Faculty Conflicts of Interest
In an Age of Academic Enterpreneurialism:

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 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, 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 they serve, 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 – which have no direct affect on the institution that employs them. 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.

While leaders in government and academe 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 individuals 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, 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 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 - 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, 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) and then summarize 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 will be a discussion of 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. Following that is 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, in Part III of the paper, the conflict of interest policies currently in place at ten leading public and private universities will be summarized, and their main similarities and most notable differences will be discussed.

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 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

1. 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 agreement ("CRADAs") between universities and private industry increased from 110 to more than 400 between 1988 and 1991. It has been estimated that in 1986, university-industry relationships accounted for as much as twenty-four percent (24%) of all external support for university research in biotechnology. 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, 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.

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 providing the hospital with over $70 million 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. A similar long term deal between the Monsanto Corporation and the medical school at Washington University of Saint Louis provided the school with $150 Million in research report over the 16 year period between 1982 and 1998. A more recent $ 25 Million 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 in that provided funding funding to an entire academic department (Berkely’s department of plant 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.

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. 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 in 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 leading to useful and economically valuable products or processes. 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 have made it increasingly difficult for scientists at different institutions to collaborate on scientific problems by openly sharing data, ideas and research tools and materials. Both of these trends, they point out, can inhibit the performance of the kind of essential 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 their possibly losing their 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 they want to play in the start-up company; if they want to remain a full-time faculty member, they
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, they will also try to keep performing work in their university lab that furthers the scientific process being pursued by the company. This, of course, creates great potential for tricky conflict of interest problems. And the 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 succesful. 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 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 NIH last year when it issued guidelines encouraging the inter-institutional sharing of "research tools" developed with NIH funds. However, conflicts policies 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 a 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 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 9 out of 10 university faculty members earned some sort of supplemental income over and above their salary. Linnell also found that between 32 and 44 percent of faculty surveyed reported that the remuneration they received for consulting constituted the first or second largest source of their outside income, with those percentages in the 68 to 78 percent range for faculty in engineering. Faculty at Ph.D. granting institutions who responded to Linnell's survey reported that their "outside" earnings were equal to roughly 30% of their base salary. Data from a separate 1975 study performed by the Carnegie Council on Policy Studies in Higher Education, showed that 19 percent of academics reported that they consulted at least one-half day a week, and 6 percent reported consulting more than one day a week. Both of these studies are rather old, however, and both are based on data reported by faculty but not independently verified, and thus may significantly underestimate the actual amount and value of income-generating outside activities by faculty. But the point here is not to catalogue 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 them or the extent to which receipt of research support from private industry may result in breaches by faculty members 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 and 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, which was undertaken by David Blumenthal and others and was 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 activity...commitment to teaching or 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." Their survey of 1200 faculty researchers at 40 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 has resulted in trade secrets and that commercial considerations had influenced their choice of research projects.15 A later survey published in 1996 by Blumenthal and his colleagues of private "life-sciences" companies showed that ninety percent of those 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. 16

Other published studies examining into 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 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).17 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, as well as a 1999 study showing 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. 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 have advocated for the implementation of stricter conflict of interest disclosure policies by academic medical journals.

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 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."

Seventeen years later, the presidents of a number of the country's leading research universities, in a statement issued following a conference on biotechnology and academia held at Pajaro Dunes, California, 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." 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.".

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", including two separate cases involving researchers at Harvard - one in which 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 and another in which researchers participating in a clinical drug trial involving a certain kind of "thrombolytic therapy" had a financial interest in the company that made one of the drugs being studied."

Following these congressional hearings, and at the urging of congressional committee members, the National Institutes of Health ("NIH") issued in September of 1989 a set of proposed conflict of interest guidelines which would have, 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"; (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. These guidelines touched off a
firestorm of protest by many academics who judged them to be overly burdensome and far too restrictive and they were subsequently withdrawn. Nonetheless, the issuance of those guidelines helped spur universities to develop and implement their own comprehensive conflict of interest policies 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. 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. Similar regulations have subsequently been adopted by the Department of Defense, the National Science Foundation and the Food and Drug Administration.

2. 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. 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. 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...[which] involvement demands great concentration and commitment." Second, he said, "when a faculty member becomes substantially involved in a company, the conflict of 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 more than even the most responsible faculty member can be expected to shoulder." Finally, he added, "such [substantial] involvement risks putting one's students and research associates in ambiguous circumstances, such that the graduate 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."

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 the [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." 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. 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."

It is important to remember that the term "conflict of interest" is generally understood, at least in the academic context, to encompasses two separate concepts: conflicts of interest, which generally have to do with private financial gain, and conflicts of commitment, which generally involve time. 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 activities) 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...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."

Under both of these definitions, it is clear that a faculty researcher will have a "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 potentially problematic conflict of interest; the AAMC definition implicitly recognizes this, while 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."

However, it is not always clear 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."

A number of academic associations, seeking to assist their members in their 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 ("AAHC") and the Association of American Medical Colleges ("AAMC"). One commentator comparing those two sets of guidelines observed that, while they are different in focus, both are entirely compatible with one another. That commentator’s analysis of the more comprehensive AAHC guidelines led to his observation that they were based upon and structured around five essential "sets of principles" which he identified as follows:

The first and overarching principle is that of primary commitment to the university. The [AAHC] document states that "a person who accepts a full-time appointment to the faculty, or a 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 protection of students and research staff.

Other academic and scientific associations have gone further and called for even stricter standards. The American Society for Gene Therapy, for example, adopted a new research ethics policy in April of this 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. 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 other adverse clinical outcomes) to their institutional human
subject committees and the FDA. 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.

It is interesting to note that the publicity surrounding the UPenn controversy appears to have been instrumental in the defeat of an effort by some members of the Harvard Medical School ("HMS") faculty to cause a loosening of that school's relatively strict conflict of interest policy. Apparently, a faculty committee at HMS was scheduled to vote on a proposed amendment to the school's conflict of interest policy in June of this year. However, the meeting was cancelled and a statement was issued by the the 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. Martin also took that opportunity to call for "a national debate on the proper limits of financial conflicts of interest for medical researchers."

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 appearances 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." 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 aimed at allowing universities to control more of the proceeds from university-based research and to more closely control all aspects of sponsored research, allowing faculty to become more truly "full-time" employees of universities (with compensatingly higher salaries) and removing current incentives and loopholes which entice faculty into ethically dubious external entanglements."

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." It appears, in any event, that (with some notable exceptions) very few institutional policies place outright bans on faculty employment or financial links to research sponsors in the manner recommended by Varrin and Kucich and choose instead to allow "de minimus" links with disclosure and review of links above designated thresholds." 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." 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. 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.

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 or do harm to academic freedom or other traditional academic interests and norms. In its 1990 "Statement on Conflicts of Interest", 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 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 within 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, in making judgments about faculty salaries, tenure and promotion, from 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."

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.

It should also be noted, however, that while 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 well be appropriate to suit the special circumstances and traditions of different institutions."

3. **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"), the principal health agency of the Federal Government 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"). 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 "might reasonably appear to be affected by their research" to an appropriately designated university official; (3) ensure that such designated official will review 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".

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"). 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. The regulations further provide that "a conflict of interest exists when the designated official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS funded research." Finally, the regulations list the following as "examples of conditions or restrictions that might be imposed to manage conflicts of interest."

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.

The National Science Foundation ("NSF") has published an "Investigator Financial Disclosure Policy" which 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 misconduct" and report in a timely fashion any "suspected or possible violations of law...to appropriate government officials." The FDA has also recently promulgated regulations requiring medical researchers conducting studies of unapproved drugs and medical devices to disclose to the agency and "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...

While federal conflict of interest regulations enacted to date have required conflict disclosures to the researchers' employing institution and/or to the relevant federal funding or regulatory agency, 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. While it appears that human subjects research committees (i.e 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 now legally mandated to impose any such requirement. It looks like this is about to change quite soon, however. The Department of Health and Human Services announced this past June 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."
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 by its officers, directors and others are consistent with the educational, scientific or other charitable purposes of the institution and do not result in "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. While 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 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.

Faculty and 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. Presumably all states have some kind of ethics law which would be generally applicable to all state and municipal employees and officials. It appears that a number of those state statutes and regulations have provisions aimed specifically at faculty research and publication activities at state colleges and universities. 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."

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 which was representing clients that had sued the state over the segregation of the state's public schools." The court in that case, 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."

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." 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 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.79

There appear to be few other published cases which 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 which was reported in 1997 merits some attention, however. In that case, the Texas Faculty Association challenged the legality of policies enacted by the Texas A & M University System that barred professors and other university employees from serving as expert witnesses in legal disputes if doing so "would conflict with state interests."80 According to one report, the case began when the university attempted to prevent a marketing professor at the school from testifying on behalf of the tobacco industry in a case in which the state was an adverse party. The university's conflicts policy reportedly contained not only specific provisions against such expert witness activities but also a more general prohibition against employees "engaging in outside employment that would bring them into conflict with the state."81 It seems a good possibility that the court would find the university policy to unreasonably restrict the free speech rights of its faculty. Unfortunately, there does not appear to have been any published decision in the case, indicating that the case may have been resolved without a trial. A ruling adverse to the university in that case would have been quite significant, it seems, since many public universities in the country appear to 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 will be focused 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 difference in the scope, comprehensiveness, specificity and degree of prescriptiveness of the various policies. 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.

1. Methodology

Letters were sent in July of 1997 to 22 private and 15 public "research" and "doctoral-granting" universities in the United States with enrollments in excess of 10,000 students requesting 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 (14) of the public and eleven (11) of the private universities. Of these, three public university and two private university policies were eliminated from consideration for various reasons. 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 which fairly represented the range of policies received, in terms of
their scope and comprehensiveness. Selection was also guided in part by a desire to include policies which were unique or different in their approach to the problem. The ten policies which were more carefully analyzed and are discussed below are those of Harvard, Yale, Duke, NYU, Miami University, the University of California, University of Massachusetts, University of Illinois, University of North Carolina, and the University of Missouri - Columbia. Nine of these institutions are classified as "Research I" universities; one - Miami University - is classified as a "Doctoral I" university. It should be noted that all policies discussed here were received between August of 1997 and February of 1998 and no effort was made by the author prior to publication to determine if those policies have since been amended by their institutions.

2. 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 which 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 purposes 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 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) and which 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 of
the more comprehensive policies, also provide a variety of
examples of the various types of conflicts that most commonly
arise.

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
only 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 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.

3. 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 in 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 conflicts of commitment resulting form excessive
devotion of time and energy to outside activities, while the
other 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".

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. While each policy of the ten policies being reviewed is organized slightly differently, virtually all of them contain each of those elements.

4. Relation to Other Laws, Codes and Policies

As mentioned above, some policies were apparently instituted for the sole purposes 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. While
the PHS regulations require disclosure of "financial interests" over $10,000.00 or 5% of the total value of the sponsoring entity, NYU sets a threshold of $10,000.00 or 1% of total value, and Miami imposes a threshold of $5,000.00 or 5% of total value. These thresholds were evidently chosen to insure 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 applicable Federal regulations." Harvard's policy, like many others, makes no reference to federal standards at all.

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, 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."

Other public university policies, while not mentioning or citing to 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 some Missouri state law pertaining to freedom of information or governmental ethics.

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. Although the NYU policy was amended in 1984 to include new, more specific requirements, the AAUP statement was retained and is still included.

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, while the University of North Carolina policy makes reference in a number of places to relevant provision of the University "Code". 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 which are consistent with, but possibly more restrictive or detailed than, the university-wide policy. Other universities have, like NYU, 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.

5. **Statements of Purpose and Definitions**

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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 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."

The terms "conflict of interest" and "conflict of
commitment" are defined somewhat differently in each policy which
defines them. Some policies contain no precise definition at
all, but rather simply 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" and require review of all research projects where the
investigator has such an interest for purposes of determining
whether the interest "will in my way affect or impair the conduct
of research in accordance with the applicable university policies
and professional standards." 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.

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 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 judgement 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).

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 the "substantive" policy provisions which are discussed elsewhere in this paper.

6. 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, however, 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 which 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."

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 the research proposed "promises significant contributions
to scholarship and knowledge", (2) whether selection of students
for participation in the research project will be inappropriately
influenced by the sponsoring firm; and (3) whether the potential
public benefits to be gained outweigh any potential erosion of
academic freedom, collegiality or public trust. The policy of
the University of Miami 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."

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.

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 employees 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 review.

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).

7. **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." 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. Harvard has a two-tier system which requires written disclosure for potentially "significant" conflicts and mandated "consultation" for potentially "serious" conflicts. 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."

Most of the policies require disclosure to be made initially only to the faculty member's department chair or dean. Those universities that have created an institutional conflicts committee require that all disclosures be filed with such 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 forms on a monthly basis to the "University-Wide Conflicts Committee" for its review. Some of the policies reviewed had standard disclosure forms attached, other did not. 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.

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 $250.00 or
more, whereas Duke University requires such reporting beginning at $5,000.00. 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.

8. 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 the decision at least once to a more senior university official or administrative body. While 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."

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." 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."

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. While little
empirical evidence exists which 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. But regardless of the reason, all commentators appear to be in agreement that a greater level of regulation than 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 which could result in an unhealthy bureaucratization of the conflicts resolution process. Some commentators have suggested that the federal government should play a leading role in the establishment of 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 which 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.

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 which 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 they 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 arrangements with private industry and as faculty entrepreneurship 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? and (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? (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 and do so in the most effective and efficient way.
ENDNOTES


7. Id.


12. Id.


15. *Id.*


28. See, e.g., Gostin and Witt, *supra*, at p. 547 (in which the authors argue that "federal 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, at p. 176 (in which the author "recommends that primary responsibility for developing detailed policies to identify and manage conflicts of interest remain with individual universities.")


31. Id. at 1279.

32. Id.

33. Id.


40. Korn, p. 122-123.


45. White, supra at note 6.

46. 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 Publications: Report of the Clearinghouse on University-Industry Relations Association of American Universities, February, 1985," Journal of College and University Law 12(2): 175, 183 (1985). However, it now appears that at least some number of university policies, such as the Syracuse University policy (see, Syracuse University Faculty Manual; January, 1995) absolutely prohibit their faculty from consulting for external organizations on projects which are the subject of sponsored research agreement between that organization and the University.


48. Id.


50. Id.


54. 42 CFR 50.603.

55. Id.

56. 42 CFR 50.605(a).
57. Id.

58. 60 FR 35820 (July 11, 1995).

59. 48 CFR Part 203.

60. 21 CFR Part 54 (2/2/98).


63. S.H.A. 110 ILCS 100/1 (1994).

64. Tristor v. University of Mississippi, 420 F.2d 499 (5th Cir. 1969).

65. Id. at 504.


67. Id. at 43.


69. Id.

70. The terms "research" and "doctoral granting" refer to and are based on the institutional classifications set forth in the 1994 publication of the Carnegie Foundation for the Advancement of Teaching entitled "A Classification of Institutions of Higher Education" (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, according to the 1998 Higher Education Directory. See note 60, infra.

71. Of the fifteen 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 ten 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.

72. The titles, effective dates (and in some cases, sources) of those policies are as follows: (1) University of North Carolina (System) - 2 policies entitled "Conflicts of
Interest and Commitment Affecting University Employment" and "External Professional Activities of Faculty and other Professional Staff", both adopted on April 16, 1993; (2) 
University of Massachusetts Amherst - 2 policies entitled "Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures" and "Policy on Faculty Consulting and Outside Activities", both enacted on April 2, 1997; (3) University of Missouri-Columbia - 2 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; (4) 
University of California(System) - 2 policies (with a separate attached set of administrative "Guidelines" implementing each of the policies) entitled "Outside Professional Activities of Faculty Members" and "Disclosure of Financial Interest in Private Sponsors of Research", dated April 26, 1984 and August 16, 1995, respectively, 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; (6) Miami University (of Ohio) - policy entitled "Policy on Management of Conflicts of Interest in Projects with External Funding," dated April 29, 1995; (7) New York University - 2 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; (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; (9) 

73. 1998 Higher Education Directory (Falls Church, VA: Higher Education Publications, Inc., 1998). The classifications referred to are based on definitions in the 1994 "Carnegie Foundation Report" (See note 57, supra) 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.