Norman Latker

From: Latker, Carole (NIH/NIGMS) [LATKERC@nigms.nih.gov]
Sent: Thursday, April 21, 2005 5:09 PM
To: Norman Latker
Subject: and the saga goes on

Howard Bremer is getting a lot of press.

Bad Information Makes Implementing New NIH Conflict Of Interest Regs Harder

The Washington Fax
April 20, 2005

Bad communication, misinformation, misinterpretation and misunderstandings are only a few of many things adding to confusion surrounding the HHS conflict of interest (CoI) regulations that were put in place at NIH on Feb. 3, 2005.

One serious, strategic implementation error of , and perhaps the cause of most of the bad communication, is the removal of hands-on decisionmaking, oversight and enforcement of the ethics regulations from the level of NIH administrators to the departmental level at HHS and even higher to the Office of Government Ethics.

In a recent interview, Howard Bremer, of the Wisconsin Alumni Research Foundation and the man credited with bringing about the Bayh-Dole Act, was staunch in his belief that CoI management is best achieved through strict rules and stringent reporting enforced at the institutional level by peer scientists in conflict of interest panels. (see Washington Fax 4/14/05)

It is hard to understand what the officials, lawyers, and bureaucrats downtown were thinking when they insisted that administration of and judgments concerning the new CoI regs not be done fully at the NIH level. Removing local authority from NIH to the desktop of perhaps conservative legal interpretation is a disservice to the agency and certainly to its employees.

More to the point, the fact that the decisions are made downtown tells NIH employees and officials that the appeals process is useless, since the final arbiter made the original decision.

This "downtown" strategy removes at least one step in direct human judgment. As an example, an individual at NIH might be in conflict because of their financial holdings and certain of their duties. Better than divesture of stock, the answer might be simply to move them from the conflicted position and replace them with an equally talented employee who is not conflicted. This cannot be accomplished now, because NIH does not have the authority.

In hundreds of areas related to the day-to-day running of NIH, officials, including the director, carry out their duties through authority designated by the HHS secretary to the director, so enforcing the regs at the departmental level is not necessarily a demand of law.

From the get-go it was not really clear when and how the CoI regs would be implemented. In fact, there is much erroneous information floating around about the rules in general.

In a recent interview with Washington Fax, NIH Deputy Director Raynard Kington, MD/PhD, cited specific areas in which the confusion is focused.

The outside activities area is the most complicated part of the reg, Kington said.

"There are three types of activities with four types of organizations that are prohibited and then there are five exemptions," he explained.

"The three types of activities are employment, paid or unpaid; compensated teaching, speaking [or] writing; [and] self-employment, like a personal services contract or a business."

"The four types of organizations are substantially-affected organizations, which are primarily pharmaceuticals and biotech, grantee institutions, health care providers and insurers, and professional or trade organizations," he said.

"The five exceptions are clinical practice, clerical, teaching a course that falls under a number of categories, teaching, speaking, writing and editing a peer-reviewed journal, and CME-type education. All of those are allowed, [but] you still have to get prior approval, and you still have to meet other criteria."

"For example," he explained, "you can't go out and teach a course that's entirely about your research that you're paid to do here and do that as an outside activity for compensation. Most courses aren't like that, but if you wanted to go spend an entire course teaching just your research, you couldn't do that because that violates actually criminal statutes that prohibit employees from getting paid for activities directly related to what they're being paid to do by the federal government."

wrong

4.28.05

First on his list of misunderstandings is "the belief that giving talks at universities and grantee institutions is not allowed."

A number of outside activities are allowed if they fall into certain categories, he explained. Even activities for compensation, such as giving general talks at a CME professional development-type activity, are allowed.

However, many of these activities, in fact the vast majority, are now and have always been done as a part of an employee's official duties. Employees can continue to do those duties and even receive travel reimbursements by grantee institutions -- just as long as the money does not come from an NIH grant, Kington said.

The second common misconception is that you have to get prior approval in order to be a Girl Scout troop leader, Kington said. "Non-professional services at social, fraternal, religious, political organizations do no require prior approval - if unpaid."

"It is true that as the rule is currently written, for paid activities and activities that involve professional services with any type of organization, the rules technically require prior approval," he said. But, we're in the process of obtaining an exemption for a series of broad classes of activities, including sports-related activities, real estate sales....things that are really not related to the core mission of the agency. And those existed before. Before, there was an exemption for serving on a condo board, for example."

Kington listed other misunderstandings about outside activities. For example, "that you won't be able to practice medicine or work part-time as a nurse. The way the rules are written, certain activities are prohibited and then there are classes of activities that are exempted. And clinical practice involving one-on-one patient care is one of the activities that is exempted under the new reg -- explicitly."

The fourth misconception he noted is "that you can't get involved in editing, can't be editors for compensation. [Editing] too, is one of the classes of activities that's explicitly exempted from the prohibitions. And it isn't even prohibited...it wouldn't fall under the rules at all if it's not with a publication that is published by a university or a grantee institution."

The final misconception Kington pointed to is that "NIH employees can't receive awards of over $200." Kington said the rules really have not changed dramatically for the awards policy.

"What we have is a policy that says there's a federal-wide prohibition against receiving payment for doing your federal job from a third party, but there's an exception written into the rules....There was a exception that had already been written into the rules that allows under certain circumstances employees to receive the award. Employees could also receive the honor, but they also could receive, under exceptions, cash over $200," he said.

"There were criteria set up for what constituted a bone fide award," Kington said. However, "even if it's an exceptional award that has an independent committee and clear objectives and all the criteria for a bone fide award, but the organization has a matter pending before you where you are about to make a decision about that organization - [you are] not going to be allowed to do that."

"We're creating exceptions for broad categories of distinguished awards that any NIH employee could receive, like the Nobel. But then senior employees are more restricted in what they receive, because they're more likely to have conflicts with organizations that might give awards. They can still receive the honor of an award and under some circumstances could receive the money," he continued..'

"A subcommittee of the Advisory Committee to the Director will sort of certify a pre-approved list of bone fide awards, which basically allows us to have an outside group review awards to make sure they meet the criteria that are put forth in the regs. It's really a tool for employees because there'll be a pre-approved list. [It] doesn't mean if your award isn't on that list you can't get it, it just means that all awards have to be scrubbed by that subcommittee."

Kington also discussed prohibited holdings. He explained that the rule creates two classes of employees at NIH. Filers are the 6,000 to 7,000 employees who every year file either public financial disclosure statements in which they disclose their financial situation, or confidential disclosures, which are disclosed to the agency but not to the public.

Filers have a complete prohibition against owning a substantially affected organization.

"Everybody else in the agency, with some footnotes, but everybody else in the agency...can hold up to $15,000," Kington said.

"We're currently trying to move some categories of people who are currently filers into the other category for the purposes of this rule because they may be a filer for a reason that has nothing to do with their ability to have one of these conflicts."

The idea that employees will be prohibited from investing in mutual funds is wrong, Kington said. "If it's a diversified mutual fund, you can have a mutual fund that holds stock in a substantially affected organization."

Another bit of misinformation is "that an employee would have to divest holdings related to a spouse's current or past employment with a substantially-affected organization or their own past employment with a substantially-affected organization, like a pharmaceutical [company]. There's an explicit exception built into the rules to allow that to occur. So, we don't expect people to divorce their spouses because of this reg,." Kington said.

These regulations are one place where scientists' favorite admonishment, "Don't throw the baby out with the bath

water," must prevail.
-- Bradie Metheny

High Court Is Set to Hear Case of Research vs. Patents

By Denise Gellene
The LA Times
April 20, 2005

Michael D. Pierschbacher remembers the moment in 1982 when he discovered a tiny peptide that guides human cell growth and migration. "I ran from the lab and down the hallway shouting, 'Eureka!' " recalled the former Burnham Institute scientist.

Some time later, David Cheresh, a scientist at Scripps Research Institute - right across the street from Burnham in San Diego - became convinced that the peptide, a string of three amino acids, had promise as an anti-cancer drug. In 1994 Cheresh started collaborating with German drug maker Merck on a brain cancer medicine.

Then the company that owned rights to the Burnham discovery sued Merck for patent infringement - and won a jury trial in 2000. Merck appealed, so far unsuccessfully.

Today, the U.S. Supreme Court will hear arguments in the case, which has taken on broad significance for drug development and left the biotechnology industry deeply divided.

Merck - not related to U.S. pharmaceutical giant Merck & Co. - argues its research was permitted under a "federal exemption" for all work aimed at getting Food and Drug Administration approval for drugs.

Some big pharmaceutical companies and the seniors organization AARP - typically opponents - are urging the court to side with Merck. They worry that unless the court acts, patents could be used to delay or completely block potentially life-saving medicines.

The Department of Health and Human Services also has gotten behind Merck. In a friend-of-the-court brief, the department asserted that federal law protected many of the experiments performed by Cheresh in collaboration with Merck. "There is no question that the [appeals] court's holding would restrict significantly the development of new drugs," the government's brief said.

Integra Lifesciences Holdings Corp., the New Jersey company that owns the Burnham patents, said worries about research delays were nonsense. Integra offered to license the patents to Merck, but negotiations with the German firm were not successful, said Cathryn Campbell, a lawyer for Integra.

The case has split the biotechnology industry, which includes a handful of drug giants and hundreds of smaller, research-focused companies.

Siding with Integra are small biotech companies that produce and sell equipment and other products used in drug research, including Applera Corp. and Invitrogen Corp. They worry that big drug companies could run all over their patents if the lower court ruling is overturned.

Two of the largest biotechs, Genentech Inc. and Biogen Idec Inc., are aligned with Merck.

At the center of the dispute is a federal law known as Hatch-Waxman, which was passed in 1984 to foster drug development. The law granted a "federal exemption" from patent laws for research needed to obtain FDA approval of a drug. The law has been used to shield generic drug companies from patent infringement suits while they prepare to bring knock-off drugs to market.

Merck claims that the Hatch-Waxman exemption should also apply to its research, but a federal jury disagreed, awarding $15 million in damages to Integra, which an appeals court reduced to $6.4 million in 2003.

In upholding the verdict, the appeals court said that Merck and Scripps used the peptide in experiments that weren't needed to obtain FDA approval of the brain-cancer drug. The court said the exemption applied only to drugs in clinical trials, while Merck was using the peptide in laboratory studies.

Merck said the appeals court decision was too narrow. "Our argument is there is a period of time that begins the moment it can be demonstrated that a drug candidate has the potential to cure disease in humans. From that point on, the research is protected," said E. Joshua Rosenkranz, attorney for Merck.

The suit revolves around a 23-year-old discovery that is now a hot area of research. The peptide discovered by Pierschbacher passes information to cells by binding to receptors on cell membranes, called integrins.

"It is not an exaggeration to say that nothing works in cells without the [peptide] recognition system," said Erkki Ruoslahti, who supervised Pierschbacher in the 1980s.

Back then, Ruoslahti had become convinced that a peptide controlled important cell functions and assigned Pierschbacher to find it.

Integra eventually acquired the patents, and Pierschbacher now is a senior vice president at the company.

Ruoslahti continued to study the peptide and how it interacted with cells, collaborating at times with Cheresh at Scripps.

In 1994, Cheresh published a paper showing that he could inhibit the growth of blood vessels to tumors by blocking a specific integrin. After that, Cheresh began collaborating with Merck on the brain-cancer drug.

Cheresh said he had no idea the peptides sent to him by Merck were covered by Burnham's patents. After the lawsuit was filed in 1996, Scripps obtained an injunction to keep his lab open, Cheresh said, and he was ordered not to work on the peptides.

"My reaction was shock and disbelief," Cheresh said. "A federal marshal served me with papers; I thought it was a gag."

"Obviously, there are two sides to the issue," said Cheresh, now a scientist at UC San Diego. "Hopefully, there will be some closure on it."

Supreme Court Expansion Of Bolar Amendment Would Hurt Research - Universities

The Washington Fax
April 20, 2005

The Supreme Court will hear oral arguments April 20 in a case that could have wide-reaching effects on the research community, universities and research groups argue in an amicus brief.

The brief was submitted in connection with a patent dispute between Merck KGaA and Integra Lifesciences. At issue in the case is the breadth of section 271(e)(1) - commonly known as the Bolar Amendment - and what research it protects from patent infringement claims. (see Washington Fax 1/11/05a)

Merck KGaA is appealing a Federal Circuit Court of Appeals decision that the Bolar Amendment's "safe harbor" protections did not extend to the preclinical studies it sponsored. In June 2003, the appeals court had upheld a jury's verdict that Merck-sponsored research aimed at identifying drug candidates that would inhibit angiogenesis infringed Integra patents.

Under the Bolar Amendment, it is not considered infringement to make, use or sell a patent invention "solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs or veterinary biological products."

The case has received widespread attention from the pharmaceutical/biotech, intellectual property and research communities, with approximately 19 amicus briefs being filed with the high court.

The amici in the universities' brief include: the Wisconsin Alumni Research Foundation; the Regents of the University of California; the American Counsel on Education; Research Corporation Technologies; the Salk Institute for Biological Studies; Boston University; the University of Oklahoma; and the University of Alberta.

The groups argue that expanding the safe harbor section of the Bolar Amendment to include general pharmaceutical research would negate the value of research patents.

"Diminishing or eliminating the value of research patents owned by universities and university-related research institutions via the section 271(e)(1) safe harbor would thwart the...aims of the Bayh-Dole Act," which allows universities to patent federally funded inventions and license the technologies to companies for commercial development, they argue.

The effect would be to leave "universities without an effective means of protecting technology generated from their research efforts through the patent laws, and substantially [hinder] their ability to commercialize the results of such research," the brief argues.

The group also maintains that extending the safe harbor would likely force universities to follow the industry practice of protecting their discoveries as trade secrets instead of furthering the advancement of science by disseminating their research.

In addition, "effective patent protection ensures the continued ability to publish, and share with the public, such results," the brief states, noting that publishing is vital for advancement in academics.

"The proposed expansion of the safe harbor risks contravening express Congressional language and intent that section 271(e)(1) interfere only nominally with the rights of the patent holder," the brief concludes.

"Should the afore-described devaluation of drug research patents result from the urged expansion of the section 271 (e)(1) safe harbor, the result would be the impairment of the drug discovery process, as well as the frustration of the purpose of another section of the Patent Act, the Bayh-Dole Act," the brief adds.

NIH Delay In Implementing Ethics Rules Called For By Reps. Van Hollen, Davis

The Washington Fax
April 19, 2005

NIH conflict of interest rules should be suspended for 90 days in order to assess the impact the regulations will have on the agency, Reps. Chris Van Hollen (D-Md.) and Tom Davis (R-Va.) assert in an April 14 letter to NIH Director Elias Zerhouni, MD.

Van Hollen and Davis praise Zerhouni in the letter for his recent extension of the filing period for financial disclosure forms but maintain that the action does not address the central problems with the new interim rules. In March, NIH granted a blanket 90-day extension for submitting financial disclosure forms and exempted clinical research fellows from stock divestment requirements. (see Washington Fax 3/18/05b)

Van Hollen and Davis express particular concern that the rules will impact recruitment and retention of scientists. "We believe that the proposed regulations are overbroad and, unless refined, could dangerously undermine the mission of NIH," the congressmen state.

The representatives support certain parts of the new rules, the letter notes. The interim final CoI regulations, which went into effect Feb. 3, require many NIH employees to divest financial holdings over $15,000 in pharmaceutical and biotechnology companies. The rules also prohibit outside consulting and limit speaking arrangements.

The letter asks Zerhouni to immediately suspend the rules to "review and carefully consider the proposals offered by the Assembly of Scientists and other comments submitted in response to these regulations." Representatives from Van Hollen's office have been in touch with the organization's legal counsel, staff member Joan Kleinman said in an interview April 18.

The Assembly of Scientists represents NIH intramural researchers. They released alternative conflict of interest rules in March. (see Washington Fax 3/14/2005)

The NIH campus is located in Rep. Van Hollen's district. "Dozens" of letters from scientists and non-scientists have been received by the congressman's office, Kleinman said. "The overwhelming majority opposes the rules especially as they apply to the divestiture requirements," she stated.

The congressmen have asked that the 90-day suspension of the rules be effective immediately, Kleinman said.

Zerhouni told the Senate Appropriations/Labor-HHS Subcommittee April 6 that the stock divestiture rule may have a "deleterious impact" and are being reevaluated. (see Washington Fax 4/7/05)

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Sent: Friday, April 22, 2005 11:20 AM
To: Norman Latker
Subject: and the saga goes on

NIH Assembly Of Scientists Retain Law Firm To Contest Conflict Of Interest Rules

The Washington Fax
April 22, 2005

Arent Fox, a Washington, D.C.-based law firm, is seeking to change the HHS interim final conflict of interest rules on behalf of the NIH Assembly of Scientists, Arent Fox Chairman Marc Fleischaker said in an April 21 interview.

If discussions with NIH fail, the firm is prepared to litigate challenges. The current priority, however, is to find ways to soften the prohibitions outlined in the conflict of interest regulations, Fleischaker remarked.

Arent Fox filed a petition for review with the U.S. Circuit Court of Appeals for D.C. earlier in April because there was a 60-day time limit for filing.

The notification simply serves as a "place-holding" for potential legal proceedings, Assembly of Scientists member Steve Holland, MD, said in an interview.

Fleischaker said that his firm still is trying to determine whether or not to dismiss the petition, which he explained is not a "complaint" about the CoI regulations, but a "request" for the court to review them.

The Arent Fox chair declined to comment on how the assembly has paid for the firm's services.

The Assembly of Scientists, a group of intramural tenured and tenure-tracked agency scientists, protested the CoI rules when they were first issued Feb. 3, saying the prohibitions on financial holdings and stock ownership will negatively impact NIH's ability to recruit top-tier scientists. (see Washington Fax 3/4/05a)

The group's complaints apparently are not going unheard. At an April 6 Senate Appropriations subcommittee hearing, NIH Director Elias Zerhouni, MD, testified that the financial holding prohibitions may need to be reevaluated. (see Washington Fax 4/7/05)

Rep. Chris Van Hollen (D-Md.), a former Arent Fox partner, is requesting Zerhouni suspend implement-ation of the regulations for 90 days to better assess their impact on NIH.

Van Hollen sent his first letter to NIH about the CoI rules before Arent Fox was retained by the assembly, Fleischaker said. He also noted that his firm currently is not directly working with the Maryland congressman.

-- Andrew J. Hawkins

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Deafness Institute Director to Quit Over New NIH Rules

By GRETCHEN VOGEL AND JOCELYN KAISER
Science Now
March 31, 2005

The new conflict of interest rules at the National Institutes of Health (NIH) are driving one institute's director to leave. James Battey, director of the National Institute on Deafness and Other Communication Disorders, told Science today that he has informed NIH officials that he plans to quit before the rules' provisions concerning investments take effect this fall.

Battey says he is unable to comply with the new rules--which prohibit senior employees, their spouses, and dependent children from owning any biomedical stock--because of a family trust fund. "I manage it on behalf of my whole family, and I can't abandon that responsibility," he says.

Although Battey has not yet resigned, NIH officials have removed him from his post as chair of the NIH Stem Cell Task Force. Battey says that when he told officials that he was looking for jobs outside NIH, they decided his search would cause potential conflicts of interest with his role on the task force--set up in 2002 to coordinate and encourage stem cell research at NIH within the Bush administration's restrictions (Science, 7 March 2003, p. 1509). Indeed, the California native confirmed that he is "one of many candidates" for a top position at the California Institute for Regenerative Medicine, which will distribute the state's $3 billion Proposition 71 funding for stem cells and cloning.

Yesterday, the Washington Post reported that pulmonary researcher David Schwartz of Duke University in Chapel Hill, North Carolina, has said that the new rules were causing him to have second thoughts about taking the helm at the National Institute of Environmental Health Sciences (NIEHS) on April 11. NIH deputy director Raynard Kington confirmed that Schwartz recently sent a letter to NIH director Elias Zerhouni describing his concerns, particularly about the stock rule. Schwartz referred a reporter to NIH, but said in an e-mail that he still plans to come to NIEHS and is "confident that my concerns can be addressed."

Schwartz Still On Track To Take Over NIEHS, NIH Deputy Director Kington Says

By Shirley Haley
The Washington Fax
April 1, 2005

NIH is working through the first test case of its ability to recruit research superstars under rigorous new conflict of interest regulations the agency implemented Feb. 3.

Issues raised by David Schwartz, MD, who is in line to replace Ken Olden, PhD, as director of the National Institute of Environmental Health Sciences, are being resolved, an agency official said.

"It's always a complicated process recruiting senior employees [and] this was a little bit more complicated than usual because the new regulations were implemented in the middle of his recruitment," NIH Deputy Director Raynard Kington, MD/PhD, explained in an interview.

Schwartz raised concerns about the regulations in a letter to NIH Director Elias Zerhouni, MD.

"We will try to respond as quickly as possible and try to do the things we have to do...to maintain the public's trust while retaining our ability to recruit and retain the best scientists. And we think [Schwartz] is one of the best scientists out there," Kington said.

The NIH deputy director declined to go into detail about the specific issues raised by Schwartz, commenting only that NIH "has every expectation that he will assume the position of NIEHS director." Schwartz was tentatively set to take over at NIEHS April 11.

When contacted at Duke University, where he currently is director of the Pulmonary, Allergy and Critical Care Division and vice chair of research in the Department of Medicine, Schwartz deferred comment to NIH.

Acknowledging NIH is "going through a difficult transition stage," as it implements the "complicated" new regulations, Kington nevertheless defended the new level of oversight. "We did have conflict of interest" not just the perception of conflict, and we have an obligation to the public to be an unimpeachable source of information, he stressed.

Kington said the agency is striving to implement the regulations in a way that is "reasonable and fair" while also serving the public by recruiting and retaining the best scientists on its behalf.

HHS made a commitment from the beginning in the preamble to the new regulations that "within a year there would be a review of particularly the outside consulting and the prohibited holdings components of the regulations," he said. (see Washington Fax 2/2/05)

Adjustments already have been made within the confines of the current interim final rule, Kington pointed out. On March 15, a memo went out from the NIH deputy director's office announcing a blanket extension on reporting and divesting prohibited financial holdings and that research fellows would be exempt from the prohibited holdings rules. (see Washington Fax 3/18/05b)

Kington said Schwartz plans to move his lab and ongoing research to the NIEHS campus in Research Triangle Park, N.C., which means his scientific team also must make the adjustment from "the extramural world to an intramural setting."

It is not unusual for a senior-level recruit who has an existing lab at a university to want to maintain an active role as a scientist, Kington said. "Many people find that's essential for keeping up with science."

NIEHS' FY 2005 appropriation was for $645 mil. The institute's FY 2006 request is for $648 mil. Along with NIEHS, Schwartz is slated to assume leadership of the National Toxicology Program, which among other duties publishes the federal Report on Carcinogens.

Outside Evaluation Of NIH Conflict Of Interest Reg Impact Called For By FASEB

By Andrew J. Hawkins
The Washington Fax
April 1, 2005

An agency-wide, independently conducted evaluation of the impact of the recently implemented NIH conflict of interest regulations is recommended by the Federation of American Societies for Experimental Biology.

In comments to the HHS Office of General Counsel on the interim final rule published in the Feb. 3 Federal Register, FASEB President Paul Kincade, PhD, urges the office to conduct an analysis of NIH hiring and retention in the wake of the rules that prohibit outside activities with industry and most financial holdings in drug and biotechnology companies.

"The implementation of the rule without due process has had immediate negative effects on the agency and its scientists," Kincade contends. "The final regulations should be carefully considered and rigorously monitored to assess both negative and positive consequences."

FASEB worries that far-reaching repercussions of the CoI rules will affect NIH's ability to remain competitive in the market for biomedical talent, a concern that was echoed by intramural scientists at a February NIH town hall meeting. (see Washington Fax 2/3/05)

In addition to analyzing the regulation's effects on recruitment and retention, Kincade suggests the agency adhere to a NIH Blue Ribbon Panel on Conflict of Interest Policies recommendation to publish an "annual agency-wide statistical report of the number and types of outside activities approved for its employees." (see Washington Fax 5/7/04)

FASEB's other recommendations for changes in the regulations mirror those of the NIH Assembly of Scientists, whose alternative CoI rules propose lifting restrictions on owning stock for most employees. (see Washington Fax 3/14/05)

The CoI regulations are not appropriately aligned with risk of conflict and therefore fail to protect the integrity of NIH, Kincade maintains. "The provisions limit, without corresponding gain in protection from conflicts of interest, the ability of NIH scientists to engage in critically important teaching and professional activity."

FASEB is the largest coalition of biomedical research associations in the U.S., and a prime constituency is NIH scientists. Over 1,000 agency employees are members of FASEB, Kincade notes.

The CoI regulations, which went into effect Feb. 3, require all NIH employees to divest stock and financial holdings in biomedical companies, although non-senior employees are allowed a $15,000 investment cap. NIH recently granted a blanket extension for divestitures, allowing employees until July to submit financial disclosure reports. The agency also exempted clinical fellows and trainees from the regulations. (see Washington Fax 2/2/05, 3/18/05b)

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From: Latker, Carole (NIH/NIGMS) [LATKERC@nigms.nih.gov]
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May be some hope

NIH Conflict Of Interest Rules "Over-Regulate" Employees, AAMC Says

The Washington Fax
April 4, 2005

The HHS interim final conflict of interest regulations, directly largely at employees of NIH, create "sharp restrictions and absolute prohibitions" that amount to an overly regulated environment for researchers and scientists, the Association of American Medical Colleges charges March 31.

In the group's comments on the supplemental ethics rules, formally titled "Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services," AAMC President Jordan Cohen, MD, criticizes the department for extending the restrictions throughout the ranks of NIH employees without focusing on those positions that have influence over agency decisions, programs and activities.

AAMC, which represents 126 medical schools and 94 academic and professional societies representing 109,000 faculty members, "strongly endorses the responsible regulation of NIH employees through the promulgation and effective enforcement of unambiguous ethical standards." The HHS interim rules, however, do not meet these standards, Cohen asserts.

"Necessary efforts to avoid conflicts of interest must not prevent NIH scientists from engaging in legitimate activities that are beneficial to the scientists, NIH, biomedical science and the broader public, when the activities are not realistically associated with risk of conflicts of interest," Cohen maintains.

"Rank and file" employees should not be subject to the same rules prohibiting financial interests. Instead, these employees and others who are not in policy-making positions should be subject to modified regulations more proportionate to their risk, Cohen says.

The ethics regulations went into effect Feb. 3. NIH employees recently were granted a blanket extension on the deadline to submit their financial disclosure reports and divest financial interests in biotechnology or drug firms. (see Washington Fax 2/2/05, 3/18/05b)

AAMC suggests tailoring the regulations restricting outside relations and financial interests to the different roles employees of NIH fill. Modifying the rules to accommodate better the diversity of NIH employees would lift some of the burdens on those in less influential positions, Cohen states.

Amending the rules to allow NIH employees to engage in outside activities on behalf of academic and professional societies also should be considered, Cohen recommends. AAMC suggests exempting "single presentations by guest lecturers" from the list of prohibited activities. Currently, only multiple lectures that are part of an established curriculum are exempted.

AAMC's comments were not entirely critical of the interim rules. The organization applauds NIH for quickly taking steps to evaluate the impact of the interim rules on its ability to recruit and retain top-tier scientists.

"We encourage NIH to move forward with a plan to evaluate effects on hiring, retention, quality of science and technology transfer resulting from the interim standards," Cohen declares. "HHS and NIH must take action promptly to interdict negative effects by appropriate modifications of the interim rules over both the short- and longer-terms."

AAMC is not alone in its dissatisfaction with the conflict of interest regulations. The Federation of American Societies for Experimental Biology issued comments on the interim rules that in many ways mirror those submitted by AAMC. (see Washington Fax 4/1/05a)

Like FASEB, AAMC urges the agency to carefully consider all comments received on the interim rules to ensure appropriate revisions and "diligent implementation."

-- Andrew J. Hawkins

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He is getting lots of flack.

NIH Considers Relaxing Ethics Standards to Retain Scientists

BERNARD WYSOCKI JR. Staff Reporter of THE WALL STREET JOURNAL
The Wall Street Journal; Page A4
April 8, 2005

WASHINGTON -- The director of the National Institutes of Health, facing defections of senior scientists over tough new ethics standards, is considering softening the most onerous rules. Elias Zerhouni, testifying before a Senate subcommittee this week, said restrictions on stock ownership have alienated NIH employees, led to the resignations of high-level administrators and delayed the appointment of a new NIH official. The rules, announced in February, would prohibit or restrict NIH employees from holding stock in drug or medical companies, forcing them to divest.

"That part of the rule, frankly, is the one I think we need to re-evaluate very quickly," Dr. Zerhouni told the Senate panel. He said Health and Human Services Secretary Mike Leavitt had agreed to delay putting that part of the ethics guidelines into effect. Dr. Zerhouni said he is in active talks with HHS on the issue.

Dr. Zerhouni's softening stance was cheered by a group of NIH scientists who have been rallying support within NIH for a revision of the rules. "We're thrilled" by the latest turn of events, said Cynthia Dunbar, one of the leaders of the group, called the Assembly of Scientists.

In his testimony, Dr. Zerhouni reiterated his strong support for the new rules' ban on consulting with any drug, biotech or medical devices company, or any institution that does substantial business with NIH. The ban covers all 18,000 NIH employees.

The new rules were announced after disclosures in late 2003 and 2004 that some NIH scientists and administrators enjoyed lucrative consulting arrangements with industry, or accepted honoraria. Embarrassed and seeking to restore the agency's image as a bastion of integrity and the crown jewel of U.S. research, Dr. Zerhouni proposed increasingly tough rules.

The standards announced in February, however, were tougher and more sweeping than earlier versions, and were crafted in part by HHS and the Office of Government Ethics, which oversees ethics in the executive branch.

Yesterday Dr. Zerhouni faced a far more sympathetic group of lawmakers, several of whom thought the rules went too far. Among them were Sens. Arlen Specter (R., Pa.) a longtime NIH backer, and Tom Harkin (D., Iowa). At one point in the hearing, Sen. Harkin said to Dr. Zerhouni, "I think you're doing a great job in leading the institution, but I must chastise you. These are too onerous. They've got to be redone, and they've got to be redone soon, before you start losing more people out of there."

Carole

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Norman Latker

From: Latker, Carole (NIH/NIGMS) [LATKERC@nigms.nih.gov]
Sent: Thursday, April 21, 2005 4:30 PM
To: Norman Latker
Subject: all the chatter, but no results

Pressure Is Building on NIH to Reconsider Conflict Rules

By Rick Weiss
The Washington Post
Sunday, April 17, 2005

Two members of Congress have asked National Institutes of Health Director Elias A. Zerhouni to delay for 90 days the implementation of controversial new rules that aim to minimize conflicts of interest among NIH scientists.

The request to place the pending rules on hold, faxed to Zerhouni late last week by Reps. Chris Van Hollen (D-Md.) and Thomas M. Davis III (R-Va.), echoes a similar bipartisan call by senators who recently told Zerhouni that the proposed rules, while well intentioned, "go overboard."

The letter arrived as yet another prominent NIH scientist let it be known he would resign: Arthur J. Atkinson Jr., a clinical pharmacologist who advises the director of the agency's newly expanded $635 million clinical research center. Atkinson, 67, had been considering retirement, but the looming rule changes precipitated his decision, sources said.

Among other changes, the new rules will require thousands of NIH employees and their spouses to divest all stock holdings in medical and biotechnology companies -- a move that many employees have said will place them in serious economic jeopardy, especially given the market's current slump.

"Our concern centers around the likelihood that the regulations in their current form will seriously erode the ability to recruit and retain scientists and medical professionals," wrote Davis and Van Hollen, whose Maryland district includes the NIH's Bethesda campus. "We urge you to immediately suspend the new regulations for 90 days until you have had time to fully assess the impact these regulations will have on NIH."

Zerhouni announced the new rules in February after learning that some NIH scientists had not properly disclosed consulting arrangements with drug and biotechnology companies. The changes were negotiated with the Department of Health and Human Services and the Office of Government Ethics.

The new rules ban all biomedical company consulting; severely restrict other paid and unpaid outside professional activities; and place strict limits on -- and, for thousands of employees, totally ban -- ownership of biomedical company stocks.

Last week, in an e-mail that drew a fresh round of groans from NIH scientists, some research leaders were advised to file formal "outside activity" requests for every scientific journal for which they occasionally review article submissions -- a routine, unpaid professional activity not previously subject to oversight.

The stock rules, which have been most divisive, were delayed for 90 days in early April by HHS Secretary Mike Leavitt and are now set to take effect July 3.

A handful of scientists, including one institute director, have already said they will depart because of the new rules. A Duke University researcher selected last fall to direct the agency's environmental science institute also recently told Zerhouni he was reconsidering that appointment, which was to begin this month, in light of the changes.

On April 6, the two ranking members of the Senate Appropriations Subcommittee on Labor, Health, Human Services and Education -- Sens. Arlen Specter (R-Pa.) and Tom Harkin (D-Iowa) -- criticized Zerhouni about the changes.

"These are too onerous. They've got to be redone, and they've got to be redone soon before you start losing more people out of there," Harkin said to Zerhouni after relating a story of an NIH scientist who was leaving the agency because the divestiture rule would gut the nest egg she'd saved for her retirement and for her child's college education. "I mean, sometimes we tend to see a conflict of interest and we go overboard," Harkin said, "and I think we've gone overboard here."

Zerhouni has recently begun to emphasize in his comments that he is not personally responsible or even supportive of the divestiture rules, which are virtually the same as those in place for regulatory scientists at the Food and Drug Administration. "I'm as concerned as you are," he told Harkin at the hearing. "That part of the rule, frankly, is the one that I think we need to reevaluate very quickly."

In a brief interview yesterday, Zerhouni said the rule changes are still "a work in progress" and noted that "nobody has been asked to divest anything yet." He said Leavitt has been "very responsive and is very concerned that we end up with a fair and balanced rule that protects the public trust while not creating an undue burden on our employees."

Atkinson, the latest to depart from NIH, could not be reached for comment yesterday. In addition to his advisory duties at the clinical center, he has been serving as director of the clinical pharmacology research associate training program -- a role that won him plaudits from PhDs for his teaching abilities.

In 2000, he was named a "master" in clinical pharmacology by the American College of Physicians-American Society of Internal Medicine, "for his distinguished contributions to internal medicine." In 2003, he was the recipient of a distinguished service award from the American Society for Clinical Pharmacology and Therapeutics, of which he once served as president.

Staff researcher Meg Smith contributed to this report

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From: Latker, Carole (NIH/NIGMS) [LATKERC@nigms.nih.gov]
Sent: Friday, May 13, 2005 10:58 AM
To: Norman Latker
Subject: FYI

HHS Conflict Of Interest Regulations May Go Against Earlier Tech Transfer Laws

The Washington Fax
May 13, 2005

Conflict of Interest regulations at issue now at the National Institutes of Health are at the very least in violation of the intent and spirit of the 1986 Federal Technology Transfer Act, if not the law itself, maintains Norman Latker, a chief drafter of the legislation.

Latker was the agency's first patent counsel in the early 1960s. He then became the Patent Counsel for the Department of Health, Education and Welfare, as the Department of Health and Human Services was then known. In 1980, he became director of Federal Technology Policy; his office was then located in the Department of Commerce.

In a interview, Latker cited as one possible HHS violation of the Tech Transfer Act (PL 99-502) taking the hands-on decision making, oversight and enforcement of the ethics regulations away from the level of NIH administrators and moving it to the department level or, higher, to the Office of Government Ethics. (see Washington Fax 4/20/05)

The April 10, 1987 Executive Order (#12591) implementing the act directs the heads of executive departments and agencies to delegate authority to their government-owned, government-operated federal laboratories to "enter into cooperative research and development agreements" with other entities, including universities and private industry, and apparently delegates the authority to carry out all the business those agreements would entail, Latker explained.

On the level of individual conflicts, Latker said that under Section 12 of the law, oversight clearly is the responsibility of the agency, which, according to the law, "shall review employee standards of conduct for resolving potential conflict of interests to make sure they adequately establish guidelines for situations likely to arise through the use of the authority."

Latker argues that "it was not the employees at fault, but rather the NIH management was at fault" in the events that precipitated the current crackdown. NIH had neither "adequate processes and procedures, nor review committees and other safeguards in place to avoid conflict of interest situations."

He made it clear he was addressing only those CoI regulations that relate to consulting arrangements between industry and NIH investigators where the effort is to attempt to further capitalize on an investigator's NIH research.

In a 2004 interview, NIH Deputy Director for Intramural Research Michael Gottesman spoke of the importance of those "cross-fertilizing" interactions to scientific productivity and progress. (see Washington Fax 6/21/04)

It is the responsibility of government scientists and engineers under the law to engage in technology transfer, Latker stressed. Under Section 4, "Utilization of federal Technology,' (2), the law states, "Technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional."

Further, under the law, their advancement should depend on how well they carry out that responsibility. "Under (3), each laboratory director shall ensure that efforts to transfer technology are considered positively in laboratory job descriptions, employee promotion policies and evaluation of the job performance of scientists and engineers in the laboratory."

Relating to the point in the current CoI discussion that it is a violation of a criminal statue for an employee to receive payment for activities directly related to what they are being paid to do by the federal government, Latker insists that is "just not true." In fact, their tech transfer activities should be rewarded.

He referred Washington Fax to the act's implementing law, 15 USC 3710b Sec 13, on "Rewards for Scientific, Engineering, and Technical Personnel of Federal Agencies."

There it states that the heads of federal agencies with government-operated laboratories that spend more than $50 million per fiscal year on research and development "shall use the appropriate statutory authority to develop and implement a cash award program to reward its scientific, engineering, and technical personnel for:

(1) inventions, innovations, or other outstanding scientific or technological contributions of value to the United States due to commercial application or due to contributions to missions of the Federal agency or the Federal government, or

(2) exemplary activities that promote the domestic transfer of science and technology development within the

Federal Government and result in utilization of such science and technology by American industry or business, universities, State or local governments, or other non-Federal parties."

"It is obvious that if the government is entering into technology transfer relationships, that consulting by the employee/innovator of the technology must be involved. It would be necessary to the arrangement that the employee/innovator should be compensated for their efforts in commercializing the technology," Latker said.

"The Technology Transfer Act recognizes the need to compensate the employee/innovator under its Enumerated Authority section, which reads '(4) to the extent consistent with any applicable agency requirements and standards of conduct, permit employees or former employees of the laboratory to participate in efforts to commercialize inventions they made while in the service of the united States," he argued.

If royalty income to the agency is involved, 15 USC 3710c calls for federal agencies to pay at least 15% off the top of any agreement to the inventor or inventors, again, in effect, providing payment to employees for their work beyond their salaries.

"There is nothing in the act that would preclude the employee/innovator from being compensated for involvement in the commercialization of his efforts, including consulting arrangements," Latker asserted.

Latker said that in his view the current approach to NIH employee consulting arrangements throws technology transfer "back 35 years to a program that didn't work and had to be corrected."

Latker said, "In the 70s it became clear, to the Congress especially, that despite the money they were putting into research and development, technology was not being transferred to the good of the public. The transfer of technology was going nowhere."

"There were requests from off of the Hill [asking Congress] 'what are you doing to assure that this R&D money is going to benefit the public?" Congress then asked the federal agencies what they were doing to transfer technology to the public good, Latker explained.

"The agency would then come back and say, 'There were 5,000 different publications of what investigators were doing and a couple of speeches here and there.' This was how the agencies responded to questions about transferring technology."

Latker said that "Congress next said, 'We are disappointed in this kind of report. We aren't interested in publications. We want to know what you are specifically doing with all this R&D spending to benefit the public."

At that time, Latker was at NIH. He said, "To me a lot of failure was due to scientists back then who preferred to perform in an ivory tower environment. And there will always be scientists who prefer this situation. They just want to be paid to do their research and make their publications."

"But" Latker said, "there is an extraordinary amount of evidence that this kind of effort doesn't bring results to the marketplace. It is the inner relationships between [NIH researchers and industry] that does bring the results to the marketplace."

Latker lamented, "I spent my whole professional life developing this stuff and to see an Administration come in 35 years after the fact, especially a Republican Administration that you would think would have enough sense to understand the relationships that are necessary to bring technology to the marketplace... How in the world they ever got down this path is almost beyond me. But I do know it was the articles in the Los Angeles Times."

"I read those Los Angeles Times articles, and to my mind they were mean spirited in the sense they never mentioned the benefits that emerged from all this stuff. And, they found a few extreme problems. But the other ones were basically complaining about the fact that a person earned money. Further, pursuing something in my mind is not a conflict because in technology transfer that is what you would want the person to do."

Allegations of improper ties between NIH researchers and industry leveled by the L.A. Times led Director Elias Zerhouni, MD, to convene a blue ribbon panel to reexamine the agency's ethics rules. (see Washington Fax 12/10/03)

The articles focused on scientists who, while ranking officials at NIH, allegedly collected consulting fees and stock options from biomedical companies. The arrangements reportedly were kept from the public.

It was the incentives given by technology transfer laws to the science and engineering people that made technology transfer work. It was the passage of the Bay-Dole Act in 1980, the Technology Transfer Act of 1986 and several others that got rid of the terrible problem stopping technology transfer in the 1960s and 1970s, Latker said.

What should happen next to resolve the NIH CoI issue? Latker said, "For more than three decades the university community and private industry have worked well in transferring technology. Find out what they are doing and do it."

-- Bradie Metheny

Carole

5.13.05

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March 7, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse on
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Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036

Dear April:

This material responds to AAU's request for information dated January 10, 1984. We are pleased to provide AAU with information on UCLA's policies and practices with industry. In an effort to expedite Clearinghouse analysis of our response, we have screened policy documents and other materials to provide excerpts relevant to the initial two areas under study. However, if any of the documents referenced are desired in their entirety, we will gladly provide them.

The enclosed materials constitute the majority of our written policy information in each area. Since these enclosures do not specifically discuss practices or experiences illustrated by the hypothetical situations described, some additional information related to the two areas under study may be useful.

Conflict of Interest

In May of 1982, new policies were implemented by the University in compliance with regulations of the California Fair Political Practices Commission. The full nature of the policy and its implementation should be evident from material enclosed.

An Independent Substantive Review Committee ("ISRC") formed in accordance with FPPC regulations has functioned for nearly two years to review the propriety of the University's acceptance of grants, contracts, or gifts, from non-governmental entities in which the principal investigator has a financial interest. We have had a few situations similar to the hypothetical situation described and information on the resolution of two of them may be helpful to other Universities.

Over the past two years, approximately 3% of disclosures of financial interests were "positive" and were therefore reviewed by the ISRC. Only in one case, did the ISRC recommend that an ongoing project be ended because the agreement and the conduct of the work was inconsistent with the University's policies dealing with conflict of interest. The letters enclosed dated March 4, 1983 and March 31, 1983 convey in detail, the reasons for the Committee's recommendations and the final determination in the matter. The correspondence has, however, been modified to eliminate identification of the faculty member and the company.

I will summarize a second situation which may also be of interest. A faculty member had disclosed a consulting agreement with the company under which he was to receive a consulting fee of $10,000 per year, $12,000 per year for any renewal periods, and under which he had also received an option to acquire 5,000 shares of company stock at a specified price per share. A research agreement was proposed between the company and the University for support of a project in the faculty member's University laboratory.

In this case, the ISRC found that the research agreement did not pose a conflict of interest and that the faculty member's acceptance of a consulting fee also did not constitute a conflict of interest. The fee was determined to be consideration for services provided by the faculty member and such service was distinct from the work proposed under the research agreement. The ISRC further found that the stock option did not constitute a conflict of interest, but was consideration for the consulting services provided by the faculty and therefore no different in principle from a cash payment. The ISRC found no evidence that the faculty's financial interest in the company would cause him to use University resources to further his own financial interests rather than to engage in impartial research for expanding scientific knowledge.

In the course of ISRC review of this case, however, the consulting agreement between the company and the faculty member was examined and found to contain some provisions which were contrary to University policy (particularly in regard to intellectual property) and were also in conflict with the research agreement. Accordingly, the University requested, and the company and the faculty member agreed, to revise their agreement to bring it into conformance with University policy and to make it consistent with the research agreement. University officers participated in redrafting a new consulting agreement to assure consistency with University policy.

One last matter should be noted regarding requested information in this area. Our policies do not require University review, approval, or retention of individual faculty contracts for consulting with outside entities. The one situation described above was atypical. Accordingly, no individual consulting agreements with industry are provided.

Publication Delay

In our experience, the freedom to publish has never been an issue which, by itself, has prevented any agreement with industry. Most firms we have worked with can, and do, accept the basic tenet of openness and the right of publication by the University.

Duke University
DURHAM
NORTH CAROLINA
27706

Office of the University Counsel

TELEPHONE 919-684-3955

May 25, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse on
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Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036

Dear Ms. Burke:

I am writing in response to Robert Rosenzweig's letter to President Terry Sanford, dated March 20, 1984. In that letter and the attached request memorandum we were asked to provide information concerning Duke University's activities with industrial sponsors of research. The two particular areas of interest were (a) conflict of interest and (b) delay of publication. Our policies and practices in these areas are as follows:

CONFLICT OF INTEREST

Duke has two specific conflict of interest policies in effect, both of which are discussed and set forth in the University's Faculty Handbook. A general discussion of the policies is included in that section of the Handbook dealing with "Professional Affairs of the Faculty." A copy of that discussion is attached to this letter at Index Tab 1. The policies themselves address two different concerns. The first policy is the Joint Statement of the American Council on Education and the Council of the American Association of University Professors on Preventing Conflict of Interest in Government- Sponsored Research, a copy of which is attached at Index Tab 2. This policy focuses primarily on problems that may develop as a result of faculty members' outside financial or consulting interests as they relate to their participation in government-sponsored University research.

The second policy, a copy of which is attached at Index Tab 3, focuses on contractual relationships between the University and outside business interests in which faculty or staff members, or members of their families, are associated. For example, several members of our faculty have established computer supply or service businesses as family enterprises. Should these businesses contemplate selling goods or services to the University, this policy would apply.

In addition to these two policies, it should be noted that the general discussion of Consulting Activities and Conflicts of Interests at Index Tab 1, in its last paragraph, requires that faculty and administrative staff engaged in consulting report their activities to the Provost or the Vice President (now Chancellor) for Health Affairs with a copy to the appropriate department chairman. Thus, while the consulting conflict

of interest policy set forth at Index Tab 2 is limited to conflicts of interest in government-sponsored research, this general reporting requirement applies across the board and serves as some protection against conflicts of interest in industry-sponsored research.

DELAY OF PUBLICATION

While Duke does not have a specific written policy on delaying publication at the request of an industrial sponsor, we do try to adhere to a maximum three month guideline designed to allow the appropriate implementation of legal protection for proprietary information. This three month guideline is based on analogous provisions in the University's "Policy on Inventions, Patents and Technology Transfer," published in the Faculty Handbook a copy of which is attached at Index Tab 4. Under Section V.C. of that policy (Index Tab 5), "Inventions resulting from research or other work conducted by University employees in whole or in part on University time or with significant use of University funds or facilities shall be considered the property of the University." In order to both protect the University's interests under this section, and to assist our researchers in protecting their own interests, we have included two items in the policy. The first is an informational statement included as Article VII as follows:

> "Inventors shall be aware that publication prior to the filing of a U.S. Patent Application is a bar to the grant of certain foreign patents and can bar the grant of a U.S. patent if it occurred a year earlier than the filing date." (Index Tab 6)

The second item is an interpretation of this Article VII statement (Index Tab 7), which grants the University the right to delay publication for a short period of time in order to perfect patent rights. In no event will this delay be longer than three months.

Based on the fact that the University itself cannot ask an inventor to delay publication more than three months, we do not feel that an industrial sponsor should be able to obtain a longer delay. While we zealously protect the right to publish in all of our agreements, we feel that this three month period is a reasonable compromise. In order to demonstrate how this has worked in practice, we have attached a copy of a publication clause from one of our recent agreements as Index Tab 8.

We hope that this material will prove helpful to you. If you have any questions, or if we can do anything further to assist, please contact us at your convenience.

Very truly yours,

Ralph McCaughan

Ralph McCaughan
Associate University Counsel

MNW:mem

1 2 3 4 5 6 7 8

Appendix O
Preventing Conflicts of Interest in Government-Sponsored Research at Universities

A Joint Statement of The Council of the American Association of University Professors and The American Council on Education

The increasingly necessary and complex relationships among universities, government, and industry call for more intensive attention to standards of procedure and conduct in government-sponsored research. The clarification and application of such standards must be designed to serve the purposes and needs of the projects and the public interest involved in them and to protect the integrity of the cooperating institutions as agencies of higher education.

The government and institutions of higher education, as the contracting parties, have an obligation to see that adequate standards and procedures are developed and applied; to inform one another of their respective requirements; and to assure that all individuals participating on their respective behalfs are informed of and apply the standards and procedures that are so developed.

Consulting relationships between university staff members and industry serve the interests of research and education in the university. Likewise, the transfer of technical knowledge and skill from the university to industry contributes to technological advance. Such relationships are desirable, but certain potential hazards should be recognized.

I. Conflict Situations

A. Favoring of Outside Interests. When a university staff member (administrator, faculty member, professional staff member, or employee) undertaking or engaging in government-sponsored work has a significant financial interest in or a consulting arrangement with a private business concern, it is important to avoid actual or apparent conflicts of interest between his government-sponsored university research obligations and his outside interests and other obligations. Situations in or from which conflicts of interest may arise are the:

1. Undertaking or orientation of the staff member's university research to serve the research or other needs of the private firm without disclosure of such undertaking or orientation to the university and to the sponsoring agency;
2. Purchase of major equipment, instruments, materials, or other items for university research from the private firm in which the staff member has the interest without disclosure of such interest;
3. Transmission to the private firm or other use for personal gain of government-sponsored work products, results, materials, records, or information that are not made generally available (this would not necessarily preclude appropriate licensing arrangements for inventions, or consulting on the basis of government-sponsored research results where there is significant additional work by the staff member independent of his government-sponsored research);
4. Use for personal gain or other unauthorized use of privileged information acquired in connection with the staff member's government-sponsored activities. (The term *privileged information* includes, but is not limited to, medical, personnel, or security records of individuals; anticipated material requirements or price actions; possible new sites for government operations; and knowledge of forthcoming programs or of selection of contractors or subcontractors in advance of official announcements);
5. Negotiation or influence upon the negotiation of contracts relating to the staff member's government-sponsored research between the university and private organizations with which he has consulting or other significant relationships;
6. Acceptance of gratuities or special favors from private organizations with which the university does or may conduct business in connection with a government-sponsored research project, or extension of gratuities or special favors to employees of the sponsoring government agency, under circumstances which might reasonably be interpreted as an attempt to influence the recipients in the conduct of their duties.

B. Distribution of Effort. There are competing demands on the energies of a faculty member (for example, research, teaching, committee work, outside consulting). The way in which he divides his effort among these various functions does not raise ethical questions unless the government agency supporting his research is misled in its understanding of the amount of intellectual effort he is actually devoting to the research

in question. A system of precise time accounting is incompatible with the inherent character of the work of a faculty member, since the various functions he performs are closely interrelated and do not conform to any meaningful division of a standard work week. On the other hand, if the research agreement contemplates that a staff member will devote a certain fraction of his effort to the government-sponsored research, or he agrees to assume responsibility in relation to such research, a demonstrable relationship between the indicated effort or responsibility and the actual extent of his involvement is to be expected. Each university, therefore, should—through joint consultation of administration and faculty—develop procedures to assure that proposals are responsibly made and complied with.

C. Consulting for Government Agencies or Their Contractors. When the staff member engaged in government-sponsored research also serves as a consultant to a federal agency, his conduct is subject to the provisions of the Conflict of Interest Statutes (18 U.S.C. 202-209 as amended) and the President's memorandum of May 2, 1963, *Preventing Conflicts of Interest on the Part of Special Government Employees.* When he consults for one or more government contractors, or prospective contractors, in the same technical field as his research project, care must be taken to avoid giving advice that may be of questionable objectivity because of its possible bearing on his other interests. In undertaking and performing consulting services, he should make full disclosure of such interests to the university and to the contractor insofar as they may appear to relate to the work at the university or for the contractor. Conflict of interest problems could arise, for example, in the participation of a staff member of the university in an evaluation for the government agency or its contractor of some technical aspect of the work of another organization with which he has a consulting or employment relationship or a significant financial interest, or in an evaluation of a competitor to such other organization.

II. University Responsibility

Each university participating in government-sponsored research should make known to the sponsoring government agencies:

A. The steps it is taking to assure an understanding on the part of the university administration and staff members of the possible conflicts of interest or other problems that may develop in the foregoing types of situations, and

B. The organizational and administrative actions it has taken or is taking to avoid such problems, including:

1. Accounting procedures to be used to assure that government funds are expended for the purposes for which they have been provided, and that all services which are required in return for these funds are supplied;
2. Procedures that enable it to be aware of the outside professional work of staff members participating in government-sponsored research, if such outside work relates in any way to the government-sponsored research;
3. The formulation of standards to guide the individual university staff members in governing their conduct in relation to outside interests that raise questions of conflicts of interest; and
4. The provision within the university of an informed source of advice and guidance to its staff members for advance consultation on questions they wish to raise concerning the problems that may or do develop as a result of their outside financial or consulting interests, as they relate to their participation in government-sponsored university research. The university may wish to discuss such problems with the contracting officer or other appropriate government official in those cases that appear to raise questions regarding conflicts of interest.

The above process of disclosure and consultation is the obligation assumed by the university when it accepts government funds for research. The process must, of course, be carried out in a manner that does not infringe on the legitimate freedoms and flexibility of action of the university and its staff members that have traditionally characterized a university. It is desirable that standards and procedures of the kind discussed be formulated and administered by members of the university community themselves, through their joint initiative and responsibility, for it is they who are the best judges of the conditions which can most effectively stimulate the search for knowledge and preserve the requirements of academic freedom. Experience indicates that such standards and procedures should be developed and specified by joint administrative-faculty action.

INDIRECT COST RECOVERY ON GRANTS AND CONTRACTS FUNDED BY THE FEDERAL GOVERNMENT

Direct costs of federally sponsored grants and contracts include the salaries and wages of personnel working on these projects, the cost of supplies and materials they consume, and other expenses such as travel and equipment that are required for the projects undertaken. In addition to these direct costs, however, the University incurs a significant number of indirect costs which are required to support these projects. These indirect, or support, costs cannot be related precisely to any individual grant or contract in that they include such items as: (1) the cost of cleaning, heating, lighting, insuring, and maintaining the buildings in which the sponsored programs are carried out, (2) the administrative costs of the University as represented by such components as the Accounting Department, Personnel Department, Purchasing Department, etc., and (3) central support services and facilities such as the library.

The federal government recognizes its obligation to reimburse the University for these indirect expenses as well as the direct expenses that are incurred in our performance of these grants and contracts. This reimbursement is accomplished through the annual calculation of an indirect cost or overhead rate which is applied on a pro rata basis against certain direct costs charged to all such grants or contracts. Without this recovery significant amounts of University funds derived from tuition, endowment, and unrestricted gifts would have to be diverted from the support of other University needs. As a result, it is the University's policy to require the inclusion of full overhead recovery in all grant and contract applications. Deviation from this policy is not permitted without special approval as outlined in Duke General Accounting Procedure #162 (described above), a copy of which may be obtained upon request from the Office of Sponsored Programs.

PRIVATE SECTOR CONTRACTS

Contracts with private industries may include provisions that are contrary to University policy or put the University at risk. To protect against this principal investigators should contact the Office of the University Counsel or the Office of Sponsored Research before concluding a contract with the private sector.

PATENT POLICY AND PATENT AGREEMENT—INTERNAL AND EXTERNAL

The University has adopted a Patent, Invention, and Technology Transfer policy to encourage invention and to ensure that inventions developed at the University are utilized for the common good. All faculty members and other employees, and all students who work on research projects under University control, are expected to sign agreements incorporating the terms of the policy. The policy and agreement are attached as Appendix Q.

CONSULTING ACTIVITIES AND CONFLICTS OF INTEREST

The increasingly frequent and complex relationships between faculty members and the University, other universities, government, and industry require intensive attention to avoid actual or apparent conflicts of interest. In general, full disclosure of information concerning any potential conflict of interest is required. The University Counsel is available for advice as to whether a particular situation involves a conflict of interest and, if so, what the appropriate course of action would be.

Two specific conflict of interest policies are in effect, and they are attached to this *Handbook* as Appendices O and P. The first, the Joint Statement of the American Council on Education and the Council of the American Association of University Professors on Preventing Conflict of Interest in Government-Sponsored Research, focuses primarily on problems that may develop as a result of faculty members' outside financial or consulting interests as they relate to their participation in government-sponsored university research. In accordance with the provisions of the joint statement, at the time a faculty member initiates a new consulting assignment, he should inform the University of the nature of the activity in a letter addressed to his department chairman or, in divisions where there are no departments, to the appropriate dean, with a copy to the Provost or the Vice President for Health Affairs. The second policy focuses on proposed contractual relationships between the University and outside business interests in which faculty or staff members or members of their families are associated.

The distribution of a faculty member's effort among, for example, research, teaching, committee responsibilities, and outside consulting will not ordinarily raise problems of conflict of interest unless the University or the government is misled in its understanding of the amount of intellectual effort actually being devoted to the activity in question. Any faculty member planning to do research for the government under an agreement which contemplates that a specified fraction of his effort will be devoted to the research should check with the Office of Sponsored Research regarding procedures to ensure demonstrable compliance with the indicated requirements.

Faculty and senior administrative staff members may spend up to four days per month in outside activities or consulting work, averaged over an annual period of service (the academic year for faculty on a nine-month basis). Such activities are to be reported to the Provost or to the Vice President for Health Affairs, with a copy to the department chairman. Lectures or brief consulting activities to assist another educational institution need not be reported.

Appendix P
Conflict of Interest

1. University faculty or staff members, within existing policies concerning outside duties and interests which do not interfere with University responsibilities, may have outside business interests. These enterprises may have occasion to sell goods or services to the University, thus creating a conflict-of-interest situation.

2. The University requires prior information concerning any potential conflict of interest which may arise. A member of the faculty or staff must inform the University in the event of any proposed contractual arrangements between the University and any business association in which he or a member of his family is associated, with the exception of publicly held corporations in which his stock interest does not exceed 10 percent of the issued stock. Compliance with this rule would be effected by a letter from the staff member to the Vice President for Business and Finance indicating the extent of his interest and the proposed contractual relationship.

3. The faculty or staff member must not participate in the decision of whether the University should contract with the business association in which he or a member of his family has an interest. Failure to disclose ownership interests or engaging in improper dealings shall be grounds for disciplinary action.

4. Any contractual arrangement between the University and a faculty or staff member in which a conflict of interest, as defined above, exists shall be reviewed by the Conflict of Interest Committee. No contract may be consummated without the prior written approval of this committee, which is charged to determine that any such contract is in the best interest of the University.

5. The committee shall be composed of three members, with three alternates. One member and one alternate shall be named by the Vice President for Business and Finance. Two members and two alternates shall be named by the Executive Committee of the Academic Council; of these, one member and one alternate shall be chosen from the faculty of the Medical School, and one member and one alternate from the faculty outside the Medical Center. Each faculty member and his alternate shall be drawn from different departments.

6. In a review involving a departmental colleague, a member shall withdraw, substituting his alternate.

UNIVERSITY OF VIRGINIA
CHARLOTTESVILLE

OFFICE OF THE PRESIDENT

May 9, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036

Dear Ms. Burke:

I am delighted to respond to your request for information on issues in university-industry relations. This is an appropriate time for the AAU to be undertaking the effort. The attached document was prepared by Drs. Rodney L. Biltonen and William R. Wilkerson, and they may be contacted at the following address and phone number for additional information:

Office of Associate Provost
for Research
University of Virginia
Monroe Hill House
Charlottesville, Virginia 22903

804-924-3606.

Sincerely,

Frank L. Hereford, Jr.
President

FLH:lal

Enclosures

CC: Dr. Rodney L. Biltonen

UNIVERSITY OF VIRGINIA
CHARLOTTESVILLE
22903

ASSOCIATE PROVOST FOR RESEARCH
MONROE HILL HOUSE
(804) 924-3606

University of Virginia
Policies and Practices Regarding Conflict of Interest and Publications in University-Industry Relations

Conflict of Interest

The University of Virginia, as an agency of the Commonwealth, is subject to the state law regarding conflict of interest. The law was developed and is primarily intended to apply to situations under which the Commonwealth seeks bids on items it wishes to buy. The law is quite restrictive and inappropriate as the Commonwealth seeks to encourage high technological economic development. One of the sample situations you outlined would be illegal if it began after the effective date of the law (July 1, 1983). The law would preclude anyone who received compensation or owned more than 3% of a corporation from participating in negotiation of a contract between that corporation and the University. Thus, someone who was a consultant might be in difficulty if he also served as a principal investigator on a grant. The primary responsibility resides with the individual to interpret the law and his situation. University policies and procedures attempt to explain and simplify the situation to a certain extent. The law was modified by the General Assembly during this year's session and a draft revised University document is enclosed.

Publications

The University routinely approves (with the concurrence of the faculty involved) a ninety (90) day delay for patentability determination. A further ninety day delay would be acceptable while patent applications are filed. The University has considerable latitude in modifying these guidelines under special circumstances but they do constitute the usual framework for agreements.

TITLE: CONFLICT OF INTERESTS **POLICY: XV.A.**

NOTE: This policy applies to employment contracts, employment renewals, or other contracts entered into July 1, 1983 or later.

Employee Responsibilities

This policy has been established to ensure that each employee (faculty, staff and officer) is aware of his/her responsibilities when performing duties for the University. It is intended to incorporate and also supplement the requirements of the Comprehensive Conflict of Interests Act of the Code of Virginia § 2.1-599 through § 2.1-634, and the Virginia Public Procurement Act, Article 4, "Ethics in Public Contracting", Code of Virginia § 11-35. However, this policy does not restate those Acts verbatim; and employees who have questions about conflict of interests may wish to consult the Acts themselves. Copies are available in the Department of Materiel Management and the Office of the Legal Adviser.

Employees should disclose actual or potential conflict of interests and should not initiate any related contract or transaction to which the University is a party until approval is received from the University Comptroller.

See University Procedure 15-1.

EMPLOYEES SHOULD BE AWARE THAT FAILURE TO ABIDE BY THE TERMS OF THESE LAWS MAY MAKE THEM SUBJECT TO LEGAL PENALTIES, INCLUDING FORFEITURE OF EMPLOYMENT. THE LANGUAGE OF THESE ACTS IS COMPLEX, AND THE EMPLOYEE MAY NEED THE ASSISTANCE OF HIS/HER PERSONAL ATTORNEY.

Departmental Responsibilities

It is the responsibility of the dean/department head to investigate and report to the University Comptroller any potential conflict of interests affecting contracts or transactions to which the University is a party.

It is also the responsibility of the dean/department head to certify that a conflict of interests does not exist in employment situations having the appearance of conflict.

See University Procedure 15-2.

Definitions

"Official Responsibility" - Administrative or operating authority, whether intermediate or final, to initiate, approve, disapprove, or affect a procurement transaction or any resulting claim.

TITLE: CONFLICT OF INTERESTS **POLICY: XV.A.**

"Employment Activities" - The terms and conditions of employment, including salary, job description, term of employment, and performance evaluation. "Employment activities" do not include academic or scientific conduct of instruction or research. The instructor or principal investigator of a research project is responsible for the academic or scientific work and for technical leadership.

"Personal Interest" - A personal or financial benefit or liability of an employee or of his/her spouse, or of any relative who resides in the same household. Specifically, personal interest is defined as:

Ownership in real or personal property, tangible or intangible, of any value.

Ownership in a corporation, firm, partnership, or other business entity, exceeding three percent of the total equity.

Annual income from a corporation, firm, partnership or other business entity, and/or property or use of such property, exceeding $10,000 or expected to exceed $10,000, i.e., dividends, interest, rent, royalties, etc.

Personal liability on behalf of a corporation, firm, partnership or other business entity exceeding three percent of the entity's total assets.

"Contract" - Any agreement to which the University is a party, or an agreement between or on behalf of the University or any subdivision and a third party for payment from any University fund.

"Personal Interest in a Contract" - Being party to a contract or having a "personal interest" in the firm, corporation, partnership, or other business entity which is a party to the contract.

"Transaction" - Any matter considered by the University or one of its sub-divisions on which official action is taken or contemplated.

"Personal Interest in a Transaction" - Where an employee or his/her spouse, or other relative residing in the same household, has a "personal interest" in property, or in either a firm, corporation, partnership or business entity, or in one representing an entity, which is the subject of the transaction in question, or will benefit or suffer from the transaction.

"Specific Application Transaction" - A transaction affecting the personal interest of an employee. Specific application transactions do not affect the public in general, but general public transactions may include the personal interest of the employee.

"Immediate Family" - An employee's spouse, children, parents, brothers, sisters, and any person living in the same household as the employee.

Employment Restrictions

No employee of the University may control, or have authority to control, the employment contract or the employment activities of his/her spouse, or any other relative who lives in his/her household.

NOTE: Under the prior Conflict of Interests Act, an employee was permitted to supervise his/her spouse, as long as the spouse's salary did not exceed $10,000. If an employee entered into an employment contract before July 1, 1983, which entailed supervision by his/her spouse but was legal under the old Act, then that employment remains legal through the term of the contract, the new Act notwithstanding. When, on or after July 1, 1983, the term of the employment contract ends, supervision by a spouse becomes a violation regardless of the salary involved, and the contract may not be renewed.

See University Procedure 15-2.

Restrictions on Procurement Activities

No employee having official responsibility for a procurement transaction shall participate in the procurement when the employee knows that:

He/she is also employed by the bidder, offeror or contractor.

The employee, the employee's partner, or any member of the employee's "immediate family":

Holds a position with the bidder, offeror, or contractor.

Is employed by the bidder, offeror, or contractor in a capacity involving substantial participation in the procurement transaction.

Owns or controls an interest exceeding five percent of the bidder, offeror, or contractor.

Has a "personal interest" in the bidder, offeror, or contractor.

Is negotiating, or has an arrangement concerning prospective employment with the bidder, offeror, or contractor.

TITLE: CONFLICT OF INTERESTS **POLICY: XV.A.**

No employee or former employee having official responsibility for procurement transactions shall accept employment with any bidder, offeror or contractor with whom he/she has dealt in an official capacity concerning procurement transactions for a period of one year after termination of the employee's University employment.

Exception: An exception is allowed if the employee/former employee notifies his/her Vice President/former Vice President, the Assistant Vice President for Personnel Administration, and the Director of Materiel Management in writing before starting the new position.

Prohibited Conduct Regarding Contracts

No employee shall have a "personal interest in a contract" with:

The University other than one's own contract of employment.

Any other State Agency, unless the contract is awarded through a competitive process as defined by the Virginia Public Procurement Act.

Exceptions: An employee may have a "personal interest" in:

The regular employment contract of one's spouse or of one's relative living in the same household if the employee neither exercises control nor has authority to control the employment or employment activities of the spouse or relative.

One's own contract of employment with another State agency.

A University contract to sell goods or services at uniform prices to the general public.

The sale, lease, or exchange of real property between the employee and a State agency, if the employee does not participate in any way in the sale, lease or exchange, and such is stated as a matter of public record.*

University contracts involving the publishing of official notices.

Contracts between the University and a contracting firm when the employee, his/her spouse, or any relative residing in the same household receives income from that firm in excess of $10,000, BUT:

Neither participates in nor has authority to participate in the procurement or letting of the contract for the contracting firm, AND

TITLE: CONFLICT OF INTERESTS **POLICY: XV.A.**

Either does not have authority to particpate in the contract for the University, or disqualifies him/herself as a matter of public record and does not participate in the negotations or approval of the contract for the University.

Contracts between the University and public service corporations, financial institutions, or public utilities in which the employee has a "personal interest", if the employee disqualifies him/herself as a matter of public record and does not negotiate or approve the contract.*

Contracts purchasing goods or services when the contract does not exceed $500.

* NOTE: All employees with "personal interests in contracts" should disclose this fact as required and not initiate the contract to which the University is a party until approval is received from the University Comptroller.

See University Procedure 15-1.

Prohibited Conduct Regarding "Transactions"

Each employee shall disqualify him/herself from representing the University in a "transaction" when:

He/she has a "personal interest in the transaction", and the "transaction" has "specific application" to the employee.

In this situation, the employee will not vote or represent the University in the "transaction," and the University will record the disqualification in writing. Even after disqualifying oneself, the employee may still represent him/herself, one's spouse, or any relative in the "transaction." The employee must not be compensated for his/her representation and must comply with the disqualification and recording requirements above.

NOTE: All employees with "personal interests in transactions" should disclose this fact as required. See University Procedure 15-1.

If an employee's disqualification leaves less than the required number of persons needed to act on the "transaction," the remaining members will have authority to act by majority vote or unanimous vote of the remaining members, as required. If action is taken when these above conditions are not met, the University may rescind the action, as required.

TITLE: CONFLICT OF INTERESTS **POLICY: XV.A.**

NOTE: The above disqualifications and disclosures are in addition to the disclosure of economic interest required for certain positions designated by the Governor. The Department of Personnel Administration sends out the disclo sure form annually to select employees.

Solicitation and Acceptance of Gifts, Travel, etc.

An employee of the University shall not:

Solicit or accept money or other things of value, for services performed within the scope of his/her official duties except for compensation, expenses or other remuneration paid directly to him/her or approved for him/her by the University. This prohibition will not prohibit the acceptance of special benefits authorized by law.

Accept any money, gift, loan, advance, favor, special discount, or service of material value that might reasonably tend to influence him/her in the discharge of his/her duties.

Offer or accept money or anything of value for or in payment of employment, an appointment, a promotion, or a privilege with the University.

Accept a business or professional opportunity for financial benefit, if he/she knows or should know that the opportunity is offered to influence the discharge of his/her official duties.

Accept a business or personal trip paid for by a vendor, for any reason whatsoever, without first obtaining written approval from the executive director of the Hospital or the employee's Vice-President as applicable. SEE NOTES IMMEDIATELY BELOW.

NOTE: The Department of Materiel Management can arrange, through the procurement process, for vendors or potential vendors to pay for travel to inspect or be trained on new equipment. Such arrangements should be approved BEFORE Materiel Management issues the request for proposal or invitation to bid.

NOTE: If a department wants an employee to travel at a vendor's expense and the arrangements were not part of the procurement process, several measures should be taken. AT LEAST TWO WEEKS PRIOR TO THE TRAVEL, the department head should:

Request the Director of Materiel Management to issue an opinion to the applicable Vice-President(s) on the appropriateness of the vendor-paid travel.

TITLE: CONFLICT OF INTERESTS **POLICY: XV.A.**

Notify the applicable Vice-President(s) or Executive Director of the Hospital.

An employee having authority to conduct or influence the buying of goods or services for the University must not solicit or accept any gift, payment, loan or anything else, other than miscellaneous items bearing advertising, such as matches, calendars, rulers, note pads, or other items of nominal or minimal value from a bidder, offeror, contractor or subcontractor. This rule does not prohibit employees from buying goods or services, or obtaining loans, for their personal use where they pay equal consideration for the goods, services or loans; nor does it prohibit employees from accepting meals or beverages from vendors when offered to a large group of people at a trade show, exhibit or other professional meeting.

Other Restrictions:

An employee of the University shall not:

Use confidential information not available to the public and acquired through one's University position for one's own or another's economic benefit.

The University shall not:

Purchase building materials, supplies or equipment for a University building or structure from any independent contractor who is providing architectural or engineering (non-contruction) services to the University, or from any partnership, association or corporation in which the architect or engineer has a personal interest, except in cases of emergency.

Penalties and Remedies

Any employees who violates the provisions of the mentioned Acts is guilty of a misdemeanor, and may be fined up to $1,000 and sentenced up to a year in jail. Any employee may NOT be prosecuted if:

The employee made full disclosure of the facts, AND

The employee relied on a written opinion by the Attorney General stating his/her actions did not violate the Comprehensive Conflict of Interests Act.

TITLE: CONFLICT OF INTERESTS **POLICY: XV.A.**

If convicted for this violation, the employee shall, in addition to any other fine or penalty provided by law, forfeit his/her employment. In addition, any employee who violates the requirements of this policy may otherwise be disciplined by the University.

Any money or other thing of value derived from a violation of the above policies will be forfeited to the appropriate source of funds, i.e., State Treasurer, University Bursar, etc. If the money, etc., increased in value between the time of violation and the discovery of the violation, the greater value will be forfeited.

Any purchase made in violation of the above policies may be rescinded by the University within five years of the date of such purchase.

Any contract made in violation of the above policies may be declared void by the University within five years of the date of such contract. The contractor or subcontractor will retain or receive only the reasonable value, with no increment of profit or commission, of the property or services rendered prior to receiving notice the contract had been voided. In voiding contracts of sale, any refund will be made to the appropriate source of funds, i.e., State Treasurer, University Bursar, etc.

TITLE: PROVIDING NOTICE OF POSSIBLE CONFLICT OF INTERESTS

PROCEDURE: 15-1

Financial Policy Reference: XV.A.

Purpose

To provide a means of notification of an actual or potential conflict of interests affecting contracts or transactions to which the University is a party or in which the University's interests may be affected.

Background

The employee should address a letter to the appropriate department head covering the following points:

The nature of the employee's "personal interest" in the contract or transaction.

The employee's authority, if any, to participate in contracts or transactions on behalf of the University.

The measures taken to comply with State requirements for competitive procurement.

Any permissions or opinions obtained from the Attorney General.

A copy of the contract and other related documents in question should be attached.

NOTE: The Legal Adviser's Office is not authorized to give personal legal advice to employees; advice from the Legal Adviser's Office must relate to University legal issues. Therefore, an employee with an actual or potential conflict of interests should also consider contacting his/her personal attorney for advice.

Instructions

Process as indicated.

TITLE: PROVIDING NOTICE OF POSSIBLE CONFLICT OF INTERESTS **PROCEDURE: 15-1**

Responsibility	Action
Employee	1. Addresses a letter to his/her department head describing the situation and requesting approval for his/her participation.
	2. Forwards letter, a copy of any related contract or subcontract, and all supporting documents to the department head.
Department Head	3. Reviews material forwarded from employee.
	4. Endorses the employee's letter recommending approval or disapproval.
	5. Forwards all material:
	5a. If approval is recommended, to the University Comptroller.
	5b. If disapproved, to employee.
University Comptroller	6. Reviews material forwarded from department head.
	7. Contacts Legal Adviser if assistance is needed.
	8. Approves or disapproves.
	9. Notifies department head of action taken.
	10. Directs request packet to the appropriate office for filing in contract file, personnel file, etc.

TITLE: CERTIFICATION THAT NO CONFLICT OF INTEREST EXISTS

PROCEDURE: 15-2

Financial Policy Reference: XV.A.

Purpose

To provide certification that a conflict of interest does NOT exist in employment situations that have the appearance of a conflict.

Background

The University wishes to avoid the appearance of conflicts of interest in employment situations. If, however, the employment of spouses or relatives in the same department or unit is in the best interest of the institution and a conflict of interest will not exist, the department head should address a letter to the appropriate dean or vice president covering the following points:

That neither spouse nor any relative living in the same household:

Has exercised or will exercise any control over the employment of the other;

Has any control over, or is in a position to influence, the employment activities of the other, as such activities are defined in the University's Financial Policy XV.A; and

The employment is in the best interest of the University and the Commonwealth.

Prior to the offer or renewal of an employment contract, the certification request shall be reviewed by the dean and a recommendation for approval made to the appropriate vice president for final decision, with an information copy being sent to the University Comptroller.

Instructions

Process as indicated.

TITLE: CERTIFICATION THAT NO CONFLICT OF INTEREST EXISTS

PROCEDURE: 15-2

Responsibility	Action
Department Head	1. Addresses a letter to the dean concerning the points on page 15.1.1 and requesting approval of the appointment/offer or renewal.
	2. Forwards letter and copies of all supporting documents to the appropriate dean.
Dean	3. Reviews material forwarded by department head.
	4. Endorses letter recommending the appointment/offer or renewal.
	5. Forwards all material:
	5a. If approved to the Vice President.
	5b. If disapproved, to the department head.
Vice President	6. Reviews material forwarded from the Dean.
	7. Contacts Legal Adviser if assistance is needed.
	8. Approves or disapproves.
	9. Notifies dean and University Comptroller of action taken.

CHAPTER 196

An Act to amend and reenact § 2.1-608 of the Code of Virginia, relating to exceptions to the Virginia Comprehensive Conflict of Interests Act.

Signed by Governor on 3/12/84 [S 304]

Approved MAR 12 1984

Be it enacted by the General Assembly of Virginia:

1. That § 2.1-608 of the Code of Virginia is amended and reenacted as follows:

§ 2.1-608. Further exceptions.—A. The provisions of §§ 2.1-604 through 2.1-607 shall not apply to:

1. The sale, lease or exchange of real property between an officer or employee and a governmental agency, provided the officer or employee does not participate in any way as such officer or employee in such sale, lease or exchange, and this fact is set forth as a matter of public record by the governing body of such governmental agency or by the administrative head thereof; or

2. The publication of official notices; or

3. Contracts between the government or school board of a town or city with a population of less than 10,000 and an officer or employee of that town or city government or school board when the total of such contracts between the town or city government or school board and the officer or employee of that town or city government or school board or a business controlled by him does not exceed $10,000 per year or such amount exceeds $10,000 and is less than $25,000 but results from contracts arising from awards made on a sealed bid basis and such officer or employee has made disclosure as provided for in § 2.1-613; or

4. An officer or employee whose sole *personal* interest in a contract with the agency is by reason of ~~employment by~~ *income from* the contracting firm or governmental agency *in excess of $10,000 per year* , provided such officer or employee or his spouse, or other relative residing in the same household does not participate and has no authority to participate in the procurement or letting of such contract on behalf of the contracting firm and such officer or employee *either* does not have authority to participate in the procurement or letting of the contract on behalf of his agency *or he disqualifies himself as a matter of public record and does not participate on behalf of his governmental agency in negotiating the contract or in approving the contract* ; or

5. Contracts between an officer's or employee's governmental agency and a public service corporation, financial institution, or company furnishing public utilities in which the officer or employee has a personal interest, provided the officer or employee disqualifies himself as a matter of public record and does not participate on behalf of his governmental agency in negotiating the contract or in approving the contract; or

6. Contracts for the purchase of goods or services when the contract does not exceed ~~$100~~ *$500* .

B. The provisions of this chapter shall not apply to those employment contracts *or renewals thereof* or any other contracts entered into prior to July 1, 1983, which were in compliance with the Virginia Conflict of Interests Act, Chapter 22 of Title 2.1 of the Code of Virginia at the time of their formation and thereafter. Those contracts shall continue to be governed by the provisions of that Act.

2. That an emergency exists and this act is in force from its passage.

1983 SESSION

CHAPTER

An Act to amend the Code of Virginia by adding in Title 2.1 a chapter numbered 40, consisting of sections numbered 2.1-599 through 2.1-634, and to repeal Chapter 22 of Title 2.1 of the Code of Virginia, consisting of sections numbered 2.1-347 through 2.1-358, relating to conflict of interests; penalties.

[S 23]

Approved

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 2.1 a chapter numbered 40, consisting of sections numbered 2.1-599 through 2.1-634, as follows:

CHAPTER 40.

COMPREHENSIVE CONFLICT OF INTERESTS ACT.

Article 1.

Declaration of Intent.

§ 2.1-599. Short title; declaration of legislative intent; statement of policy; repeal of less stringent laws, provisions and ordinances.—This chapter may be cited as the Comprehensive Conflict of Interests Act. The General Assembly of Virginia, recognizing that our system of representative government is dependent in part upon its citizens' maintaining the highest trust in their public officers and employees, finds and declares that the citizens are entitled to be assured that the judgment of public officers and employees will not be compromised or affected by inappropriate conflicts.

For the purpose of establishing a single body of law applicable to all state and local government officers and employees on the subject of conflict of interests, the General Assembly enacts this Comprehensive Conflict of Interests Act so that the minimum standards of conduct of such officers and employees may be uniform throughout the Commonwealth.

It is the intention of the General Assembly that this chapter be liberally construed to accomplish its purpose and any exception or exemption to its applicability shall be narrowly construed.

This chapter shall supersede all general and special acts, charter provisions and local ordinances which purport to deal with matters covered by this chapter.

§ 2.1-600. Definitions.—As used in this chapter:

REWRITE

"Advisory agency" means any board, commission, committee or post which does not exercise any sovereign power or duty, but is appointed by a governmental agency or officer or is created by law for the purpose of making studies or recommendations, or advising or consulting with a governmental agency.

"Contract" means any agreement to which a governmental agency is a party, or any agreement on behalf of a governmental agency which involves the payment of money appropriated by the General Assembly or political subdivision, whether or not such agreement be executed in the name of the Commonwealth of Virginia, or some political subdivision thereof.

"Employee" shall include all persons employed by a governmental or advisory agency, unless otherwise limited by the context of its use.

"Governmental agency" means each component part of the legislative, executive or judicial branches of state and local government, including each office, department, authority, post, commission, committee, and each institution or board created by law to exercise some regulatory or sovereign power or duty as distinguished from purely advisory powers or duties.

"Officer" shall include any person appointed or elected to any governmental or advisory agency, whether or not such person receives compensation or other emolument of office. Unless the context requires otherwise, officer shall include members of the General Assembly and of the judiciary.

"Personal interest" means a personal and financial benefit or liability accruing to an officer or employee or to such person's spouse, or any other relative who resides in the same household. Such interest shall exist by reason of (i) ownership in real or personal property, tangible or intangible; (ii) ownership in a corporation, firm, partnership or other business entity; (iii) income from a corporation, firm, partnership or other business entity; or (iv) personal liability on behalf of a corporation, firm, partnership or other business entity; however, unless the ownership interest in an entity exceeds three percent of the

CALIFORNIA INSTITUTE OF TECHNOLOGY

OFFICE OF THE PRESIDENT

May 23, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, DC 20036

Dear Ms. Burke:

Dr. Rosenzweig's letter of March 20, 1984, enclosed the first request from the AAU Clearinghouse on University-Industry Relations for information regarding our policies and practices in certain areas. The two areas covered in that first request were (a) conflict of interest and (b) delay of publication.

We are delighted to be able to respond to Dr. Rosenzweig's request and to assist in this study of university-industry relationships. It involves a set of subjects of great importance to the future of research-oriented universities in the United States which deserves further study.

Enclosed is a Caltech response to each of the two subjects discussed in Dr. Rosensweig's letter. If you should desire, or need, a clarification or any further information, please do not hesitate to contact Dr. Robbie Vogt (our Vice President and Provost), Dr. Don Fowler (our General Counsel), or me. We all participated in the preparation of this response.

Sincerely,

Marvin L. Goldberger

Marvin L. Goldberger

cc: D. N. Fullerton
D. R. Fowler
R. E. Vogt

CALIFORNIA INSTITUTE
OF TECHNOLOGY

May 23, 1984

CONFLICT OF INTEREST

Policy and Practices

Caltech's policy on Faculty conflict of interest was extensively revised and restated in March 1983. The revised policy reflects the rather considerable amount of discussion and reevaluation of this subject which had taken place at Caltech during the two year period following the 1980-81 academic year, at which time this issue first began to receive prominent national attention, particularly among the academic community. A copy of the restated Caltech policy, now entitled "Conflict of Interest and Conflict of Commitment" so as to reflect that a conflict of commitment or dedication can be as much of a problem as a financial conflict of interest, is enclosed. The 1983 policy is being applied as written by the Caltech Administration and, in general, the policy appears to have the continuing support of the Faculty.

A key to the Caltech policy is that the primary responsibility for seeing that outside consulting or business activities do not result in conflicts of interest or commitment remains with the Faculty member involved. Across-the-board reporting is not required for all outside consulting or business activity, as is the case at some other institutions.

Nevertheless, the Faculty member is obligated to make a full disclosure at any time upon request by the cognizant Division Chairman, the Provost, or the President. Furthermore, no agreements for research support or licenses granting exclusive rights to Caltech patents, copyrights or "know-how" may be entered into with outside organizations in which a Faculty member has an equity interest or with which the Faculty member has a continuing consulting arrangement, if the proposed arrangement would be detrimental to Caltech's interests or pose a real or apparent conflict of interest. The Provost is charged with the responsibility of determining whether such arrangements would involve a conflict of interest. In making these determinations, the Provost does consult with an appropriate advisory group of Faculty members to ensure uniformity and continuity of policy.

In applying the 1983 policy, no arrangements or licenses have been approved to date by the Provost where the Faculty member has an equity interest in or a continuing consulting agreement with, the outside organization and where that organization would receive an exclusive right (or option for such right) to Caltech patents, copyrights or "know-how." On occasion, where the Faculty member has such a relationship with the outside organization, an arrangement or license involving nonexclusive rights has been approved, with the appropriate safeguards.

In general, conflict of interest and conflict of commitment are regarded as matters to be resolved between Caltech and the Faculty member prior to completion of the Caltech arrangement with the outside organization. Therefore, contractual language with the other organization is usually not needed nor appropriate. However, Caltech is prepared to include, and has included, a provision in agreements with outside organizations where special concerns are present. Such a provision would read as follows (modified as necessary to fit the specific facts of the case):

CALTECH PERSONNEL

As part consideration for this exclusive licensing agreement _____ covenants and agrees that neither it nor any related corporation or organization will, during the term of this agreement, directly or indirectly employ or retain in any capacity any CALTECH faculty member, student, officer, or employee without the written consent of CALTECH. _____ further covenants and agrees that, while _____ is a privately-held corporation, it will not knowingly permit any such person, or any members of his or her immediate family, to own any stock or interest in _____ or in any related corporation or organization. If and when _____ becomes a publicly-held corporation or, becomes a part of a publicly-held corporation, then _____ covenants and agrees that it will not knowingly permit any such person, or any members of his or her immediate family, to own any stock or interest in

_____ or in any related corporation or organization, unless such stock is purchased in the open market at not less than the then existing market prices. In the latter event, _____ agrees that it will promptly notify CALTECH of any such purchases that come to the actual attention of _____'s officers or directors.

CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT

The acceptance of a full-time appointment to the Faculty of the Institute involves a commitment which is full-time in the most inclusive sense, with the appointee expected to accord the Institute his or her professional loyalty, and to arrange outside obligations, financial interests, and activities so as not to conflict or interfere with this primary, overriding commitment to the Institute.

Conflict of interest can arise particularly in situations where Faculty members are consultants for, or have an interest in the ownership of, business ventures that are more or less directly related to their fields of research at the Institute. In such situations, there is the danger that academic principles and educational priorities may become distorted because of the possibility for economic gain by the Faculty member, by the Division in which the research is done, or indeed the Institute itself. Furthermore, if proprietary information is introduced into research activities on the campus, its protection will surely foster secrecy or hinder open discussion about research among colleagues within the Institute and at other academic institutions, as well as with personnel at institutions or agencies that contribute substantial support to the Institute. Whenever organizations having Faculty members as consultants, substantial shareholders, or part owners wish to make arrangements with the Institute for support of research, patent licensing and related matters, both real and apparent conflicts of interest with respect to the obligations of the Faculty member to the Institute and of the Institute to its educational goals must be avoided.

Responsibility for establishing that activities in business ventures do not conflict with Institute commitments rests first with the Faculty member. Further, on request from cognizant Division Chairmen, the Provost, or the President, the Faculty member shall make a full disclosure of all such ventures including the names of companies, the nature of agreements, the responsibilities assumed by the Faculty member, and the time involved. It is the policy of the Institute (see also Chapter 7, Consulting Activities) that acceptance of a full-time Institute appointment precludes a Faculty member's assuming a position of line responsibility in outside organizations for pay or profit.

Irrespective of what agreements have been made in the past, it is the Institute's policy that no agreements for research support, or for the granting of exclusive rights to the use of Institute patents, copyrights or "know-how" will be made with any company or institution where a current Faculty member consults (or is totally or partially owned by the Faculty member), if the proposed arrangements would be detrimental to the Institute's interest or pose a real, or an apparent, conflict of interest with respect to the obligations of the Faculty member to the Institute.

It is not practical to write specific rules covering all possible situations that might constitute potential or real conflicts of interest. The Provost is charged with the responsibility of determining whether proposed agreements for support of research or for the licensing of patents, applicable copyrights (see Chapter 7, Patent Policy and Royalties and Copyrights) or "know-how", would involve conflict of interest

Faculty members should notify the Provost of their participation (as consultants, shareholders, owners, and so on) in business ventures in which the Institute might become involved in any way, including preferential transfer of research results obtained at the Institute in advance of publication. It is especially important that such notification be given before any commitment is made that could bind the Institute, either ethically or legally.

The Provost will consult with an appropriate advisory committee of Faculty members to ensure uniformity and continuity of policy in making decisions with respect to conflicts of interest and conflicts of commitment. A Faculty member wishing to appeal a decision of the Provost has recourse to the grievance procedure described in the Faculty Bylaws.

With respect to obligations assumed under grants and contracts awarded by governmental agencies, the Institute subscribes in principle to the 1965 statement on conflict of interest issued jointly by the American Association of University Professors and the American Council on Education.

PURDUE UNIVERSITY OFFICE OF THE PRESIDENT

22 August 1983

EXECUTIVE MEMORANDUM NO. C-1

To: Deans, Chancellors, Directors, and Heads of Schools, Divisions, Departments, and Offices

Subject: Compliance with New "Conflicts of Interest" Disclosure Requirements

GENERAL SCOPE OF THE REQUIREMENTS

The General Assembly, in its recent 1983 Session, enacted various amendments to the Indiana "conflicts of interest" law, including new provisions which will require the filing of disclosure statements by "public servants" (including all persons in positions to which they were appointed by "the board of trustees of a state-supported college or university" or who are staff employees "empowered to contract or purchase on behalf of the governmental entity" of which they are employees), as to any "pecuniary interest" or "financial interest" or potential "profit" which they may have in any "contract or purchase connected with an action by the governmental entity which [they] serve..."

In general terms, these new amendments require that all Purdue officers and employees employed in positions to which they were appointed by the Board of Trustees, or in any positions involving any authority to purchase or contract on behalf of the University, must file disclosure statements with the Board of Trustees, stating any financial interest which they may have in any University contract or purchase. The Board must then decide whether to approve such interests and must forward all approved disclosure statements to the State Board of Accounts.

A person who "knowingly or intentionally" has a financial interest in, or expects to derive a profit from, a University contract or purchase and who fails to make the required disclosure, can be charged with commission of the statutory

Frederick L. Hovde Hall of Administration
West Lafayette, Indiana 47907

crime of "conflicts of interest", which is a felony punishable by fine and imprisonment.

PURDUE STAFF WHO ARE COVERED

This disclosure requirement applies to all Faculty, Administrative, and Professional staff members, but especially to those who have the authority to make purchases or sign contracts for Purdue University.

1. Staff members delegated authority to make purchases shall include anyone who initiates or signs a requisition or purchase order or has the form signed on his behalf.

2. Staff members delegated authority to sign contracts shall include anyone who signs the contract (including staff members of the Purdue Research Foundation who sign contracts which are subcontracted to Purdue University).

TYPES OF INTERESTS WHICH MUST BE DISCLOSED

The statute does not specifically define the terms "financial interest" or "pecuniary interest". However, based on preliminary opinions of our Legal Counsel, the following general guidelines are offered. (Obviously, individual situations will require individual consideration. Assistance in answering individual questions will be furnished by the Treasurer's Office.)

1. University Counsel advises that the terms "financial interest" and "pecuniary interest" would not include the mere ownership of small amounts of stock in large, publicly-owned corporations with which Purdue does business. Thus, no disclosure is required. However, if any employee, or his/her spouse, does own stock in such a corporation, and if the employee is aware that the corporation makes sales to or does business with that department or area of the University within which he or she has contracting or purchasing duties, he/she may opt to make a disclosure voluntarily.

2. The terms "financial interest" and "pecuniary interest" would clearly include any ownership interest in a smaller business or corporation, where a contract or sale to Purdue could be expected to have some direct effect on the owner's interests. Disclosure of any such ownership interest, held by the employee or his/her spouse, must be made.

3. The terms "financial interest" and "pecuniary interest" could also mean creditors' interests. If a Purdue employee, or his/her spouse, has made a loan to, or guaranteed an obligation of, a person or corporation who is doing business, or is seeking to do business, with Purdue, disclosure of such interest must be made.

   Ownership of publicly-held bonds or other debt securities of a large corporation would not amount to an interest requiring disclosure as discussed in Item 1 relating to stock ownership.

4. A person who is a paid officer, director, employee or consultant of a corporation, whether it be large or small, and who knows of business being done by the corporation with Purdue, would be considered to have a "financial" or "pecuniary" interest in the particular contract or purchase, by reason of the salary or fees received from the corporation. Disclosure of all such interests must be made.

TYPES OF DISCLOSURES

There are two basic types of disclosures that may be made:

a. Annual disclosure to be used when transactions occur on a regular basis throughout the year.

b. Single disclosure to be used when a specific single transaction occurs which is not one of a series of transactions made on a regular basis and disclosed through a current "annual disclosure" statement.

PROCEDURES TO BE FOLLOWED

Responsibility for administration of the requirements of the statute on conflict of interest has been assigned to the Executive Vice President and Treasurer. Copies of the Conflict of Interest Disclosure Form may be obtained from that office.

Vice Presidents, Chancellors, Deans, Directors and Department Heads are responsible for compliance with these disclosure requirements by staff members within their areas of administrative jurisdiction.

The statute requires that final approval of all potential conflicts of interest be given by the Board of Trustees, which accordingly will evaluate each specific situation disclosed. If the Board of Trustees finds that the situation involves a conflict of interest which in its opinion

would be unlawful, or detrimental to or not in the best interests of the University, so that approval cannot be given, the officer or employee involved will be required to discontinue or divest himself/herself of the outside interest creating the conflict.

Completed forms (original and one copy) are to be returned to the Treasurer's Office through the organizational structure with approvals being required at each level. Completed and approved forms will be submitted by the Treasurer to the Board of Trustees for final approval and then transmitted to the State Board of Accounts as required by the statute. One copy will be kept on file in the Treasurer's Office.

Questions concerning conflict of interest and the statutory requirements should be referred to the Treasurer's Office. Appropriate legal advice will be provided when necessary.

Steven C. Beering
President

PURDUE UNIVERSITY

CONFLICT OF INTEREST DISCLOSURE STATEMENT

Name of person submitting statement: _____

Title or position with Purdue University: _____

This statement, in duplicate, is submitted (check one):

a. ☐ as an annual disclosure statement, as to my financial interest in any University contracts or purchases, related to my University duties or functions, which are made on a regular basis with or from particular contractors or vendors; or

b. ☐ as a "single-transaction" disclosure statement, as to my financial interest in a specific contract or purchase, related to my University duties or functions, proposed to be made by the University with or from a particular contractor or vendor.

The phrase "my financial interest" as used in this Disclosure Statement, includes any interest of myself or my spouse.

==========

Name of Contractor or Vendor	Description of Contract or Purchase	Description of My Financial Interest

(Attach extra pages if additional space is needed)

I affirm the truth of the statements made above, under penalty of perjury. I understand that if any such interest is not approved by the Board of Trustees of The Trustees of Purdue University, pursuant to the statute, I will be required to discontinue it or divest myself of it.

_____ _____
Signature of person submitting this statement — Date

Approval Recommended:

_____ _____
Department Head — Date

_____ _____ _____ _____
Dean or Director — Date — Vice President/Chancellor — Date

Note: Please submit this form through organizational channels to the Office of the Treasurer.

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Office for Corporate and Industrial Research · Administrative Services Bldg.
Suite 123 · Busch Campus · P.O. Box 1089 · Piscataway · New Jersey 08854 · 201/932-2864

May 2, 1984

Ms. April Lewis, Director
Clearinghouse on University-Industry Relations
Association of American Universities
One DuPont Circle, N.W., Suite 730
Washington, D. C. 20036

Dear Ms. Burke:

Dr. Bloustein, President of Rutgers University, has asked me to keep you informed of Rutgers policies regarding University-Industry Relations. This letter is in response to a letter dated March 20, 1984, from Robert M. Rosenzweig of the Association of American Universities to Dr. Bloustein.

I am pleased to enclose copies of our current policies with regard to publication delay and conflict of interest regarding research interactions with corporate and industrial sponsors. I have also included some general information regarding our approach to industrial liaison and will be happy to keep you informed of our progress and changes in our policies when and if they occur.

Sincerely yours,

Phillips V. Bradford, Sc.D.
Director

PVB/lb
Enclosures.

CONFLICT OF INTEREST

The Code of Ethics of the American Association of University Professors, incorporated in its entirety into University Regulations at 3.91, adjures members of the faculty to recognize that their "paramount responsibilities" lie within the University.

University Regulations 3.80/3.85 specifically address the question of conflict of interest, requiring that faculty members recognize and report to their academic superiors prospective conflict of interest situations, including their relationships with outside organizations with which the University has contractual relationships [including research relationships]. The University reserves the right to require that a faculty member withdraw from those relationships which it judges to involve a conflict of interest.

Although Rutgers is an "instrumentality" rather than an agency of government of the State of New Jersey, University Regulations [3.71] adjure faculty to observe "any pertinent statutes and regulations of the State of New Jersey." Thus, conflict of interest is governed both by the regulations of the University and the statutes of the state.

::: Source: University Regulations, 3.80/3.85 :::

Note: The State of N.J does not allow its employees to own more than 10% of equity (stock) in companies with which they do business for the State. Rutgers professors are N.J. State Employees.

CONTROVERSIAL FILMS

Controversial films and their use in courses and in recreational activities under Unviersity sponsorship or on University premises are the subject of an April 1976 memorandum

New York University
A private university in the public service

Office of Sponsored Programs

15 Washington Place, Apt. 1-H
New York, N.Y. 10003
Telephone: (212) 598-2191

April 12, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse
of University-Industry Relations
Association of American Universities
One Dupont Circle N.W., Suite 730
Washington, D.C. 20036

Dear Ms. Burke:

I am responding to the March 20 announcement and request to President John Brademas regarding the newly initiated University-Industry Clearinghouse.

As for the specific problem areas identified:

Conflict of Interest - A faculty committee is in the process of developing a new policy statement, which is expected to be presented to the University's Board of Trustees in the Fall of 1984. Currently, we are operating under Conflict of Interest Policy adopted in 1966, which is based on the 1964 AAUP/ACE Joint Statement. The policy has been implemented over these years through the disclosure requirements of the attached University Synopsis Form 3, filing of which is mandatory for all faculty seeking external funding for university-based research projects and programs.

To date, University policy with regard to faculty or institutional participation in limited partnerships and other venture capital groups on the research funding scene has been developed on an ad hoc basis after review of the specific elements involved. The outcome of negotiations to date has, in each case, been conversion to a research agreement. We are currently engaged in several such negotiations and, if the outcome is different, will provide you with specifics upon completion of negotiations.

Delay of Publication - New York University has operated under the guidance provided by the attached Board of Trustees Policy Statement since its issuance. In practice, we have on an ad hoc basis negotiated agreements with industrial sponsors for

APR 24 1984

Yale University

OFFICE OF COOPERATIVE RESEARCH

252 JWG
P.O. Box 6666
New Haven, Connecticut 06511

203 436-2317

ROBERT K. BICKERTON
Director

April 14, 1984

Ms. April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036

Dear Ms. Burke:

I am responding to Robert Rosenzweig's letter of March 29th to President Giamatti.

A faculty committee at Yale, The Committee on Cooperative Research, Patents and Licensing has been deliberating many of the issues on which your 'Clearinghouse' is seeking information. Their initial report has recently been released and I have enclosed a copy for your use. I think you'll find that it does address Yale's position on these important issues. I have also enclosed a copy of a prototypical license agreement (with names deleted) as an example of one which Yale might use in granting an exclusive license to some of it's technology to a commercial organization. I hope this is useful to your needs.

As Yale finalizes it's policies based on the faculty committee report, I'll be happy to share copies with you. These policies, together with appropriate revisions to the faculty handbook, are in draft form only at this point.

I had the opportunity to hear your comments and plans for the "Clearinghouse" at the recent AAU Research Administrators meeting in Washington and I wish you success. Please feel free to contact me if I might offer assistance and the benefit of Yale's experiences.

Sincerely,

R. Bickerton

Robert K. Bickerton

RKB/vs

REPORT OF THE COMMITTEE ON COOPERATIVE RESEARCH, PATENTS, AND LICENSING

Recent developments in molecular biology, genetics, computer science, and other disciplines promise a significant shortening of the time between the creation of new scientific ideas and their widespread commercial application. A closer link between university research and applied industrial technology creates, for the university and its faculty, intellectually exciting and financially attractive opportunities for the practical application of ideas with potentially enormous social benefit. Yet along with these new opportunities comes concern that close involvement in commercial activities may threaten the principles of free and objective inquiry to which the University and its faculty are fundamentally committed.

Mindful of both the potential benefits and problems created by greater involvement with private industry, the Committee on Cooperative Research, Patents, and Licensing has met regularly for two years to reexamine and, where necessary, to recommend clarification or revision of the University's policies regarding research sponsored by outside organizations, outside activities of the faculty, and patent and licensing practices. Our committee has consulted with several faculty members engaged in university research sponsored by commercial enterprises and with other faculty members engaged in outside commercial activities related to their university research. We have monitored the

University's negotiations with industrial firms seeking to sponsor research; we have advised the Provost and the Office of Cooperative Research on the appropriate disposition of patents owned by the University, and we have assisted in the resolution of disputes concerning the distribution of patent royalties. In light of our study of the issues involved and our accumulated experience, we are now prepared to recommend a number of revisions of the University's patent policy and of its regulations concerning sponsored research and the outside activities of the faculty. Our specific recommendations are embodied in a revised draft of the *Faculty Handbook* sections dealing with these subjects and in a revised Patent Policy. These documents are available from the Provost's Office upon request.

Our recommendations derive from a reaffirmation of the essential purpose of the University: "to preserve and enlarge humanity's store of knowledge and to impart it." Pursuit of this goal requires that the University preserve an environment conducive to free inquiry and free exchange of ideas. Such an environment depends crucially upon mutual trust and openness among colleagues. Free and open discussion and generous collaboration are essential in supporting the University's mission.

Relationships with outside organizations must be governed in a manner consistent with these central principles of free inquiry, open communication, and collegiality. Collaborative research with industry offers opportunities to bring the products of the laboratory into rapid commercial use, but such

undertakings cannot be permitted to subordinate the principles of free inquiry, openness, and collegiality to the pursuit of commercial gain. Similarly, though it may on occasion be appropriate for a faculty member to pursue the commercial application of his or her university research through ownership or management of an outside company, vigilant care must be taken to assure that such outside involvement does not distort the direction of university research, color the supervision of graduate students, or convert an environment of openness and trust into one of secrecy and striving for personal financial advantage.

In the paragraphs that follow, we discuss our proposed revisions of the University's policies under three headings: sponsored research, outside activities of the faculty, and patent policy.

Sponsored Research

To keep matters in perspective, it is important to observe that the Federal government now provides, and it is likely to provide in the foreseeable future, the overwhelming majority of outside funds for support of research at Yale. Nonetheless, private industry has for many years assisted in the support of university research, and the scale of this activity has increased significantly in recent years. To the extent that companies sponsor university research with an eye to the eventual commercial possibilities of work undertaken, such arrangements help to make the benefits of University research widely available to the public. At the same time, the sponsor's interest in

commercial success may come into conflict with the University's norms of free inquiry and open communication.

In reviewing the University's present policies concerning sponsored research, we find the principles enunciated in the Faculty Handbook (Section XIII. B.1) to be a satisfactory guide. The University's prohibition of secret or classified research projects derives directly from its essential purpose: to enlarge humanity's store of knowledge and to impart it. We reaffirm this commitment to free discussion and open communication.

To make this commitment clear to the faculty, as well as to potential private sponsors of research, we propose to add a brief additional section to the Faculty Handbook. In the proposed new section, we reaffirm that Yale shall not enter into any agreement that prohibits free and open discussion of ongoing research. Similarly, faculty and students must be free to publish their research results. As a practical consideration, companies will sometimes request the right to review research results prior to publication, to consider whether a patent should be sought. The Committee sees no problem in permitting company sponsors to review pre-publication drafts of research papers, but such reviews shall not delay publication beyond a brief, pre-agreed and specified time period. In several recent research agreements reached with outside organizations, Yale has agreed to pre-publication review periods of 30 to 45 days. Since in most cases such a period is shorter than the period from submission of an article to publication, we believe that restrictions of this sort

do not constitute a significant abridgment of the right to publish research results.

In negotiating research agreements, several companies have sought provisions to restrict unduly the right of faculty members to withdraw from sponsored research programs, and they have also sought to constrain the subsequent research activities of those who withdraw. Yale has not agreed to such restrictions of freedom of inquiry, and we recommend that this policy be stated explicitly in the Faculty Handbook.

Outside Activities of the Faculty

It is the policy of the University to encourage faculty participation in outside activities of benefit to society and the University. We reaffirm the principle that involvement in outside professional activities should be guided by a faculty member's overriding obligation to the University and to its mission of research, teaching, and the dissemination of knowledge.

To be consistent with this principle, faculty members should conduct relationships with outside organizations so as to avoid conflicts of interest and conflicts of commitment. A conflict of interest exists when a faculty member's activities within the University could be biased so as to provide direct or indirect financial benefit to the individual from an outside organization. A conflict of commitment exists when a faculty member engages in outside activity to an extent that precludes meeting his or her obligations to the University. We reaffirm that these

obligations are not discharged solely by meeting classes; the faculty member is also obliged to be available to students outside of the classroom, to carry his or her share of committee work, and to keep his or her research in constant progress.

Certain outside activities are an integral part of a faculty member's responsibilities. Within reasonable bounds, for example, site visits or peer review evaluations of research programs at the request of the government or non-profit organizations, committee work for professional associations, and editorial work for professional journals are encouraged, as are voluntary contributions of a faculty member's expertise to foundations and community organizations.

In addition to such activities of clear public benefit, faculty members frequently provide paid consulting services to business concerns and other organizations. Such services often benefit the individual, the University, the organization requiring the services, and the larger public. Consulting activities are encouraged to the extent that they enhance a faculty member's professional competence and thus better equip that individual to serve the University as a researcher, teacher, and colleague. Time spent in these activities, however, must be limited in order to assure that faculty members are able to discharge fully their obligations to the University. We reaffirm the University's policy that on average no more than one day per seven day week should be spent on outside gainful professional activities during a semester or during months for which a faculty member receives off-term compensation administered by the

University. Circumstances believed to merit exceptional treatment should be referred in writing to the Provost.

Occasionally, consulting relationships may bring a faculty member into conflict with the University's guiding norms of free inquiry, open communication, and collegiality. For example, consulting activities, with the government as well as with business organizations, sometimes require that faculty members sign agreements of confidentiality. Where the nature of the information kept in confidence does not intrude on the faculty member's research program or teaching, confidentiality may be warranted. It should be recognized, however, that confidentiality agreements conflict in principle with a faculty member's commitment to free and open exchange of ideas. Under no circumstances should the communication of results of University research be suppressed in consideration of an outside organization's proprietary interest.

We do not believe that the University is well served by a system of prior approval of consulting relationships, or any formal mechanism of policing such activities. It is the responsibility of the individual faculty member to see that outside activities do not diminish the time and energy devoted to fulfilling his or her overriding obligations to the University. Similarly, it is the individual's responsibility to insure that involvement with outside organizations, especially where such involvement is prolonged or involves confidentiality, does not attenuate his or her commitment to full freedom of inquiry, open communication, and collegiality in the conduct of research and teaching.

To preserve an atmosphere of openness and collegial trust, we have recommended to the Provost that faculty members disclose the nature and extent of their outside professional and consulting activities in writing to their chairman for inclusion in the chairman's annual report to the President. This policy was adopted by the University last spring, and we have proposed a revision to the Faculty Handbook to reflect this new policy.

Additional special considerations arise when a member of the faculty seeks to commercialize the results of his or her university research through an ownership or management position in a private enterprise. Such an outside involvement may require great concentration and effort, rendering it difficult for the faculty member to avoid a conflict of commitment. It is doubtful, though not impossible, that even our most energetic faculty members can do adequate justice to teaching, research, and University citizenship, and also manage or direct a commercial enterprise. Moreover, significant involvement in a commercial enterprise risks distorting the direction of the faculty member's university research, as well as that of his or her students and junior colleagues. Students, postdoctoral fellows, and junior faculty must be free to choose research problems within an environment of free inquiry, independent of the personal financial consequences for their supervisors or mentors. Faculty ownership or management of commercial enterprises also presents a heightened potential for suppression of open communication among colleagues. This problem becomes especially acute when the faculty member/entrepreneur conceives a

new idea that has both general scientific importance and potential for rapid commercial application.

We recognize that the maintenance of an environment of free inquiry, openness, and collegiality depends above all upon the good faith and voluntary commitment of the faculty. Nonetheless, faculty ownership or management of a private enterprise presents a sufficiently serious potential for distortion of the University's aims and for disruption of its collegial environment that we believe some monitoring of these activities is appropriate. Thus, we recommend that a faculty member be required to disclose to the President or the Provost any management or significant ownership position in an enterprise that makes commercial use of the results of his or her academic or professional endeavors. We recommend that activities so disclosed, and their relationship to the faculty member's activities in the University, be reviewed for conformance with University policies and the principles underlying them by a committee designated by the Provost. Ordinarily, a subcommittee of the Committee on Cooperative Research, Patents, and Licensing should be so designated, augmented when necessary by persons with relevant expertise. The committee should review the status of any continuing ownership or managerial relationship with a private enterprise on a periodic basis.

We expect that in most cases a review of this type will find that the faculty member is faithfully discharging his obligations to the University. But were the committee to determine that a faculty member's involvement in the commercial enterprise entailed a significant conflict of commitment, we believe that the

faculty member should either modify or terminate his outside activity or reduce his or her obligation to the University. If the latter course is chosen, the individual may request a half time appointment or a leave without pay for a period of one year. At the end of the period, the faculty member may return to full time status if obligations to the outside enterprise have been discharged or sufficiently reduced. If the faculty member wishes to maintain commitment to the private enterprise, he may resign from the faculty or he may seek conversion of his appointment to adjunct status. In either case, reappointment to full time status would require approval through the University's ordinary appointment practices. These recommendations are embodied in a proposed new section of the Faculty Handbook.

Patent Policy

Yale's current patent policy was adopted by the Corporation in 1974. In the years following, changes in patent law and the opportunities for enhanced cooperation with private industry have made necessary a reexamination of existing policy. Until recently, ownership of patents resulting from federally sponsored research vested in the government in the absence of a specific waiver of the government's claim. The "Patent and Trademarks Amendments Act of 1980", as implemented by Office of Management and Budgets Circular A-124 in March 1982, granted ownership of patents resulting from federally-sponsored research to the University, although the government retained the right to hold non-exclusive licenses for certain purposes. To assert its rights

under the new patent law, the University must meet certain obligations, including prompt disclosure of any invention to the funding agency, and assurance by a written agreement that investigators will promptly disclose any inventions to the University. We have proposed revisions to the patent policy of the University to make the requirements of the new law explicit.

Opportunities for cooperative research with industrial enterpriseshave also motivated some changes in the University's patent policy. In the past, disclosures of inventions made under University auspices were turned over to a non-profit organization, Research Corporation, for evaluation. If a decision was made to apply for a patent, Research Corporation prepared the application on the University's behalf and sought appropriate licensees. In return, Research Corporation received a share (47%) of gross royalties from any licenses issued. The University split the remaining share of royalty income, after expenses, with the inventor(s) on a 50-50 basis. At present, with the establishment of the Office of Cooperative Research and the widespread interest of corporate sponsors of research in obtaining licenses to University patents, the University has a greater capability to evaluate patents and seek licensees on its own behalf. Generally, therefore, the University will hereafter handle its own patent and license affairs.

The new institutional arrangements make necessary a re-evaluation of the procedures for division of royalty income. Since the University will now retain, after expenses, a far larger share of any gross royalties than it would have received from Research Corporation, we have recommended a formula for the

division of royalty income that is roughly consistent with the incentives to inventors provided under the old policy. This provides the inventor with 30% of net royalty income up to $200,000 and 20% of net income in excess of $200,000. In addition, another 30% of all net income will be allocated directly to the inventor's department or facility for the support of research. The remaining funds will be allocated by the Provost to the general support of research.

To encourage collaboration and collegiality in research that may lead to patentable results, we have also recommended an additional incentive. Where all participating investigators in a department or facility agree in advance, in writing, to share equally in royalty income, regardless of which individuals are designated as "inventors" for legal purposes, the University will commit an additional 50% of its residual share of royalty income (20% or 25% of the total) to that department or facility. We make this recommendation because the law has very specific requirements concerning the designation of inventors, and these must be met to uphold the validity of a patent. Yet in the University it is well understood that many individuals contribute to the success of a research program without being legally qualified as "inventors." Such an extra inducement for prior division of royalties rewards all collaborators, and it may help to remove tendencies toward secrecy and isolation that quest for a patent might engender. Even where collaborators in a patentable discovery do not reach prior agreement on the division of royalties, it is hoped that they will, in a spirit of generous

collaboration, share a portion of any royalties with co-workers who have made significant, if not "inventive", contributions to the relevant research program. Where disputes do arise, however, we recommend that they be resolved by the Provost with the advice of the Committee on Cooperative Research, Patents, and Licensing. We would expect all those involved with a patentable invention to accept any adjudication by the Provost in a spirit of generosity and collegiality.

With regard to the licensing of patents, we recommend that the University seek the most effective means of insuring that the public reap the potential benefits of its research. Ordinarily, the University will prefer to grant non-exclusive licenses. Sometimes, however, the costs and risks of commercializing a patented invention will be such as to deter companies with relevant skills and experience from proceeding without the protection afforded by an exclusive license. We recommend that the University should be prepared to grant limited term exclusive licenses where this is clearly the most effective means for arranging public access to the benefits of an invention. Any agreement to grant an exclusive license should require the licensee to surrender the license if he fails to carry out effective development and marketing of the invention within a specified period of time.

Having proposed these revisions to the University's Patent Policy, the Committee on Cooperative Research, Patents, and Licensing is continuing to consider the University's treatment of non-patentable forms of intellectual property. The University has no formal copyright policy, and the traditional practice has

been for the University to waive its right to copyright on written scholarly materials and textbooks authored by the faculty. Computer programs are sometimes patentable, but they are more commonly protected by copyright. The creation of computer programs, like the discovery of patentable inventions, typically involves the use of costly University facilities and resources. Moreover, to the extent that computer programs and associated written manuals have potential commercial value in industrial application, they are more akin to "useful" inventions than to scholarly publications. We, therefore, recommend that faculty members and other University employees disclose to the University any potentially licenseable computer programs and associated materials. If the University chooses to assert its claim to copyright, licensing arrangements and the division of royalty income shall be governed by the terms of the Patent Policy. As in the case of patentable inventions, the University will make no claim to copyright any program that is unrelated to the activities for which the author is employed and has not involved the use of University facilities.

UNIVERSITY OF MARYLAND

CENTRAL ADMINISTRATION

OFFICE OF THE PRESIDENT

ADELPHI, MARYLAND 20783
(MAIN OFFICE) (301) 853-3601

BALTIMORE, MARYLAND 21201
(301) 528-7000

April 23, 1984

Dr. Robert M. Rosenzweig, President
Association of American Universities
Suite 730, One Dupont Circle
Washington, D.C. 20036

Dear Bob:

I am writing in response to your request for information for the AAU Clearinghouse on University Relations. I note that this initial request asks for information on two problems only: conflict of interest, and delay of publication.

The University of Maryland is currently developing formal policies that bear on both subjects. The first one under development is a policy on Secret Work. It will include a statement on delay of publication. I enclose an excerpt from the draft policy which describes our thinking on the subject. The length of delays we will accept may still be altered in later revisions.

I am enclosing the clause on publications from a research contract we had with a major industrial firm. The firm's name has been deleted. This clause indicates the flexibility with which we have approaching the issue in the past.

The second policy we are developing is on conflicts of interest and commitment. A draft has been discussed on our campuses, but it remains in such an early stage of development that I prefer not to share it. Our existing consulting policy simply states that consulting must avoid conflicts of interest.

Sincerely yours,

John S. Toll
President

JST:mm

Attachments

cc: Dr. David S. Sparks
Dr. Samuel Price

WASHINGTON UNIVERSITY IN ST. LOUIS

FEB 6 1984

Office of the Chancellor

February 1, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036

Dear Mrs. Burke:

In response to Bob Rosenzweig's letter of January 10th, we are pleased to provide information on Washington University's policies and practices relating to research relations with industrial firms.

As requested, the enclosed information is confined to the specific topics of conflict of interest and delay of publication. While such matters as these do represent potential problem areas for the faculty of a research university, it is interesting to note that applicable policies addressing these issues are neither new nor specific to the current era of research relations with industry. In the mid-1960's our Faculty Senate adopted the AAUP and ACE joint statement "On Preventing Conflicts of Interest in Government Sponsored Research at Universities." Furthermore, this institution has long subscribed to a policy of not accepting classified research projects on the grounds that research results must be made freely available to all.

Thus, I believe that the enclosed information reveals that at Washington University sensitivity to the issues of conflict of interest and freedom to publish has developed over many years as part of the fabric of academic life, not as a reaction to recent public concerns. In general we have not found the application of these long standing policies to current industrial research arrangements to be especially troublesome, nor have the officials from corporations with whom we deal been insensitive to the issues involved.

I hope that the information on our policies and practices will be of some assistance to the AAU Clearinghouse. Should you require additional information, Edward MacCordy, Associate Vice Chancellor for Research, will be pleased to provide it.

Sincerely yours,

William H. Danforth
Chancellor

Enclosure

Washington University
Campus Box 1192
St. Louis, Missouri 63130
(314) 889-5100

January 31, 1984

POLICY AND PRACTICE IN INDUSTRIAL RESEARCH RELATIONS at WASHINGTON UNIVERSITY

CONFLICT OF INTEREST

The fundamental policy which provides guidance to the faculty in the area of personal activity is the policy on "Academic Freedom, Responsibility, and Tenure" which has been approved by the Faculty Senate and by the University's Board of Trustees. This policy is voluntarily accepted by each faculty member and is comparable to a "condition of employment" agreement at some other academic insitutions. In addressing the faculty member's primary responsibility to his academic duties it states:

> "II. RESPONSIBILITIES OF FACULTY MEMBERS
>
> "A. Teaching and Research
>
> "The faculty member has an obligation to fulfill his teaching and research responsibilities. The faculty member's primary responsibility to his subject is to seek and to state the truth as he sees it. To this end he devotes his energies to developing and improving his scholarly competence. The faculty member accepts the obligation to exercise critical self-discipline and judgment in using, extending, and transmitting knowledge. He practices academic honesty. As a member of this University, the faculty member seeks above all to be an effective teacher and scholar. Although he may follow subsidiary interests, these interests must not seriously hamper or compromise his scholarly pursuits. The faculty member determines the amount and character of his activities outside the University with due regard to his paramount responsibilities within it."

The University's policy statement regarding "External Professional Activity" further defines the faculty member's responsibility when engaged in extra-university activities in the following terms:

> "It has been Washington University practice since the 1940's that a faculty member may engage in such external activities not to exceed an average of one day per week, with the understanding that his/her scheduled University activities including, of course, classes, oral examinations, and scheduled advising activities take precedence in scheduling of his/her time.

"When a faculty member engages in external professional activity, the activity should contribute significantly to the professional growth and development of the individual and to the individual's professional service to Washington University, the normal responsibility and contribution of the individual to Washington University should not thereby be diminished, University equipment and supplies should not be utilized without appropriate approval and charges, the affiliation of the individual with Washington University should not be inappropriately invoked, and the activity should not appear to conflict with the interests of Washington University."

This policy statement goes on to prescribe appropriate administrative responsibility for monitoring faculty external activities and for providing consultation regarding questionable matters as follows:

"If questions with regard to these matters should arise, the faculty member promptly should consult the administrators concerned (department head or chairperson and/or dean). The department chairperson is held responsible for monitoring these activities in his/her department."

Finally, the Faculty Senate in 1966 adopted as a policy on conflict of interest the joint AAUP/ACE statement "On Preventing Conflicts of Interest in Government Sponsored Research." Although this statement is now twenty years old and its title might indicate preoccupation with Government sponsored research, its authors were sensitive to the issues which today surround university-industry research relations as indicated in the following excerpts from its introduction:

"The increasingly necessary and complex relationships among universities, Government, and industry call for more intensive attention to standards of procedure and conduct in Government-sponsored research. The clarification and application of such standards must be designed to serve the purposes and needs of the projects and the public interest involved in them and to protect the integrity of the cooperating institutions as agencies of higher education.

"Consulting relationships between university staff members and industry serve the interests of research and education in the university. Likewise, the transfer of technical knowledge and skill from the university contributes to technological advance. Such relationships are desirable, but certain potential hazards should be recognized."

This policy goes on to provide specific detailed guidance for avoidance of the hazards stemming from financial interests in and consulting arrangements with private business including matters of:

a) wrongfully orienting the direction of sponsored research to serve the needs of other parties
b) favoritism in purchasing equipment, supplies and services
c) misappropriation of research results for personal gain
d) misuse of privileged information obtained in connection with sponsored activities
e) influencing or participating in university negotiations with firms in which the faculty member has a financial or consulting involvement
f) accepting or offering inappropriate gratuities
g) withholding of professional effort committed to a sponsored project
h) personal consulting activities in conflict with university responsibilities.

This policy on Preventing Conflicts of Interest is primarily addressed to the faculty. Supplementing this is a policy statement directed at employees involved in the University's business dealings with outside organizations. This policy statement, "Avoiding Conflicts of Interest," deals more specially with proper conduct in the purchasing function.

In specific research arrangements with industrial firms on occasion it has been found desirable to precisely define, for the benefit of the firm and faculty participants, conditions which could involve a faculty participant in a conflict of interests. On such occasions the faculty participant is required to sign a statement acknowledging the definition of acceptable and unacceptable activities and agreeing to promptly disclose in advance activities which might lead to a conflict situation. An example of such a statement is:

"Other Support:

"It is understood that Investigators receiving funds from this contract may, during the tenure of this contract, apply for and accept research and contract funds from public and private agencies. Support from other sources is permitted during the tenure of this contract only to develop products that in no way duplicate or diminish the commercial value of products developed under this contract. Any additional support involving hybridoma research from any source should be reported to the Advisory Committee under item No. 10 of the Investigator's project request, or if occurring after this request at the earliest time such proposal to another sponsor is planned or submitted."

If used sparingly and limited to the most likely and specific sources of potential conflict this approach is felt to have value in aiding faculty participants to avoid conflicts in which they might unintentionally become entangled.

DELAY OF PUBLICATION

The preeminent importance of academic freedom, including the right to freely publish, is firmly established in the policy on "Academic Freedom, Responsibility, and Tenure" as is the University's dedication to protect that right. The policy states:

"I. ACADEMIC FREEDOM

> "The right of faculty members to academic freedom is of fundamental importance to an academic institution. That right shall be protected at Washington University.
>
> "Academic freedom is the particular freedom of scholars, teachers and students within the University to pursue knowledge, speak, write and follow the life of the mind without unreasonable restriction."

In furtherance of this right the University will not accept a research agreement which prohibits publication of research results. This position of long standing is set forth in the "Policy on Classified Research" as follows:

> "A university has the general obligation to make research results freely available to all. Graduate students working toward advanced degrees are required to publish the results of their dissertation research in order to earn their degrees. Projects in which the subject matter or the results are to be kept secret are evidently not in harmony with the foregoing principles. As a consequence, Washington University will not accept classified research projects except in extreme national emergency."

In undertaking research projects sponsored by industrial firms, the right of faculty participants to freely disseminate the results of their research is explicitly stated in the research agreement. Prepublication review and brief delay in publication is acceptable for either of two reasons: (a) to identify and initiate the legal process to claim potentially patentable inventions and (b) to allow the industrial sponsor to screen a manuscript for unauthorized disclosure of the sponsor's proprietary information (possibly revealed to the faculty member during the research collaboration).

To avoid any publication delay several provisions are normally incorporated in industrial research agreements. First, the sponsor is charged with anticipating and detecting potentially patentable inventions, as well as with the filing of patent applications thereon, as early as possible based on continuous monitoring by the sponsor of research progress, not just prepublication review of manuscripts. Second, faculty researchers are required to make manuscripts available to the sponsor for review, usually two to four weeks prior to submission to a publisher. Third, the sponsor is required to promptly review such manuscripts and also to promptly notify the University in writing if a delay in submission is deemed necessary. Failure to give such notification within the allotted time leaves the faculty researcher free to start the publication process. Finally, the minimum delay necessary, with a limit of ninety days, will be granted by the University if such delay can be well justified on a case by case basis.

A sample set of contract clauses reflecting this practice is set forth below. This approach has succeeded in effectively eliminating any departure by faculty researchers from their planned publication schedules.

SAMPLE

"ARTICLE VI - PUBLICATIONS

"6.1 Program participants are at liberty to publish or disclose the results of their research, but the Company will be advised of the results before such results are disclosed to others outside of the University for purposes of protecting proprietary rights.

"6.2 Through the mechanism set forth in paragraph 6.4 below, the Company shall seek to anticipate project results to minimize the need for delay of disclosure by promptly initiating actions to establish such rights, and to advise Program participants as early as possible of minimum practical precautions necessary to protect such proprietary rights. These precautions shall seek to minimize the material temporarily withheld from disclosure as well as the period of such temporary delay. Program grants will require the Program participants to provide copies of articles being submitted for publication to the Advisory Committee at least two (2) weeks before submission to the publishers for the

purpose of screening for inventions on which patent applications have not been filed and for unauthorized disclosure of Company proprietary information. On written request by Company, University agrees to delay any such publication for up to three (3) months from the date of transmittal to the Advisory Committee to allow filing of applications or deletion of Company proprietary information.

"6.3 The Company shall promptly review pre-publication articles to determine if potentially patentable inventions are disclosed and shall promptly thereafter inform the University of the Company's interest in obtaining patent rights to such inventions as provided for in Article VIII hereof.

"6.4 The pre-publication reporting and evaluations as provided for in paragraphs 6.2 and 6.3 notwithstanding, the Company representative on the Advisory Committee is exposed to all Project plans before commencement of these Projects and such representative shall have the full opportunity and right to follow the progress of any and all Projects. Through this mechanism the Company shall determine as early as practicable the potential for establishing patent rights and its interest in obtaining a license of such rights. As soon as such potential is determined by the Company the parties shall cooperate on immediate actions necessary to the establishment of such rights. In this connection, the Project Investigators shall confer fully with Company regarding the performance of the Program hereunder, and shall make available for Company's inspection, at such reasonable times as the Project Investigators and Company determine all Technical Developments developed under this Agreement."

Charles Koltz
Campus Box 1142
Washington Univers
St. Louis, MO 63
(314) 889-5408

THE MONSANTO-WASHINGTON UNIVERSITY AGREEMENT:
DETAILS FROM THE RESEARCH CONTRACT

The five-year, $23.5 million agreement between Monsanto Company and Washington University provides the framework necessary for an extensive biomedical research program.

The contract establishes an eight-person advisory committee made up of four Washington University School of Medicine faculty, and four members from Monsanto. This committee will solicit research proposals from the faculty-at-large, review and approve such proposals on the basis of individual merit, distribute appropriate funding, and act as a liaison between the University and Monsanto.

The chairman of the advisory committee will be David M. Kipnis, M.D., Busch professor and head of the department of internal medicine at the Washington University School of Medicine. In addition, the three University committee members will be Luis Glaser (head of the department of biological chemistry), Paul Lacy (Mallinckrodt professor of pathology and head of the department of pathology) and Joseph Davie (head of the department of microbiology and immunology).

For Monsanto, the four advisory committee members will be Louis Fernandez (vice chairman of Monsanto), Howard Schneiderman (senior vice president, research and development), G. Edward Paget (director, biomed program) and David Tiemeier (science fellow). Any action to approve or disapprove funding, to set funding amounts, and to discontinue funding will come about by a decision of this committee.

--more--

The advisory committee will allocate 30 percent of its funding to exploratory or fundamental research in proteins and peptides. The other 70 percent will go toward the support of more applied "specialty" projects for which there is significant public need and potential commercial utility in terms of technologies and/or products.

The guiding rule for all this research is that it intersects the strengths and interest of both Monsanto and the University.

The University faculty members will be at liberty to publish the results of any research they do under the Monsanto funding. Monsanto, however, will exercise the right of prior review of such material if it contains potentially patentable technical developments. If so, Monsanto can request a short delay of submission for publication or other public disclosure in order to begin the patent process. Such review is necessary because many foreign patent laws require the filing of patent applications before public disclosure of inventions.

Although Monsanto will have the right to an exclusive license of any patents on an invention that comes from the funded research, the University will maintain the patents as its sole and exclusive property and receive royalties from Monsanto licenses. Furthermore, the resulting royalties will go to the University for support of its educational and research programs -- not to individual researchers. Monsanto will pay for and carry out the entire patenting process. If Monsanto does not elect to license a patent, the University is free to license such patents to others.

The contract also contains important provisions for cooperative efforts between Monsanto and Washington University. Monsanto scientists and technicians will spend time in University laboratories learning new techniques and information. On the other hand, Monsanto will provide access to its facilities -- such as its isolation and tissue culture facilities -- and use of

--more--

Background

unique biological and other materials.

The schedule for funding, which is indexed to 1982 dollar values, will be carried out approximately as follows:

Contract Year	Exploratory Projects	Specialty Projects	Contract Year Total Budget
82-83	$1,500,000	$1,500,000	$3,000,000
83-84	$1,600,000	$2,200,000	$3,800,000
84-85	$1,700,000	$3,000,000	$4,700,000
85-86	$1,800,000	$3,800,000	$5,600,000
86-87	$1,900,000	$4,500,000	$6,400,000
Total	$8,500,000	$15,000,000	$23,500,000

In the third year of the agreement, and every two years thereafter, Monsanto and the University will have an independent scientific review panel made up of distinguished scientists (not connected with either institution) review the scientific merit of the projects being funded and the impact of the program on both participating institutions. In the third year, it will also be determined if it is in the best interests of both parties to continue funding beyond the presently agreed-upon five years.

--end--

WASHINGTON UNIVERSITY
IN ST. LOUIS

News Release

Contact

Glenda Rosenthal or Don Clayton
Washington University School of
Medicine Public Relations
Campus Box 8065
St. Louis, MO 63110
(314) 454-2515

WASHINGTON UNIVERSITY AND MONSANTO COMPANY SIGN FIVE-YEAR BIOMEDICAL RESEARCH AGREEMENT

St. Louis, Mo., June 3, 1982 -- Washington University and Monsanto Company in St. Louis announced today they have entered into a five-year agreement to conduct biomedical research focused in the areas of proteins and peptides which regulate cellular functions.

The two institutions have signed a general contract totaling $23.5 million, under which individual research projects will be carried out by cooperative arrangements involving faculty at the Washington University School of Medicine and Monsanto scientists. About 30 percent of the efforts will be directed toward fundamental research and 70 percent toward research which is directly applicable to major human diseases.

Selection of projects to be pursued under the agreement will be made by an advisory committee composed of individuals appointed by Monsanto and Washington University.

Monsanto's participation in the program will begin with a $3 million grant during the first year and rise annually to accommodate expansion in the number and scope of research projects involved. Although the agreement provides for a continuing research program over five years, it can be renewed for a longer period.

- more -

David Kipnis, M.D., Adolphus Busch professor and head of the department of internal medicine at the Washington University School of Medicine, will direct the program and serve as chairman of the advisory committee. He said: "This is an extraordinary opportunity to expand the support and depth of research in areas which are widely recognized as important to the treatment and diagnosis of disease. We are enlarging the roles of both institutions -- Washington University and Monsanto -- in the pursuit of basic and applied research. On one hand, we have a research-oriented academic institution and, on the other, a high-technology industry combining resources in the investigation and development of knowledge and useful applications for the public benefit."

Howard A. Schneiderman, Monsanto's senior vice president, research and development, said, "We expect that new therapies developed through this exciting drug-discovery partnership will rapidly be brought into public use. With the extensive biomedical skills of Washington University plus Monsanto's ability to turn inventions into valuable products, this joint research venture should ultimately benefit society on a scale not possible by each institution working alone."

During the third year of the five-year agreement, the entire program will be reviewed by a panel of distinguished scientists who are independent of both Monsanto and Washington University. The purpose of this panel will be to examine the scientific excellence of the programs and their value to both institutions, according to Luis Glaser, Ph.D., head of the department of biological chemistry at Washington University School of Medicine and a member of the advisory committee.

As part of the collaborative program, a number of Monsanto scientists will be working in Washington University laboratories to facilitate the transfer of technology to Monsanto.

Under the agreement, faculty members participating in the projects are at liberty to publish results of their research. Patents on any inventions arising from the projects will be held by Washington University with exclusive licensing rights to Monsanto.

This is the second program of this nature under way between Monsanto and Washington University. Earlier this year, the two institutions signed an agreement in which Monsanto will provide $1.5 million for faculty research in the field of hybridomas, materials which may have valuable diagnostic uses.

Chancellor William H. Danforth said, "Washington University and Monsanto have shared a continuing relationship for many years. The firm and its founding family have helped construct major buildings for research and instruction on both our campuses and have encouraged academic programs and research which benefit humankind. We have tried to learn from the recent experience of others to create a prototype for future collaborative efforts between industry and higher education -- an agreement which protects fully the integrity of both parties."

# # #

APR 03 1984

THE UNIVERSITY OF UTAH

VICE PRESIDENT
FOR RESEARCH
304 PARK BUILDING
SALT LAKE CITY, UTAH 84112
801-581-7236

30 March 1984

Refer to: 84-144

April Lewis Burke, Esq.
Director of the Clearinghouse on
University/Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036

Dear Ms. Burke: April

In response to Dr. Rosenzweig's recent request, please find enclosed "Research for Industry at the University of Utah". Our industrial research policy and procedures are epitomized in the Standard Research Agreement in the Appendix. Often we depart from these provisions, upon request by the potential sponsor or the Principal Investigator. So, for example, it is not unusual for us to grant exclusive patent licensing and to permit only a 30-day review before publication.

Our conflict of interest policy is described in the enclosed excerpt from our Policy and Procedures Manual. Also, the policy is expanded in "Commercialization of Scientific Discoveries" statement. We do not allow, for example, a company to support a Principal Investigator's research if he has a major position in the company (officer, director, etc.), as mentioned in your write-up.

Both conflict of interest and industrial research policies are treated in our Principal Investigator's Handbook, also enclosed. You may also be interested in the brochure "A Thriving Partnership: The University and High Tech Industry".

As you requested, I have also included the legislation and by-laws of the Utah Technology Finance Corporation. It is currently funded at $1.2M plus a $500,000 grant from HUD. I expect to call on you later in the year for a run-down on the activities of other States in connection with a panel discussion on University/State cooperation at the November NCURA meeting in Washington, D.C.

Sincerely,

James J. Brophy
Vice President for Research

JJB:mh
Attachments

UNIVERSITY OF UTAH

OFFICE OF VICE PRESIDENT FOR RESEARCH
GRANT AND CONTRACT INSTRUCTION

19 July 1982

SUBJECT: Commercialization of Scientific Discoveries

The University of Utah encourages dissemination and utilization of scientific and technical discoveries arising from academic research. Corporate or individual commercialization of these discoveries is often the most rapid and effective way for such intellectual properties to benefit the public. A broad range of services are available to aid in the initial stages of such development including the Patent and Product Development Office, the University of Utah Research Institute, and the University of Utah Research Park.

While faculty members are free to participate in corporate endeavors, such activity is subject to University patent policy and to disclosure of potential conflict of interest situations in accordance with University policy, which states, in part, "the purpose...of the regulations and guidelines set forth herein, is to promote the public interest and strengthen public confidence in the integrity of the university by establishing standards of conduct for university personnel in areas where there are actual or potential conflicts of interest between their duties to the university and their private interests." Furthermore, faculty so engaged are expected to meet their academic obligations in full measure with that level of dedication traditionally expected of University faculty.

The University does not participate in the operation of for-profit corporations established for the purpose of developing scientific or technical discoveries. Where appropriate, patent royalty income from or equity interest in such corporations is assigned to the University of Utah Research Foundation. Net income of the Foundation is used to support the scientific and educational purposes of the University. These practices do not change existing policies and procedures for accepting gifts of stock or other assets from private donors.

James J. Brophy
Vice President for Research

JJB:m

Distribution:
All Principal Investigators
Deans
Directors and Department Chairpersons
Administration

UTAH TECHNOLOGY AND INNOVATION ACT

1983

GENERAL SESSION

Enrolled Copy

S. B. No. 329

By Charles W. Bullen
Glade M. Sowards
Karl N. Snow, Jr.
Richard J. Carling
Wilford R. Black, Jr.
Bryce C. Flamm
Brent C. Overson
E. Verl Asay
Haven J. Barlow
Jack M. Bangerter
Karl G. Swan
Lowell S. Peterson
Fred W. Finlinson
W. L. Sandberg
Omar B. Bunnell
Eldon A. Money
Terry Williams
Dona M. Wayment
William T. Barton
Dix H. McMullin
Miles 'Cap' Ferry
Ivan M. Matheson
Arnold Christensen
Dale E. Stratford
Cary G. Peterson

AN ACT RELATING TO STATE AFFAIRS IN GENERAL; CREATING THE UTAH TECHNOLOGY FINANCE CORPORATION; AND GRANTING AUTHORITY TO

THE CORPORATION FOR THE CONTRACTING OF, DEALING IN AND ENCOURAGEMENT OF ECONOMIC GROWTH AND IMPROVEMENTS WITHIN THE STATE OF UTAH OF TECHNOLOGICAL AND INNOVATIVE BUSINESS, COMMERCIAL AND INDUSTRIAL ACTIVITIES WITH THE INTENTION OF BROADENING THE ECONOMIC BASE WITHIN THE STATE AND ENCOURAGING THE CREATION OF JOBS FOR RESIDENTS OF THE STATE.

Be it enacted by the Legislature of the State of Utah:

Section 1. This chapter shall be known and may be cited as the "Utah Technology and Innovation Act."

Section 2. As used in this chapter "small business" means small business as defined by the United States Small Business Administration, and "corporation" means the Utah technology finance corporation provided for in this chapter.

Section 3. There is established a non-profit corporation under the laws of Utah to be known as the "Utah technology finance corporation." Articles of incorporation shall be filed for the corporation with the lieutenant governor. The corporation shall, subject to this chapter, have all powers and authority permitted non-profit corporations by law, including but not limited to the power and authority:

(1) To take all action necessary or desirable to encourage and assist in the research, development, promotion and growth of emerging and developing technological and innovative small businesses throughout Utah;

(2) To provide from its funds matching sources of capital for equity investment in or direct loans to emerging and developing technological and innovative small businesses in accordance with this chapter;

(3) To coordinate and cooperate with the department of community and economic development, all other state agencies and its political subdivisions, colleges, universities, other academic and research sources, both private and public,

agencies and entities of the United States government, and all other public or private entities;

(4) To obtain, hold, and own royalties, stock and other ownership interests and proprietary rights in companies, patents, copyrights, licenses, projects and other developments and businesses which have been encouraged, established or fostered through the efforts, contacts, money or other resources of the corporation;

(5) To make arrangements with various businesses and technological development companies for additional sources of funding and with federal, state and other governmental entities, as well as private and public foundations, and other donors for sources of grants to assist the corporation and other corporations, small businesses, and high technology projects to obtain the necessary capital and other assistance to accomplish the purposes of this chapter;

(6) To invest and reinvest its funds for the purposes provided in this chapter;

(7) To expend its money for the operation of the corporation and its purposes;

(8) To contract with public and private entities and agencies, individuals and companies, for the carrying on of the activities and powers provided in this chapter, including the granting of research contracts;

(9) To receive appropriations from the legislature, as well as contributions from other public agencies, private individuals, companies and other donors and contributors; and

(10) To seek federal and state tax exemptions, and to take all related actions, as determined by the board of trustees of the corporation.

Section 4. (1) The corporation shall be governed by a board of trustees consisting of at least seven but no more than eleven trustees appointed for staggered three-year terms and consisting of the following:

(a) A member of the Utah state senate, appointed by the president of the senate;

(b) A member of the Utah state house of representatives, appointed by the speaker of the house of representatives; and

(c) The remaining trustees appointed by the governor with consent of the senate, selected from representatives of the academic, banking and finance, venture capital, engineering, scientific, legal and accounting communities and from the general public.

(2) The corporation may:

(a) Adopt bylaws and rules and exercise all other powers permitted under the laws of Utah not in conflict with this chapter;

(b) Hire a full-time director and all other employees which the trustees determine necessary for the conduct of the business of the corporation, and to compensate the director and the other employees from the funds of the corporation or from other resources available to the corporation; and

(c) Establish an advisory board consisting of persons experienced and knowledgeable in science, business, banking, law, government, academics, and accounting, and consisting of others whom the board of trustees deems desirable to assist in the accomplishment of the purposes of this chapter.

Section 5. The corporation, in connection with its operations and duties, shall comply with the following criteria:

(1) If the corporation provides money to high technology small businesses or projects in Utah in the form of research contracts, unless otherwise determined by the board of trustees, royalty payments shall be retained and provision made for ultimate conversion of all rights so acquired into equity in the high technology small business or project;

(2) If the corporation provides money for direct capital investment in high technology small businesses or projects, the

corporation shall require, as a condition thereof, matching funds from private sources in amounts at least equal to the money invested by the corporation;

(3) The proprietary rights and interests of the corporation in such high technology small businesses and projects shall remain a non-controlling minority interest;

(4) The corporation shall, by written contract, ensure that it is given regular status reports on the use of the money it has invested or loaned or research contracts it has awarded to high technology, small businesses and projects and on the status of the small business or project in which it has become so involved;

(5) The assistance and investment by the corporation in high technology businesses and projects is limited to those small businesses and projects having their primary place of business and projects, as well as their primary business operations, within Utah; and

(6) The corporation shall encourage the development and growth of businesses and technology which are not detrimental to the quality of the land, air, water, or general environment of Utah.

BY-LAWS

OF

UTAH TECHNOLOGY FINANCE CORPORATION

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ARTICLE I

Offices

The principal office of the Corporation in the State of Utah shall be located in Salt Lake City, Utah. The Corporation shall have such other offices, either within or without the State of Utah, as the Board of Trustees may designate or as the business of the Corporation may require from time to time.

The registered office of the Corporation required by the Utah Non-Profit Corporation and Cooperative Association Act to be maintained in the State of Utah may, but need not, be identical with the principal office in the State of Utah, and the address of the registered office may be changed from time to time by the Board of Trustees.

ARTICLE II

Trustees

Section 1. Board of Trustees. The Corporation shall be governed by a Board of Trustees consisted of at least seven (7) trustees and no more than eleven (11) trustees appointed for staggered three year terms and consisting of the following:

(a) .. member of the Utah State Senate, to be appointed by the President of the Senate.

(b) A member of the Utah State House of Representatives, to be appointed by the Speaker of the House of Representatives.

(c) The remaining trustees as appointed by the Governor with consent of the Senate, such trustees to be selected from representatives of the academic, banking and finance, venture capital, engineering, scientific, legal and accounting communities and from the general public.

Section 2. Duties. The Board of Trustees shall have the control and general management of the affairs and business of the Corporation. Such Trustees shall in all cases act as a Board, except as otherwise provided herein, regularly convened, by a majority, and they may adopt such rules and regulations for the conduct of their meetings and the management of the company, as they may deem proper, not inconsistent with these By-Laws, the laws of the State of Utah, and the provisions of Section 501(c)(3) of the Internal Revenue Code of 1954 (or the corresponding provision of any future United States Internal Revenue Law) governing exempt organizations.

Section 3. Trustees Meetings. Regular meetings of the Board of Trustees shall be held at such times and places as the Board of Trustees may determine. Special meetings of the Board

of Trustees may be called by the President at any time, and shall be called by the President or the Secretary upon the written request of three Trustees.

Section 4. Notice of Meetings. Notice of meetings shall be given by service upon each Trustee in person, or by mailing to each Trustee at that person's last known address, at least ten (10) days before the date therein designated for such meeting, including the day of mailing, of a written or printed notice thereof specifying the time and place of such meeting, and the business to be brought before the meeting. At any meeting at which every member of the Board of Trustees shall be present, although held without notice, any business may be transacted which might have been transacted if the meeting had been duly called.

Any Trustee may waive notice of any meeting under the provisions hereof. The attendance of a Trustee at a meeting shall constitute a waiver of notice of such meeting except where a Trustee attends a meeting for the express purpose of objecting to the transaction of any business because the meeting is not lawfully convened or called.

Section 5. Voting. At all meetings of the Board of Trustees, each Trustee is to have one vote. The act of a majority of the Trustees present at a meeting at which a quorum is present shall be the act of the Board of Trustees.

Section 6. Vacancies. Vacancies in the Board occurring between annual meetings shall be filled for the unexpired portion of the term by that person who originally appointed that Trustee.

Section 7. Quorum. The number of Trustees who shall be present at any meeting of the Board of Trustees in order to constitute a quorum for the transaction of any business or any specified item of business shall be a majority of the then serving Trustees.

The number of votes of Trustees that shall be necessary for the transaction of any business or any specified item of business at any meeting of the Board of Trustees shall be a majority of those attending such meeting.

If a quorum shall not be present at any meeting of the Board of Trustees, those present may adjourn the meeting from time to time, until a quorum shall be present.

Section 8. Executive Committee. By resolution of the Board of Trustees, the Trustees may designate an executive committee of not less than three Trustees, to manage and direct the daily affairs of the Corporation. The Executive Committee shall have and may exercise all of the authority that is vested in the Board of trustees as if the Board of Trustees were regularly convened, except that the Executive Committee shall not have authority to amend these By-Laws.

At all meetings of the Executive Committee, each member of that committee shall have one vote and the act of a majority of the members present at a meeting at which a quorum is present shall be the act of the Executive Committee.

The number of Executive Committee members who shall be present at any meeting of the Executive Committee in order to constitute a quorum for the transaction of any business or any specified item of business shall be a majority.

The number of votes of Executive Committee members that shall be necessary for the transaction of any business or any specified item of business at any meeting of the Executive Committee shall be a majority.

Section 9. Committees. The Board of Trustees, by resolution of the Board, may establish such other committees to assist the Corporation in an advisory or assisting role as it may determine.

Section 10. Compensation. By resolution of the Board of Trustees, the Trustees may be paid their expenses, if any, of attendance at any meeting of the Board of Trustees or a reasonable compensation for services rendered. No such payment shall preclude any Trustee from serving the Corporation in any other capacity and receiving reasonable compensation therefore.

Section 11. Presumption of Assent. A Trusteee of the Corporation who is present at a meeting of the Board of Trustees at which action on any corporate matter is taken shall be presumed to have assented to the action taken unless his dissent shall be entered in the minutes of the meeting or unless he shall file his written dissent to such action with the person acting as the Secretary of the meeting before the adjournment thereof or shall forward such dissent by registered mail to the Secretary of the Corporation immediately after the adjournment of the meeting. Such right of dissent shall not apply to a Trustee who voted in favor of such action.

Section 12. Director and Employees. The Board shall be entitled to hire a full time director and all other employees which the Trustees determine necessary for the conduct of the business of the Corporation, and to compensate the director and other employees from the funds of the Corporation or from other resources available to the Corporation. The director and other employees shall serve at the pleasure of the Board.

Section 13. Advisory Board. The Board shall also have the right to establish an advisory board consisting of persons experienced and knowledgable in science, business, banking, law, government, academics, accounting, engineering and consisting of others whom the Board of Trustees deems desirable to assist in the accomplishment of the purposes of the Corporation.

Section 14. Other Activities. In order to obtain expertise to further the purposes of the Corporation and its legislative powers and mandate, Trustees, Advisory Board members, officers, employees and other agents of the Corporation may or shall be appointed or selected from areas of business, government, education, science, law and other businesses and professions directly or indirectly engaged in or acquainted with persons engaged in technological, innovative and emerging businesses and pursuits for which the Corporation has been established to foster and encourage. These circumstances may result in any or all such persons, associated with the Corporation, indirectly receiving some benefit from results of the Corporation's activities. Such conflicts or benefits shall not limit or disqualify the right of any such person to assume and carry out his or her role and responsibilities on behalf of the Corporation; provided, however, that all of the Corporation's activities shall be conducted in a manner not to conflict with the provisions of Section 501(c)(3) of the Internal Revenue Code of 1954, as amended (or the corresponding provisions of any future United States Internal Revenue law); and, provided further, that the Corporation shall take all reasonable action to ensure the prevention of any abusive, predatory, or unethical practices by all persons associated with the Corporation.

ARTICLE III

Officers

Section 1. Number. The officers of this Corporation shall be: President, Vice-President, Secretary and Treasurer.

Any officer may hold more than one office.

Section 2. Election. All officers of the Corporation shall be elected annually by the Board of Trustees, and shall hold office for the term of one (1) year or until their successors are duly elected. Officers need not be members of the Board.

The Board may appoint such other officers, agents and employees as it shall deem necessary, who shall have such authority and shall perform such duties as from time to time shall be prescribed by the Board.

Section 3. Duties of Officers. The duties and powers of the officers of the company shall be as follows:

PRESIDENT

The President shall preside at all meetings of the Board of Trustees and members.

He shall present at each annual meeting of the Trustees, a report of the condition of the business of the Corporation.

He shall cause to be called regular and special meetings of the Trustees in accordance with these By-laws. He shall appoint and remove, employ and discharge, and fix the compensation of the director and of all servants, agents, employees and clerks of the Corporation other than the duly appointed officers, subject to the approval of the Board of Trustees.

He shall sign and make all contracts and agreements in the name of the Corporation.

He shall see that the books, reports, statements, and certificates required by the statutes are properly kept, made and filed according to law.

He shall sign all notes, drafts or bills of exchange, warrants or other orders for the payment or money duly drawn by the Treasurer.

He shall enforce these By-laws and perform all the duties incident to the position and office, and which are required by law.

VICE-PRESIDENT

During the absence or inability of the President to render and perform his duties or exercise his powers, as set forth in these By-laws or in the acts under which this Corporation is organized, those duties shall be performed and exercised by the Vice-President and when so acting, he shall have all the powers and be subject to all the responsibilities hereby given or imposed upon such President.

SECRETARY

The Secretary shall keep the minutes of the meetings of the Board of Trustees in appropriate books.

He shall give and serve all notices of the Corporation.

He shall be custodian of the records and of the seal and affix the latter when required.

He shall present to the Board of Trustees at their stated meetings all communications addressed to him officially by the President or any officer of the Corporation.

He shall attend to all correspondence and perform all the duties incident to the office of Secretary.

TREASURER

The Treasurer shall have the care and custody of and be responsible for all the funds and securities of the Corporation, and deposit all such funds in the name of the Corporation in such bank or banks, trust company or trust companies or safe deposit vaults as the Board of Trustees may designate.

He shall exhibit at all reasonable times his books and accounts to any Trustee of the Corporation upon application at the office of the Corporation during regular business hours.

He shall render a statement of the conditions of the finances of the Corporation at each regular meeting of the Board of Trustees, and at such other times as shall be required by him.

He shall k p at the office of the C rporation, correct books of account of all its business and transactions and such other books of account as the Board of Trustees may require.

He shall do and perform all duties appertaining to the office of Treasurer.

Section 4. Bond. The Treasurer shall, if required by the Board of Trustees, give to the Corporation such security for the faithful discharge of his duties as the Board may direct.

Section 5. Vacancies, How Filled. All vacancies in any office shall be filled by the Board of Trustees without undue delay, at any regular meeting or at a meeting specially called for that purpose. In the case of the absence of any officer of the Corporation or for any reason that the Board of Trustees may deem sufficient, the Board may, except as specifically otherwise provided in these By-laws, delegate the powers of or duties of such officers to any other officer or Trustee for the time being, provided a majority of the entire Board concurs therein.

Section 6. Compensation Of Officers. The officers shall receive such compensation for services rendered as may be determined by the Board of Trustees.

Section 7. Removal Of Officers. The Board of Trustees may remove any officer, by a majority vote, at any time with or without cause.

ARTICLE IV

Seal

Section 1. Seal. The seal of the Corporation shall be as determined by the Board of Trustees.

ARTICLE V

Bills, Notes, Etc.

Section 1. How Made. All bills payable, notes, checks, drafts, warrants, or other negotiable instruments of the Corporation shall be made in the name of the Corporation, and shall be signed by such officer or officers, agent or agents of the Corporation and in such manner as shall from time to time be determined by resolution of the Board of Trustees.

ARTICLE VI

Amendments

Section 1. How Amended. These By-laws may be altered, amended, repealed or added to by the vote of the Board of Trustees of this Corporation at any regular meeting of the Board, or at a special meeting of the Trustees called for that purpose; provided a quorum of the Trustees, as provided by law and by the Articles of Incorporation, is present at such regular meeting or special meeting; and provided, further, that no amendment to these By-laws may be made which is contrary to the terms of the Articles of Incorporation or of any provision of law.

ARTICLE VII

Fiscal Year

Section 1. The fiscal year shall begin January 1 and end on December 31.

ARTICLE VIII

Waiver of Notice

Section 1. Whenever any notice is required to be given to any Trustee of the Corporation under the provisions of these By-laws or under the Articles of Incorporation or under the provisions of the Utah Non-Profit Corporation and Cooperative Association Act, a waiver thereof in writing signed by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice.

ADOPTED this 22nd day of September, 1983.

BY: Sidney J. Green

ITS: President

ATTEST:

CERTIFICATE OF SECRETARY

I, the undersigned, do hereby certify:

(1) That I am the duly elected and acting Secretary of Utah Technology Finance Corporation, a Utah Corporation; and

(2) That the foregoing By-laws, comprising eleven (11) pages, constitutes the By-laws of that Corporation as duly adopted at a meeting of the Board of Trustees thereof duly held the 22nd day of September, 1983.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed the seal of said Corporation, this 22nd day of September, 1983.

(Seal)