Policies on Faculty Conflicts of Interest at US Universities

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Context Despite federal regulations on faculty conflicts of interest in federally funded research, academic-industry ties are common, and evidence exists that financial considerations bias the research record. Public scrutiny of these ties is increasing, especially in cases where researchers have financial interests in the corporate sponsors of their clinical research.

Objective To review policies on conflict of interest at major biomedical research institutions in the United States.

Design Cross-sectional survey and content analysis study conducted from August 1998 to February 2000.

Setting and Participants The 100 US institutions with the most funding from the National Institutes of Health in 1998 were initially sampled; policies from 89 institutions were available and included in the analysis.

Main Outcome Measures Process for disclosure, review, and management of conflicts of interest and specified management strategies or limitations, according to the institutions' faculty/staff conflict of interest policies.

Results Content of the conflict of interest policies varied widely across institutions. Fifty-five percent of policies (n=49) required disclosures from all faculty while 45% (n=40) required them only from principal investigators or those conducting research. Nineteen percent of policies (n=17) specified limits on faculty financial interests in corporate sponsors of research, 12% (n=11) specified limits on permissible delays in publication, and 4% (n=4) prohibited student involvement in work sponsored by a company in which the faculty mentor had a financial interest.

Conclusions Most policies on conflict of interest in our sample of major research institutions in the United States lack specificity about the kinds of relationships with industry that are permitted or prohibited. Wide variation in management of conflicts of interest among institutions may cause unnecessary confusion among potential industrial partners or competition among universities for corporate sponsorship that could erode academic standards. It is in the long-term interest of institutions to develop widely agreed-on, clear, specific, and credible policies on conflicts of interest.

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In the 20 years since the Bayh-Dole Act was passed,[1] US academic institutions have developed a variety of relationships with industry. In fulfilling its intended goal of encouraging transfer of technology from universities to the private sector, this act and associated legislation have fostered the rapid growth of patents held by nonprofit institutions, such as universities, and the licensing of these patents to for-profit companies. The number of university-generated patents increased from approximately 250 per year prior to the Bayh-Dole Act[2] to more than 4800 (and >3000 licenses) in 1998.[3] This new pathway of technology transfer has resulted in development by private companies of technologies such as the cancer drug paclitaxel and the Lycos Internet search engine.[3] It also has created opportunities for conflict of interest for university faculty members because academic-industry partnerships can offer direct financial rewards to individual faculty members in the form of consulting fees, royalties, and equity in companies while simultaneously funding these faculty members' research. These financial interests are now prevalent: Krimsky et al[4] found that 34% of articles published in 14 leading biology and medical journals in 1992 had at least 1 lead author with a financial interest in a company with activities related to the published research, although virtually all of these interests were undisclosed in the articles.

See also pp 2156, 2193, 2209, 2234, and 2237.

Conflicts of interest are of concern because of their potential effect on the quality, outcome, and dissemination of research,[5] as well as their effects on the public's perception of and trust in researchers and universities. We define *conflicts of interest* as situations in which primary and secondary interests coexist,[6] rather than as situations in which the coexisting interests have led to an undesirable outcome, such as research misconduct. There is a growing body of literature showing that faculty who have industry ties are more likely to report research results that are favorable to a corporate sponsor,[7-10] are more likely to conduct research that is of lower quality,[11,12]

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Table 1. Data Abstraction Items

General
Institution
Source of policy (eg, Web site, institutional office)
Effective date
To whom policy applies
Types of conflicts (eg, financial, time commitment, external activities)
Review and management process
Reviewer of disclosed conflicts
Decision maker following review
Strategies for managing conflicts of interest
Financial interests allowed
Financial interests presumptively allowed with review
Financial interests not allowed
Existence of sanctions
Existence of appeals process
Disclosure
Decision maker who decides whether disclosed interests are a conflict
Types of interests required to be disclosed (eg, those related to research only, those related to all professional activities, any)
Specific interests required to be disclosed (eg, research support, consulting fees, equity, patents, royalties)
About whom information must be disclosed (eg, all faculty, faculty engaged in research, principal investigators in research, family members, trainees)
To whom disclosures are made
When disclosures must occur
Whether disclosure to research sponsors is required
Other
Existence of policy on suppression or delay of publication
Existence of specific policy for clinical research
Existence of separate policy for only Public Health Service/National Science Foundation–funded research

and are less likely to disseminate their results to the scientific community.[13,14] Other findings suggest that faculty with some research support from industry may publish at higher rates than faculty without such support. However, faculty who receive more than two thirds of their research support from industry publish less than faculty with lower levels of industry support.[15] The extent to which conflicts of interest are directly responsible for these outcomes is unclear.

The US government has attempted to address the concern over conflicts of interest by implementing a federal regulation mandating the disclosure of financial interests of individuals who apply to the Public Health Service (PHS) or the National Science Foundation (NSF) for research funding.[16] This regulation is limited in scope because it requires disclosure only to institutional officials, not to the public. Furthermore, disclosure is required only for financial interests related to research proposed for PHS or NSF funding. Thus, faculty members with financial interests related to research funded solely by private companies are not necessarily affected by these regulations; therefore, grants for which one might expect the greatest conflict may be excluded from regulation. However, the federal regulation also requires institutions that apply for PHS or NSF funding to have institutional policies for reviewing and managing the financial interests of their researchers. This leaves the specifics of policy making up to individual institutions. However, the institutions themselves are also in a situation of conflicting interests to the extent that institutions also collect a share of industry research grants and royalties from patents generated by their faculty.

Institutional policies, and the variation among them, are of increasing interest for 3 reasons. First, institutions have changed their policies in recent years because of the increasing frequency and complexity of academic-industry ties and the implementation of the aforementioned federal regulation regarding conflicts of interest. Second, public awareness of academic-industry ties is increasing, as is interest in how universities set limits on, or otherwise manage, conflicts of interest.[17] Third, the institutional stance toward academic-industry ties may be a factor in faculty members' willingness to work at the institution. For example, Harvard University reviewed its policy limiting faculty financial interests in companies that sponsor their research, presumably because some faculty felt that the limits are too restrictive.[18] For these reasons, we performed a comprehensive review of institutional conflict of interest policies at 100 major US research institutions.

METHODS

Study Design and Sample

We performed a content analysis of conflict of interest policies from 100 US research institutions, collected between August 1998 and February 2000. These institutions had the highest levels of funding from the National Institutes of Health (NIH) in 1998 (as a proxy for PHS/NSF funding) as determined from lists publicly available from the NIH Office of Extramural Research (available at: http://grants.nih.gov/grants/award/award.htm). We collected policies from institutional Web sites or from institutional officials. At institutions where a Web site was not available, we attempted to contact institutional officials up to 5 times by telephone and letter. These policies were generally available from institutional offices of research administration. Because we were also interested in clinical research and publication, we requested a variety of policies, including those regarding faculty conflict of interest, conflict of commitment, or external activities; intellectual property; clinical research; and academic freedom. If policies were updated during the period of data collection, we used the updated version. We included policies on faculty conflict of interest where available, otherwise we included policies on staff conflict of interest.

Content Analysis

We developed a 22-item data abstraction instrument covering several topics including the process for disclosure, review, and management of faculty conflicts of interest and any specified management strategies or limitations (TABLE 1). If we could not find information pertaining to an instrument item in the published policy, we classified it as "unspecified." We pilot tested the instrument using 10 policies. One author (R.S.) abstracted data from all policies, and another (M.K.C.) independently abstracted a subsample of 10 policies to determine interrater reliability of the abstraction. For those policies, the agreement of each instrument item ranged from 80% to 100%. The average agreement for all items was 93.7%. All but 1 disagreement was due to abstractor oversight of the item in the policy.

RESULTS

Of 100 institutions selected from the NIH ranking, 3 were excluded be-

cause the institution no longer existed or had conflict of interest policies identical to a parent institution in our sample. Of the 97 remaining institutions, we obtained a total of 89 policies (92% response rate): 54 (61%) from institutional Web sites and 35 (39%) from institutional officials. The effective dates of the 72 policies for which a date could be determined ranged from 1984 to 2000. Of the 72 policies, 29 (40%) were established in 1995 (the year that the federal regulation was introduced),[16] 17 (24%) were dated prior to 1995, and 26 (36%) were dated after 1995. Those dated during or after 1995 could have been established before 1995 and subsequently modified. All policies addressed financial conflicts of interest, 36 (40%) addressed conflicts of commitment, and 47 (53%) addressed issues related to the effects of either conflicts of interest or conflicts of commitment on trainees or educational activities.

Disclosure, Review, and Management Process

Forty-nine policies (55%) required disclosures from all faculty, while 40 (45%) required disclosures only from those conducting research or serving as principal investigators. Seven (8%) also required disclosure about financial interests of trainees and 78 (88%) required disclosure about financial interests of family members. Sixty-two institutions (70%) asked for disclosure of all interests related to professional activities (including research and teaching), while 24 (27%) asked for disclosure only of interests related to research or sponsored research. Only 2 institutions asked for disclosure of all financial interests.

Seventy-five institutions (84%) asked for disclosure either annually and/or when conflicts of interest arose. Six (6.7%) asked for disclosure only when conflicts of interest arose in the context of external funding for research. The administrative processes for review and decision making about disclosed conflicts of interest are summarized in TABLE 2.

Table 2. Process of Review and Decision Making of Disclosed Conflicts of Interest (N = 89 Policies)

	No. (%)	
	Who Reviews Disclosed Conflicts of Interest?	Who Decides on a Management Strategy?
Department chair, dean, or supervisor	22 (25)	20 (22)
Institutional committee*	34 (38)	13 (15)
University official	14 (16)	42 (47)
Legal counsel	0	0
Other	10 (11)	6 (7)
Unspecified	9 (10)	8 (9)

*With or without additional review by department chair, dean, or supervisor.

Forty-seven institutional policies (53%) specifically stated that there was a process by which faculty could appeal decisions about conflict of interest, and 62 (70%) specified sanctions for faculty who did not comply with the policies.

Strategies for Managing Conflicts of Interest

Many policies listed methods by which institutions could potentially manage disclosed conflicts of interest. Institutions were not necessarily limited to these methods, and the situations in which the methods would be used were generally not specified. The frequencies with which these methods were described in policies are listed in TABLE 3. The method most frequently stated was disclosure to institutions, followed by disclosure to the public, monitoring or oversight of research activities, and divestiture or prohibition of financial interests. *Disclosure to the public* included statements requiring disclosure in public presentations or publication of research and did not include disclosure that might have been required by state laws on public access to information at public institutions. Other methods included assigning another investigator to lead a research project or asking the faculty member to take a leave of absence from the university.

Activities Specifically Allowed by Policies. Thirty-two policies (36%) specifically described activities that were allowed and generally not considered conflicts of interest. These included paid or unpaid directorships or similar roles in organizations unrelated to professional responsibilities; receiving royalties, honoraria, or prizes for scholarly work; paid consulting for private or nonprofit organizations (within institutional limits); membership on professional review panels or societies, and providing expert testimony for judicial or legislative bodies.

Table 3. Methods Potentially Used by Institutions to Manage Disclosed Conflicts of Interest (N = 89 Policies)*

Method	No. (%)
Disclosure to institution	79 (89)
Disclosure to public†	52 (58)
Monitoring/oversight of research	52 (58)
Divestiture/prohibition of financial interests	51 (57)
Disqualification from/discontinuation of research	42 (47)
Modification of research	41 (46)
Refusal of funding	3 (3)
Placing equity in escrow	3 (3)
Giving proceeds of sale of equity to other organization	3 (3)
Other	16 (18)
Unspecified beyond disclosure to institution	20 (22)

*Policies could have indicated more than 1 method.
†This included statements requiring disclosure in public presentations or publication of research.

Activities Specifically Prohibited by Policies. Institutional policies typically described several kinds of activities that were specifically prohibited. Many of these activities were not specific to academic research or teaching activities but applied to external activities related to professional roles, such as consulting, or to nonacademic activities conducted on behalf of the university, such as purchasing equipment or negotiating agreements. Prohibited activities typically included excessive consulting, using university facilities or the university name in consulting, employ-

ment by outside entities, using confidential information for personal benefit, accepting personal gifts from companies with which the university does business, and negotiating agreements with companies in which the individual has a financial interest.

We searched the policies for specific prohibitions or limits on activities related to research and teaching (TABLE 4). We found such activities in only 17 policies (19%). The activity that was most often specifically prohibited or limited was a faculty member having financial interests in a company sponsoring their research. Other prohibited activities included involvement of students in work sponsored by a company in which the student's advisor had a financial interest, faculty membership on the board of directors of a company sponsoring the faculty's research or giving gifts to the institution, and students being hired by companies as paid consultants. The remaining 81% of policies made no mention of prohibitions on such activities in the context of research.

We also searched policies for any mention of considerations of conflicts of interest particular to clinical research. Of the 17 policies (19%) with such language, 8 included faculty limits on equity holdings in companies sponsoring their research. Five had other policies specific to clinical research, including requiring disclosure of financial interests in published work, having a "zero threshold" for disclosure of financial interests in company sponsors, using oversight committees to monitor research sponsored by companies in which faculty have financial interests, and requiring the institution to inform the human subjects review committee of identified conflicts of interest. The remainder of the policies had a general statement that clinical research required more stringent limitations or management strategies than nonclinical research. None included a requirement for disclosing faculty financial interests in informed consent forms for human subjects.

Table 4. Activities Related to Research and Teaching Specifically Prohibited in Institutional Conflict of Interest Policies

Prohibited Activity	No. of Institutions	Specific Limitations of Policies*
Faculty member having financial interests in a company sponsoring the research	17	3 Prohibited any financial interests of payments (including royalties) 3 Prohibited ownership of any stock 3 Allowed stock valued at up to $20 000 3 Prohibited stock or significant financial interests only in companies sponsoring clinical research 2 Prohibited "significant financial interests" 1 Allowed stock up to 5% of the company's equity 1 Allowed stock up to 10% of the company's equity 1 Allowed stock up to 50% of the company's equity 1 Prohibited any consulting fees 1 Prohibited consulting fees of more than $10 000
Involvement of students in faculty consulting or sponsored research	4	4 Prohibited assigning students to research sponsored by companies in which faculty have financial interests 1 Prohibited involvement of students in faculty consulting activities
Faculty member being on board of directors (BOD) of a company sponsoring research or giving gifts to the institution	3	1 Prohibited BOD membership, stock, or scientific advisory board membership in a company that is a competitor of a company sponsoring faculty member's research 1 Prohibited BOD membership in a company sponsoring faculty member's research 1 Prohibited BOD membership in a company giving a gift to the faculty member or department
Involvement of students in paid consulting	1	1 Prohibited students from participating in paid consulting

*Sum of column is greater than number of institutions because they could have more than 1 prohibition.

Policies on Delays of Publication

Only 11 policies (12%) specified a time limit for delay of publication or presentation of research results to allow review by corporate sponsors or to allow patents to be filed. The specified time limits ranged from 0 to 12 months, with 8 institutions limiting delays to 3 months or less. The other 78 policies (88%) did not mention delay of publication or presentation or included a nonspecific statement that academic activities should not be delayed longer than needed to obtain intellectual property protection. Twenty-four institutions (27%) had a separate policy that pertained only to PHS/NSF-funded research (mirroring the federal guidelines).

Differences Among Public and Private Institutional Policies

Forty-six policies (52%) were from private institutions and 43 (48%) were from public institutions. Approximately twice as many private as public institutions had specific limits on publication delay and limits on financial interests in corporate sponsors of research (TABLE 5), but these differences were not statistically significant.

COMMENT

The vast majority of the institutions in our sample had written conflict of interest policies that pertained to research activity of its faculty or staff, in compliance with federal regulations. We do not know whether the 8 institutions that did not respond to our request lacked a policy or were merely nonresponders. Three quarters of the policies we analyzed were established or modified around the time that federal regulations on researchers' conflict of interest were introduced in 1995, suggesting that most research institutions have recently established or changed the way they handle conflict of interest. More than 70% of institutions have policies that cover situations beyond those mandated by the federal regulations (researchers apply-

ing for funding from PHS or NSF), suggesting that the federal policies have had an influence well beyond federally funded research.

Disclosure, Review, and Management Process

The processes for disclosing, reviewing, and managing conflicts of interest varied widely among institutions, as described by the policies. A survey of academic institutions published earlier also found that academic conflict of interest policies varied widely.[19] Then and now, this variation probably reflects overall differences among institutional administrative processes. However, a typical institution solicits disclosure of faculty financial interests annually and/or when new interests arise. Institutions rely on faculty to fully disclose all relevant financial interests. These disclosures are typically reviewed by a university-level committee, and final decisions on the handling of the disclosed cases typically are made by a designated institutional official, such as a provost or dean of research. Only 38% of universities appear to have established institutional committees (almost always made up of the institution's faculty members) specifically to review conflicts of interest, and many of these committees require the involvement of faculty at the department, school, and university levels as well. This suggests that while some institutions have felt the need to develop elaborate infrastructures to comply with conflict of interest regulations, the majority have not.

Strategies for Managing Conflicts of Interest

Most institutional policies did not specifically limit or prohibit particular kinds of activities, but many outlined the kinds of activities that would require disclosure and review and a broad range of methods that might be used to mitigate any conflicts of interest. Less than a fifth of institutions specified limits or prohibitions on faculty activities in their written policies. Other institutions might, in practice, also place similar limits on faculty, but have not codified such limits.

Table 5. Differences Among Policies of Private and Public Institutions (N = 89 Policies)

	No. (%) of Institutions		
	Private	Public	Total
Specified Limits on Publication Delay*			
Specified limit	8 (17)	3 (7)	11 (12)
No specified limit	38 (83)	40 (93)	78 (88)
Specified Limits on Financial Interests in Corporate Research Sponsors†			
Specified limit	11 (24)	6 (14)	17 (19)
No specified limit	35 (76)	37 (86)	72 (81)

*P = .20 (using 2-tailed Fisher exact test).
†P = .28 (using 2-tailed Fisher exact test).

Whereas more than half the policies suggested that conflicts of interest might be mitigated by disclosure of financial interests to the public, monitoring or oversight of research, or divestiture of financial interests, the extent to which these strategies are actually used is not known. Krimsky et al[4] found that a third of articles in 14 leading biomedical journals analyzed had a lead author with financial interest in a company whose activities were related to the field represented in the published work, but that only 1 of 267 articles analyzed disclosed any financial interest. Their findings suggest that public disclosure in publications may often not be required (we did not find this requirement in 42% of policies) or is weakly enforced. Alternatively, faculty members might be disclosing conflicts of interest to journals, but the disclosures might not be published and thus would not be communicated to journal readers. If institutions are relying on public disclosure through publication, better policy coordination with journals may be needed.

Although most of the institutions in our sample conduct clinical research, few made any policy distinctions between conflicts of interest in clinical vs nonclinical studies. However, clinical research carries unique considerations because there is a growing body of evidence that financial interests may have an effect on the quality and outcome of certain kinds of clinical studies, and because there is an added ethical obligation to protect the safety and well-being of human research participants. Thus, for clinical research, policies that encourage clear disclosure to patients and the public and more limits on investigators having financial interests in research are warranted. For example, the death last year of Jesse Gelsinger,[20] a participant in a clinical trial of gene therapy, led at least 2 professional organizations to call for their members to abstain from having financial interests in their sponsors,[21,22] suggesting that these organizations recognized that financial considerations might diminish the protections afforded to research participants.

Few of the policies we analyzed included specific limits on the amount of delay that would be permitted for publication of research results for purposes of securing intellectual property rights or allowing review by sponsors. Such limits may have been specified in other policies, but they were generally not mentioned or referred to in the conflict of interest policies we studied. Dissemination of knowledge for the public good is the main mission of universities, especially institutions that receive large amounts of public funding. The finding that faculty participating in research relationships with industry are more likely to delay publication, at least among life science faculty,[13] suggests that universities should be more active in ensuring that dissemination of knowledge is not unduly delayed by faculty ties with industry. This would include developing more specific policies on limits to any delay of publication of research results and shorter limits to such delay. Although relatively few institutions specified limits on permissible delays of publication or on financial interests with corporate research sponsors, private institutions were more likely to have such limits than

public institutions, although this difference was not statistically significant. Public institutions might be less willing to specify limits on industry relationships if they must also fulfill state mandates to enhance technology transfer and to encourage local businesses or particular industries important to the state.

Few policies specifically addressed the role of trainees in research or educational activities sponsored by companies in which their faculty advisors had a financial interest. The effect of such arrangements on trainees is not known, but given the central role of training and education in the university mission, it is striking that so few policies mentioned them in contrast to the implicit or explicit concern about integrity of the research addressed by the policies. Although the policies analyzed in this study applied specifically to conflicts of interest of individual faculty, as institutional policies they reflect institutional values. To the extent that institutions also have financial interests stemming from ties with industry, care must be taken not to be unduly influenced in the development and implementation of faculty policies on conflict of interest.

Limitations of the Study

This study has several limitations. First, policies pertinent to the specific items we sought might have been contained in policies other than those we analyzed. Although in addition to policies that specifically addressed conflict of interest we requested policies on intellectual property, clinical research, and academic freedom (where available), statements relevant to our study might have been contained in institutional policies that we did not locate. Furthermore, other relevant regulations, such as state or local laws pertaining to conflict of interest of state employees, might not have been included in institutional policies and therefore would not have been reflected in our data. Second, written institutional policies do not necessarily fully reflect practice. Especially in the area of conflict of interest, many institutions review situations and make decisions about how to manage them on a case-by-case basis. The lack of specified prohibitions does not necessarily mean that all activities are allowed. Third, our sample was drawn from institutions with the highest amount of NIH funding, so we do not know whether smaller institutions or those that are primarily industry-supported would have had different policies. Fourth, policies on institutional conflict of interest were not included in this study. However, in the case of industry funding, the short-term interests of researcher and institution may be similar. Therefore, we believe that our analysis provides important information that reflects the academic institutional view of its own mission and its stance toward its relationship with industry.

CONCLUSION

Most policies on conflict of interest at major US research institutions lack specificity about the kinds of relationships with industry that are permitted or prohibited. Such lack of specificity enhances the flexibility of institutions to address complex and rapidly evolving academic-industry ties. However, it would be to the long-term benefit of faculty, institutions, and companies to develop clear and specific policies based on agreed-on principles that protect universities' primary missions of education, research, and dissemination of knowledge. Wide variation in management of conflicts of interest among institutions may cause unnecessary confusion among potential industrial partners or competition among universities for corporate sponsorship that could erode academic standards and lessen public confidence in university research. Further research on the actual practices of all institutions is necessary to form a more complete picture of academic-industry ties.

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