Minutes*

Senate Research Committee
Monday, November 24, 2003
1:15 - 3:00
238A Morrill Hall

Present: Gary Balas (chair), Dianne Bartels, Victor Bloomfield, Sharon Danes, Kathy Ensrud, Steven Gantt, David Hamilton, Michael Hughey, Katherine Klink, Andrew Koch, James Luby, Mark Paller, Maria Sera, Virginia Seybold, Thomas Schumacher, Barbara VanDrasek, (a representative for) Michael Volna

Absent: Darryn Beckstrom, Kathleen Conklin, James Cotter, Christopher Cramer, Dan Dahlberg, Robin Dittman, Paul Johnson, Phillip Larsen, James Orf, Charles Spetland, George Trachte, Jean Witson

Guests: Senior Vice President Frank Cerra, Assistant Vice President Richard Bianco (Office of Regulatory Affairs), Barbara Shiels (Office of the General Counsel); Moira Keane (Institutional Review Board), Win Ann Schumi (Office of Oversight and Accountability in Research), Ed Wink (Sponsored Projects Administration), Mark Bohnhorst (Office of the General Counsel); Assistant Vice President Tony Strauss (Office of Patents and Technology Marketing)

Other: John Ramsay (American Council on Education Research Fellow)

[In these minutes: (1) stem cell research; (2) essential medicines; (3) briefly, technology park and investment in business incubators]

1. Stem Cell Research

Professor Balas convened the meeting and welcomed Senior Vice President Cerra, Assistant Vice President Bianco, and Ms. Shiels, who joined Vice President Hamilton in discussing the University's policies dealing with stem cell research.

Dr. Cerra began by explaining that stem cell research is part of the core research conducted in the Academic Health Center (AHC) and has been for some time. It is driven by the research interests of the faculty, not by any administrative directive. The Stem Cell Research Institute wants to do this research using all types of stem cells. They spent a lot of time with a broad-based set of individuals--the faculty, the Office of the General Counsel, Sponsored Projects Administration, the Controller, the Institutional Review Board, and the Office of Regulatory Affairs--developing the policies that are being presented today. Because this research takes place at the intersection of law, regulations, and research funding, the University believed it needed to bring all the factors affecting the research into one place.

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate or Twin Cities Campus Assembly; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Senate or Assembly, the Administration, or the Board of Regents.

Dr. Cerra described stem cells and the research. The following bullets are drawn directly from the handout Dr. Cerra distributed to Committee members.

-- What are stem cells? Stem cells are the parent cells for all tissues and organs of the body; they are not specialized; some are capable of becoming any cells of the body and some are only capable of making a few cells types; they are found in animals and humans.

-- Where do stem cells come from? Embryo (embryonal) stem cells--ESC--are derived from a 4 to 5-day-old embryo, called a blastocyst; human ESC come from families who have chosen and knowingly given consent to donate their left-over embryos from in vitro fertilization for research purposes; ESC are pluripotent--they can become any cell of the body; ESC can grow forever and do not age.

-- Adult stem cells--general: Bone marrow and umbilical cord blood: both are known to possess blood stem cells and have been used for decades to replace the blood system of adults and children with cancer and blood diseases. Various organs: stem cells have been isolated from different organs such as brain, skin, eyes. Some of them are being used for treatment or therapies. Adult stem cells cannot grow indefinitely and age.

-- What about the U of MN stem cells? Catherine Verfaillie and researchers in the Stem Cell Institute discovered a certain type of Adult stem cells known as Multipotent Adult Progenitor Cells (MAPCs); their work is known around the world for research on these cells. University investigators isolated adult stem cells from human and animal bone marrow that under the right laboratory conditions behave a lot like embryonic stem cells. In animal models, research on these cells suggests they can differentiate into all cell types of the body. They appear to grow without differentiating and not to age.

-- How do MAPCs compare with ESCs? The MAPC cells replicate for more than a year; ESC cells for 5-30 years. MAPCs can become most (?) cell types; ESCs can become all cell types. It is not known if MAPCs can be passed on; ESCs can. MAPCs do not (yet?) cause tumors; ESCs do. MAPC cells are the patient's own; ESC cells are not unless they are cloned. Too many basic questions and unknowns remain unanswered to decide that either adult or ES cells will be most suitable for patient care. Until research can discover which cells work best for what, there needs to be research on both kinds of cells, Dr. Cerra told the Committee.

-- What is the potential of stem cells? Today: basic studies to understand potential and risks of stem cell treatments; they have obtained FDA approval for phase 1 and 2 studies (e.g., gene defects, with hematopoetic--blood--stem cells). Future: treat and cure diseases, replace organ system, test drug therapies for toxicity and other effects in the laboratory before human trials, deliver gene therapy (e.g., a cancer-killing gene).

-- There are several areas of focus on stem cell research at the University of Minnesota, using all types of animal and human stem cells to further regenerative medicine research in the following areas:

- -- inherited diseases (Hurler's Fanconi Anemia, hemophilia, muscular dystrophy; for the latter, the University just opened the Wellstone Center for MD);
- -- neurodegenerative diseases such as Parkinson's, stroke, ALS;
- -- diabetes (the cells can differentiate into islet cells that make insulin);

-- cardiovascular disorders, including heart attacks (the University just recruited from Duke the world's leader in this area to the Medtronic Bakken Chair in Cardiovascular Repair); and
-- liver disease.

-- How soon will this be real? In order (but without any predicted dates), the advances will likely come in gene therapy (hemophilia, Hurler's), then stroke/Parkinson's/diabetes/artificial liver/MD, then heart attack/liver replacement/Alzheimer's/Huntington's/spinal cord injury. Dr. Cerra affirmed, in response to a question from Dr. VanDrasek, that each in the progression will build on the science that has developed.

-- Dr. Cerra outlined the structure of the Stem Cell Institute, noting that it has four advisory boards (ethics, community, external scientific, and internal scientific). His office appoints the ethics advisory, which consists of international experts on law, ethics, and religion, to advise researchers.

Dr. Cerra then turned to embryo development. At day 0, there is fertilization and the zygote. At day 3 there is the morula (more than 30 cells). Option 1 for morula is implantation. Option 2 for families with genetic diseases is pre-implantation genetic diagnosis at day 2 and 3 and implantation within 24 hours. This is the Molly Nash case, he said.[1] At days 4-5 there is the blastocyst, the stage at which families choose one of four options: hold for future use (frozen), donate to other families, destroy, or donate to research.

-- What is fetal transplantation research? Fetal tissue is sometimes used as a source of cells, including stem cells; fetal tissue from spontaneous or induced abortion or stillbirth is donated for purpose of fetal transplantation research; a clinician/researcher who is separate from the woman's provider transplants the tissue into a human recipient for therapeutic purposes; fetal transplantation research shows much promise as a source of bone marrow stem cells to treat genetic disease.

-- Legal and funding requirements for fetal transplantation research: research is legal and eligible for federal funding if recipient is unknown to donor and all other federal requirements are met; research is legal but not eligible for federal funding if tissue from spontaneous abortion/stillbirth is transplanted into donor-designated recipient; research is illegal and will not be performed at the University where tissue from induced abortion is intended for donor-designated recipient.

-- Research at the University: The University is responsible for the creation and maintenance of an environment that maximally encourages and supports research productivity. Therefore:
-- if it is in an area of interest to one or more faculty,
-- if it is within existing legal and regulatory parameters,
-- if the faculty has resources to conduct the research,
-- if the University has the facilities and services to support the research, and
-- if the research has been approved by the appropriate oversight agencies,

[1] According to the Denver Post: "Molly was born to Lisa and Jack Nash 8 years ago. Molly was born with Fanconi anemia, a rare and fatal disease, treatable only by a blood transfusion from a sibling's umbilical cord. Lisa and Jack, using in vitro fertilization, created twelve embryos. By genetic screening, it was determined that two had Franconi's and were discarded. One of the remaining ten was a tissue match to Molly, and eventually became Adam Nash, now age 2. Molly was treated and instead of dying by age 7 is expected to have a relatively normal life."

then it can be done. Consistent with other public research institutions, the Board of Regents does not act to approve or disapprove areas of faculty research interest or individual research projects conducted at the University. It has always been that way, Dr. Cerra said.

The University has a lot of oversight of stem cell research; if a faculty member is going to do research in the area, he or she must follow the regulations (which is normal). There are a number of internal oversight mechanisms in place, including the Institutional Review Board (for research involving use of human subjects), IACUC (for research involving animals), the Stem Cell Ethics Advisory Board, conflict of interest and disclosure management, the Office of Oversight and Accountability in Research, the Office of Regulatory Affairs, and the Office of the Controller.

-- Legal requirements for stem cell research: For adult stem cells, there are no legal or funding restrictions; for embryo stem cells (from blastocysts), research is lawful under state law because the embryo shows no evidence of life through movement, heart or respiratory activity, or presence of electroencephalographic or electrocardiographic activity. Federal law provides that the research is lawful but federal funding is restricted.

-- Federal funding requirements for human embryonic stem cell research: On August 9, 2001, President George Bush announced that federal funds may be awarded for research using federally-approved human embryonic stem cells that meet the following criteria: the derivation process was initiated prior to 9:00 p.m. EDT on August 9, 2001; the stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed; informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements. If a researcher uses other lines of stem cells, federal funds may not be used, and the University must have an accounting system to be sure that no such use occurs either directly or indirectly. That is why they have brought the Controller, Mr. Volna, into the picture, in order to ensure the adequacy of the University's accounting system.

Does any other research require separate accounting, Professor Balas asked? Possibly classified research, Dr. Hamilton said. Dr. Cerra said that in general the University cannot commingle private and public funds, so the accounting system must isolate them. This, however, is a unique situation. It will NOT mean a change in the accounting system, he said, it will be a way the University ensures that anyone using embryonic stem cell lines is not using federal funds--and also that they are not using state funds. The major source of funding for this research is private funds. If a lab has been set up with federal funds, that lab cannot be used, Dr. VanDrasek asked? Yes and no, Dr. Cerra said; for a large piece of equipment that may have been purchased with federal funds, the researcher must log in the time and not attribute the costs of use to the federal government. The research is in a state-owned building, Professor Balas noted. They must figure out the costs of the research (utilities, etc.) attributable to stem cell research and charge them accordingly--which the University can do. The practices the University uses fall within NIH interpretations. Ms. Shiels explained that there used to be the belief that the University had to have a separate building; the federal government said that was not necessary and that existing accounting standards can be used to ensure federal funds are not used to support embryonic stem cell research with unapproved lines. The University must charge the costs to private sources and be able to document that it has done so. This is not new, Dr. Paller pointed out; it is done for other activities as well, such as in the lease of space to the hospital or to a private organization.

One challenge, Dr. Cerra said, is that researchers want the stem cell research results to remain in the public sector. That is more difficult to achieve if the research is funded only with private dollars.

The University's current policies are to support all stem cell research allowable under existing law and regulations, to support the use of private funding for human embryo, embryonal stem cell research, and fetal transplantation research, to cost-allocate, in accordance with all federal guidelines, for all research with non-federally-funded ES cells and fetal tissue, and to prohibit the use of federal and state dollars to support non-federally-approved ESC research.

In terms of what the states are doing, California has proposed a $3 billion bonding initiative to support stem cell research, a proposal driven by UCLA and UCSD; Massachusetts favors stem cell research. Restrictions on cloning and stem cell research have been introduced in Michigan, Wisconsin, North Dakota, Illinois, Indiana, and Nebraska. Bills have been passed in Iowa and South Dakota that researchers could not use human embryonic stem cells; as a result, an entire research group left Iowa.

Ms. Shiels next reviewed the policy statement language of two proposed policies, one governing research with human embryos or embryonic stem cells and the other with fetal transplantation. They are parallel but not identical, she said. The policies largely elaborate the points that Dr. Cerra made in his presentation.

Does the University have federal money for these kinds of research, Professor Balas asked? For embryonic stem cell research on approved cell lines but not for fetal transplantation research, Ms. Shiels said. Dean Bloomfield asked about the rationale in the fetal transplantation policy for language that provides that federal and state funds may not be used for research "where the recipient of the transplant is a relative of the donor or has been designated by the donor." Ms. Shiels explained that the law was designed to either make illegal or discourage such research because it does not want a child conceived and aborted to treat a specific person's disease. The law does allow use of tissues from a spontaneous abortion or stillbirth for this purpose.

Why restrict the use of state money, Professor Balas asked? The state law does not impose the restrictions that the federal law does. Federal and state funds are public, Dr. Cerra said, and the University wanted to be sure it avoids the use of public funds. It could be that the state will say the funds should be used for such purposes (as has been proposed in California), Dr. Hamilton said, in which case the University would take a different position. Dr. Cerra reflected that given the sensitivities of this research, the University would get it going, using private dollars, show that it can isolate the funds and conduct the appropriate audits, and then perhaps reconsider its position. This is a conservative position, but they thought it best to take this approach while the research gets up and running.

Dr. Cerra also explained that most of the 65 stem cell lines approved by President Bush in 2001 were not good for the kinds of research being done at the University. Dr. Paller said that NONE of them are available for clinical trials because all were grown in mouse cells; the FDA will not allow the use of such cells for trials involving human beings.

Does the University have any of those lines, Dr. Balas asked? They currently use some federal money to support the research, but not for any research the federal government says it cannot be used for, Dr. Cerra said.

Ms. Shiels highlighted one additional provision of the fetal transplantation research policy. "There are circumstances when such research is a crime under federal or state law and cannot be conducted at the University. University researchers cannot: (1) receive or use fetal tissue which is obtained through an induced abortion for the purpose of transplantation into a relative of the donor or other recipient designated by the donor; (2) conduct research on a fetus which shows evidence of life . . . and (3) buy or sell human fetal tissue, except reasonable payments are permitted associated with the transportation, implantation, processing, preservation, quality control or storage of human fetal tissue." The ban under item (1) does not apply to fetal tissue from stillborns or spontaneous abortions, Ms. Shiels noted. Dean Bloomfield commented that one cannot use work-study students on the research because work-study funds are federal.

There is only a small group of people who will be doing this research, Professor Balas observed, but there will be a lot of oversight. Will there be people at SPA and other units with expertise so that people can get answers to their questions? Mr. Wink said that SPA and IRB forms will be modified so that any questions will be caught and there will also be training for investigators. All of the studies will be registered with the Office of Regulatory Affairs and questions can go to Mr. Bianco, Ms. Shiels, or Mr. Wink, Dr. Cerra told the Committee. Mr. Bianco noted that there are four people doing this research and eight administrators to help them. It would nice to have a support system in place, Professor Balas said. Dr. Cerra said the University expects the regulations to change, which is why they are being proposed as administrative policies, which will allow the University to keep them up to date.

Professor Balas asked about the logic of calling for new equipment when cost accounting can attribute costs. Mr. Wink said it depends on the equipment; if it is very expensive, the University may set up a center and pay for its use through charges to grants. It is not practical to use cost accounting for smaller items.

Is the mother's informed consent sufficient for fetal transplantation research, Professor Seybold asked? The consent of both parents is required, Ms. Shiels said, but if one parent is unable to consent because of "unavailability, incompetence, or temporary incapacity," then one parent's consent is sufficient. If there is only a short period of time when action must be taken, the mother alone can provide consent, Professor Balas asked? She can, but if both parents are present and both are competent, both must agree to donating the tissue for research, Ms. Shiels said.

Is this limited to research, Professor Bartels asked? The Molly Nash case was treatment; what is the policy on treatment? The law looks at all of the fetal transplantation procedures as experimental, Ms. Shiels explained. It is all considered research until it is accepted as standard treatment.

Professor Sera asked what the Committee was being asked to approve. Dr. Cerra said they are asking the Committee to consider these two policies because there are none in place to permit the research they govern. The policies will allow it. The University must abide by federal law, Professor Sera pointed out. She is asking what is different about these policies, Dr. Cerra said; it is the accounting requirements (which are not technically different but which require a lot more scrutiny) and that the research will be conducted only with private funds. Are the four individuals currently doing this research supportive of the policies, Professor Balas asked? Ms. Shiels said they have been meeting with the investigators, who have seen all of the materials and weighed in on them to the extent they wished. They asked the same question about state funds but do not have a problem with the policies.

These are all good questions, Dr. Cerra said. The University is trying to move ahead on this research and get experience; this has been a two-year process that involved a large cross-functional team, including those who work with ethics. The researchers have been kept in the loop, Ms. Shiels assured the Committee.

Dr. Cerra indicated that the University's partner Fairview has a sizeable in vitro fertilization program and has a lot of frozen embryos; there are applications in to study them. There are other faculty interested in this research, so they do not expect the number who are involved to stay at four, although it is not likely there will be a huge number.

The Committee voted unanimously to approve the two policies. Dr. Cerra said he would provide a follow-up to the Committee as soon as they have experience with the policies and the research.

2. Essential Medicines

Professor Balas next circulated copies of a draft resolution/statement on essential medicines that had been forwarded by the Senate Committee on Social Concerns for the Senate docket. The Business and Rules Committee returned it to Social Concerns because it was not in a format that would allow the Senate to vote on it, so it is being rewritten. But the Faculty Consultative Committee has asked this Committee to review the statement and provide its views on the subject.

There has been no Research Committee resolution on the issue of essential medicines, Professor Balas clarified in response to a query from Dr. Paller, because the Senate has not been asked to vote on the issue in the past.

Assistant Vice President Strauss said that from his perspective, the statement from the Social Concerns Committee raises a key question but that many of the elements of the statement would likely be counterproductive in terms of the goal of getting medicines out to benefit the public. If there are too many rules, companies will choose to develop other medicines. Or they will develop the medicines themselves, and they will be even more expensive, Vice President Hamilton added.

Dr. Paller reported that since the Committee last discussed this issue last year, the McKnight and Rockefeller Foundations and several research universities established PIPRA (Public-Sector Intellectual Property Resource for Agriculture) to jointly work on the problem of crop-related IP and needs of developing nations. No university should be forced to take the lead position on these issues, he said.

Dr. Hamilton said the University has information about GlaxoSmithKline and what the University had to go through to get its license acknowledged. Mr. Strauss said that he sometimes feels like he is an apologist for pharmaceutical companies, which he emphatically is not. The original compounds were licensed to Glaxo and the University thought they would be a big deal. Then Glaxo dropped development, and it took the University two years to terminate the agreement and then license the compounds to Burroughs. Those were very difficult negotiations. One lesson he learned was that universities are not in the driver's seat to dictate the terms and conditions of a license; if they include a proviso about getting drugs to developing countries, that would kill any agreement. Finally the drug (Ziagen, for treatment of AIDS) was developed, but then--during which time Glaxo bought Burroughs--Glaxo told the University it would not pay any royalties, so the University had to sue them. That took another year. The entire process was very difficult. The University's purpose is to get a drug or

technology developed in a way that it is useful to the public. Ziagen is a major seller for AIDS and it benefits the public. Mr. Strauss said he agreed that getting drugs to developing countries is a huge issue but said that universities are the wrong point to approach it. This statement approaches the problem from the wrong end.

Dr. Bloomfield reflected that the University's international success with Ziagen is atypical; other universities, by and large, do not confront this problem because they have not had a product on the market that was so widely used. Most universities have products that are less useful so they are less likely to sell a license of this kind. Was the University's experience with Glaxo typical or not, he asked? Mr. Strauss said that he believed it was typical, but companies are different. Typically, the university is involved at the beginning of the pipeline, with the research; the timeline from research to the market is very long, (about eleven years from first patent filing to product sales in the case of Ziagen), and the probability of success is low. For every 50 or 100 compounds discovered, only one will be a Ziagen, if that many. In the last 20 years, since passage of the Bayh-Dole Act, at most perhaps half a dozen such discoveries have been at the level of carbovir (Ziagen).

What are the obligations of a university under Bayh-Dole, Professor Balas asked? The legislation REQUIRES universities to commercialize a product if they retain title to it, Dr. Paller said. It also allows the federal government non-exclusive rights to federally-funded research outcomes if it believes exercise of such rights would be in the public good. He thought the federal government had never exercised the right, but Dr. Hamilton reported that the federal government did give a license to a company for something the University holds the license to, and the University could do nothing about it. If the federal government determined that GlaxoSmithKline had not acted in the public interest, it could have marched in, Mr. Strauss said.

Is there any similarity to this discussion and the discussions the Committee has had about the "sensitive but unclassified" category of research, where the University pushed back, Professor Klink asked? Are there similar actions universities could take in this arena, so the University of Minnesota or any other institution would not be alone in advocating the principles articulated in the Social Concerns resolution? Is there any move afoot to do so? There is a move, Dr. Hamilton reported, but he said he cannot figure out where it is. Mr. Strauss said that the Association of University Technology Managers has discussed the issue but nothing has coalesced around it as an action item. Is that because the University's experience is atypical, Professor Klink asked? Only a handful of universities have had big hits like carbovir, Mr. Strauss agreed. The University's big hit was in AIDS, which is a significant issue for developing countries, so the University is in the spotlight. For the rest of the institutions, with few funds generated by research in this fashion, the view is that it is fine for the University of Minnesota to "get religion" on the issue but they don't have the luxury of doing do because they do not have the revenue stream that Minnesota does. There is a split in the perspective on this issue, he concluded.

The more general response, Dean Bloomfield said, is that in the pharmaceutical arena, pharmaceutical companies spend a lot more money on research than universities do. In the defense arena, universities collectively have more muscle than the federal government, so when the federal government looks for research, universities have some say. In the pharmaceutical area, with less research, infrastructure, and so on, the companies can do without the universities.

Professor Sera said she was not sure what the University could do. Could it say that as part of a license, a product must be provided to developing countries? Are there companies that have policies on

this issue, so that the University could deal only with the "good guys"? Vice President Hamilton said he would think twice before dealing with GlaxoSmithKline again. Glaxo was EXTREMELY aggressive, Mr. Strauss agreed. But in most cases, the University is glad if there is even ONE company interested in a product. There is almost never more than one; it is a very idiosyncratic business. The University often finds that it must work with companies that it does not believe are good partners or let a technology/product sit on the shelf and go nowhere. Even the University has limits, however, on whom it will work with. One must remember, Mr. Strauss said, that the goal is to get something out to benefit the public. The patent and technology marketing officers take the position that if something will not serve a public purpose, a university should not do it. He said they worry that if universities try to change agreements, it will limit their ability to get products out to the public.

Professor Balas recalled that there was information at the May meeting that MIT had a proposal about essential medicines, but it could not be provided to the Committee because it had not been adopted. Did anything happen? One periodically hears that some institution has done something, Mr. Strauss said, but the action can never be verified. Examples are held up, but then no one can get hold of them.

Are essential medicines defined somewhere, Professor Sera asked? They are defined by the World Health Organization, Dr. Hamilton said, and there is a long list. One of the items on the list is carbovir, the University's AIDS drug.

Professor Balas said the Committee could urge that "universities act together to establish norms and implement strategies and best practices to promote access to essential medicines in developing countries," as the last paragraph of the Social Concerns document suggests. That may be the best avenue for the Committee to suggest, he said. If all do it, that would be fine, Dr. Paller said. But it would not be appropriate for this Committee to send the message that THIS university must do it. These compounds must be developed by large companies, some of whose behaviors the University is not happy with.

What does the Committee wish to do, Professor Balas asked? It could say it disagrees with the resolution and why, it could offer an alternative resolution, or it could say it agreed with the resolution with modifications. Mr. Hughey suggested that the Committee do no more than encourage universities to work together to address questions about essential medicines. Professor Sera expressed doubt that universities play a crucial enough role in the development of essential medicines. What percentage of essential medicines began life as a university product or invention, Professor Balas asked? Mr. Strauss said he did not know but guessed that the percentage would be very small. And how many such medicines could make it without the link to drug companies, Dr. Paller asked? The drug companies do the development, at a cost of several hundred million dollars; no UNIVERSITY can do large scale clinical trials and bring a drug to market. And there is also the role of the government, Professor Seybold pointed out. The government transfers title to the university, Dr. Paller said, but it does not require that the university issue a non-exclusive license. That does put a university in a position to do its best, it could be argued.

His feeling is that the University has reaped extraordinary success in an area where there are a lot of contentious issues, Mr. Strauss said, but he questioned whether universities are the right organizations to lead the effort with respect to essential medicines. The University could, however, play a leadership role in starting the discussions. Dr. Hamilton urged that Mr. Strauss work through the patent and technology managers to get a sense of their views, after which the University could think about a strategy.

It may be that there is only one company interested in a product, Professor Klink said, but would it hurt while negotiating to seek provisions about providing reduced-cost drugs to developing countries? Or is that not done? It is not done, Mr. Strauss said, which does not mean it could not be done. But the University should not head down that path and get a license rejected. This is a fundamental question that should be addressed with peer institutions and corporations to see if it is possible to craft language that is acceptable and that also has teeth, language that both big universities and companies can support. Companies do have an interest in this, he said; they get sued and people try to break patents. They do not want any outcry so great that the government steps in.

It was agreed that the Committee would put this issue on hold until it can review the motion that will come from the Social Concerns Committee.

3. Other Business

Professor Balas inquired of Vice President Hamilton if any changes had been made in the agreement concerning a technology park. Dr. Hamilton said the document had not been changed, on advice of counsel. It has been approved by the Minneapolis City Council and it will be approved by the St. Paul City Council. There may be a signing ceremony that may include the Governor.

Dr. Hamilton said he had another policy to bring to the Committee that required prompt action. It deals with the use of royalty income to invest in business incubators for the University. He said he did not want to bring the policy to the Board of Regents before it is reviewed by the governance system.

The Committee agreed it would meet on December 15 to review the policy.

Professor Balas adjourned the meeting at 3:00.

-- Gary Engstrand