff, and it ranks among the top 5 in National Institutes of Health (NIH) funding, receiving more than \$374 million annually in research grants. In 1999, approximately 900 faculty members were principal investigators for externally funded research projects.²¹

As employees of a state university receiving Public Health Service or National Science Foundation funding, UCSF researchers are subject to both state and federal regulations regarding disclosure of financial relationships that are (or reasonably appear to be) related to their externally funded research projects. TABLE 1 summarizes the federal and state disclosure guidelines, as well as UCSF's clinical trial policy.

The state and federal guidelines establish financial disclosure as the primary means through which personal faculty relationships with industry are monitored. If a faculty researcher meets any of the criteria outlined in Table 1, additional information is required from the researcher. This additional information includes a description of the scientific and financial nature of the relationships between researcher and company, the scientific directions of the company, whether patent or intellectual property rights are involved, how students and postdoctoral fellows are involved, and what contributions to the university the relationship affords. These supplemental questions are de-

signed to address concerns that the research relationship be "appropriate to the university."²⁰

The UCSF Chancellor's Advisory Panel on Relations with Industry was formed in 1980 to review cases of disclosed financial interest and to advise the vice chancellor for research of possible conflicts of interest. The current committee consists of 17 members, including faculty from clinical and basic sciences, administrators from the Offices of Grants and Contracts and Technology Transfer, legal counsel, and 2 public members. Since the mid-1980s, the committee has met monthly to review positive disclosures and assess whether a faculty member's financial interest could affect research integrity. The committee's role is explicitly advisory and it recommends to the vice chancellor specific actions to manage the conflict. In all but 1 case during the study period, the vice chancellor has implemented the recommendations of the committee.

The archived files from which we extracted our data contain preliminary disclosure forms, detailed subsequent forms, correspondence between the researcher and university representatives, and the committee's recommendations to the vice chancellor. Since the files consist of publicly available documents, the study was granted exempt status from the UCSF Committee on Human Research.

Files on positive disclosures are maintained permanently; negative disclosures may be kept for up to 7 years. The data for this study consist of all positive disclosures from December 1980 through October 1999. All files except those pending a decision (n=35) at the time of data collection were examined. Because we are primarily interested in the nature of disclosed financial relationships and the university's response to those relationships, we considered only positive disclosures from principal investigators.

Major Variables

The extent of faculty relationships was determined by the number of positive financial disclosures by individual prin-

cial investigators. The standards for disclosure remained constant between 1982 and 1999, as did the administrative procedures for reporting and evaluating disclosures. All UCSF faculty (which consisted of clinical, basic, and social science faculty) were included (eg, biomedical faculty but not structural engineers were included, bioinformatics but not computer science faculty were included). Types of personal financial relationships were extracted based on the principal investigator's report of his/her financial relationships with a sponsor. Advisory panel decisions and management recommendations were extracted based on correspondence between administrators, the panel, the vice chancellor, and the principal investigator. The complete list of extracted variables appears in TABLE 2.

Data Analysis

The first author (E.A.B.) extracted data related to the nature and management of positive disclosures. Descriptive statistics are reported.

RESULTS

Extent of Faculty Relations With Industry

The first record of a positive financial disclosure was dated December 1980. Through October 1999, there were 488 positive disclosures from 225 researchers. Thirty-seven percent of researchers (83/225) had more than 1 positive disclosure; 1 had 28 positive disclosures and most had fewer than 4. As the FIGURE shows, the number of positive disclosures increased most dramatically in the last 6 years of the 1990s.

Proportionately, the percentage of principal investigators (based on the total number of university investigators with external funding per year) with personal financial ties to their industry sponsors has increased from 2.6% (15/577) in 1985 (the first year for which such calculations are possible) to 7.1% (63/888) in 1997. Including the 35 pending positive disclosures from 1999, the percentage of principal investigators with personal financial ties

in 1999 was 7.6% (68/896). Investigators represented 47 different departments and research units.

Of the 488 positive disclosures, most involved research projects sponsored by private companies or foundations (n=437). The remainder (n=51) involved federally sponsored National Institutes of Health research projects and special federally sponsored projects, such as those sponsored by the Small Technology Transfer Research or Small Business Innovation Research programs, designed to encourage small business growth and the transfer of technology from academe to industry. Pharmaceutical companies funded 43% of the sponsored projects; nonprofit agencies, including departmental research foundations and extramural nonprofit agencies, funded 31%; biotechnology firms funded 9%; and medical device manufacturers sponsored 6%. An additional 8% were funded by others (eg, oil or software companies) and 2% were unknown. These projects totaled \$72 650 000 for the 20-year period. The mean size of a sponsored project was \$149 179, with a median of \$40 000 and a range of \$250 to \$1 500 000. The mean size of a federal grant was \$623 226 and that of a privately funded project was \$94 940.

As shown in the Figure, positive disclosures related to clinical trials steadily increased in the past 6 years. Of the 488 total positive disclosures, 128 (26%) involved clinical trials.

Characteristics of Positive Financial Disclosures

We characterized the types of relationships disclosed by academic investigators. These categories are not mutually exclusive. Twelve percent (59/488) of the cases involved investigators with multiple interests in the sponsoring (or related, in the case of federal support) entity (for instance, consulting income, a management interest, and equity).

Three types of relationships were commonly disclosed. First, 34% (167/488) involved an occasional speaking engagement. Investigators most com-

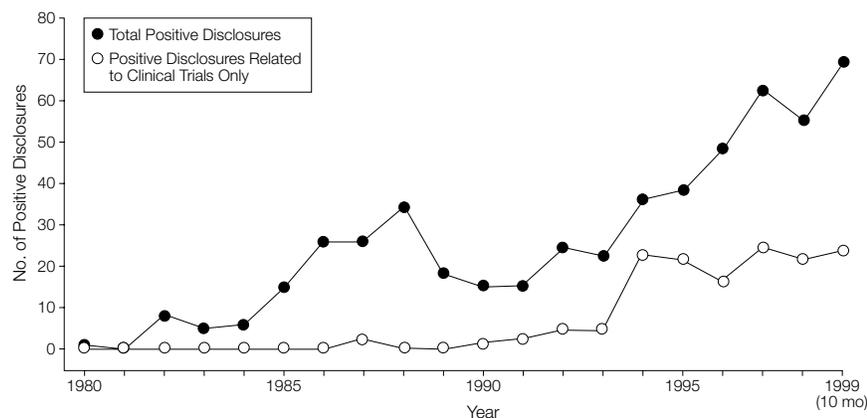
Table 2. Extracted Variables and Coding Options*

Identification number
Investigator name
Date of disclosure [month/year]
Investigator's department
Funder name
Funding company type [pharmaceutical/ biotechnology/medical devices/nonprofit/ other]
Private funding [yes/no]
Federal funding [NIH/NCI/NIDDK/STTR/other]
City in which funder is located
State in which funder is located
Clinical trial [yes/no]
Public company [yes/no]
Amount of funding [in dollars]
Project title
Relationship to sponsor/company:
Founder [yes/no]
Scientific advisory board or board of directors [yes/no]
Consultant [yes/no]
Sponsored lectures/talks [yes/no]
Equity [yes/no]
Amount of yearly income from sponsor [in dollars]
Number of shares owned
Number of stock options
Value of stock [in dollars]
Contractual conflicts [described]
Other relationships of investigator [described]
Long-term or patterned relationship with sponsor [yes/no]
Direct and significant effect [yes/no]
Panel recommendation [accept/decline/no decision]
Time to decision [in months]
Management strategy recommended by panel [described]
Follow-up [described]
Panel's rationale for decision [described]

*Data shown in brackets are coding options. NIH indicates National Institutes of Health; NCI, National Cancer Institute; NIDDK, National Institute of Diabetes and Digestive and Kidney Disorders; and STTR, Small Business Technology Transfer Program.

monly reported giving 1 or 2 talks and receiving an estimated \$2500 annually (range, \$250-\$20 000 per year) as honoraria. More than 90% of these investigators reported receiving less than \$10 000 annually. This amount is below the federal disclosure threshold but is captured by the more stringent state reporting guidelines.

Second, 33% of cases (161/488) involved a paid consulting arrangement, either formally (with a signed contract) or informally (on an occasional basis). In the case of clinical trials, investigators often reported consulting on protocol design for an upcoming trial. Other consulting arrangements included contracts in which the investigator provided regular services for a monthly fee. Overall, the pay-

Figure. Number of Total Positive Disclosures and Positive Clinical Trial Disclosures by Year, 1980-1999

ment for consulting ranged from less than \$1000 to \$120 000 per year. Of those investigators who consulted, 61% reported receiving less than \$10 000 per year for their services.

Third, 32% of cases (160/488) involved an investigator in a paid position on either a scientific advisory board or board of directors of the company or agency from which he/she received research funding. Positions on these boards ranged from president to non-voting member. More than half of these instances involved investigators in positions on the boards of nonprofit agencies that were funding their research. Prior to 1994, most of these nonprofit agencies were departmentally based research foundations, but these were phased out during the early 1990s. Since 1994, all funding from nonprofit agencies came from external private or public foundations.

Fourteen percent of cases (71/488) involved investigators reporting equity in the sponsoring company. The value of that stock ranged from nothing (in the case of virtual companies) to more than \$1 million. The mean value of stock owned by an investigator was less than \$100 000, and most had an investment valued at less than 5% of the company's value. Twenty-one percent reported owning less than \$10 000 worth of stock. Two percent of cases (12/488) and less than 1% of cases

(1/488) owned intellectual property or had an outstanding loan from the sponsor, respectively.

Institutional Response and Management Strategies

Although state and federal guidelines establish financial thresholds above which institutional review is necessary, the guidelines do not provide clear strategies for managing cases that exceed those thresholds. According to federal policy, the institution is responsible for determining whether the investigator's financial interests would have a "direct and significant" effect on the design, conduct, or reporting of the research¹⁹; state policy requires the institution to decide if the disclosed financial interests would interfere with an open academic environment, free exchange of ideas, intellectual freedom of students, appropriate use of university resources, fair licensing of new technologies, and appropriateness of the research to the university's mission.²⁰

The committee made decisions regarding the presence or absence of conflicts of interest and recommended management strategies to mitigate or eliminate conflicts. Overwhelmingly, the committee recommended that the research funding be accepted, with or without management. In only 8 instances did the committee recommend declining the funding; 1 decision was

later overturned by the committee on clarification of requirements by the NIH. However, in 26% of cases (128/488), the committee recommended some strategy to manage the perceived or potential conflict of interest, and the proportion of cases for which management was recommended increased significantly during the 20-year period. Between 1980 and 1984, 15% of cases (3/20) were managed; between 1990 and 1994, the proportion increased to almost 18% (20/112); and between 1995 and 1999, 43% of the cases (102/237) were managed.

The recent increase in managed cases is in large part due to the implementation of UCSF's clinical trial policy.²² Of the 102 cases managed during 1995-1999, 71 (69%) involved clinical trials. Typically, investigators reported receiving income for lectures or occasional consulting activities. Prior to 1996, the committee usually accepted such relationships as involving "payment for services rendered," or a conflict that was "technical in nature" and, therefore, acceptable. However, following the 1996 campuswide ban on acceptance of any income from companies funding clinical trials during the course of the trial, the committee required investigators to agree to forgo any type of payment from a trial's sponsor while the clinical trial was in progress.

The reasons for the committee's selection of a particular management strategy for nonclinical trials were not consistently documented in the written record. By examining letters of recommendation made to the chancellor, in which some rationale for the decision was provided, the following characteristics of a case were considered relevant by the committee: (1) length or nature of the investigator's involvement with the sponsor (eg, a 1-time consulting fee was not considered problematic, nor were seminars or honoraria); (2) nature of the sponsoring agency (eg, funding from nonprofit agencies was not considered problematic, as long as the investigator could offer some assurance that he/she did not participate in the decision to grant the

funding); and (3) the estimated degree of separation between the investigator's project and consulting activities (eg, payment for consulting services was not considered problematic if the consulting was not directly related to the sponsored research).

Furthermore, unrestricted gifts, regardless of size, were not usually considered problematic. In only 1 case regarding a gift did the committee ask for proof that it was truly unrestricted in nature. This unusual request by the committee was prompted by the relatively large size of that gift, \$85 000, and by the concern that the gift might actually be intended to support a funded research project, which would conflict with the investigator's personal financial relationship with the company. To summarize, the committee consistently determined financial relationships of limited duration or in which there was some degree of separation between the investigator and the financial or substantive decision-making process to be nonproblematic and, therefore, not conflicts of interest.

Cases involving more extensive financial ties were considered problematic, and the committee usually recommended a management strategy to mitigate or eliminate the conflict rather than decline the funding altogether. These strategies included public disclosure of the financial interest, sale of stock, resignation from a board, and appointment of an oversight committee to monitor research design and activity. The strategies chosen were intended to address the specific problems of a particular case; the committee did not use standardized management practices.

Nonclinical trial cases that required management most often involved either a contractual conflict that violated university policy or stock holdings that were viewed as significant. Cases involving contractual conflicts were managed with strategies that eliminated the conflict. For instance, investigators who entered consulting agreements that contained publication delays of more than 90 days—a violation of

university policy—were instructed to modify their consulting agreements to reduce the delay to less than 90 days. In the case of excessive stock holdings (>5% equity in the company), investigators were instructed to sell the excess stocks and provide proof of sale to the committee.

The more extensive the investigator's ties with a company, the more likely the committee was to believe that there was a potential for conflict and recommend management of the potential conflict. So, in instances in which the principal investigator held a position on the scientific advisory board, received consulting income, and held equity in a company, the committee would recommend resigning from the scientific advisory board, reducing the stock holdings to less than 5%, and separating consulting activities from research activities. Occasionally (n=3), an investigator was asked to remove himself/herself as the principal investigator for the project; this involved investigators who were founders, directors, and held significant equity in the company.

Finally, the committee increasingly used disclosure of financial interests in publications and presentations as a management strategy. This strategy was most often used when the investigator had a single but significant interest in the sponsor (eg, consulting income >\$10 000). This strategy was also used in conjunction with other strategies.

In only 3 instances did the committee call for the formation of an oversight committee to manage the conflicts. These cases involved investigators who had founded the involved companies and had retained close financial and management ties to the company, but whose research was deemed by the committee to be of such importance that the conflicts should be managed rather than the funding declined. The oversight committee was charged with evaluating the research for its compliance with the principles of appropriate research, its ethical nature, its basic value, and its appropriateness to the

university. These reports were reviewed by the committee 1 year later.

COMMENT

This article describes researchers' personal financial ties to industry sponsors and the response of a major research university to those ties. Our data document the growing number of researchers who report personal financial relationships with industry sponsors beyond grants for an individual research project. This growth in positive disclosures in part reflects the federal disclosure requirements implemented in 1995; however, the number of disclosures required by state guidelines, which have remained constant since 1982, has risen as well.

Because UCSF is subject to relatively stringent state or campus policies, the extent and nature of the observed relationships may be fewer or simpler than that in other similar academic health centers or on campuses with non-life science faculty. Future research must determine the effect of institutional policies and management strategies on academic research and sponsorship, as well as on faculty behavior.

This study relies on faculty members' compliance with state and federal regulations regarding financial disclosure. Researchers sign state and federal disclosures under penalty of law, so we have no a priori reason to suspect serious underreporting of financial interests. Further administrative checks are in place to discover incorrectly completed forms. Similarly, although we know that the university implemented the committee's recommendations, we do not know the extent to which individual researchers complied with the recommendations. Again, because these recommendations carry with them the potential for disciplinary action, we have no reason to suspect noncompliance among faculty researchers.

Our study shows a set of intricate financial relationships between faculty researchers and private sponsors extending beyond the funding of particular

research projects. Most faculty researchers reported personal relationships that were short-term or involved a minimal amount of money, such as payment for participating in a meeting, 1-time consulting, or serving as a member of a nonprofit agency's advisory board. These relationships are rarely considered problematic by the institution; indeed, they may be viewed as positive since they may help foster initial and, perhaps, subsequent sponsorship of the investigator's research projects. On the other hand, complex relationships, such as founding a company, serving on the advisory board, and owning stock, were not unusual and were viewed as problematic, though not completely unacceptable.

As many universities, states, and the federal government encourage researchers to foster relationships with industry, these types of financial relationships and their accompanying risks to research integrity will likely increase. At the same time, however, specific guidelines regulating faculty relationships are lacking. Our study shows that in the absence of such guidelines, a local committee was forced to define acceptable

relationships and appropriate management strategies in the face of each new positive disclosure. For example, the committee itself defined what level of financial interest was a conflict in need of management, and those definitions were frequently more stringent than the federal \$10,000 threshold. This finding suggests that the dollar-amount cutoff that defines a financial conflict could be interpreted differently among different institutions. Committees or other mechanisms to assess the financial ties of faculty are required to balance the competing pressures of traditional academic values with economic pressures. The UCSF committee worked to accommodate all but the most overtly conflicting relationships in the interest of encouraging its faculty and, presumably, encouraging future outside investment in the university.

Furthermore, decisions are subject to change over time, as committee members respond to a range of new pressures and concerns. In our study, although the thresholds set by state and federal policies for disclosure remained constant throughout the study period, committee members' deci-

sions regarding what level of financial involvement constituted a conflict of interest did change. These changes are likely to continue until consistent and explicit definitions exist about financial conflicts of interest and how they should be managed. Thus, our findings raise questions for university, state, and federal policymakers who are concerned about enforcing consistent standards of behavior among faculty researchers.

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