

Article

***775 FACULTY CONFLICTS OF INTEREST IN AN AGE OF ACADEMIC ENTREPRENEURIALISM:
AN ANALYSIS OF THE PROBLEM, THE LAW AND SELECTED UNIVERSITY POLICIES**

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I. INTRODUCTION

The topic of faculty conflicts of interest, particularly as it relates to conflicts in biomedical or other scientific research, has received a tremendous amount of attention over the past two decades from scholars, scientists, government policymakers and university administrators. This has resulted in an explosion of scholarly books and articles, governmental regulations and guidelines and university bylaws and policies relating to the subject. It appears that the primary impetus for all of this professional attention and effort has been the remarkable growth, in the decades following World War II, of various kinds of research-related partnerships and collaborative endeavors entered into between universities and private industrial organizations. This growth has been greatly accelerated in the last fifteen years by the promulgation of federal and state "technology transfer" laws and similar enactments designed to increase the patenting and commercialization of inventions and discoveries developed by university researchers with the assistance of public funds - laws which typically require, among other things, that researchers be awarded a significant percentage (e.g. thirty percent) of all profits derived from their discoveries and inventions. One of the first and certainly the most influential of those enactments was the 1980 federal law known as the Bayh-Dole Act [\[FN1\]](#) which for the first time permitted universities to retain ownership of, and arrange for the commercialization of, all patentable discoveries arising out of federally-funded research.

The term "faculty conflicts of interest" is generally understood to refer to all situations or sets of circumstances in which the personal interest of a faculty member - including the person's financial, professional, familial, or other individual interests - may be at odds with what their peers, their employer, ***776** the government, or even the society at large see as their responsibilities as a scientist, scholar, teacher, or member of an academic community. As so defined, faculty conflicts of interest are much broader than traditional "business conflicts of interest" generally applied to directors and officers of business and nonprofit organizations. While business conflicts of interest typically arise in a more limited variety of situations when a corporate official or fiduciary makes a business or strategic decision on behalf of the corporation he or she serves, faculty conflicts of interest can also arise when a faculty member takes actions - such as choosing or designing a research question, publishing research results, or assigning research work to graduate students - that have no direct affect on the institution that employs him or her. Such activities, rather than affecting the institution's financial or business interests, primarily implicate the interests that the scientific or academic community and the society at large have in ensuring the freedom of researchers to publish their work, the open and unfettered pursuit of knowledge, the accuracy and integrity of research, and even the safety and welfare

of citizens. And these interests can be compromised, for example, when a faculty member stands to gain a substantial financial benefit if his or her research results in one outcome as opposed to another.

Although leaders in government and academia have long recognized that the liberalization of laws and policies governing the commercialization of faculty inventions has increased the likelihood that university researchers may become embroiled in conflict of interest situations, and that such conflict situations often pose significant threats to the principles of objectivity in research and freedom of academic inquiry, as well as to the education of students and the advancement of the interests of individual institutions, both government agencies and individual academic institutions were nonetheless fairly slow to enact regulations and institutional policies designed to deal with such conflicts. Resistance within the academy to the idea of increased bureaucratic infringement on faculty autonomy and privacy certainly contributed to this reluctance to regulate, as did the heightening of pressures favoring university-industry partnerships created by government policy initiatives, increased faculty entrepreneurship, and growing financial constraints on universities.

That reluctance has given way more recently to a desire to create some more definite ground rules in this area and it now appears that most, if not virtually all, of the leading research universities in the country have adopted some kind of faculty conflict of interest policy. This trend is no doubt due, at least in part, to the great amount of negative publicity in recent years surrounding certain egregious cases of conflict of interest and self-dealing by researchers at prestigious universities, some of which became the subject of Congressional hearings, as well as to the promulgation of regulations by the Public Health Service and other federal funding agencies requiring all institutions receiving grant funding to have conflict of interest policies in place which meet certain minimal requirements. A number of very recent and highly publicized controversies involving allegations of lax institutional oversight *777 of high risk medical experiments - most notably relating to two separate gene therapy trials conducted at the University of Pennsylvania and Tufts University in which researchers were revealed to have had financial interests in the companies sponsoring their research [FN2] - have also contributed to a heightened interest in the subject of researcher conflict of interest.

The purpose of this paper is to describe the problem of faculty conflict of interest in general terms, to briefly examine the evolution and current context of the problem, including the legal and regulatory contexts, to discuss the views of scholars, academic associations and others concerning how the problem can and should be dealt with by universities, and to analyze and summarize the specific conflict of interest policies that have been instituted at a number of the country's leading research universities. To that end, this paper will, in Part II.A., first discuss the relationship of the conflict of interest issue to recent trends in the areas of sponsored research and technology transfer (including the advent of the "faculty start up" as a business phenomenon). That discussion will include a summary of the results of certain research studies which have attempted to assess the scope, nature, and quantity of faculty consulting activities and the private funding of faculty research and the impact of those activities and funding sources on various academic requirements and norms. This will be followed by a brief description of the federal government's growing interest in the problem and its recent responses to it. Next, Part II.B. will discuss the views of various scholars, advocates and other observers about the proper definition of the problem and the appropriate purpose and scope of university conflict of interest policies. Part II.C. will then provide a brief analysis of the "legal environment," including a discussion of the impact that federal and state statutory and regulatory enactments, constitutional protections, and court decisions have had and may have on university conflict of interest policies, both in terms of prescribing certain minimum requirements for such policies and in placing limits on them. Finally, Part III will summarize the conflict of interest policies currently in place at ten leading public and private universities, and discuss their main similarities and most notable differences.

This paper is intended primarily to address the subject of conflicts of interest

which relate to the research activities of faculty members and the "outside" business and professional activities of faculty members. Since most conflicts seem to arise in the contexts of faculty involvement in sponsored research arrangements with industry and faculty consulting and managerial relationships with external business organizations, those activities will serve as the main focus for much of the discussion. This paper is not intended to address conflict of interest issues relating to such private activities of faculty members as political activities, membership in organizations, personal advocacy on matters of public interest, or personal relationships. Although some mention may be made of conflicts in those areas, and of institutional policy *778 provisions relating to them, no attempt will be made to treat those particular sub-topics in any depth.

II. THEORETICAL AND PRACTICAL CONSIDERATIONS IN CONFLICT OF INTEREST REGULATION

A. The Context of the Problem

Collaborations between universities, university research departments and individual university-based researchers, and private industry, particularly in the area of biomedical research, have recently been growing at a precipitous rate. A 1991 report of the President's Council on Competitiveness stated that the number of federally supported cooperative research and development agreements ("CRADAs") between universities and private industry increased from 110 to more than 400 between 1988 and 1991. [FN3] It has been estimated that in 1986 university-industry relationships accounted for as much as twenty-four percent of all external support for university research in biotechnology. [FN4] Given the more recent boom in university-industry collaboratives, that figure is no doubt significantly higher today. A major impetus for these collaborations has been federal legislation like the Bayh-Dole Act and Stevenson-Wydler Technology Innovations Act of 1980, [FN5] both of which encouraged or required universities to participate or assist in the commercial development of federally funded basic research through patenting, licensing, or other appropriate means. [FN6]

The size of the grants and contributions received by individual universities through cooperative arrangements with industry in recent years have sometimes been staggering. An early example was a 1980 agreement between the German clinical company Hoechst A.G. and Harvard University's Massachusetts General Hospital that provided the hospital with over seventy million dollars in exchange for providing the donor with an exclusive option to market any potentially profitable technologies developed by the famous researcher Howard M. Goodman over a ten-year period. [FN7] A similar long-term deal between the Monsanto Corporation and the medical school at Washington University of St. Louis provided the school with one hundred fifty million dollars in research support over the sixteen year period between 1982 and 1998. [FN8] A more recent twenty-five million dollar agreement between the University of California, Berkeley, and a subsidiary of the Swiss biotechnology firm Novartis, while slightly less notable in terms of funding level, was unique *779 in that it provided funding to an entire academic department (Berkeley's Department of Plant and Microbial Biology), gave university scientists access to company technology, and gave the company a say in which research proposals would be able to receive funding under the company's grant. [FN9]

Of course, not all university-industry collaborations are so sizable in economic terms or involve such a potentially broad range of research or such close scientific collaboration with industry sponsors. Indeed, university-industry collaborations may fall anywhere along a size-scope continuum ranging from full-scale cooperative research programs and formal, multi-million dollar research partnerships down to much smaller-scale individual and small group consulting contracts. [FN10] At the lower end of the scale are simple arrangements whereby an individual faculty member may agree to review and comment on industry research proposals in exchange for a modest fee or retainer. Nonetheless, all "deals" between faculty and industry share the potential for skewing the faculty member's research agenda, for compromising his or her objectivity, and for creating conflicts between the university's and the private company's competing interests in the time and effort commitment of the faculty member and in the intellectual property arising out of the researcher's

research and expertise. These arrangements also give rise to a public perception that faculty researchers are increasingly "selling out" their objectivity and independence in exchange for money or prestige and have led, in the view of many, to an increasing suspicion or distrust of the results of scientific research. This erosion of the public's faith in the reliability of scientific findings may in fact be one of the greatest harms resulting from the strengthening of ties between industry and academia.

Others have pointed to some of the additional harms that can result from an excessive entanglement between industrial sponsors and academic scientists and their institutions. Writing recently in the Atlantic Monthly, Eyal Press and Jennifer Washburn make the point that increased reliance by universities on industrial sources of funding for their research activities has skewed research at many institutions away from the kind of "basic" research that traditionally predominated in academe toward the kind of "applied" research normally associated with private industry, which focuses more exclusively on research that holds the promise of useful and economically valuable products or processes. [FN11] They also repeat the criticism that the tightening of controls by both universities and their industrial partners on the intellectual property derived from faculty research has made it increasingly difficult for scientists at different institutions to collaborate on scientific problems by openly sharing data, ideas, research tools, and materials. Both of these trends, they point out, can inhibit the performance of the kind of essential *780 basic science and the kind of important scientific collaboration on which most truly "breakthrough" advancements are based.

The main engine driving these trends, it is commonly believed, is money. More specifically, it is - to adopt a phrase popularized in another context by Senator John McCain - an "iron triangle" consisting of industrial sponsors seeking products and profits, competing universities seeking revenues for their operations, and academic scientists seeking financial rewards for their intellectual ability and labor. The vehicle that is often used to satisfy all three of these interests is what has come to be known as the "faculty start up company."

In the typical "start-up" scenario, a scientist working under a federal grant makes a discovery, which, with further refinement, could lead to commercial applications of great value. The university, seeing this value, partners with the scientist to create a new company in which they both take an equity interest. While these arrangements are being structured, the scientist is likely to be unwilling to publish his or her discovery, and the university is likely to discourage the scientist from publication, for fear of possibly losing its crucial intellectual property rights in the discovery. Once the start-up company is established, the university will then license the new technology to the start-up which in turn either will sublicense it to an established industrial partner who will develop it or will hire its own staff to develop it with funding from venture capitalists. Early on in the process, patent applications will be filed, usually by the university; the patents will later be "prosecuted" and secured by the start-up company or its industrial partner.

As these deals are being structured, the academic inventor will have to decide what role he wants to play in the start-up company; if he wants to remain a full-time faculty member, he cannot be active in the day to day management of the company but will probably stay involved by serving as a part-time scientific advisor. Typically, he will also try to keep performing work in his university lab that furthers the scientific process being pursued by the company. This, of course, creates great potential for tricky conflict of interest problems. Conflicts in such cases are not limited to the faculty member, because the university itself also stands to gain if the discovery ultimately bears economic fruit and the start-up venture is successful. It is not hard to see that these arrangements, or the promise of such arrangements, have the potential to make faculty members and their universities more interested in applied research, more interested in "favorable" research results, and less tolerant of cross-institutional collaborations and the early publication of research results.

Faculty conflict of interest policies are not the appropriate tools with which to

solve the "macro" problems of insufficient basic research or diminishing scientific collaboration, which are broader problems requiring public policy responses. Indeed, the latter problem was formally addressed by the National Institutes of Health (NIH) in December of 1999 when it issued guidelines encouraging the inter-institutional sharing of "research tools" developed *781 with NIH funds. [FN12] Conflicts policies, however, are appropriate tools to deal with many of the other "micro" problems that faculty start-up arrangements can cause. When properly drafted and implemented, such policies can, for example, make clear that full-time faculty members cannot spend any more than one day per week working for the start-up company, cannot pressure their graduate students to work on start-up projects, and must disclose all arrangements under which the start-up will be funding or collaborating on research work the faculty member undertakes at the university. Such policies will thus help ensure that the university's students get the education and academic freedom they deserve, that the university's resources are not misused, and that the university's intellectual property and research opportunities are not wrongly diverted to an outside business entity.

It has been established that nearly all full-time faculty in American colleges or universities earn additional income from at least one "outside" source. Studies done in the early 1980's by Robert Linnell and others showed, among other things, that nine out of ten university faculty members earned some sort of supplemental income over and above their salary. [FN13] Linnell also found that between thirty-two and forty-four percent of surveyed faculty reported that the remuneration they received for consulting constituted the first or second largest source of their outside income; those percentages ranged between sixty-eight to seventy-eight percent for faculty in engineering. [FN14] Faculty at Ph.D.-granting institutions who responded to Linnell's survey reported that their "outside" earnings were equal to roughly thirty percent of their base salary. [FN15] Data from a separate 1975 study performed by the Carnegie Council on Policy Studies in Higher Education showed that nineteen percent of academics reported that they consulted at least one-half day a week, and six percent reported consulting more than one day a week. [FN16] Both of these studies are rather old, however, and both are based on data reported by faculty but not independently verified; thus, the studies may significantly underestimate the actual amount and value of income-generating outside activities by faculty. But the point here is not to catalog all of the different kinds of arrangements that exist or to provide precise figures about the volume or value of such arrangements, but rather to give some general indication of what is known about them.

Just as there is little reliable information about the extent of faculty "outside" activities or interests, there is also relatively little empirical information available about the extent to which those activities or interests may conflict with or have a negative impact on the activities faculty members are expected to perform on behalf of the colleges and universities that employ *782 them or the extent to which receipt of research support from private industry may result in breach of academic norms and values such as objectivity, academic freedom, publication and scientific collaboration. The relative paucity of research relating to those questions is probably attributable in part to the relative "newness" of the issues as well as to the inherent difficulties in measuring "outcomes" like faculty productivity and objectivity in research.

Nonetheless, faculty conflict of interest issues appear to be a growing area of interest to researchers. As a result, a number of relevant studies have been published recently with some interesting results. In one of the first studies in this area, researchers sought to measure faculty perceptions about the influence of private research sponsorship on faculty adherence to academic norms and institutional requirements. That study, undertaken by David Blumenthal and others and published in 1985, sought to determine whether the receipt of "industry support" by faculty members in disciplines associated with biotechnology had any effect on the faculty members' "scholarly or commercial productivity," or on their commitment to "teaching or their participation in ... administrative activities," and whether university-industry relations tended to "encourage secrecy among scientists, disrupt relationships among scientific colleagues, or lead faculty to shift the direction of their research toward applied or commercially oriented projects[.]" [FN17] Their

survey of 1200 faculty researchers at forty leading research universities in the United States revealed: (1) that those faculty researchers who were recipients of "industrial support" published at higher rates, obtained patents more frequently, participated in more professional and administrative activities and earned more than their colleagues who did not receive such support, but also (2) that the faculty who received industrial support were much more likely than other biotechnology faculty to report that their research had resulted in trade secrets and that commercial considerations had influenced their choice of research projects. [FN18] A later survey published in 1996 by Blumenthal and his colleagues showed that ninety percent of "private life sciences" companies had funding relationships with universities, that sixty percent of those companies received "patents, products and sales" resulting from those relationships, that their links with academia increased between 1984 and 1994, and that the funding agreements between these companies and universities typically prohibited disclosure of research results by faculty investigators for periods longer than was necessary for the company to obtain patent protection on research discoveries. [FN19]

Other published studies examining the question of researcher objectivity in medical research have provided some disturbing evidence of a relationship between funding sources and research outcomes. In a 1986 study comparing the published outcomes of clinical drug trials funded by pharmaceutical industry *783 sponsors and other non-industry sources, one investigator found that researchers supported by industry sponsors were more likely than researchers funded by other sources to report findings which favored "new therapies" (i.e. the sponsor's new experimental drug) over "traditional" therapies (i.e. previously approved and currently used drug). [FN20] Similar results were produced in a 1998 study showing that medical researchers studying the use of "calcium-channel antagonist" drugs in the treatment of cardiovascular disorders were more likely to report favorable outcomes from the use of such drugs when they had financial relationships with a manufacturer of those drugs than they were when they had no such relationship. [FN21] A 1999 study showed that researchers studying the economic cost-effectiveness of new anti-cancer drugs were more likely to find that the new drugs were cost effective when their research was funded by the pharmaceutical industry than when it was funded by nonprofit organizations or public agencies. [FN22] While these studies provide some support for the theory that research outcomes are influenced by investigator conflict of interest, their findings are quite limited in scope and can be explained by factors other than conflicts of interest, according to Sheldon Krimsky, an academic who has written widely on the topic of research ethics and investigator financial conflicts. Krimsky has pointed out the need for more research on faculty conflicts of interest and has advocated the implementation of stricter conflict of interest disclosure policies by academic medical journals. [FN23]

Despite the absence (until just recently) of any significant empirical evidence relating to such questions, it appears to be a widely-held article of faith in the academic and regulatory communities that, given the amount, scope, and nature of faculty entanglements with outside interests, and the probability that those entanglements will create conflicts which have the potential of undermining institutional and governmental objectives, universities must take strong steps to ensure that faculty conflicts of interest are avoided, or at least detected and either eliminated or appropriately "managed." As early as 1965, the American Association of University Professors ("AAUP"), noting the "increasingly necessary and complex relationships among universities, Government and industry ... in Government-sponsored research" recommended that universities develop standards and procedures "to guide the individual university staff members in governing their conduct in relation to outside interests that might raise questions of conflict of interest." [FN24]

*784 Seventeen years later, the presidents of a number of the country's leading research universities issued a statement following a conference on biotechnology and academia held at Pajaro Dunes, California. The statement recommended that "each university should address the [conflict of interest] problem vigorously and make efforts to publicize widely and effectively the rules and procedures it adopts to avoid compromising the quality of its teaching and research." [FN25] This recommendation was later echoed by the Association of Academic Health Centers, which

stated in a 1992 policy paper that all research universities "share a need to develop clear policies and comprehensive procedures regarding conflicts of interest." [\[FN26\]](#)

The problem of researcher conflict of interest in federally funded research came to the attention of Congress and became the subject of congressional committee hearings in 1989. It is generally agreed that these hearings were the result of a few highly publicized cases of "questionable arrangements between industry and federally funded researchers," [\[FN27\]](#) including two separate cases involving researchers at Harvard. In the first, researchers were accused of holding up negative results from clinical tests of an eye medication that was to be sold to a company in which the researchers had a financial interest. In the second case, researchers participating in a clinical drug trial involving a certain kind of "thrombolytic therapy" also had a financial interest in the company that made one of the drugs being studied. [\[FN28\]](#)

Following these congressional hearings, and at the urging of congressional committee members, the NIH issued (through publication in the NIH Guide for Grants and Contracts) in September of 1989 a set of proposed conflict of interest guidelines which, among other things: (1) prohibited any researcher involved in an NIH-funded project from having "personal equity holdings or options in any company that would be affected by the outcome of the research or that produces a product or equipment being evaluated in the research project;" [\[FN29\]](#) (2) required NIH-funded researchers and their dependents to fully disclose all of their financial interests and outside professional activities to their institutions and to update such information annually. [\[FN30\]](#) These guidelines touched off "a firestorm of protest" by many academics who judged them to be overly burdensome and far too restrictive [\[FN31\]](#) and they were subsequently withdrawn. [\[FN32\]](#) Nonetheless, the issuance of those guidelines helped spur universities to develop and implement their own comprehensive *785 conflict of interest policies [\[FN33\]](#) and also engendered a public debate about whether the regulation of faculty conflict of interest was a matter best left to the government or to the universities themselves. [\[FN34\]](#) That question was answered in equivocal fashion by the Public Health Service ("PHS"), the parent agency of NIH, when it issued final regulations in 1995 (discussed below) which established certain minimal financial disclosure requirements for researchers and certain basic procedural requirements for universities receiving federal research funds, but left most of the details of conflicts regulation to the individual institutions. [\[FN35\]](#) Similar regulations and guidelines have subsequently been adopted by the National Science Foundation and the Food and Drug Administration. [\[FN36\]](#)

B. Theories, Principles and Objectives

A thoughtful, theoretical approach to the problem of faculty conflict of interest was provided by the late A. Bartlett Giamatti in a 1982 article appearing in Science magazine. [\[FN37\]](#) In that article, the then Yale University president articulated three basic considerations which he suggested should guide the formulation of university conflict of interest policies. [\[FN38\]](#) First, he said, "I doubt that a faculty member can ordinarily devote the time and energy the university requires and also pursue a substantial involvement in [an] ... outside company. Such involvement ... demands great concentration and commitment" [\[FN39\]](#) Second, he said,

When a faculty member becomes substantially involved in a company, the conflict in norms governing the dissemination of knowledge becomes very difficult to reconcile. The burden of maintaining a teaching program and two separate research programs, where the results of one research program are to be widely disseminated and the results of the other may have to be kept secret in the pursuit of commercial success, is *786 more than even the most responsible faculty member can be expected to shoulder. [\[FN40\]](#)

Finally, he added,

[S]uch [substantial] involvement risks putting one's students and research associates in ambiguous circumstances, such that the graduate or postdoctoral student would not know, when working with a professor, for whom he or she was

working - the university, the professor or the company. Of all the members of the university community, the student especially ought to be working for himself or herself and ought to be guided in research and trained in skills and techniques that are designed to produce a first-rate scholar, not profit for a company in the private sector. [FN41]

Giamatti then went on to say that a faculty researcher should be presumed to have a "substantial" involvement in a company sponsoring or seeking to sponsor the researcher's investigations, and thus to have an "unacceptable" conflict of interest, "if a [researcher] becomes a manager of the company ... or acquires, through gift or purchase, stock shares in [the] company in such proportion to the total number of shares that he or she can have a significant effect on the decision making of the company." [FN42] In order for the university to identify and eliminate, reduce, or manage these kinds of unacceptable conflicts, Giamatti recommended that appropriate disclosure and review procedures be put in place. [FN43] He proposed similar standards for "consulting" by faculty members:

There are relationships of individual faculty members to commercial companies, even those using the results of university-based research, that traditionally the university has allowed and will continue to allow. In these "consulting" relationships members of the faculty provide advice to companies but do not directly manage corporate research. "Consulting" can enhance a person's professional competence and further the mission of the university. Our rule is that a faculty member may spend not more than 1 day in a 7-day week in such a role. Thus, there is a limit on the commitment of time and energy.

Serving as a consultant to a company or, within the rule of reason, accepting payment in equities from some cash-poor, idea-rich company, is less likely to create conflicts of commitment or conflicts of interest than serving in a role that has a significant effect on corporate decision-making. A faculty member who has gone beyond any reasonable definition of "consulting" has reached the point where the question arises whether he or she should remain a full-time member of the faculty. [FN44]

***787** It is important to remember that the term "conflict of interest" is generally understood, at least in the academic context, to encompass two separate concepts: conflicts of interest, which generally have to do with private financial gain, and conflicts of commitment, which generally involve time. [FN45] Virtually all institutional conflicts policies recognize this distinction and treat the two categories differently. A good functional definition of these terms has been provided by the Association of American Medical Colleges:

The term conflict of commitment relates to an individual faculty member's distribution of effort between obligations to one's academic appointment (normally "full-time" in teaching, research, and/or patient care) and one's commitment to "outside" activities

A conflict of commitment arises when these [outside] or professionally removed activities (e.g., outside teaching or business) come to interfere with the paramount obligations to students, colleagues, and the primary missions of the academic institution by which one is appointed and salaried

* * *

The term conflict of interest in science refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research. The bias such conflicts may conceivably impart affects not only collection, analysis and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol and use of statistical methods

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Conflicts of interest also have the potential to bias other aspects of academic life, particularly when faculty are in a position to set university or hospital

policies, manage contracts, select equipment and supplies, involve students in sponsored projects, or have other administrative roles in which objectivity and integrity are paramount. [FN46]

Under both of these definitions, it is clear that a faculty researcher will have an actual "conflict of interest" if he or she owns a controlling interest in, or has the ability to influence the decisionmaking of, a private entity sponsoring his or her research. However, if a faculty member has any kind of significant financial interest in a sponsoring company - even one less than a controlling interest - or receives significant compensation of any kind from a sponsoring company, he or she is normally considered to have a potential conflict of interest; the AAMC definition implicitly recognizes this, while *788 Giamatti's seems not to. It also seems clear that a faculty member will have a conflict of commitment if he or she does not keep regular office hours or spends too little time in preparing for class because of his or her time commitment to an outside consulting project. According to at least one commentator, it is likely to be a more common occurrence for faculty researchers to be faced with conflicts of commitment rather than conflicts of interest in connection with their privately sponsored research. [FN47] It is not always clear, however, how those two terms are being defined and applied by the persons using them. For example, one observer has identified the following three "typical" research-related conflict situations as conflicts of commitment, but it seems one could reasonably argue that they more properly fall under the category of conflicts of interest:

1) The concern that the industrial sponsor will attempt to improperly control the scientific or technical approach to the work funded by the sponsor, thereby invading and diminishing the objectivity and independence of the scientific investigator;

2) The problem that faculty investigators, induced by proprietary concerns on the part of the industrial sponsor, may become improperly secretive about their work, not only to the detriment of free and open dissemination of any scientific and technological developments, but also to the detriment of interaction with and among their students;

3) The concern that the industrial sponsor will improperly attempt to influence or control the choice of, or approach to, future research in the same or related areas. These problems are regarded as acute if the faculty investigators ... have ... an equity or some other on-going financial interest in the industrial sponsor. [FN48]

A number of academic associations, seeking to assist their members' attempts to develop conflict of interest policies, have issued various reports and model guidelines on the subject. Two of the more prominent and frequently cited sets of association guidelines are those of the Association of Academic Health Centers ("AHC") [FN49] and the Association of American Medical Colleges ("AAMC"). [FN50] One commentator comparing those two sets of guidelines observed that, while they are different in focus, both are entirely compatible with one another. [FN51] That commentator's analysis of the more comprehensive AHC guidelines led to his observation that they were based upon and structured around five essential "sets of principles" which he identified as follows:

*789 The first and overarching principle is that of primary commitment to the university. The [AHC] document states that "a person who accepts a full-time appointment to the faculty, or full-time research position ... has an obligation to devote his/her primary professional effort and allegiance to the university It is inappropriate for faculty or academic staff members, without prior approval, to divert to other entities or institutions opportunities for research, education, clinical care or financial support which otherwise might flow to the university." The report goes on to urge that "each university should develop policies that identify those activities which require prior approval and those for which disclosure is sufficient."

The next set of principles addresses disclosure: "Faculty, researchers, staff and students should be required upon initial affiliation, and periodically thereafter, to disclose significant financial, personal or professional relationships that raise a potential conflict of interest between their academic role and outside interests, as defined by university policies Significant financial, personal or professional relationships that raise a potential conflict of

interest should be fully and accurately disclosed in all speeches, writings, advertising, public communications or collegial discussions relating to the sponsored research."

Another set of principles is concerned with the promotion of technology transfer and is based on the premise that the university has an obligation to ensure the dissemination of knowledge. The principles state that each university should have policies concerning patents and licensing. The next set of principles is concerned with the encouragement of the free exchange of information, "a fundamental value underlying the university's mission," and emphasizes the need to avoid restrictions on such information flow, whether those restrictions emanate from federal sponsors or from commercial sponsors interested in the protection of proprietary interests. Finally, there is a set of principles that deals with the necessary protections of students and research staff. [FN52]

Other academic and scientific associations have gone further and called for even stricter standards. The American Society of Gene Therapy, for example, adopted a new research ethics policy in April of last year which recommends that universities prohibit investigators involved in gene therapy studies from owning any (as opposed to "any significant") equity interests in the companies that sponsor their studies. [FN53] Its actions coincided with the appearance in the popular press of reports about separate cases involving allegations that gene therapy researchers at Tufts University and the University of Pennsylvania had admitted medically ineligible patients into their studies and/or had failed to properly report the deaths of some trial participants (or *790 other adverse clinical outcomes) to their institutional human subject committees and the FDA. [FN54] In each case, both the investigators and the universities they worked for were found to have had financial interests in the companies sponsoring the research, and in each case the research was terminated following these public disclosures. [FN55]

It is interesting to note that the publicity surrounding the University of Pennsylvania controversy appears to have been instrumental in the defeat of an effort by some members of the Harvard Medical School faculty to loosen that school's relatively strict conflict of interest policy. [FN56] Apparently, a faculty committee at the medical school was scheduled to vote on a proposed amendment to the institution's conflict of interest policy in June of last year. [FN57] The meeting was cancelled, however, and a statement was issued by the medical school's dean, Joseph Martin, announcing that the school's policy, rather than being weakened, would be strengthened through the addition of specific new rules designed to protect medical students and post-graduate trainees from exploitation by mentors who have a financial interest in companies that sponsor their research. [FN58] Martin also took that opportunity to call for "a national debate on the proper limits of financial conflicts of interest for medical researchers." [FN59]

The Harvard Medical School dispute highlights the fact that there is, not surprisingly, a difference of opinion within the academic community about the degree of danger posed by faculty conflicts of interest and the severity of restrictions that should be placed upon them. Some observers and scholars believe that universities must be very strict in their regulation of conflicts and should impose outright prohibitions on certain kinds of activities that result in a conflict of interest or even the appearance of a conflict of interest. For example, two research administrators who have written about this issue, Robert Varrin and Diane Kucich, have recommended that faculty should never be permitted to consult with their outside research sponsors and that a "faculty entrepreneur's" company should never be permitted to sponsor his or her research on campus. [FN60] This recommendation certainly cannot be faulted for its purity and lack of ambiguity, but it seems quite unrealistic given the realities of the current environment and the undeniable economic benefits that have resulted in recent years from the increase in the commercialization of academic research. A slightly less absolutist, but probably equally unrealistic proposal has been made by Robert Linnell, who has called for a drastic restructuring of the entire university research system. This approach is aimed at allowing universities to control more of the proceeds from *791 university-based research and to more closely control all aspects of sponsored research, allowing faculty to become truly "full-time" employees of universities (with higher salaries) and removing current incentives and loop-holes that entice faculty into

ethically dubious external entanglements. [FN61]

Others are less alarmed by the trend toward greater faculty entrepreneurship and increased private sponsorship of research. One writer has pointedly criticized Linnell's prescriptions as being far too restrictive and unrealistic. [FN62] It appears, in any event, that (with some notable exceptions) very few institutional policies place outright bans on faculty employment by or financial links to research sponsors in the manner recommended by Varrin and Kucich and choose instead to allow "de minimis" links with disclosure and review of links above designated thresholds. [FN63] Another observer has suggested that the threat conflicts of interest are said to pose to science may be somewhat exaggerated, due to the fact that many people fail to consider or fully appreciate the general postulate that "bad science" will almost always be "found out" and discredited. [FN64] Even that scholar acknowledges, however, that limitations on resources and scientific manpower often impede the kinds of follow-up research needed to test scientific discoveries and that harm can result in the short term from practical applications of flawed research, particularly in the biomedical field where applications often include therapeutic drugs and diagnostic devices used to treat people. [FN65] In addition, this response seems to ignore another harm caused by "bad science" - namely the erosion of public trust in the credibility and reliability of science. [FN66]

The AAUP has also cautioned that university faculty and administrators must exercise restraint and be guided by basic principles of fairness when developing and implementing conflict of interest policies, and in doing so must always act in a manner which properly respects and supports the principles of faculty privacy and autonomy. At the same time, it has also acknowledged that universities need to take steps to ensure that faculty conflicts and external research funding do not threaten academic freedom or other traditional academic interests and norms. In its 1990 "Statement on Conflicts of *792 Interest," [FN67] the AAUP offered its own balanced set of five "considerations" which it suggested should help guide the formulation of institutional policies in this area. Those considerations can be summarized as follows: (1) any disclosure requirement should be "carefully focussed [sic] on legitimate areas of concern and not improperly interfere with the privacy rights of faculty members and their families;" (2) steps should be taken to ensure that any cooperative venture with "outside" entities "respects the primacy of the university's principal mission, with regard to the choice of subjects of research and the reaching and publication of results;" (3) "external interests should not be allowed to shift the balance of academic priorities in a university" in the absence of thorough internal debate and approval by all appropriate faculty bodies; (4) universities must maintain a commitment to fairness in the allocation of resources and academic assignments between those departments more and less able to attract outside support; (5) universities must refrain from, in making judgments about faculty salaries, tenure and promotion, giving undue or excessive weight to a person's "ability [or lack of ability] to procure private or government funding" and may consider such factors only in accordance with criteria established by the faculty. [FN68]

Notwithstanding the differences in outlook and emphasis of the various scholars, government policymakers and academic associations who have commented on the topic, there nonetheless appears to be virtually unanimous agreement that institutional conflict of interest policies need to involve at least the following three basic elements: (1) clear guidance, in the conflicts policy itself, the faculty contract, or elsewhere, about the minimum requirements of faculty positions in terms of teaching, research and institutional and other kinds of "service," about the basic academic and institutional norms to which the faculty member is expected to adhere, and about any limitations or restrictions on the faculty member's (or his or her relatives') outside activities, associations or financial interest; (2) requirements that faculty regularly disclose to designated university officials all of their (and their family's) potentially relevant outside activities, associations and financial interests that could reveal a conflict of interest and, (3) appropriate mechanisms for the review and resolution of apparent conflicts of interest.

Although there seems to be general agreement on the need to include those three elements in any institutional conflict of interest policy, there also appears to be

a general consensus that no single set of policies and procedures will be appropriate for every institution and that each one needs to develop its own particular set of rules appropriate to its unique institutional character, mission and tradition. This sentiment was voiced, for example, by the presidents of Stanford, Harvard, M.I.T., the University of California and the California Institute of Technology who, in a joint 1982 statement, expressed their views that "the development of conflict of interest rules is a matter internal to each university Different rules and procedures may *793 well be appropriate to suit the special circumstances and traditions of different institutions." [FN69]

Consideration of the "local" interests of individual institutions should not go too far, however, others have warned. One very recent study examining conflict of interest policies from over eighty of the top NIH-funded research universities found that the policies varied widely and that most of them lacked specificity about the kinds of relationships with industry that are permitted and prohibited. [FN70] The authors of that study argued that such wide variability and lack of specificity was likely to cause unnecessary confusion among potential industrial partners or competition among universities that could lead to an erosion of academic standards. They recommended that academic institutions join together to develop widely-agreed upon and sufficiently specific standards to guide individual institutions. Similar conclusions were reached by the authors of another study published in the same month which focused more narrowly on the conflict of interest disclosure policies of 250 medical schools and research institutions, forty-seven academic journals and sixteen federal agencies. [FN71] Unlike those studies, which provide very useful quantitative analyses of the conflicts policies from a large number of institutions, the study reported in Part III of this article was intended to describe, in more detailed and qualitative terms, the provisions of ten "representative" institutional policies. As you will see, however, the policies discussed here in fact demonstrate the very same degree of variability and lack of specificity noted in those two larger studies. But before beginning to analyze those ten policies, mention needs to be made of the legal environment in which they are situated.

C. The Legal Environment

A number of federal agencies have issued regulations aimed at preventing or minimizing conflicts of interest in federally funded research projects. Perhaps the most prominent of these are the regulations issued in 1995 by the Public Health Service ("PHS"), which is the principal health agency of the Federal Government and which funds a wide range of health research through subsidiary agencies like the National Institutes of Health ("NIH"), The Alcohol, Drug Abuse and Mental Health Administration ("ADAMHA") and the Centers for Disease Control ("CDC"). [FN72] Those regulations require, among other things, that all academic institutions receiving PHS research funding must: (1) maintain an appropriate written conflict of interest policy which satisfies all of the minimum regulatory requirements, (2) require all faculty researchers working on PHS funded projects to disclose all "significant financial interests" of themselves and their dependents that *794 might "reasonably appear to be affected by the research" to an appropriately designated university official; (3) ensure that the designated official reviews all such disclosures "to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced or eliminated," and (4) establish "adequate enforcement mechanisms and provide for sanctions where appropriate." [FN73]

The PHS regulations define the "significant financial interests" that must be disclosed to include virtually "anything of monetary value" (including salary, fees, royalties, intellectual property rights, stocks or other equity interests) paid or given to the researcher by someone other than the institution receiving or seeking PHS funding over and above certain threshold amounts (e.g. \$10,000.00 or five percent ownership for "equity interests" and \$10,000.00 per year for "salary, royalties and other payments"). [FN74] The term also excludes certain other categories of income such as income from seminars and lectures or for service on advisory committees sponsored by public or non-profit entities. [FN75] The regulations further provide that "[a] conflict of interest exists when the

designated official reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS funded research." [FN76] Finally, the regulations list the following as "[e]xamples of conditions or restrictions that might be imposed to manage conflicts of interest:" [FN77]

1. Public disclosure of significant financial interests;
2. Monitoring of research by independent reviewers;
3. Modification of the research plan;
4. Disqualification from participation in all or a portion of the research funded by the PHS;
5. Divestiture of significant financial interests; or
6. Severance of relationships that create actual or potential conflicts. [FN78]

The National Science Foundation ("NSF") has published an "Investigator Financial Disclosure Policy" [FN79] that in substance is virtually identical to the PHS regulations. Other federal regulations applicable to research grants and contracts may impact universities as well. For example, institutions receiving research funding from the Department of Defense ("DOD") will need to comply with that agency's regulations entitled "Improper Business Practices and Personal Conflicts of Interest" which require, among other things, that recipient institutions conduct "ethics training programs" for its employees, establish a "hotline" or other mechanism for reporting of "suspected instances of improper conduct" and report in a timely fashion "to appropriate *795 Government officials ... any suspected or possible violations of law." [FN80] The FDA has also recently promulgated regulations requiring medical researchers conducting studies of unapproved drugs and medical devices to disclose to the agency any "significant" financial interest (defined to include financial interests above certain thresholds such as equity interests valued over \$50,000.00) the researcher may have in the sponsor or the product being studied. [FN81]

While the PHS, FDA and NSF conflict of interest regulations do not contain any "penalty" provisions specifying the consequences of an institution's or investigator's failure to comply, there are nonetheless very serious legal and financial consequences that can arise from such noncompliance. For example, if a university administrator and a principal investigator both sign a grant application or renewal form certifying that the proposed research study is in compliance with all applicable federal regulations, and it later is determined that the investigator on the grant failed to fully disclose his or her study-related financial conflict of interest, in violation of federal regulations, the university and the investigator could be liable under the civil (and possibly the criminal) provisions of the False Claims Act for submission of fraudulent claims and could be required not only to repay funds received under the grant, but to pay fines and penalties as well. Even worse, the investigator could be debarred, and the institution excluded, from receiving any further federal grants for a period of time.

Federal conflict of interest regulations enacted to date have required conflict disclosures to be made to the researchers' employing institution and/or to the relevant federal funding or regulatory agency; however, none have required disclosure to third parties - such as human research subjects participating in research studies - who arguably have good reason to be informed of those conflicts. Although it appears that human subjects committees (IRBs) at a number of institutions require their faculty investigators to disclose their financial conflicts of interest to their research subjects, many do not. The question of whether to require such disclosures is currently left to the discretion of each individual institution; they are not currently legally mandated to impose any such requirement. It appears that this practice is about to change quite soon, however. The Department of Health and Human Services (DHHS) announced in June of last year that it has directed the NIH and the FDA (two of its subsidiary agencies) to "work together to develop new policies for the ... biomedical research community, which will require ... that any researcher's financial interest in a clinical trial be disclosed to potential participants." [FN82] DHHS has provided further leadership in this area by issuing, in January of this year, its own "Draft Interim Guidance" on the subject *796 of "Financial Relationships in Clinical Research." [FN83] That guidance document provides a detailed set of principles and suggestions designed "to

assist Institutions, Clinical Investigators and IRBs in their deliberations concerning potential and real conflicts of interest, and to facilitate disclosure, where appropriate, in consent forms," and it includes recommendations of "best practices" that go well beyond what is currently required by regulations pertaining not only to the issue of disclosure of conflicts to research subjects, but also to issues such as IRB member conflicts, educational programs and management of institutional conflicts of interest in clinical research. [FN84] Although these guidelines are technically nonbinding recommendations that do not have the force of law, they are bound to be very influential in shaping future amendments to the FDA and PHS regulations and in steering the development of new policies at the institutional level.

Even if clinical researchers are not currently required by statute or regulation to disclose their financial conflicts to their patients, they and their institutions should nonetheless still be concerned about their potential liability to their patients that could arise as a result of nondisclosure under the common law. At least one court has ruled that physicians have a fiduciary duty to disclose to their patients any relevant personal interests, including financial interests, they may have in any particular research or treatment option they recommend to their patients if that personal interest may affect that physician's medical judgment. [FN85] It was also reported last year that the parents of Jesse Gelsinger, the teenager who died in 1999 while participating in a gene therapy trial at the University of Pennsylvania, have filed a lawsuit against members of the research staff, the institution and other institutional officials claiming among other things that they and their son had not been informed that certain key members of the research team stood to gain financially if the study was successful and that the researchers' failure to inform them of these financial interests, and the institution's failure to ensure proper disclosure was made, played a part in their son's enrollment in the study and ultimately in his death. [FN86] The victim's father has also stated that he believes the researchers never told them about the prior lack of success of the experimental therapy and about the safety problems indicated in animal studies of the therapy. [FN87] The lawyer representing the Gelsinger family in that case, Alan Milstein, has subsequently filed lawsuits in two other cases on behalf of patients (*797 or their next of kin) allegedly harmed as a result of participation in separate studies conducted at the University of Oklahoma Health Sciences Center and the Hutchinson Cancer Research Center in Seattle. [FN88] In the Hutchinson case, it is alleged that three physician-researchers failed, in violation of state consumer protection laws, to disclose to the more than eighty patients enrolled in a high-risk cancer study that they had significant financial interests in the study sponsor and the study drugs being tested. The plaintiffs' complaint also contains counts claiming intentional misrepresentation, fraud, assault and battery and breach of the patients' rights to be "treated with dignity." [FN89] If and when these kinds of cases go to trial, the patients' lawyers are very likely to argue that the researchers' failure to disclose their financial conflicts - or more specifically their failure to describe the risks to the patient arising from the researcher's conflicting interests - not only violated state consumer protection laws but also violated the researchers' fiduciary duty to fully disclose all relevant information bearing on the patient's treatment decisions and to provide unbiased patient-centered medical care and advice and resulted in the researchers' de facto failure to obtain the patient's informed consent to participate in the study. Although it would probably be very difficult in most of these cases to prove that nondisclosure of a financial conflict was by itself a significant contributing cause of a patient's injury, evidence of such a conflict could be used to show that a researcher had a motive to enroll a patient in a trial or to continue a patient in a trial when it was not in the patient's best interest to do so and thus could be persuasive in helping prove that a researcher committed medical malpractice. In any event, the fear of these kinds of lawsuits may prompt medical schools to begin implementing stricter conflicts policies which require the disclosure of researcher conflicts of interest to patients participating in clinical research studies.

Faculty conflict of interest policies can also help private institutions ensure their own compliance with federal tax laws pertaining to nonprofit corporations. The IRS recommends that all nonprofit organizations - including universities and hospitals - enact conflict of interest policies which are directed toward ensuring

that actions taken on behalf of the nonprofit organization by its officers, directors and others are consistent with the educational, scientific or other charitable purposes of the institution and do not result in the "private inurement" of any third party. For that reason, it is likely that all nonprofit universities have separate "business" conflicts of interest policies governing their officers and directors in addition to their "faculty" conflicts policies. Although avoidance of the private inurement problem is probably the primary goal of such "business" conflicts policies, it is also one of the four or five main goals of the "broader" faculty conflicts policies. Faculty conflict *798 of interest policies can also help academic medical centers ensure compliance with Medicare and Medicaid "fraud and abuse" laws aimed at prohibiting suppliers of medical products and services (e.g. pharmaceutical companies) from providing "remuneration" (e.g. excessive compensation for research services) to doctors or hospitals in exchange for their commitment to purchase or prescribe the supplier's products or services.

Administrators at public colleges and universities will also need to fashion their policies in accordance with the provisions of any applicable state conflict of interest statutes and regulations. Virtually every state has some kind of ethics law which is generally applicable to all state and municipal employees and officials. [FN90] It appears that a number of state ethics statutes have provisions aimed specifically at faculty research and publication activities at state colleges and universities. [FN91] For example, the Illinois Governmental Ethics Act contains a provision prohibiting any full-time faculty member from receiving any remuneration from outside sources for "research or consulting services" unless the faculty member has disclosed the nature and extent of these services, and her expected income from it, to the president of her institution and the president has approved it. [FN92]

Institutions should also take care to ensure that their conflict of interest policies do not infringe on any of their faculty members' constitutionally protected rights. A poorly drafted, overly broad, or improperly administered policy may, for example, subject the institution to claims that it has violated a faculty member's First Amendment rights to freedom of speech or freedom of association, or Fourteenth Amendment rights to due process or equal protection. In one 1969 case, the University of Mississippi was found to have violated the equal protection rights of two part-time law professors when it attempted to prohibit them from continuing their part-time employment relationship with a legal services organization that was representing clients that had sued the state over the segregation of the state's public schools. [FN93] The United States Court of Appeals for the Fifth Circuit, after noting that the "instructional efforts [of the plaintiff faculty members] had not been hampered as a result" of their outside work, held that the plaintiffs were being treated differently than other part-time faculty and that the university's basis for treating them differently - their representation of unpopular clients - was an impermissible one under the Fourteenth Amendment. [FN94]

In a more recent case, however, the Second Circuit held that a state medical school could reasonably restrict the amount of income its full-time faculty earned through their private practices. [FN95] The plaintiff, a physician and full-time faculty member at the state medical school, had sued alleging that the school's policy, if enforced, would result in an unlawful "taking" of his *799 outside income and would violate his rights to equal protection and free association. The appellate court upheld the district court's denial of his motion for a preliminary injunction on the grounds that (1) the state's policy was rationally related to the state's "legitimate interest in promoting devotion to teaching," (2) the plaintiff was treated no differently than any other full-time faculty member, and (3) the policy restrictions complained of did not implicate any rights of association protected by the Constitution. [FN96]

There appear to be few other published cases that speak directly to the question of the permissible legal bounds of university conflict of interest policies. One case brought in federal district court in Texas merits some attention, however. In that case, the Texas Faculty association and four professors at Texas A & M University challenged the legality of policies enacted by that university that barred professors and other university employees from serving as expert witnesses in legal disputes, and generally from engaging in any outside employment, when such

activities brought them into conflict with the interests of the state. [FN97] Three of the individual plaintiffs in the case were professors who had been retained as expert witnesses for the tobacco industry in a case brought against the industry by the state of Texas; the fourth individual plaintiff was a law professor who had volunteered his services to a community environmental group that was opposing the state's approval of a proposed waste incinerator facility. [FN98] After the professors and the faculty union won a preliminary injunction barring the university from enforcing its conflict of interest policies against them, the university appealed. [FN99] In a brief, unambiguous written opinion, the Fifth Circuit of Appeals upheld the lower court's decision and ruled that the university's policies were "impermissibly overbroad" and that the state's "amorphous interest" in "preventing state employees from speaking in a manner contrary to the state's interests," was not a sufficiently compelling interest to outweigh the professors' First Amendment rights to free speech. [FN100] This ruling would seem to be a fairly significant one for public universities, since many of them presumably have "state loyalty" provisions in their faculty conflict of interest policies similar to those being challenged in that case.

III. ANALYSIS OF SELECTED UNIVERSITY POLICIES

In this part, the conflict of interest policies currently in effect at ten of the country's larger universities will be briefly analyzed and compared. The analysis focuses on the most significant provisions of those policies, including key word definitions, disclosure requirements, prohibitions, review procedures and appeal rights, and will attempt to describe differences in the scope, comprehensiveness, specificity and degree of prescriptiveness of the various policies. *800 Where a university's policy displays a unique approach to the problem, mention of that approach will be made. In addition, differences in the policies of public and private universities will be noted whenever possible.

A. Methodology

Letters were sent in July of 1997 to twenty-two private and fifteen public "research" and "doctoral-granting" [FN101] universities in the United States with enrollments in excess of 10,000 students. The letters requested copies of all "university by-laws, policies or guidelines" relating to "faculty conflicts of interest and/or conflicts of commitment." Policies and other related documents containing conflict of interest and conflict of commitment provisions applicable to university faculty were obtained from fourteen of the public and eleven of the private universities. Of these, three public university and two private university policies were eliminated from consideration for various reasons. [FN102] The remaining eleven public university policies and nine private university policies were reviewed. Six of the public university policies and four of the private university policies were chosen for closer analysis and comparison. Selection of those ten policies was based on a desire to conduct a more intensive analysis of policies that would fairly represent the range of policies received in terms of their scope and comprehensiveness. Selection was also guided in part by a desire to include policies that were unique or different in their approach to the problem. The ten policies which were more carefully analyzed and discussed below are those of Harvard, Yale, Duke, New York University, Miami University, the University of California, University of Massachusetts, University of Illinois, University of North Carolina, and the University of Missouri - Columbia. [FN103] Nine of these institutions are *801 classified as "Research I" universities; one - Miami University - is classified as a "Doctoral I" university. [FN104] It should be noted that all policies discussed here were received between August 1997 and February 1998 and no effort was made by the author prior to publication to determine if those policies have since been amended by their institutions.

*802 B. Scope and Comprehensiveness

The policies reviewed reflected some significant differences in terms of the range

of faculty activities covered and the comprehensiveness and level of detail of the guidance provided. At one end of the continuum were policies that covered only conflicts of interest relating to externally funded research projects. It appears that these policies may have been put in place for the sole purpose of assuring institutional compliance with the recent NSF and PHS regulations governing research projects funded by those agencies. The policy of Miami University, for example, closely tracks the PHS regulations in its structure and language and covers only those matters which the PHS regulations [FN105] require to be covered. At the other end of the continuum are comprehensive policies, like the one in effect at Yale, which cover all professional activities of faculty members (i.e. not just research). [FN106] These policies provide fairly extensive guidance as to which situations do or may give rise to conflicts of interest and commitment, and provide a detailed and precise description of the procedures that must be followed regarding disclosure and review. The Yale policy, like other more comprehensive policies, also provides a variety of examples of the various types of conflicts that most commonly arise. [FN107]

It appears that there are three main differences between the policies at the low and high ends of the "comprehensiveness" continuum. First, the less comprehensive policies normally deal with conflicts of interest while the more comprehensive ones also deal with conflicts of commitment. Second, the more comprehensive policies tend to provide far more detail about procedural matters. This may be due to the fact in some cases - as it is in the cases of Harvard and the University of California - that the university has created a special committee to oversee and review conflicts of interest and has included in its conflicts policy a fair amount of detail concerning matters like committee membership and committee procedures. Finally, it appears that some universities prefer that their policies serve only as a "bare bones" statement of basic principles, while others prefer that it serve as a more prescriptive document that will provide faculty with more specific guidance on the question of which kinds of situations will and will not be considered problematic.

C. Structure and Organization of Policies

University policy pronouncements relating to the subject of this paper - faculty conflicts of interest and commitment in research and other professional activities - were set forth in a single policy document in roughly half of the cases, but in two or more separate policy documents for the other half. Where two policies were used, one would typically address "external faculty activities" and deal with limits on faculty use of institutional resources and *803 conflicts of commitment resulting from excessive devotion of time and energy to outside activities. The other policies, meanwhile, would address "conflicts of interest" arising out of faculty members' financial interest, in or managerial control of, or influence over, organizations that have business dealings with the university. A good example is the University of North Carolina, which has separate policies entitled, respectively, "Conflict of Interest and Commitment Affecting University Employment" and "External Professional Activities of Faculty and Other Professional Staff." [FN108]

Institutional policies are structured in a variety of ways. The structure of the University of Illinois policy is typical of most of the detailed policy documents. It begins with a preamble, or statement of purpose, and is followed by two main parts: a "policy" section covering definitions, general principles and provisions relating to the respective responsibilities of faculty and administrators for compliance with the policy; and a "procedures" section containing mechanisms and standards for disclosure and review of conflicts for the prior approval of certain activities, for decisions and appeals and for the imposition of sanctions. [FN109] While each of the ten policies being reviewed is organized slightly differently, virtually all of them contain each of those elements.

D. Relation to Other Laws, Codes and Policies

As mentioned above, some policies were apparently instituted for the sole purpose of complying with recently promulgated federal regulations relating to publicly

funded research. Those policies closely trace federal regulatory requirements and are obviously intended to assure that faculty researchers are made aware of them and comply with them. The conflict of interest policies of NYU and Miami University, for example, were both enacted or revised in 1995 (the same year the PHS regulations were promulgated) and contain definitions and disclosure thresholds very similar to those in the PHS regulations. [FN110] While the PHS regulations require disclosure of "financial interests" over \$10,000 or five percent of the total value of the sponsoring entity, NYU sets a threshold of \$10,000 or one percent of total value, and Miami imposes a threshold of \$5,000 or five percent of total value. [FN111] These thresholds were evidently chosen to ensure that the university's requirements were either at or below the federal requirements.

Most other university policies, however, do not "incorporate" or repeat the federal standards and apparently leave it to faculty researchers or their supervisors or sponsored program administrators to ensure compliance with federal regulatory requirements. The Yale policy makes reference to the existence of "external" requirements and states that "research sponsored by PHS, NSF or any other Federal agency must be conducted consistently with *804 applicable Federal regulations." [FN112] Harvard's policy, like many others, makes no reference to federal standards at all. [FN113]

Only two of the six public universities' policies that were reviewed contained explicit references to state laws. The University of Massachusetts policy makes clear that most faculty members and university administrators are governed by the provisions of a special state law applicable to them, [FN114] while certain other high ranking university officials (including all Vice Chancellors for Research) had to comply with the "more restrictive provisions" of the general state law applicable to all other public employees in the state. The University of Illinois conflicts policy explicitly states that it "implements an Illinois law requiring university faculty members to obtain prior written approval before engaging in remunerated private consulting or research for external persons or organizations." [FN115]

Other public university policies, while not mentioning or citing state law, clearly contain provisions relating to state laws. A good example is the "public disclosure" section of the University of Missouri-Columbia policy (requiring the filing of financial disclosure statements in a "registry located for public scrutiny") which appears intended to meet the requirements of a Missouri state law pertaining to freedom of information or governmental ethics. [FN116]

It should also be noted that some university policies refer to or incorporate the conflicts policies of non-governmental organizations. Until just recently, the NYU policy consisted exclusively of a verbatim reproduction of the 1965 "Joint Statement" on conflicts of interest of the AAUP and American Council on Education. [FN117] Although the NYU policy was amended in 1984 to include new, more specific requirements, the AAUP statement was retained and is still included. [FN118]

Finally, many institutions have multiple rules, statements, or policies bearing on the conflict of interest issue. The University of Illinois Policy refers to and is said to be based on certain "university statutes" and other "general rules" of the University, [FN119] while the University of North Carolina policy makes reference in a number of places to relevant provisions of the University "Code." [FN120] Certain universities, such as Duke and the University of California, have enacted "umbrella" policies for the entire university which either require or permit subsidiary schools to enact their own policies that are consistent with, but possibly more restrictive or detailed than, the university-*805 wide policy. [FN121] Other universities, like NYU, have enacted administrative "guidelines" on conflicts of interest intended to supplement and provide additional instructions for compliance with the official conflicts "policy" approved by the University's governing board. [FN122]

E. Statements of Purpose and Definitions

With few exceptions, university conflicts policies begin with provisions describing the purpose and intent of the policy. These provisions, some brief and

others quite lengthy, generally stress that the university recognizes the importance of faculty involvement in outside professional activities and encourages such activities to the extent they do not conflict with the faculty member's primary obligation of loyalty and commitment to the university. They also typically acknowledge and express a favorable view toward the increasing prominence of private industry involvement in scientific research and development, but at the same time caution about the correspondingly increased potential for faculty conflicts of interest. Primarily, however, each of the "purposes" sections generally attempt to make clear that the overall intent of the standards and procedures is to ensure that faculty avoid situations and entanglements which tend to threaten academic freedom, the open communication of research results, student teaching and faculty loyalty, and commitment to the institution. Many policies contain statements similar in basic content, if not in language, to the following statement found in the Yale University policy:

Yale University believes that a great university should reach out to the world. Accordingly, the University encourages its faculty to seek and participate in sponsored research, to consult widely, and to engage in other activities which may benefit not only the participants but also the University itself, and the larger public. In many cases, non-faculty employees also consult or engage in other outside activities. However, while Yale recognizes the benefit of such activities, it is also committed to ensuring that they are conducted properly and consistently with the principles of openness, trust, and free inquiry that are fundamental to the autonomy and well-being of a university and with the responsible management of the University's business.

In recent years, the number of faculty and staff engaged in sponsored research, in consulting, or in other interactions with external organizations has increased substantially. The interests and commitments of the various parties engaged in such activities or affected by them--the individual, the University community, industry, the government, and the public--are complex and not necessarily coincidental; occasionally, these interests may conflict and compromise the atmosphere of free inquiry that Yale considers vital. It is sometimes difficult to draw the line between the responsibilities of a faculty or staff member to Yale and to ***806** external organizations. Under these conditions the possibility of perceived or real conflict of interest or conflict of commitment is significantly heightened.

In pursuit of its own mission, and consistent with the requirements of external agencies, particularly the Federal Government, Yale University has formulated the following policy to identify and address potential, actual and apparent conflicts of interest and commitment. The fundamental premise of this policy is that each member of the Yale community has an obligation to act in the best interest of the University, and must not let outside activities or outside financial interests interfere with that obligation. This policy is intended to increase the awareness of faculty, staff and students to the potential for conflicts of interest and commitment, and to establish procedures whereby such conflicts may be avoided or properly managed. [FN123]

The terms "conflict of interest" and "conflict of commitment" are defined somewhat differently in each policy that defines them. Some policies contain no precise definition at all, but rather identify "situations in which conflicts may arise" and require that disclosures be made in such situations. Other policies, like that of the University of California, simply define the term "significant financial interest" [FN124] and require review of all research projects where the investigator has such an interest for purposes of determining whether the interest "will in any way affect or impair the conduct of research in accordance with the applicable university policies and the highest professional standards." [FN125] A seemingly concise definition of those terms is supplied by the University of Illinois policy, which states:

1. A "conflict of commitment" exists when the external activities of an academic staff member are so substantial or demanding of the staff member's time and attention as to interfere with the individual's responsibilities to the unit to which the individual is assigned, to students, or to the University.

2. A "conflict of interest" arises when an academic staff member is in a position to influence either directly or indirectly, University business, research, or other decisions in ways that could lead to gain for the academic staff member, the staff member's family, or others to the detriment of the University's integrity

and its missions of teaching, research, and public service. [FN126]

As an aside, one could argue that the Illinois policy, however well drafted, is nonetheless overly broad and could be read to implicate nearly all activities of a faculty member who are frequently "in a position" to influence decisions for personal gain. Perhaps a better definition would be one that focused on situations or circumstances that created a substantial incentive for a faculty *807 member to behave wrongly, like the following definition recommended by the New England Journal of Medicine:

A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain). [FN127]

Other terms that are defined in some of the university policies include "substantial financial interest," "equity," and "faculty member," but there is no need to go into them here, since they only have importance insofar as they effect "substantive" policy provisions that are discussed elsewhere in this paper.

F. Prohibited and Permitted Activities

The most central provisions of university conflict of interest policies are those describing what activities will and will not be considered an impermissible conflict of interest. Paradoxically, these provisions are often quite generally worded and lacking in specific detail. Typically, university policies broadly prohibit all activities and outside financial interests of faculty members and their families that could potentially cause the faculty member to be biased in his or her research or teaching, to devote less than adequate time and energy to university duties, to make unfair use of university resources, or otherwise to advance personal interests at the expense of university interests. Such provisions obviously implicate a very wide range of activities and financial interests. It is perhaps because of their recognition of this wide range of potential conflicts that universities have refrained from attempting to provide detailed regulations enumerating all prohibited and permissible practices, and instead have coupled broadly worded standards with more specific and detailed disclosure requirements and review standards, with the expectation that each case of potential conflict, once disclosed, can be evaluated individually and decided in conformance with the general standard.

The standards for review may be contained, as in the University of Illinois policy, in the definition of the terms "conflict of interest" and "conflict of commitment" (quoted above) and in a "Statement of Principles" section providing both general and specific rules and concepts for determining when there is a conflict and whether, and under what conditions, it should be permitted. For example, the Illinois Statement of Principles provides that "it is improper for an academic staff member, without prior written approval, to divert to external entities or other institutions opportunities for research support that could have been obtained by the University." [FN128]

In other policies, like that of the University of California, a number of principles and factors are listed to guide the review of potential conflicts by university decisionmakers. Those principles and factors include: (1) whether *808 the research proposed "promises significant contributions to scholarship and knowledge," [FN129] (2) whether selection of students for participation in the research project will be inappropriately influenced by the sponsoring firm; [FN130] and (3) whether the potential public benefits to be gained outweigh any potential erosion of academic freedom, collegiality, or public trust. [FN131] The policy of Miami University is more explicit in stating that certain conflicts of interest could be found permissible in certain circumstances. It states:

If the University Director for Scholarship and Teaching, in consultation with the Extramural Professional Activities Committee, determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public

health and welfare, then the University may allow the project to go forward without imposing such conditions or restrictions. [FN132]

It should also be noted that some policies establish different review standards for different kinds of conflicts. The University of Massachusetts policy, for example, requires a "rigorous" review where a "substantial financial interest" of a faculty member is involved, but a "less than rigorous" review when only a "significant financial interest" is involved. [FN133]

Although each of the policies reviewed generally require determinations on conflicts questions to be made on a case-by-case basis, roughly half of them also provide specific examples of faculty financial interests and activities that would be considered allowable without disclosure, allowable with disclosure but no modification, potentially allowable after disclosure and modification, and/or absolutely prohibited. For example, the University of North Carolina identified the following "allowable activities" requiring no reporting:

- A university employee receiving royalties from the publication of books or for the licensure of patented inventions subject to the UNC Patent and Copyright Policies.
- A university employee having an equity interest in a corporation, the exclusive function of which is to accommodate the employee's external consulting activities.
- A university employee receiving nominal compensation, in the form of honoraria or expense reimbursement, in connection with service to professional associations, service on review panels, presentation of scholarly works, and participation in accreditation reviews. [FN134]

*809 It also identified the following as examples of activities that were "generally not allowable":

- A university employee participating in university research which is funded by a grant or contract from a business in which the individual or a member of his or her immediate family has an ownership interest.
- A university employee assigning students, post-doctoral fellows or other trainees to university research projects sponsored by a business in which the individual or a member of his or her immediate family has an ownership interest.
- A university employee accepting support for university research under conditions that require research results to be held confidential, unpublished, or inordinately delayed in publication (other than as allowed by University Patent and Copyright Policies or by policy of the Board of Governors). [FN135]

G. Required Disclosures and Approvals

The ten policies reviewed contained a fairly wide spectrum of requirements concerning disclosure and approval of faculty outside activities and interests. A number of policies, like those of Yale and the University of California, require annual reporting by all faculty members of all "external activities." Yale specifies that "sponsored research faculty" must also submit annual disclosures of "significant financial interests." [FN136] Other universities like Harvard, Duke, and the University of Missouri-Columbia appear to have no such annual reporting requirement, and instead require the written disclosure of potential conflicts of interest as they arise. [FN137] Harvard has a two-tier system which requires written disclosure for potentially "significant" conflicts and mandated "consultation" for potentially "serious" conflicts. [FN138] A slightly different approach is taken by the University of North Carolina which encourages, but does not require, their constituent schools to obtain annual statements from faculty identifying all of their outside activities, but also mandates that faculty in all schools must both (1) file written disclosures of actual or potential conflicts as they arise, and (2) file "notices of intent" prior to "engaging in any external activities for pay." [FN139]

Most of the policies require disclosure to be made initially only to the faculty member's department chair or dean. Universities that have created an institutional conflicts committee require that all disclosures be filed with such a committee,

sometimes through a senior-level administrator. The University of Massachusetts, for example, requires faculty to make their required disclosures to the Vice Chancellor for Research, who then submits all disclosure *810 forms on a monthly basis to the "University-Wide Conflicts Committee" for its review. [FN140] Some of the policies reviewed had standard disclosure forms attached, others did not. [FN141] The University of California system-wide policy instead sets forth the minimum mandatory requirements for the contents of all disclosure forms which are to be developed by each of the campuses. [FN142]

There is a notable difference between the financial interest disclosure thresholds, or "triggers," contained in the public and private university policies that were reviewed. The public universities tend to require reporting beginning at much lower levels. For example, the University of California requires the reporting of outside income from a single source of \$250 or more, [FN143] whereas Duke University requires such reporting beginning at \$5,000. [FN144] This is no doubt a function of strict state ethics laws which require comprehensive financial reporting by designated state officials.

Finally, roughly half of the policies reviewed require prior approval of a department chair or some other administrative official or entity prior to the commencement of any "outside activity for pay" or the acceptance of any contract for external research funding (with the exception of certain enumerated contracts or activities) by a faculty member. The other half appear to require disclosure and prior approval only in the case of externally funded research contracts, and some of them only when the researcher has a significant financial interest in the sponsoring company.

H. Review Mechanisms, Decisions, Appeals and Sanctions

Virtually all of the policies reviewed contain some kind of procedural mechanism for the review of potential conflicts, the issuance of administrative decisions about them, and the taking of appeals from those decisions. As noted above, some policies require the disclosure of all outside faculty activities and financial interests. These policies exempt from administrative review those activities which do not reveal potential conflicts of interest. However, all of the policies require administrative review of activities and interests which do indicate a potential conflict, with certain policies requiring review of the more serious categories of conflicts by more senior-level administrators. All of the policies reviewed also require that attempts be made to informally resolve conflicts issues by mutual agreement with the faculty member and that conditions on the faculty member's activities be imposed whenever appropriate to reduce, minimize, or eliminate conflicts. In addition, each of the policies requires that all administrative decisions as to the existence of a conflict and the "resolution" of the conflict be in writing and each stipulates that any faculty member affected by such a decision has the right to appeal *811 the decision at least once to a more senior university official or administrative body. Although all of the other policies are silent on the issue, the University of Massachusetts policy provides that final decisions on conflicts questions by the university president may be challenged in court on the grounds that the decision was arbitrary or capricious or that due process was not followed, but not "on substantive grounds." [FN145]

Nearly all of the university policies reviewed contained some kind of a provision stating that failure to comply with the procedural or substantive requirements of the conflict of interest policy, or to adhere to decisions reached by university officials concerning conflicts-related disputes, constitutes grounds for the imposition of appropriate sanctions. The NYU policy included in its list of possible sanctions "reprimand, censure, termination of funding, ineligibility for proposal submission, suspension, dismissal or expulsion." [FN146] The University of Illinois policy specified, however, that the "severity of sanctions [must] depend upon the extent of the violation Inadvertent, unintentional and minor breaches required lesser sanctions, whereas knowing, deliberate and major violations demand the severest sanctions." [FN147]

IV. CONCLUSION

The basic elements of the foregoing discussion, and the conclusions that may fairly be drawn from it, can be summarized as follows. It seems clear that the recent growth of university-industry partnerships has led to increased concern over the growing potential for faculty conflicts of interest and to calls for increased regulation of such conflicts. Although little empirical evidence exists that shows a significant negative impact on faculty loyalty and commitment to institutional goals and interests resulting from faculty consulting or faculty receipt of research support from private sponsors, there is nonetheless some evidence that the private funding of research can influence the choice of research topics by scholars as well as the manner in which the results of research studies are reported. There is also evidence that industry funding has led to an increase in the kinds of research that result in proprietary trade secrets. Regardless of the reason, however, all commentators appear to be in agreement that a greater level of regulation than that which existed until just recently has been necessary.

A good deal of scholarly work has sought to define the types of conflicts of interest that most commonly arise in the academic setting and to stake out the basic principles which ought to guide the formulation of institutional policies seeking to regulate such conflicts. The academic community has generally accepted the premise that some level of regulation is necessary, but have cautioned against overly restrictive and invasive policies and policies that could result in an unhealthy bureaucratization of the conflicts resolution process. Some commentators have suggested that the federal government *812 should play a leading role in establishing uniform national standards, but others have argued that institutions should be allowed to develop their own policies which address their unique interests and goals. It appears that this debate was resolved, at least temporarily, five years ago when two of the leading federal research funding agencies issued regulations that took the compromise position of establishing minimum federal conflict of interest standards and leaving wide discretion to individual institutions to establish their own stronger and more comprehensive standards. [FN148]

It can be inferred from this survey of selected universities that most, if not all, of the research and doctoral granting universities in the country have adopted conflict of interest policies which, at a minimum, meet the requirements of those two federal funding agencies. The ten university policies that were analyzed and compared reflect a range of approaches in terms of scope, level of detail, problem definition, disclosure requirements, and review mechanisms. Nearly all of them include statements of purpose indicating that their policies were intended to eliminate or reduce conflicts which posed a threat to academic freedom, free and open dissemination of research results, student teaching, and institutional loyalty. All of them state an explicit preference for resolving conflicts collegially through informal consultation and agreement; and all build in ample appeal rights for faculty members who are dissatisfied with administrative decisions.

The policies reviewed also conspicuously avoid categorical statements concerning which particular kinds of activities will be absolutely forbidden, but many provide examples of conflicts that are "likely" to be found impermissible. This common avoidance of absolute rules and emphasis on informal problem resolution and strong due process protections is likely due to the desire of the institutions to foster collegiality and mutual respect among faculty and administrators, to encourage administrative flexibility, and to avoid the bureaucratization of the conflict resolution process. However, this desire to avoid inflexible rules can lead to the promulgation of vague or overly broad standards, which cause greater faculty uncertainty and fail to effectively prevent conflicts. Imprecise standards may also tend to increase the likelihood of administrative misinterpretation and overreaching, and thus may actually serve to increase the number of disputes between faculty and administrators, and to invite constitutional or other legal challenges to administrative decisions. Finally, the policies of public universities are generally different from those of private universities in the significantly lower thresholds the former create for "financial interest" disclosure, in their

requirements for reporting and prior approval of a broader range of faculty "outside activities," and in their provisions implementing state law requirements of public access to conflict of interest related disclosure forms, reports, and decisions.

By way of concluding, it seems appropriate to look ahead and speculate about possible future trends in this area. Three developments seem likely. First, as universities continue to more aggressively seek out sponsored research*813 arrangements with private industry and as faculty entrepreneurialism continues to increase, the number and types of conflicts of interest faced by faculty and administrators will also continue to grow. This will result in increased scrutiny of institutional conflicts policies and will inevitably lead to an increase in internal disagreements and, ultimately, lawsuits. Second, since many institutional policies are new and untested and since published cases are remarkably few in number, universities will need to monitor external developments very closely and measure internal reaction very carefully to identify gaps and problems in their policies and amend them accordingly. Finally, it seems very likely that faculty conflicts of interest will become the subject of a great deal more empirical research in the coming years. Some questions that seem in particular to merit increased attention are: (1) To what extent are faculty satisfied with institutional conflicts policies and procedures?; (2) What currently is the true nature and extent of faculty involvement in "outside" professional activities and interests?; (3) What currently is the true nature and extent of private sponsorship of faculty research and what conditions are most commonly attached to that private sponsorship?; (4) How do these activities, interests, and research funding arrangements actually correlate with variables like faculty productivity, teaching, publication, objectivity and lack of bias, choice of research subjects, and institutional time commitment?; and (5) What kinds of "conflicts" are most pervasive, which are perceived as most problematic and harmful, and what are considered to be the best ways of dealing with them? Such research studies would provide the kind of information university administrators and government policymakers will need to fashion even better conflict of interest policies and regulations which address the most important aspects of the problem in the most effective and efficient way.

***814 Appendix**

Excerpts from Pertinent University Codes (in alphabetical order)

DUKE UNIVERSITY

STATEMENT OF CONFLICT OF INTEREST FOR DUKE FACULTY, APPROVED BY THE BOARD OF TRUSTEES: FEBRUARY 1992.

* * *

III. In response to these concerns, Duke University has adopted three statements of policy:

* * *

B. It is the policy of Duke University that any faculty member engaging in an outside activity or possessing a personal interest that could lead to a serious conflict of interest must immediately disclose that possibility by filing a disclosure form with that member's Dean or the Dean's designate. Faculty members not engaged in such activities or possessing such interests need only affirm this fact on the school's disclosure form. If the dean, having been provided with all pertinent information, determines that the faculty member's situation presents a serious conflict of interest, that conflict must be resolved. Consultation should be sought when a faculty member is in doubt about whether an interest or activity creates a conflict of interest. Subsequent disputes can be ameliorated more readily if a written record is kept of these consultations. If the faculty member and the Dean disagree, either about the presence of a conflict or about its appropriate resolution, the faculty member may pursue the matter with an Executive Officer of the University. The University's Executive Officers are its President, Provost,

Chancellor for Health Affairs, and Executive Vice President[s]. If a Dean or Executive Officer is in a situation that may present a serious conflict of interest, consultation should occur with a person in the next highest level of University authority.

* * *

FACULTY CONFLICT OF INTEREST POLICY DISCLOSURE

Note 3: No information is required for honoraria from an occasional lecture or from isolated, non-recurring consulting activities that result in payments which do not exceed \$5,000 from a single source during any calendar year.

* * *

*815 HARVARD UNIVERSITY

PRINCIPLES AND POLICIES THAT GOVERN YOUR RESEARCH AND OTHER PROFESSIONAL ACTIVITIES, FACULTY OF ARTS AND SCIENCES, SEPTEMBER 1994

* * *

Appendix

* * *

B. ACTIVITIES THAT SHOULD BE DISCUSSED WITH THE DEAN OF THE FACULTY OR WITH THE CHAIRMAN OF THE COMMITTEE EVEN THOUGH NO IRRECONCILABLE CONFLICT OF INTEREST OR COMMITMENT IS LIKELY TO BE INVOLVED:

1. Relationships that might enable a member to influence Harvard's dealings with an outside organization in ways leading to personal gain or to improper advantage for anyone. For example, a member could have a financial interest in an enterprise with which the University does business and be in a position to influence relevant business decisions. Ordinarily, such problems can be resolved by full disclosure and by making arrangements that clearly exclude that member from participating in the decisions.

2. Situations in which the time or creative energy a member devotes to extramural activities appears large enough to compromise the amount or quality of his or her participation in the instructional, scholarly, and administrative work of the University itself. The guideline applicable to faculty members, as defined in the Fifth Statute, is that during the academic year (which extends through the summer for those who receive extra summer salary) no more than 20% of one's total professional effort may be directed to outside work.

3. Activities (research projects, conferences, teaching programs, consulting agreements, etc.) that faculty members wish to undertake on an individual basis: (a) that involve or might reasonably be perceived to involve the institution, however slightly, and (b) that violate or might reasonably be perceived to violate any of the principles governing research supported by funds administered through the University (see Principles Governing Research Conducted Within the Faculty of Arts and Science and Guidelines for Research Projects Undertaken in Cooperation with Industry) insofar as these principles are relevant to individual behavior.

4. Situations in which a member directs students into a research area from which the member hopes to realize financial gain. The difficulty, in such circumstances, of making an objective independent judgment about the student's scholarly best interest, is obvious.

C. ACTIVITIES THAT SEEM LIKELY TO PRESENT AN UNACCEPTABLE CONFLICT OF INTEREST OR COMMITMENT, AND THAT *816 MUST BE DISCUSSED WITH THE DEAN OF THE FACULTY OR WITH THE CHAIRMAN OF THE COMMITTEE.

1. Situations in which the individual assumes executive responsibilities for an outside organization might seriously divert his or her attention from University duties, or create other conflicts of loyalty. (Individuals should consult the Dean

of the Faculty or the Chairman of the Committee before accepting any outside management position.)

2. Use for personal profit of unpublished information emanating from University research or other confidential University sources, or assisting an outside organization by giving it exclusive access to such information; or consulting under arrangements that impose obligations that conflict with University patent policy or with the institution's obligations to research sponsors.

3. Circumstances in which a substantial body of research that could and ordinarily would be carried on within the University is conducted elsewhere to the disadvantage of the University and its legitimate interests.

4. Any activity (research project, conference, teaching program, consulting agreement, etc.) that a faculty member may wish to undertake on an individual basis: (a) that involves or appears to involve the institution significantly (for example, through the use of its resources or facilities, or the participation of colleagues, students, and staff, etc.); and (b) that violates any of the principles governing research supported by funds administered through the University (see Principles Governing Research Conducted Within the Faculty of Arts and Sciences and Guidelines for Research Projects Undertaken in Cooperation with Industry) insofar as these principles are relevant to individual behavior. (In particular, members may not give other organizations the right to censor research any part of which is performed under Harvard auspices.)

MIAMI UNIVERSITY

ACADEMIC FREEDOM AND RESPONSIBILITY, APRIL 29, 1995

4.72 Policy on Management of Conflicts of Interest in Projects with External Funding

* * *

PLAN FOR ADDRESSING CONFLICTS OF INTEREST.

* * *

If the University Director for Scholarship and Teaching, in consultation with the Extramural Professional Activities Committee, determines that imposing conditions or restrictions would be either ineffective or inequitable, and the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or public health and welfare, then the University may allow the project to go forward without imposing such conditions or restrictions.

*817 NEW YORK UNIVERSITY

New York University Supplemental Guidelines for Disclosure of Review of Conflicts of Interest in Research (Endorsed by the Faculty Council as the Faculty Affairs Committee of the Senate, February 9, 1995)

* * *

Procedures

* * *

6. Failure to comply with the requirements of these Guidelines may lead to sanctions, including reprimand, censure, termination of funding, ineligibility for proposal submission, suspension, and dismissal or expulsion.

UNIVERSITY OF CALIFORNIA

UNIVERSITY POLICY ON DISCLOSURE OF FINANCIAL INTEREST IN PRIVATE SPONSORS OF RESEARCH (APRIL 26, 1984)

* * *

II. Definitions

A. "Financial Interest." A "financial interest" in the sponsor of research means:

1. A direct or indirect investment in the sponsor worth more than \$1,000;
2. A position as director, officer, partner, trustee, employee of or any other position of management in the sponsor;
3. Income from the sponsor, including consulting income and gifts aggregating \$250 or more in value, received by or promised to the principal investigator within 12 months prior to the time the award is made. (For the purposes of this policy, "income" is further defined as in Gov. Code, Section 82030.)

B. "Indirect Investment" or "Indirect Financial Interest." A principal investigator has an "indirect investment" or "indirect financial interest" in a sponsor if:

1. His or her spouse or dependent child has a financial interest in the sponsor;
2. The principal investigator, his or her spouse, or dependent child own directly, indirectly or beneficially a 10 percent interest or greater in any business entity or trust which has a financial interest in the sponsor of the research.

C. "Equity (Ownership) Interest." For the purposes of this policy, an "equity (ownership) interest" shall be an investment of more than \$1,000 in the sponsor by the principal investigator, his or her spouse, or dependent children.

***818** III. Disclosure Requirement

When a principal investigator has disclosed a financial interest in a sponsor of research, the required financial disclosure statement shall contain:

A. Disclosure of Income

1. The name and address of the sponsor and a general description of the business activity, if any, of the sponsor;
2. A statement whether the aggregate value of income from the sponsor, or in the case of a loan, the highest amount owed to the sponsor, was at least \$250 but did not exceed \$1,000, whether it was in excess of \$1,000 but was not greater than \$10,000, or whether it was greater than \$10,000;
3. In the case of a gift of \$50 or more, a description of and the amount of the gift; and
4. In the case of a loan, the annual interest rate and the security, if any, given for the loan.

B. Disclosure of Equity or Ownership Interest and Disclosure of Position in Sponsor

When an investment or equity (ownership) interest is required to be disclosed, or when the principal investigator is a director, officer, partner, trustee, employee, or holds any position of management, the disclosure statement shall contain:

1. A general description of the business activity in which the sponsor is engaged;
2. A statement whether the fair market value of the investment or interest exceeds \$1,000 but does not exceed \$10,000, whether it exceeds \$10,000, but does not exceed \$100,000, or whether it exceeds \$100,000; and
3. The position held in the entity by the principal investigator.

* * *

**GUIDELINES FOR DISCLOSURE AND REVIEW OF PRINCIPAL INVESTIGATOR'S FINANCIAL
INTEREST IN PRIVATE SPONSORS OF RESEARCH (APRIL 27, 1984)**

* * *

II. Principles

* * *

B. Research is appropriate to the University

The research must be appropriate to the mission of the University, i.e., promising significant contributions to scholarship and knowledge and, when possible, providing appropriate opportunities for students. The suitability of the research would be judged according to the standards of the discipline and should be guided by the principles and policies of Regulation 4, Special Services to Individuals and Organizations.

***819** C. The teaching and research environment is open

The teaching and research environment should continue to promote the free exchange of ideas, information, and materials among students and faculty in all of their forums--classrooms, laboratories, meetings, and anywhere in the University. Selection of students for participation in the research project should not be inappropriately influenced by the interest of the sponsoring firm.

* * *

III. Procedures for conduct of committee review

* * *

E. Apply the principles set forth in II above:

Some questions which might be considered when appropriate are:

1. Do the facts and circumstances suggest that the principal investigator's financial involvement with the sponsoring organization will in any way affect or impair the conduct of the research in accordance with the applicable University policies and the highest professional standards?
2. How will the interests of the University be maintained in consideration of the principal investigator's interest in the sponsor?
3. Will the research project lead to the advancement of knowledge rather than to routine testing of primary benefit to the sponsor?
4. How will this research project contribute to the University's mission of teaching, research, and public service?
5. Do the potential public benefits to be gained from undertaking this research outweigh any potential erosion of academic freedom, collegiality, or public trust?
6. Are the best interests of the University and the public served by granting an exclusive license to the sponsor?

* * *

**GENERAL UNIVERSITY POLICY REGARDING ACADEMIC EMPLOYEES OUTSIDE PROFESSIONAL
ACTIVITIES OF FACULTY MEMBERS (REV. AUGUST 16, 1995)**

* * *

A faculty member's record is reviewed annually by the department chairman (Academic Personnel Manual Section 220-80-b). As part of that review, the

chairperson shall review the faculty member's performance in the four areas listed in the above paragraph. University policy, effective with this statement, is that information regarding outside professional activities related to a faculty member's academic specialty shall be supplied to department chairpersons or equivalent unit heads through annual reports. These annual reports shall consist of a description of the type of organization, group, or individual for which service was performed, a description of the type of service *820 performed during the period of the academic appointment, and a certification that the faculty member did not exceed the time limits specified for compensated outside professional activities. These reports will be used by chairpersons or equivalent as part of their annual review of faculty members for possible recommendation for advancement. The reports are considered to be non-confidential in nature and are subject to public inspection. Further information regarding time and effort devoted to outside professional activities shall be separately provided in accordance with guidelines to be issued by the President.

* * *

THE UNIVERSITY OF ILLINOIS

POLICY ON CONFLICTS OF COMMITMENT AND INTEREST MARCH, 1996

* * *

I. PREAMBLE

Active participation by academic staff members in external activities that enhance their professional skills or constitute public service can be beneficial to the University as well as to the individual. Because such activities can lead to conflicts of commitment or interest with regard to one's University responsibilities, the need exists for a general framework against which the propriety and advisability of non-University activities can be measured and monitored.

This University of Illinois Policy on Conflicts of Commitment and Interest provides such a framework and identifies procedures for consultation and advice on conflicts of commitment or interest matters, for resolution of situations in which a conflict may exist, and for approval of exceptions when warranted. The Policy makes every effort to balance the integrity and interests of the University of Illinois with the integrity and interests of individual academic staff members. To that end, the Policy attempts not only to identify and eliminate or manage actual conflicts of commitment or interest but, whenever possible, to prevent even the appearance of conflicts. The Policy provides for remedies to manage conflicts constructively and for sanctions when the Policy is violated.

This Policy implements an Illinois law requiring University faculty members to obtain prior written approval before engaging in remunerated private consulting or research for external persons or organizations. It also implements various policies set forth in the University Statutes and The General Rules Concerning University Organization and Procedure. Finally, the Policy accommodates federal regulations designed to protect the integrity of federally funded research. Relevant excerpts from University, state, and federal documents appear in the Appendix.

* * *

*821 III. POLICY

A. Persons Covered

This Policy applies to all paid academic staff members, whether part time or full time, of the University of Illinois. The academic staff includes the faculty ranks

of professor, associate professor, assistant professor (and all of the foregoing whose appointments contain such terms as "research," "adjunct," "visiting," or "clinical"), instructor, and lecturer, as well as academic professionals and postdoctoral associates. All covered persons are referred to herein as "academic staff members." For the purpose of this Policy, students, including medical residents, are not considered academic staff.

B. Definitions

1. A "conflict of commitment" exists when the external activities of an academic staff member are so substantial or demanding of the staff member's time and attention as to interfere with the individual's responsibilities to the unit to which the individual is assigned, to students, or to the University.

2. A "conflict of interest" arises when an academic staff member is in a position to influence either directly or indirectly University business, research, or other decisions in ways that could lead to gain for the academic staff member, the staff member's family, or others to the detriment of the University's integrity and its missions of teaching, research, and public service.

* * *

C. General Principles

* * *

2. Conflict of Interest Principles

* * *

It is improper for an academic staff member, without prior written approval, to divert to external entities or other institutions opportunities for research support that could have been obtained by the University.

* * *

IV. PROCEDURES

* * *

E. Sanctions for Violation of this Policy

Sanctions are warranted for failure to report potential conflicts or to abide by a remedy. The University has the right to impose sanctions consistent with the rights of academic staff members under the University Statutes. Severity of sanctions depends on the extent of the violations of the Policy. Inadvertent, unintentional, and minor breaches require lesser sanctions, whereas knowing, deliberate, and major violations demand the severest sanctions. Any sanctions for violations of this Policy shall be carefully examined *822 with due regard for the academic freedom and rights of the academic staff member and the interests of the University. While gross non-compliance with this Policy could constitute due cause for dismissal, this Policy does not abrogate any of the procedural protection afforded by tenure. [footnote omitted].

Sanctions shall be reduced to writing, attached to the Report of Non- University Activities and any associated documents and routed through regular reporting channels. The academic staff member will be afforded an opportunity to respond before the proposed sanction is forwarded to the next administrative level.

* * *

THE UNIVERSITY OF MASSACHUSETTS

Policy on Conflicts of Interest Relating to Intellectual Property and
Commercial Ventures

Amherst & Boston

(Passed by the BoT April 2, 1997)

Under most circumstances, conflicts of interest involving individuals associated with the University are addressed by Chapter 268A of the Massachusetts General Laws, which governs the conduct of public officials and employees. However, pursuant to Massachusetts General Laws Ch. 75 § 14A, in the area of intellectual property and technology transfer this policy is controlling. In matters not addressed by this policy, the provisions of Chapter 268A apply.

* * *

I. Definitions

* * *

B. Conflicts Committee - A five-campus committee that reviews and manages conflicts of interest, as further described in Article II.

C. Covered Individual - Any individual associated with the University, including without limitation faculty, staff, and students, but excluding members of the CVIP [The University Office of Commercial Ventures and Intellectual Property] and Vice Chancellors for Research. Anyone who is not a Covered Individual remains subject to the more restrictive provisions of Mass. Gen. Laws Ch. 268A.

* * *

L. Significant Financial Interest - Has either of the following meanings.

1. Clinical Research - In relation to Clinical Research that is performed or directed by a Covered Individual, "Significant Financial Interest" means (i) any Equity in a Company that is directly owned by, or is under the control of, a Covered Individual or a member of his or her immediate family or (ii) Non-Equity Compensation from a Company in an aggregate amount greater than \$1,000 within the prior twelve-month *823 period that is directly or indirectly received by or contractually promised to a Covered Individual or a member of his or her immediate family.

2. Non-Clinical Research - In relation to research other than Clinical Research that is performed or directed by a Covered Individual, "Significant Financial Interest" means either (i) Equity that represents more than one percent (1%) of the total equity in a Company or has a total current value of more than \$10,000 that is directly owned by, or is under the control of, such Covered Individual or a member of his or her immediate family or (ii) Non-Equity Compensation in an aggregate amount greater than \$10,000 within the prior twelve-month period that is received by or contractually promised to a Covered Individual or a member of his or her immediate family.

M. Substantial Financial Interest - Has either of the following meanings.

1. Clinical Research - In addition to Clinical Research that is performed or directed by a Covered Individual, "Substantial Financial Interest" has the same

meaning as "Significant Financial Interest."

2. Non-Clinical Research - In relation to research other than Clinical Research that is performed or directed by a Covered Individual, "Substantial Interest" means either (i) Equity that represents more than five percent (5%) of the total equity in a Company or has a total current value of more than \$100,000 that is directly owned by, or is under the control of, such Covered Individual or a member of his or her immediate family or (ii) Non-Equity Compensation in an aggregate amount greater than \$100,000 within the prior twelve-month period that is received by or contractually promised to a Covered Individual or a member of his or her immediate family.

* * *

III. Administration of Policy

* * *

B. Composition of Conflicts Committee

The University will establish a thirteen-member, University-wide Committee consisting of one member of the faculty at each campus appointed under procedures established by the campus; the Vice Chancellor for Research or his or her designee at each campus; the President or his or her designee; and two non-voting members who the President may appoint from outside the University. The President shall annually select the Chair of the Committee from among the voting members. The faculty members of the Committee shall serve three year terms and may not serve more than two consecutive terms. The Director or his or her designee and the General Counsel or his or her designee may attend all meetings of the Committee.

***824 C. Actions by Conflicts Committee**

The Committee shall hold regular meetings on a monthly basis unless there are no matters for the Committee to consider or a quorum will not be achieved. The Committee shall establish procedures for special meetings. The Vice Chancellor for Research shall collect disclosures on each campus, and the Chair shall be responsible for collecting disclosure forms from the Vice Chancellors of Research, distributing forms in advance of meetings, scheduling meetings, and setting the agenda. Members may participate in meetings using voice or video-conferencing technology, provided that all members shall receive advance notice of all meetings.

* * *

IV. Policy

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C. Management of Conflicts

Covered Individuals are generally prohibited from having a Conflict of Interest that is disclosable under Section IV.B. unless the University has reviewed and allowed both the activity and the Financial Interest. There are two different procedures for review and allowance of these Conflicts of Interest, as set forth below. If a Conflict of Interest involves a Substantial Financial Interest, it necessitates rigorous review that may result in prohibition or allowance accompanied by conditions. On the other hand, if a Conflict of Interest involves a Significant Financial Interest and not a Substantial Financial Interest, then the Conflict of Interest ordinarily requires a less rigorous review process and ordinarily will be allowed.

* * *

VI. Appeals

Any Covered Individual may appeal an initial decision of the Committee by requesting a rehearing of the matter. The rehearing shall occur at the next regularly scheduled meeting of the Conflicts Committee. At the rehearing, the Covered Individual may personally appear before the Committee and shall have the right to be accompanied by counsel or a union representative. The Committee shall establish written procedures for the conduct of rehearings. The Committee shall issue a reconsidered decision promptly after the conclusion of the rehearing.

If a Covered Individual who is a faculty member continues to disagree with the reconsidered decision of the Committee, the faculty member may request an advisory opinion from an ad hoc faculty committee composed of three members appointed by the Chancellor for that campus and three members appointed by the Faculty Senate. The faculty member and the Vice Chancellor for Research (on behalf of the Conflicts Committee) will present their views to the ad hoc committee. The committee will adopt an opinion by vote *825 of a majority of its members. In the event of a deadlock, the committee may adopt two opinions. The committee will transmit its written opinion to the faculty member and the Vice Chancellor for Research (who shall relay the decision to the Conflicts Committee). The Conflicts Committee shall consider the opinion of the ad hoc committee at its next regularly scheduled meeting and may either reaffirm or change its decision.

Any Covered Individual may make a final appeal to the President. The President shall review the documentary record of the decision and, at the discretion of the President, may meet with the Covered Individual and members of the Committee. In the case of a faculty appellant who has requested an advisory opinion from an ad hoc faculty committee, the President shall consider that opinion and shall provide a written rationale in the event of disagreement. The decision of the President shall be final.

If a Covered Individual disagrees with this final decision, the Covered Individual may exercise his or her individual legal rights to challenge the decision on the grounds that (i) due process was not followed, or (ii) the decision is arbitrary and capricious, but no Covered Individual may challenge the decision on substantive grounds. Any such challenge shall be brought in a court of law located in the Commonwealth of Massachusetts. This acknowledgment by the University that a Faculty Member has the right to pursue a legal claim is not an admission by the University that any Faculty Member actually has any actionable legal claim. Rather, the University seeks to preserve the legal rights of a Faculty Member outside of the collective bargaining process after internal appeals are exhausted.

POLICY ON FACULTY CONSULTING AND OUTSIDE ACTIVITIES

Amherst & Boston

(Passed by the BoT April 2, 1997)

Faculty members are expected to devote to the University their primary professional loyalty and to direct to the University their time and energy. As they are considered "special state employees" for purposes of the Massachusetts law governing the conduct of public officials and employees (Massachusetts General Laws Ch. 268A), however, they are permitted to engage in limited activities outside of the University during normal working hours, provided such outside activities do not interfere with their primary obligations. The University recognizes that outside activities can be of value to faculty and the University. This Policy is intended to further the mission of the University and to enrich the experiences of the faculty by facilitating appropriately limited outside activities for faculty.

UNIVERSITY OF MISSOURI-COLUMBIA

THE BUSINESS POLICY AND PROCEDURAL MANUAL

Chapter: GENERAL & ADMINISTRATIVE INFORMATION

Section: Conflict of Interest (Passed by the Board of Curators January 5, 1990)

***826 * * ***

Overlapping Business Activities - Before an employee enters into a business activity that overlaps with the University's teaching, research or service missions, the employee shall make full disclosure to her or his immediate chairperson/supervisor, and such disclosure shall be filed as required in 1:141 Conflict of Interest and Requirements for Public Disclosure. The chairperson/supervisor and her or his dean/director/supervisor must approve or disapprove in writing the proposed activity.

* * *

PUBLIC DISCLOSURE

* * *

Disclosure Required - Section 330.015, Collected Rules and Regulations of the University of Missouri [Also 1:140 Conflict of Interest Policy] requires that a University employee shall make a full disclosure in writing of her or his present or proposed outside financial interest to the appropriate University official, for filing in a registry located for public scrutiny

* * *

UNIVERSITY OF NORTH CAROLINA

**CONFLICTS OF INTEREST AND COMMITMENT AFFECTING UNIVERSITY EMPLOYMENT, ADOPTED
4/16/93**

* * *

B. Conflicts of Interest

* * *

1. Categories of potential conflicts of interest

Activities that may involve conflicts of interest can be categorized under three general headings: First, those that otherwise might appear to involve such a conflict but that in fact do not, are allowable, and need not be reported; second, those that are questionable and must be reported, but that may be allowable with administrative approval; and third, those that generally are not allowable. The following examples are merely illustrative and do not purport to include all possible situations within the three categories:

a. Activities allowable, with no reporting required

The cited examples do involve activities external to university employment, and thus may present the appearance of a technical conflict, but they in fact do have the potential for affecting the objectivity of the faculty member's performance of

university responsibilities; at most, some such situations could prompt questions about conflicts of commitment.

- A university employee receiving royalties from the publication of books or for the licensure of patented inventions subject to the UNC Patent and Copyright Policies

- ***827** • A university employee having an equity in a corporation, the exclusive function of which is to accommodate the employee's external consulting activities

- A university employee receiving nominal compensation, in the form of honoraria or expense reimbursement, in connection with service to professional associations, service on review panels, presentation of scholarly works, and participation in accreditation.

b. Activities requiring disclosure for administrative review

The cited examples suggest a possibility of conflicting loyalties that can impair objectivity, but disclosure and resulting analysis of relationship may render the activity permissible, perhaps with certain types of limitation or monitoring.

- A university employee requiring students to purchase the textbook or related instructional materials of the employee or members of his or her immediate family, which produces compensation for the employee or family member.

- A university employee receiving compensation or gratuities (other than occasional meals, gifts of desk copies of textbooks, and the like) from any individual or entity doing business with the university.

- A university employee serving on the board of directors or scientific advisory board of an enterprise that provides financial support for university research, and the employee or a member of his or her immediate family may receive such financial support.

- A university employee serving in an executive position in a for-profit or not-for-profit business which conducts research or other activities in an area related to the university duties of an employee.

- A university employee having significant equity in a for-profit business which conducts research or other activities in an area related to the employee's university duties.

- A university employee having a financial interest in a business that competes with services provided by the university.

c. Activities or relationship that generally are not allowable

The cited examples involve situations that are not generally permissible, because they involve potential conflicts of interest or they present obvious opportunities or inducements to favor personal interests over institutional interests. Before proceeding with such an endeavor, the faculty member would have to sustain the burden of demonstrating that in fact his or her objectivity would not be affected or university interests otherwise would not be damaged.

- A university employee participating in university research involving a technology owned by or contractually obligated to (by license or exercise of an option to license, or otherwise) a business in which the individual or a member of his or her immediate family has a consulting relationship, has an ownership interest, or holds an executive position.

- ***828** • A university employee participating in university research which is funded by a grant or contract from a business in which the individual or a member of his or

her immediate family has an ownership interest.

- A university employee assigning students, post-doctoral fellow or other trainees to university research projects sponsored by a business in which the individual or a member of his or her immediate family has an ownership interest.

- A university employee accepting support for university research under conditions that require research results to be held confidential, unpublished, or inordinately delayed in publication (other than as allowed by University Patent and Copyright Policies or by policy of the Board of Governors dated February 12, 1988, pages V-A-1-2 of this manual).

- A university employee making referrals of university business to an external enterprise in which the individual or a member of his or her immediate family has a financial interest.

- A university employee associating his or her own name with the university in such a way as to profit financially by trading on the reputation or goodwill of the university.

- A university employee making unauthorized use of privileged information acquired in connection with one's university responsibilities.

UNIVERSITY OF NORTH CAROLINA

EXTERNAL PROFESSIONAL ACTIVITIES OF FACULTY AND OTHER PROFESSIONAL STAFF, ADOPTED 4/16/93

* * *

SECTION 3. PROCEDURES GOVERNING EXTERNAL PROFESSIONAL ACTIVITY FOR PAY

A faculty or other professional staff member who plans to engage in external professional activity for pay shall complete the "Notice of Intent to Engage in External Professional Activity for Pay" (hereinafter referred to as "Notice of Intent," Attachment A), which shall be filed with head of the department in which the individual is employed. A separate "Notice of Intent" shall be filed for each such activity in which an employee proposes to engage. Unless there are exceptional circumstances, the "Notice of Intent" shall be filed not less than ten (10) calendar days before the date the proposed external professional activity for pay is to begin.

YALE UNIVERSITY

Policy on Conflict of Interest and Conflict of Commitment August, 1995

Yale University believes that a great university should reach out to the world. Accordingly, the University encourages its faculty to seek and participate in sponsored research, to consult widely, and to engage in other activities which may benefit not only the participants but also the University itself, and the larger public. In many cases, non-faculty employees also consult or *829 engage in other outside activities. However, while Yale recognizes the benefit of such activities, it is also committed to ensuring that they are conducted properly and consistently with the principles of openness, trust, and free inquiry that are fundamental to the autonomy and well-being of a university and with the responsible management of the University's business.

In recent years, the number of faculty and staff engaged in sponsored research, in consulting, or in other interactions with external organizations has increased substantially. The interests and commitments of the various parties engaged in such activities or affected by them--the individual, the University community, industry, the government, and the public--are complex and not necessarily coincidental;

occasionally, these interests may conflict and compromise the atmosphere of free inquiry that Yale considers vital. It is sometimes difficult to draw the line between the responsibilities of a faculty or staff member to Yale and to external organizations. Under these conditions the possibility of perceived or real conflict of interest or conflict of commitment is significantly heightened.

In pursuit of its own mission, and consistent with the requirements of external agencies, particularly the Federal Government, Yale University has formulated the following policy to identify and address potential, actual and apparent conflicts of interest and commitment. The fundamental premise of this policy is that each member of the Yale community has an obligation to act in the best interest of the University, and must not let outside activities or outside financial interests interfere with that obligation. This policy is intended to increase the awareness of faculty, staff and students to the potential for conflicts of interest and commitment, and to establish procedures whereby such conflicts may be avoided or properly managed.

* * *

Examples

The University has not attempted to develop an exhaustive list of fixed rules on potential conflicts of interest, because each situation depends upon its specific facts. The following examples are intended to illustrate the principles underlying the University policy. (FN 3: Some of the activities in these examples may also represent conflicts of commitment.) Individuals who have questions about how this policy applies to a particular activity should seek advice from the Office of the Provost.

The activities described in examples 1 through 5 below represent actual conflicts of interest that are inconsistent with University policy and may not be undertaken.

1. A researcher uses his laboratory at Yale to do product-testing research, paid for by a company in which he is a 20% owner and founder, that seeks to validate advertising claims made about a product sold by that company.
2. A clinician makes patient referrals to a diagnostic company in which she or her immediate family has a significant ownership interest.
- *830 3. An employee directs the purchase of supplies for the University toward a business in which he or his immediate family has a significant ownership interest.
4. An employee managing a design and construction project participates in the selection of an architectural firm in which her spouse is a partner.
5. A faculty member acts as thesis or dissertation advisor to a graduate student for a research project, suggested by the faculty member, that the faculty member expects to substantially enhance the value of a company in which the faculty member has a significant ownership interest.

Activities such as those in examples 6 through 9 below may represent conflicts of interest, but in many cases would be permitted to go forward after disclosure with appropriate safeguards against bias of University activities and with continuing oversight.

6. A researcher conducts Federal or foundation-sponsored research on a product developed by a company for which he is a consultant.
7. A researcher conducts clinical research on a product developed by her and licensed to an external organization in which she owns equity or has other direct relations including consulting.
8. A researcher who is a member of a company's scientific advisory board conducts research sponsored by that company.
9. An employee manages a design and construction project involving an architectural firm in which his spouse is a partner, when the Yale employee did not participate in the selection of the firm for the project.

Normally, activities such as examples 10 through 13 may go forward following disclosure without special safeguards or oversight.

10. A researcher conducts research (other than product evaluation research) sponsored by a large publicly-traded company in which she owns 500 shares.

11. A researcher conducts Federal or foundation-sponsored basic research on a University invention that has been licensed to a company for which he consults, and on which he receives a share of University royalties.

12. A researcher consults in the area of her professional expertise for a company that also makes an unrestricted gift to support research in her department at Yale.

13. A staff member is responsible for purchases from several potential suppliers, one of which employs his sister.

It is important to understand that the above examples are meant to be only that--examples--and that there are many other situations different in nature and kind from the above. It is assumed that individuals who have questions about how this policy applies to a particular activity will seek advice from the Office of the Provost.

* * *

PROCEDURE

***831** * * *

All faculty members are required annually to submit a disclosure of their external activities, and all faculty members engaged in sponsored research are required annually to submit a disclosure of their significant financial interests (a term which is used in the Federal regulations and is defined in the disclosure form)[.] The annual disclosures must be in writing, on the forms approved by the Provost. The current versions of the forms are attached as Exhibit A to this policy.

Whenever the significant financial interests or external activities change materially, the disclosures are to be updated as soon as possible, in writing. Whenever possible, individuals should attempt to disclose expected changes or newly anticipated conflicts before they occur. Whenever an application for funding of a new research project is submitted, the individual will be required to certify that he or she has submitted a complete and accurate annual disclosure, and that the new research project does not present the potential for any actual or apparent conflicts of interest not already identified in the annual disclosure.

* * *

[FN1]. The author is an Associate General Counsel with UMass Memorial Health Care, the multi-hospital clinical system affiliated with the University of Massachusetts Medical School. He concentrates his practice in the areas of regulatory and corporate compliance, patient care, clinical research and human subjects protection and he serves as a member of the university-hospital IRB. He is also enrolled as a part-time graduate student in the Higher Education Administration program at Boston College. An earlier article by him on legal issues in Catholic higher education was published by this Journal in 1999. The author wishes to thank Professor Diana Pullin, J.D., Ph.D. of Boston College for her comments and suggestions on this article.

[FN1]. 35 U.S.C. § 200 (1994).

[FN2]. See Liz Kowalczyk, *Group Hits Hub Doctor Facing FDA Scrutiny*, BOSTON GLOBE, May 13, 2000, at C1; Deborah Nelson & Rick Weiss, *Penn Ends Gene Trial on Humans*, WASH. POST, May 24, 2000, at A1.

[FN3]. See DEPARTMENT OF COMMERCE, PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 7 (1991).

[FN4]. See id.

[FN5]. 15 U.S.C. §§ 3701-17 (1994).

[FN6]. See Lawrence Gostin & Michael Witt, Conflict of Interest Dilemmas in Biomedical Research, 271 JAMA 547 (1994).

[FN7]. See Claire Turcotte Maatz, University Physician-Researcher Conflicts of Interest: The Inadequacy of Current Controls and Proposed Reform, 7 HIGH TECH. L. J. 137, 139 n.8 (1991/92).

[FN8]. See Goldie Blumenstyk, Berkeley Pact with Swiss Company Takes Technology Transfer to a New Level, CHRON. HIGHER EDUC., Dec. 11, 1998, at A56.

[FN9]. See id.

[FN10]. See Gilbert Omenn, University-Corporate Relations in Science and Technology: An Analysis of Specific Models, in PARTNERS IN THE RESEARCH ENTERPRISE 21 (Thomas Langfitt, et al., eds., 1983).

[FN11]. See Eyal Press & Jennifer Washburn, The Kept University, 285 ATLANTIC MONTHLY 39 (2000).

[FN12]. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090 (1999).

[FN13]. See Lawrence White, Book Review, 11 J.C. & U.L. 257, 263 (1984) (reviewing ROBERT LINNELL, DOLLARS AND SCHOLARS).

[FN14]. See ROBERT LINNELL, DOLLARS AND SCHOLARS 53 (1982).

[FN15]. See id.

[FN16]. See Carl Patton, Consulting by Faculty Members, 66 ACADEME 181, 183 (1980).

[FN17]. David Blumenthal, et al., University-Industry Research Relationships in Biotechnology: Implications for the University, 232 SCIENCE 1361, 1361 (1986).

[FN18]. See id.

[FN19]. See David Blumenthal, et al., Relationships Between Academic Institutions and Industry in the Life Sciences, 334 NEW ENG. J. MED. 368 (1996).

[FN20]. R. A. Davidson, Source of Funding and Outcome of Clinical Trials, 1 J. GEN. INTERNAL MED. 155 (1986).

[FN21]. H. T. Stelfox, et al., Conflict of Interest in the Debate Over Calcium Channel Antagonists, 388 NEW ENG. J. MED. 101 (1998).

[FN22]. Mark Friedberg, et al., Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology, 282 JAMA 1453 (1999).

[FN23]. Sheldon Krimsky, Conflict of Interest and Cost-effectiveness Analysis, 282 JAMA 1458 (1999).

[FN24]. On Preventing Conflicts of Interest in Government-Sponsored Research at Universities, Joint Statement of the American Association of University Professors and the American Council on Education, 51 AAUP BULLETIN 42, 43 (1965) [hereinafter Joint Statement].

[FN25]. Pajaro Dunes Conference Draft Statement (1982), reprinted in 9 J.C. & U.L. 533, 538 (1982-83) [hereinafter Pajaro Dunes Statement].

[FN26]. ASSOCIATION OF ACADEMIC HEALTH CENTERS (AHC), CONFLICTS OF INTEREST IN ACADEMIC HEALTH CENTERS 3 (1990) [hereinafter AHC].

[FN27]. Joseph Palca, NIH Conflict-of-Interest Guidelines Shot Down, 247 SCIENCE 154, 154 (1990).

[FN28]. See Joseph Palca, NIH Grapples With Conflicts of Interest, 245 SCIENCE 23 (1989).

[FN29]. Joseph Palca, Conflict Over Conflict of Interest, 245 SCIENCE 1440, 1440 (1989) (quoting NIH guidelines).

[FN30]. See id.

[FN31]. See Palca, supra note 27, at 154.

[FN32]. See id.

[FN33]. See Debra Blum, Universities, Researchers Struggle to Develop Policies Aimed at Avoiding Potential Conflicts of Interest, CHRON. HIGHER EDUC., May 2, 1990, at A1.

[FN34]. See, e.g., Gostin and Witt, supra note 6, at 547 (in which the authors argue that "[f]ederal rules are needed to require disclosure of conflicts, limit the most

troublesome forms of conflict, and create uniformity in ethical standards across the country."). But see Maatz, *supra* note 7, at 176 (in which the author "recommends that primary responsibility for developing detailed policies to identify and manage conflicts of interest remain with individual universities.").

[FN35]. See 42 C.F.R. §§ 50.601-50.607 (1995).

[FN36]. See 60 Fed. Reg. 35,820 (1995) and 21 C.F.R. §§ 54.1-54.6 (2000). It should be noted that the FDA regulations, although similar to those of the PHS and NSF, differ from them in two basic respects: they require disclosure directly to the agency rather than to the grantee institution and they require disclosure not only of the investigator's equity or compensation interest in the study sponsor, but also of the investigator's propriety interests (e.g., patents or royalty rights) in the products being tested.

[FN37]. See A. Bartlett Giamatti, *The University, Industry, and Cooperative Research*, 218 *SCIENCE* 1278 (1982).

[FN38]. See *id.* at 1278-79.

[FN39]. *Id.* at 1279.

[FN40]. *Id.*

[FN41]. *Id.*

[FN42]. *Id.*

[FN43]. See *id.*

[FN44]. *Id.*

[FN45]. See C.K. Gunsalus & Judith Rowan, *Conflict of Interest in the University Setting: I Know It When I See It*, *RES. MGMT. REV.*, Fall 1989, at 13, 15.

[FN46]. Association of American Medical Colleges (AAMC), *Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research*, 65 *ACAD. MED.* 487, 490-91 (1990).

[FN47]. See BERNARD REAMS, JR., *UNIVERSITY-INDUSTRY RESEARCH PARTNERSHIPS* 70 (1986).

[FN48]. *Id.* at 70-71 (citing Donald Fowler, *Conflicts of Interest*, paper presented at NACUA Mid-Winter CLE Workshop, Washington, D.C., March 11- 12, 1983, at 1).

[FN49]. See AHC, *supra* note 26.

[FN50]. See AAMC, *supra* note 46.

[FN51]. David Korn, Conflict of Interest: A University Perspective, in *ETHICAL ISSUES IN RESEARCH* 113, 122-23 (Darwin Cheney ed., 1993).

[FN52]. *Id.* at 122-23.

[FN53]. American Society of Gene Therapy, Policy of the American Society of Gene Therapy on Financial Conflict of Interest in Clinical Research (Apr. 5, 2000), available at <http://www.asgf.org/policy>.

[FN54]. See, e.g., Nelson & Weiss, *supra* note 2, at A1; Kowalczyk, *supra* note 2, at C1.

[FN55]. See *id.*

[FN56]. See Richard Knox, Harvard Won't Ease Research Standards, *BOSTON GLOBE*, May 26, 2000, at A1.

[FN57]. See *id.*

[FN58]. See *id.*

[FN59]. *Id.*

[FN60]. See Robert Varrin & Diane Kucich, Guidelines for Industry- Sponsored Research at Universities, 27 *SCIENCE* 385, 387 (1985).

[FN61]. See generally LINNELL, *supra* note 14.

[FN62]. See generally White, *supra* note 13, at 262-63.

[FN63]. A 1985 study by the AAUP Clearinghouse on University-Industry Relations revealed that none of the 21 university policies collected for its survey which contained provisions relating to faculty financial or managerial relationships with outside sponsors contained outright prohibitions on such relationships, but rather only mechanisms for disclosure and consultation with designated university officers. April Burke, University Policies on Conflict of Interest and Delay of Publication: Report of the Clearinghouse on University-Industry Relations Association of American Universities, February, 1985, 12 *J.C & U.L.* 175, 183 (1985). It now appears, however, that at least some number of university policies, such as the Syracuse University policy, absolutely prohibit their faculty from consulting for external organizations on projects which are the subject of a sponsored research agreement between that organization and the University. See *SYRACUSE UNIVERSITY FACULTY MANUAL*, January, 1995.

[FN64]. Roger Porter, Science, Scientific Motivation and Conflict of Interest in

Research, in ETHICAL ISSUES IN RESEARCH 103, 103-112 (Darwin Cheney ed., 1993).

[FN65]. See id.

[FN66]. See id.

[FN67]. American Association of University Professors, Statement on Conflicts of Interest, ACADEME, Sept.-Oct. 1990, at 40.

[FN68]. Id.

[FN69]. Pajaro Dunes Statement, supra note 25, at 538.

[FN70]. See Mildred Cho, et al., Policies on Conflicts of Interest at U.S. Universities, 284 JAMA 2203 (2000).

[FN71]. See S. Van McCrary, et al., A National Survey on Policies on Disclosure of Conflicts of Interest in Biomedical Research, 343 NEW ENG. J. MED. 1621 (2000).

[FN72]. See Maatz, supra note 7, at 167 n.169; see also 42 C.F.R. §§ 50.601-50.607 (1995).

[FN73]. 42 C.F.R. § 50.604.

[FN74]. 42 C.F.R. § 50.603.

[FN75]. See id.

[FN76]. 42 C.F.R. § 50.605(a).

[FN77]. Id.

[FN78]. Id.

[FN79]. 60 Fed. Reg. 35,820 (1995).

[FN80]. 48 C.F.R. § 203.7001 (1999).

[FN81]. See 21 C.F.R. § 54.2 (1998).

[FN82]. United States Department of Health and Human Services, HHS Fact Sheet: Protecting Human Research Subjects (June 6, 2000), available at www.hhs.gov/news/press/2000pres/20000_606a.html.

[FN83]. See Department of Health and Human Services, Draft Interim Guidance: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider When Dealing with Issues of Financial Interests and Human Subject Protection (Jan. 10, 2001), available at <http://ohrp.osophs.dhhs.gov/nhrpac/mtg12-00/finguid.htm>.

[FN84]. Id.

[FN85]. See Moore v. Regents of the Univ. of Calif., 793 P.2d 479 (Cal. 1990).

[FN86]. See Ben Gose, Penn, Doctors, Ethicist Named in Suit over Gene- Therapy Death, CHRON. HIGHER EDUC., Sept. 29, 2000, at A34.

[FN87]. See Judith Cregan, Light, Fast and Flexible: A New Approach to Regulation of Human Gene Therapy, 32 MCGEORGE L. REV. 261, 278-9 (2000) (citing Gene Therapy: Is There Oversight for Patient Safety: Hearings Before the Subcommittee on Public Health of the Senate Committee on Health, Education, Labor and Pensions, 106th Cong. 8 (2000) (statement of Paul Gelsinger, father of the teenager who died as a result of gene therapy trial)).

[FN88]. See Duff Wilson & David Heath, Class-Action Suit Filed Against "The Hutch," SEATTLE TIMES, Mar. 27, 2001, at A1.

[FN89]. See Compalint, Wright vs. Fred Hutchinson Cancer Research Center, No. 01-2-008376, Kitsap County Sup. Cout, Wash (Mar. 26, 2001) available at <http://www.sskrplaw.com/gene/wright/complaint.html>.

[FN90]. See e.g., Mass. Ann. Laws ch. 268A, § § 1-25 (Law. Co-Op. 1992 & Supp. 2001).

[FN91]. See WILLIAM KAPLIN & BARBARA LEE, THE LAW OF HIGHER EDUCATION 961 (3d ed. 1995).

[FN92]. See 110 ILL. COMP. STAT. § 100/1 (1994).

[FN93]. See Tristor v. University of Miss., 420 F.2d 499 (5th Cir. 1969).

[FN94]. See id. at 504.

[FN95]. See Adamsons v. Wharton, 771 F.2d 41 (2d Cir. 1985).

[FN96]. See id. at 43.

[FN97]. Mark Fiore, Texas Faculty Group Hits Expert-Witness Rule, CHRON. HIGHER EDUC., Aug. 8, 1997, at A12.

[FN98]. See Hoover v. Morales, 164 F.3d 221, 224 (5th Cir. 1998).

[FN99]. See id.

[FN100]. Id. at 226-27.

[FN101]. The terms "research" and "doctoral granting" refer to and are based on the institutional classifications set forth in Carnegie Foundation, A Classification of Institutions of Higher Education (1994), a publication of the Carnegie Foundation for the Advancement of Teaching [hereinafter Carnegie Report]. Each of the universities to which request letters were sent had total enrollments in 1998 of over 10,000 students, and were classified under the Carnegie Report definitions as "research" or "doctoral" universities. See 1998 HIGHER EDUCATION DIRECTORY (1998) [hereinafter DIRECTORY].

[FN102]. Of the 15 policies received from public universities, two were incomplete and one was simply a copy of a state government pamphlet describing the ethics laws applicable to all state employees. Two of the 10 private universities that responded requested that they not be identified in any resulting publication and therefore were not considered. In addition, one of them was in draft form.

[FN103]. The titles, effective dates (and in some cases, sources) of those policies are as follows:

(1) University of North Carolina (System), two policies entitled CONFLICTS OF INTEREST AND COMMITMENT AFFECTING UNIVERSITY EMPLOYMENT, reprinted in part *infra* Appendix [hereinafter UNC Conflicts Policy] and EXTERNAL PROFESSIONAL ACTIVITIES OF FACULTY AND OTHER PROFESSIONAL STAFF, reprinted in part *infra* Appendix [hereinafter UNC Professional Activities Policy] both adopted on April 16, 1993.

(2) University of Massachusetts Amherst, two policies entitled POLICY ON CONFLICTS OF INTEREST RELATING TO INTELLECTUAL PROPERTY AND COMMERCIAL VENTURES reprinted in part *infra* Appendix [hereinafter UMass Conflicts of Interest Policy] and POLICY ON FACULTY CONSULTING AND OUTSIDE ACTIVITIES, reprinted in part *infra* Appendix [hereinafter UMass Faculty Consulting] both enacted on April 2, 1997.

(3) University of Missouri-Columbia, two policies entitled CONFLICT OF INTEREST and CONFLICT OF INTEREST AND REQUIREMENTS FOR PUBLIC DISCLOSURE dated May 29, 1991 and March 23, 1993, respectively, taken from the University's BUSINESS POLICY AND PROCEDURE MANUAL, reprinted in part *infra* Appendix [hereinafter UMC Policy].

(4) University of California (System), two policies (with a separate attached set of administrative "Guidelines" implementing each of the policies) entitled OUTSIDE PROFESSIONAL ACTIVITIES OF FACULTY MEMBERS, dated April 26, 1984, and DISCLOSURE OF FINANCIAL INTEREST IN PRIVATE SPONSORS OF RESEARCH, dated August 16, 1995, reprinted in part *infra* Appendix [hereinafter California Disclosure Policy], taken from the University's ACADEMIC PERSONNEL MANUAL.

(5) University of Illinois (System), policy entitled POLICY ON CONFLICTS OF COMMITMENT AND INTEREST approved on February 8, 1996, reprinted in part *infra* Appendix [hereinafter Illinois Policy].

(6) Miami University (of Ohio), policy entitled POLICY ON MANAGEMENT OF CONFLICTS OF INTEREST IN PROJECTS WITH EXTERNAL FUNDING, dated April 29, 1995, reprinted in part *infra* Appendix [hereinafter Miami Policy].

(7) New York University, two policies entitled CONFLICT OF INTEREST and STATEMENT OF POLICY ON FACULTY RESPONSIBILITY TO THE UNIVERSITY, dated May 23, 1966 and December 10, 1984, respectively, and one set of Guidelines entitled SUPPLEMENTAL GUIDELINES FOR DISCLOSURE AND REVIEW OF CONFLICTS OF INTEREST IN RESEARCH, dated February 9, 1995, reprinted in part *infra* Appendix [hereinafter NYU Policies].

(8) Harvard University (Faculty of Arts and Sciences), policy entitled POLICIES RELATING TO RESEARCH AND OTHER PROFESSIONAL ACTIVITIES WITHIN AND OUTSIDE THE UNIVERSITY, as amended and approved on May 2, 1995, and GUIDELINES FOR RESEARCH

PROJECTS UNDERTAKEN IN COOPERATION WITH INDUSTRY, dated October 3, 1983, both taken from Faculty of Arts and Sciences handbook entitled PRINCIPLES AND POLICIES THAT GOVERN YOUR RESEARCH AND OTHER PROFESSIONAL ACTIVITIES, reprinted in part infra Appendix [hereinafter Harvard Policy].

(9) Yale University, policy entitled POLICY ON CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT, dated August, 1995, reprinted in part infra Appendix [hereinafter Yale Policy].

(10) Duke University, policy entitled STATEMENT ON CONFLICT OF INTEREST FOR DUKE FACULTY, approved in February, 1992, reprinted in part infra Appendix [hereinafter Duke Policy].

Each of these policies is on file with the Editors of this Journal.

[FN104]. See DIRECTORY, supra note 101. The classifications referred to are based on definitions in the Carnegie Report, supra note 101, which describes "Research I" universities to include all institutions awarding 50 or more doctoral degrees and receiving \$40 million or more in federal support each year. "Doctoral I" universities are those universities which award 40 or more doctoral degrees annually in five or more disciplines.

[FN105]. 42 C.F.R. §§ 50.601-50.607 (1995).

[FN106]. See Yale Policy, supra note 103.

[FN107]. See id.

[FN108]. See UNC Conflicts Policy and UNC Professional Activities Policy, supra note 103.

[FN109]. See Illinois Policy, supra note 103.

[FN110]. See Miami Policy, supra note 103.

[FN111]. See NYU Policies and Miami Policy, supra note 103.

[FN112]. See Yale Policy, supra note 103.

[FN113]. See Harvard Policy, supra note 103.

[FN114]. See UMass Conflicts of Interest Policy, supra note 103.

[FN115]. Illinois Policy, supra note 103.

[FN116]. UMC Policy, supra note 103; see also Mo. Ann. Stat. §§ 105.450- 105.496 (West 1997 & Supp. 2001).

[FN117]. See Joint Statement, supra note 24.

[FN118]. See NYU Policies, supra note 103.

[FN119]. See Illinois Policy, supra note 103 (Preamble).

[FN120]. See UNC Conflicts Policy and UNC Professional Activities Policy, supra note 103.

[FN121]. See Duke Policy and California Policy, supra note 103.

[FN122]. See NYU Policies, supra note 103.

[FN123]. Yale Policy, supra note 103.

[FN124]. California Disclosure Policy, supra note 103, at II (Definitions).

[FN125]. Id.

[FN126]. Illinois Policy, supra note 103.

[FN127]. Understanding Financial Conflicts of Interest, 329 NEW ENG. J. MED. 573, 573 (1993).

[FN128]. Illinois Policy, supra note 103.

[FN129]. California Disclosure Policy (Guidelines) supra note 103, at II.B.

[FN130]. See id. at II.C.

[FN131]. Id. at III.E.5.

[FN132]. Miami Policy, supra note 103.

[FN133]. See UMass Conflicts of Interest Policy, supra note 103, at I.L to M, IV.C.

[FN134]. UNC Conflicts Policy, supra note 103, at B.1.a.

[FN135]. Id. at B.1.c.

[FN136]. Yale Policy, supra note 103.

[FN137]. See Duke Policy, Harvard Policy, and UMC Policy, supra note 103.

[FN138]. Harvard Policy, *supra* note 103, at III.B.

[FN139]. UNC Professional Activities Policy, *supra* note 103, at Section 3.a.

[FN140]. See UMass Conflicts of Interest Policy, *supra* note 103, at III. B. to C.

[FN141]. The following schools' policies submitted to the editors had attached disclosure forms: Duke University, Harvard University, and Miami University.

[FN142]. See California Disclosure Policy, *supra* note 103, at III.

[FN143]. See *id.* at II.A, III.A.

[FN144]. See Duke Policy, *supra* note 103, at n.3.

[FN145]. UMass Conflicts of Interest Policy, *supra* note 103, at VI.

[FN146]. NYU Policy, *supra* note 103 (Procedures).

[FN147]. Illinois Policy, *supra* note 103, at IV.E.

[FN148]. See Joint Statement, *supra* note 24.

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