

UNIVERSITY OF MINNESOTA

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May 5, 2004

PERSONAL & CONFIDENTIAL

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OFFICE OF GENERAL COUNSEL

Leo T. Furcht, M.D.
Professor and Head
Department of Laboratory Medicine & Pathology
MMC 609

Dear Dr. Furcht:

As we have previously discussed, it is critical that as a senior faculty and department head, one set an example by adhering to the University standards regarding external business relationships and avoid conflict of interest. This letter is written to resolve outstanding issues related to your role in a July 2000 research agreement between Baxter Healthcare Corporation and a company owned by you. Your actions violated the University's Conflict of Interest Policy as indicated in the Inquiry Panel's report of December 19, 2003. These violations warrant disciplinary action under Section 10.22 of the Tenure Code. Therefore, I am providing a written reprimand and agreement for inclusion in your file.

Despite this, I value your managerial abilities as a department head and wish to retain you in this role. We have agreed upon the steps listed below to avoid future instances of misconduct arising from external business¹ relationships. These measures will be in place for three years and will be re-evaluated at the end of that time period.

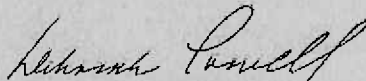
1. You will not perform business-sponsored research at the University of Minnesota. This includes use of University facilities, equipment, or animals in business-sponsored research.
2. You will not be involved with business sponsored research by faculty in Laboratory Medicine and Pathology.
3. You will refrain from entering into any consulting relationships with businesses.
4. Any business entities in which you have an ownership interest or hold board or executive positions will refrain from sponsoring research in the Medical School.

¹ Business is defined in the University's conflict policy and in this letter as any nongovernmental legal entity organized for profit, non-profit or charitable purposes, See Section IV, subd.2 of the policy.

5. You will assign another senior faculty member from Laboratory Medicine and Pathology the task of authorizing the Report of External Professional Activities (REPA) for employees in your department. This individual must be acceptable to the Medical School and the Office of Regulatory Affairs which oversees the REPA process.
6. You will not provide data from unpublished research at the University to any businesses.
7. You acknowledge a clear understanding of Regents policies on: (a) outside consulting and other professional activities, and (b) conflict of interest, and you agree to adhere to these policies, including making full disclosure of all covered activities. In addition, you acknowledge your responsibility to inform members of your department (faculty, students, and staff) of their obligations to comply with Regents policies on outside professional activities and conflict of interest.

The resolution outlined in this letter is in lieu of any further review by the ad hoc committee engaged by me to evaluate your conduct under Section 10 of the Tenure Code. Please sign below to acknowledge and accept this resolution.

Sincerely,



Deborah E. Powell, M.D.
Dean of the Medical School
Assistant Vice President for Clinical Sciences

DEP:bj

Leo T. Furcht, M.D.

Date

REPORT OF INQUIRY PANEL REGARDING DR. LEO FURCHT CONFLICT OF INTEREST

INTRODUCTION

This is an inquiry report examining whether Dr. Leo Furcht has violated the University's conflict of interest policy in connection with a July 2000 research agreement involving Baxter Healthcare Corporation. Based on the reasons detailed below, the Panel concludes that Dr. Furcht has committed a serious violation of the conflict of interest policy and recommends that he be subject to disciplinary action. Further, the Panel recommends that the Medical School consider proceeding with a full investigation to examine whether Dr. Furcht committed misconduct under the Tenure Code by misusing the powers of his professional position as a professor and department head to obtain personal benefits.

Panel members who conducted the inquiry were: Robert Cipolle, Professor of Pharmacy and Chair of the AHC Conflict Review Committee; Frances Lawrenz, Professor of Educational Psychology and member and Interim Chair of the Provost's Conflict Review Committee; and Anne Taylor, Associate Dean of the Medical School and member of the Research Relationships Review Panel. In addition, Richard Bianco, Assistant Vice President for Regulatory Affairs, and Barbara Shiels, legal advisor for the University's conflict review committees, served as ex-officio advisors to the inquiry panel.

SUMMARY OF PANEL'S WORK

The Panel met on four occasions to carry out the inquiry. There was an initial meeting on August 18, 2003, where Gail Klatt and Allen Willie of the Department of Audits provided background factual information to the Panel. The Panel interviewed [redacted] on September 18, 2003, and interviewed Dr. Furcht on September 30, 2003. There was a final meeting on October 10, 2003, with no witnesses present, where the Panel assessed the evidence collected in the inquiry and formulated the Panel's conclusions. Legal counsel for the Panel was not present at the Panel's interviews of September 18 and September 30, because neither [redacted] nor Dr. Furcht appeared with legal counsel.

EVIDENCE REVIEWED

In addition to the evidence obtained through witness interviews, the Panel reviewed numerous documents in the course of the inquiry. These documents included contracts, research reports and correspondence between [redacted] and Dr. Furcht. A complete list of the documents is attached as Appendix A.

SUMMARY OF WITNESS INTERVIEWS

A. Audit Manager Allen Willie

Allen Willie ("Auditor Willie") indicated that [redacted] and Dr. Furcht entered into a research agreement with Baxter Healthcare Corporation ("Baxter") in July 2000. The Agreement was between Baxter and MCL, a company formed by Dr. Furcht to commercialize stem cell technology developed by [redacted] in which the University had waived its interests. Dr. Furcht has an equity/ownership interest in MCL and is the president of the company, whereas [redacted] has a royalty interest only in MCL.

Under the research agreement, Baxter was to pay MCL \$501,000 to conduct research on whether [redacted] could use stem cell technology to grow red blood cells. [redacted] and Dr. Furcht signed the agreement as "investigators" and Dr. Furcht also signed separately as President of MCL. The research was performed by [redacted] and the employees in [redacted] laboratory at the University.

According to Auditor Willie, the parties to the agreement understood the research would be conducted at the University. However, the University was not a party to this agreement and it was executed without the University's knowledge. An earlier draft version of the agreement in April 2000 listed the University as a party but Dr. Furcht maintained he didn't need to continue to involve the University once the University had waived its interest in the technology in May 2001. The University became aware of the agreement in the fall of 2002 when the issue arose in connection with a proposed sale by Furcht of MCL to another company called Athersys. Also, around this time [redacted] asked the Office of the General Counsel for help in getting payment from Dr. Furcht for the research that had been performed for Baxter.

Auditor Willie reported the Baxter research had been completed in March 2001 and a final report by [redacted] and Dr. Furcht was delivered to Baxter at that time. Dr. Furcht confirmed to Auditor Willie that Baxter had made the payment of \$501,000 for the research. However, Dr. Furcht had advised [redacted] the money was used to offset legal expenses for patent prosecution and he claimed already to have funded over \$1 million of research in [redacted] laboratory through the University's BMEI.

Auditor Willie said he understood that both [redacted] and Dr. Furcht had disclosed their interests in MCL to the University through the regular conflict of interest reporting process. However, neither had disclosed the Baxter agreement or the work being done at the University on behalf of MCL and Baxter. To Auditor Willie's knowledge, Dr. Furcht had participated in the Baxter research by making a presentation to Baxter about the research, securing Baxter as a sponsor and signing off on the report of research findings to Baxter. Auditor Willie reported that Dr. Furcht stands to make several million dollars if the sale of MCL to Athersys is finalized.

B. Dr. Leo Furcht

Dr. Furcht was asked for an explanation of the study. He responded that [redacted] had been trying to make blood with what [redacted] thought were mesenchymal stem cells. In the process of trying to make blood, they made what looked like neuronal cells. All along there was [redacted]

interest in testing for hematopoiesis of the cells but that lineage was having difficulty coming to fruition. The technology is very gray as to where it begins and ends. Therefore, a protocol was developed to study hematopoiesis, both in-vitro and in-vivo.

Dr. Furcht was asked about the findings and he responded that the work was ongoing before and continued afterward. Six months into the protocol, [redacted] began to see spleen colonies in in-vivo studies. These cells are now called MAPC's. The results showed limited engraftment in-vivo. With some cytokines and growth factors it could be done in vitro but the only thing [redacted] saw was the ability to form fetal hemoglobin chains and not adult cells.

Dr. Furcht was asked what the relationship was between MCL and the University. He responded that they went to PTM in 1998 or 1999 with an abstract that is the heart of the company's technology and the University did not want to file the patent. The University had contacted Osiris and the company responded it had this and was not interested. According to Dr. Furcht, [redacted] came to him because of his experience with patents. After the University waived its rights, he worked with [redacted]. He was assured that the technology was waived and MCL was set up as a shell to hold the technology. MCL does not have a building or a lab, just the technology patent. Dr. Furcht said he decided to file the provisional patent and figure out other issues later.

In September 2001, [redacted] from PTM said there was a new disclosure, different from the original that was presented to PTM. He asked if Dr. Furcht would give [redacted] a waiver to work on that for the University. According to Dr. Furcht, what came out of that was the University accusing [redacted] of not being truthful in [redacted] disclosure to PTM. Dr. Furcht felt the University understood what it lost and wanted to get it back.

Dr. Furcht said a legal debate ensued with the University from September 2001 through May 2002 as to what the MCL patent covered. It was settled that MCL owned only a small piece of the technology and the University owned the hematopoiesis work.

Dr. Furcht was asked when the research agreement was signed for the study in question. He stated the protocol was initiated in July 2000. At that point the University had waived the patent and MCL thought it held the patent right.

Dr. Furcht was questioned why there were two versions of the research agreement and why on one the University was the institution and on the second MCL was the institution? Dr. Furcht stated that this was at the request of the legal people at Baxter who said the University could not enter into an IP agreement on something they did not own. The panel noted that Dr. Furcht signed the protocols as the President of MCL and as an investigator. Does he see a conflict in that? Dr. Furcht did not see one because the research was to be done in someone else's lab. The panel stated that he had control of the money and that is a PI role. He agreed that he controlled the money but said he never intended to participate in the research.

Dr. Furcht was asked to explain his relationship with MCL. He responded that the University owns 5% and some consultants own a little. He is the "top dog" of MCL.

has no relationship except assigning the technology. In consideration for that a royalty arrangement was made with MCL. did not want more of a financial arrangement.

Dr. Furcht was asked who funded the study in question. He responded that Baxter funded it and that he has no relationships with Baxter.

Dr. Furcht was asked why the parallel research agreement between MCL and the University was not made. He stated that Baxter wanted the agreement with MCL because MCL owned the cells. The panel asked is there documentation stating that Baxter knew they would have to license from the University if the research were successful? He stated that the Company owns only the abstract.

The panel noted that if subsequent to the interim report Baxter wanted the technology, MCL would have had to go to the University. At the time the interim report was done in March 2001, why would Baxter think they had to go to the University to license the technology from the study? Dr. Furcht stated it was novel research outside the original grant. Part of the gray area was the ongoing negotiations. It took from October to June 17 to finalize an agreement with Athersys.

Dr. Furcht was asked where the money is now. He responded we settled to the degree that patent lawyers could agree with who owned what. As part of that deal, he said he wanted to make it look like the University had licensed the technology. The University got equity and royalties. Dr. Furcht said we structured it to have sub-licensing and will close on acquiring the technology. When that happens the first phase of money will come in. Part of that deal was to close the books on money owed to the University. Athersys acquires MCL assets and liabilities.

Dr. Furcht stated that the Baxter project is done and Baxter paid the money to MCL, but that a final report was never issued. Dr. Furcht was asked again why he was listed as an investigator. He responded that it was Baxter's document.

RELEVANT PROVISIONS OF THE REGENTS POLICY

There are several provisions of the Regents policy that are relevant to this inquiry. They include the definitions of business interest and significant financial interest, disclosure requirements, enforcement through disciplinary action, research activities constituting moderate to high potential for conflict, and department head review responsibilities. These provisions are referenced in the conclusions section below and excerpted verbatim in Appendix B.

CONCLUSIONS OF INQUIRY

1. Dr. Furcht had a business interest and a significant financial interest as defined under the Regents Conflict of Interest Policy. His business interest was an executive position as founder and president of MCL, and his financial interest was chief equity holder in the company. See definitions of "business interest" and "significant financial interest" in Appendix B, item 1.

2. Dr. Furcht's involvement in research conducted at the University under the Baxter research agreement constituted a moderate to high potential for conflict of interest under the Regents Policy. Although not part of the day to day research activities in laboratory, Dr. Furcht participated in the Baxter research in several key ways: he contacted the funding agency, negotiated for external support, facilitated the use of University facilities for the research project; identified himself as an investigator on the research agreement with Baxter, presented research results to Baxter, submitted a written report about the project with his name included on the report, and controlled the funding of the project at the University. Thus, Dr. Furcht participated in the evaluation or development of stem cell technology owned by MCL in which he had a business interest and a significant financial interest in the form of equity in the company. Appendix B, item 2.

3. Dr. Furcht was required to disclose his involvement in the Baxter project prior to undertaking this activity at the University. Prior disclosure of a potential conflict of interest is a key requirement of the Regents policy. Appendix B, item 3.

4. Dr. Furcht failed to make a prior disclosure of his involvement in the Baxter project and therefore, violated the Regents policy. Failure to file a required disclosure may be the basis for discipline of an employee under the enforcement section of the policy. Appendix B, item 4.

5. Dr. Furcht's violation of the conflict policy was a serious violation by a senior University official which the panel believes warrants both corrective and disciplinary action against Dr. Furcht. There were a number of factors leading the panel to this conclusion:

- a) First, Dr. Furcht did not have a reasonable basis for believing he was in compliance with the conflict policy. Dr. Furcht's participation in the project as outlined in paragraph 2 above (e.g. obtaining research funding, identifying himself as an investigator, presenting research results, controlling the project funds, etc) is typical of the actions performed by a principal investigator. The fact that Dr. Furcht did not also perform the day to day research activities in the laboratory does not render him exempt from the conflict policy. Dr. Furcht was in a position to influence the design, conduct and/or reporting of research conducted at the University in which he had a business and financial interest and thus was subject to the restrictions of the conflict policy.
- b) Second, as a department head with administrative and oversight responsibilities under the conflict policy, Dr. Furcht is expected to know and understand the requirements of the policy. Dr. Furcht is responsible for reviewing and approving the REPA forms for each academic employee in his department and is the primary administrator responsible for determining the appropriate course of action for those external relationships that create a minimal to moderate potential for conflict. See Appendix B, item 5. Dr. Furcht either knew or should have known that his participation in the Baxter project performed at the University using

technology owned by MCL created a sizeable potential for conflict of interest.

- c) Finally, as the President and chief equity holder of MCL, Dr. Furcht had extensive business and financial interests in the MCL technology evaluated under the Baxter agreement. Dr. Furcht described himself as the "top dog" of MCL. In fact, it appears Dr. Furcht stands to personally gain several million dollars from the pending sale of MCL to Athersys. When an individual holds interests in an outside company as extensive as Dr. Furcht's interests, there is a concern under the conflict policy that those interests could give rise to an actual conflict of interest where the employee compromises his or her professional judgment in carrying out University responsibilities. Based on the magnitude of Dr. Furcht's interest in MCL, it is highly unlikely the University would have permitted any involvement by him in the Baxter project performed at the University had he complied with the conflict policy and disclosed this activity prior to undertaking the project.

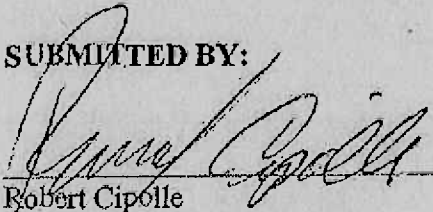
6. The panel recommends the following corrective and disciplinary action to address Dr. Furcht's violation of the conflict of interest policy:
 - a) As corrective action, Dr. Furcht re-takes the Responsible Conduct of Research (RCR) course - Parts 1 and 2 to help assure he satisfies University requirements related to any future research in which he participates at the University; and
 - b) As disciplinary action, Dr. Furcht at a minimum should not be allowed to perform the conflict of interest responsibilities of a department head. Based on Dr. Furcht's own serious violation of the conflict policy, the panel does not have confidence he can properly carry out the administrative and oversight responsibilities specified in paragraph 5(b) above that are required of a department head under the conflict policy. Further, since responsibility to monitor conflict of interest is such an important part of a department head's duties, the Panel believes that Dr. Furcht's removal as Department Head may be warranted.
7. The panel believes it has all the necessary facts to reach a conclusion about Dr. Furcht's conduct under the conflict of interest policy and to recommend appropriate action as outlined above. However, the panel acknowledges that the decision whether to proceed to a full investigation rests solely with the Dean of the Medical School.
8. On a related issue, the panel recommends that the Dean consider undertaking an investigation to examine whether Dr. Furcht committed misconduct under Section 10 of the Faculty Tenure Code. This section includes the following ground as a basis for suspension, termination or other disciplinary action against a faculty member:

Egregious or repeated misuse of the powers of a professional position to solicit personal benefits or favors. Faculty Tenure Code, Section 10.21(c).

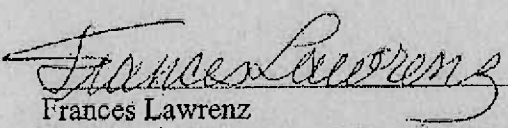
Several of Dr. Furcht's actions raise questions about possible misuse of his professional position. In particular, further review may be needed to determine whether Dr. Furcht misused his faculty and/or department head position in ways such as the following:

- a) To arrange for research to be conducted at the University to personally benefit him and his commercial interests;
- b) To delay or avoid addressing [redacted] concerns about payment of research fees for the Baxter research performed in [redacted] laboratory;
- c) To direct the use of University funds to cover research performed in [redacted] laboratory that served the commercial interests of Dr. Furcht and MCL; and
- d) To manipulate and mislead [redacted] into performing research at the University that personally benefited Dr. Furcht and his commercial interests.

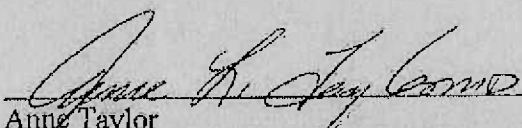
SUBMITTED BY:


Robert Cipolle
Professor of Pharmacy and
Chair of the AHC Conflict Review Committee

12/19/03
Date


Frances Lawrenz
Professor of Educational Psychology and
Member and Interim Chair of the Provost's
Conflict Review Committee

12/19/03
Date


Anne Taylor
Associate Dean of the Medical School and
Member of the Research Relationships Review Panel

12/19/03
Date