

Minutes*

**Senate Research Committee
Monday, October 28, 2002
1:15 - 3:00
238A Morrill Hall**

- Present: Gary Balas (chair), Melissa Anderson, Gerry Baldrige, Sharon Danes, Robin Dittman, Sabine Fritz, David Hamilton, Paul Johnson, Katherine Klink, Sharon Neet, James Orf, Mark Paller, Virginia Seybold, Thomas Schumacher, Barbara VanDrasek,
- Absent: Victor Bloomfield, Kathleen Conklin, James Cotter, Kris Davidson, Yev Garif, Lawrence Jacobs, Phillip Larsen, Wendy Pradt Lougee, James Luby, Scott McConnell, Mehul Vora
- Guests: Greta Bauer (School of Public Health Ph.D. candidate), Susan Craddock, Joel Albers ; Edward Wink (Sponsored Projects Administration), Winifred Schumi (Oversight Analysis and Reporting); Mark Bohnhorst (Office of the General Counsel)
- Other: none

[In these minutes: (1) in memoriam, Professor Mary McEvoy; (2) report on research issues at Penn State; (3) structure of the Vice President for Research/Dean of the Graduate School office(s); University intellectual property interests and essential medicines]

Professor Balas convened the meeting at 1:15.

1. In Memoriam: Professor Mary McEvoy

In keeping with the tradition of the Senate of recognizing deceased colleagues, the Committee observed a moment of silence in honor of Professor Mary McEvoy, killed in the plane crash that took the lives of Senator and Mrs. Wellstone and six others.

2. Report on a Visit to Penn State University

Professor Balas next asked for a report on a visit to Penn State to learn about how their committees and governance system work. The highlights were:

- At their Senate meetings, they recognize faculty (and presumably students) who have achieved national or international distinction. They introduced two at the meeting, one a MacArthur award-winner, the other recently elected to the National Academy of Arts and Sciences.
- Their committees all meet at the same time, the morning before their Senate meetings; the Senate meets at 1:30 in the afternoon. The evening before they have a meeting of committee chairs to report on what will be on the committee agendas and on the Senate agendas (the next day and upcoming). As a result, they have committee meetings only as often as they have Senate

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meetings (about every 5-6 weeks), so they meet only 7 times per year. One question was how they can adequately consult either on issues that require reasonably quick action or that are more complex than one 15-30-minute agenda item.

- They are contemplating an intellectual property agreement with undergraduates. It may be that the University's current intellectual property policy extends to undergraduates. If it does, this is not an issue for Minnesota.
- Their Senate Research Committee is looking at conflict of interest policies, both individual and institutional. They are also taking up a conflict of commitment policy
- Penn State does classified research so the research secrecy policy issues are not an item for them.

With respect to intellectual property, Dr. Hamilton commented that the University's policy says that it owns everything except for specific categories (e.g., normal faculty work products), so the University would own whatever might be produced/invented. With respect to the apparent infrequency of committee meetings, he observed, the University of Minnesota is known nationally for its commitment to consultation.

Professor Balas reported that the Faculty Consultative Committee met with the Regents' Professors. His take on the comments of the Regents' Professors was that the University gives people awards and then pushes them to the side, does not draw on them. This is not an agenda item for the Senate Research Committee but he said he thought it would be a good idea to recognize and draw on people who have received distinguished awards from the University.

Professor Balas said he had not had an opportunity to bring to FCC the view of this Committee about the makeup of the standing subcommittee to consider requests for exceptions to the research secrecy policy. He commented that FCC let new athletic director Joel Maturi speak for nearly half an hour without interruption--a courtesy it NEVER extends to senior administrators! With that, he turned to Executive Vice President Maziar, waiting to join the meeting for the next item.

3. Structure of the Vice President for Research and Dean of the Graduate School Offices

With the change in the central administration, Professor Balas explained, the offices of the Vice President for Research and Dean of the Graduate School had been split. The Committee concluded it should weigh in on how the offices should be structured once a new president is appointed so it has asked Dr. Maziar, the former occupant of the office(s) when they were joined, to provide her insight about the wisdom of separate versus combined offices.

Dr. Maziar began by observing why the positions were divided. Being appointed as provost came as a surprise because the process went so quickly. When she was Vice President and Dean, there were two symbiotic organizations, one for research and one for graduate education. The University did not have a vice president's office that worked through Graduate School policies and a Graduate School that worked through research policies--but they did have a Graduate School associate dean with an intimate association with Graduate School issues (Dr. Bloomfield) and an Associate Vice President for Research who knew the research issues (Dr. Hamilton), so those individuals took over the two positions on an interim basis.

When she was recruited to come to Minnesota, Dr. Maziar related, she said she would not consider the Vice President for Research appointment unless it included the position of Dean of the Graduate School. After four years, she still held both positions, but that view might not be true of everyone who might hold the positions. To keep them separate could allow the University to identify people who have a passion for research or for graduate stud and separation would allow a broader range of people to be considered for the Dean position. One would not expect a Vice President for Research to come from the humanities; a Dean of the Graduate School could.

The next president has a lot of flexibility in arranging the administration. The structure works well either way, Dr. Maziar said. The schools of the Big Ten have both arrangements; the pattern is that the two positions come together at an institution, then are separated, then put together, and so on. There is no optimal solution.

Does one model have more stature in the University administration, Dr. Paller asked? Does holding a combined position mean one would get more attention than if the positions were held by two people? The combined position might give graduate education a higher profile, Dr. Maziar replied, but it would have no effect on the status of the Vice President for Research. She added that the reporting line for the Vice President for Research varies across the country. At some institutions the individual reports to the president, at others to the provost. In her view, at Minnesota the Vice President for Research should report to the president "since everyone but God reports to the provost."

At Minnesota, the Vice President for Research reports to the president with a dotted-line relationship to the Executive Vice President and Provost, Dr. Maziar said in response to a query from Professor Balas. The Dean of the Graduate School reports through the Provost, as with the other deans. In this instance, Dr. Bloomfield, the Interim Dean, is also Vice Provost for Research in the Office of the Executive Vice President and Provost.

When she was in the combined position, what was the split in time commitment between the two responsibilities, Professor Balas asked? It varies, Dr. Maziar said; there were unusual events during her tenure (such as getting off exceptional status, the collective bargaining drive by graduate assistants). If averaged over four years, realistically the Vice President for Research position takes about 70% of the time and the Dean of the Graduate School about 30%. Is that a good division or is it simply driven by the demands of the job, Dr. VanDrasek asked? The demands on the Vice President for Research do not allow the time committed to that position to be less, Dr. Maziar said; there are too many institutional liabilities.

Dr. Maziar commented that when she moved to the office of Executive Vice President and Provost she did not face as steep a learning curve as she had when she had been appointed as Vice President for Research and Dean of the Graduate School--in part because she was not changing institutions but also in part because she had been in the Provost's office at Texas. In some ways, however, the job of Vice President for Research is a more complex position than that of provost; some issues run counter to one's instincts. She said she worries that the Vice President for Research can be driven by metrics that are not helpful to graduate education. In an age of accountability numbers, it is easy to be driven by the number of research dollars the faculty brings in because it is simple to report and describe; it is more difficult to describe the work of scholars in the humanities. But the Dean of the Graduate School is bound to do so and to ensure the scholarly potential of graduate students supported through the excellence of the faculty, so there can also be a danger in separating the two positions. It might have been more difficult as Vice President for Research to use funds from the Ziagen patent to set up graduate

fellowships across the University (the dollars are not specifically designated for research) but she could comfortably do so as Dean of the Graduate School. So there are potential tensions, she concluded.

In terms of funding, Professor Balas said, both positions are at the table if combined in one person; if the positions are divided, they could play off against one another. Does the financial strength of the Graduate School suffer if separated from the Vice President for Research? The Ziagen dollars were an exceptional opportunity that she does not expect to see on a regular basis, Dr. Maziar said. Both the Vice President for Research and Dean of the Graduate School are lump-sum funded rather than funded by some formula. One can question if the initial division of the funds was appropriate, although they tried to divide the budgets as fairly as possible; the next president can review the allocation before making any decision.

Did she make the decision about dividing the money, Professor Orf asked Dr. Maziar? With the change to IMG, Dr. Maziar said, the Vice President for Research/Dean of the Graduate School was taken out of the business of collecting indirect cost funds; there is no automatic increase for the Vice President for Research. When the offices were split, they looked at different budget elements and divided responsibilities between the two offices. Dr. Hamilton said he thought the split was very equitable, although it could be negotiated again in the future. The Graduate School was assured of having flexible funds for programs; the Vice President for Research received flexible funds for grant matches, etc., and he works closely with Interim Dean Bloomfield.

Why is Dr. Bloomfield also Vice Provost for Research, Professor Balas asked? That is very important, Dr. Hamilton said, because it puts Dr. Bloomfield on the research administration group, so he is at all meetings. That existed before the two positions were divided, Dr. Maziar pointed out. The calendars of the Provost and the Vice President for Research do not permit many meetings that both attend so Dr. Bloomfield was appointed to keep information flowing between the two offices.

Would conflicts flow from having two positions, Professor Johnson asked? One could imagine proposals that would emphasize one side or the other while she, he suggested, worked hard to include both. Her bias is that both should always be included, Dr. Maziar said; research must be used to teach graduate students.

Dr. VanDrasek said she was concerned that dividing the positions would leave the Dean of the Graduate School as an orphan. If the individual is only the dean, and not the vice president, the person might be the least among deans because of way the offices are funded. She said she was not hearing any mission argument about keeping graduate education at the vice presidential level; it should not lose status. One cannot assume that there will be such good relationships between the two offices in the future. Dr. Maziar said that makes sense but at the same time there are a number of institutions around the Big Ten that have highly-regarded graduate schools and about half of them have separate positions of dean and vice president. When she attends graduate deans meetings, she said, she is struck by the broader range of disciplines represented than she sees at meetings of research officers (where there are large amounts of federal funds flowing to the institutions). Placing the Dean of the Graduate School in the Provost's office can provide it additional influence, she said, but the Dean does not hire and promote faculty so is different from college deans.

Both models work around the country, she concluded, and neither is permanent.

Dr. Paller said it sounds like the situation may depend on who the individuals are and the emphases the institution decides on; either role can be enhanced or diminished. Dr. Maziar said she did not see the Dean of the Graduate School at risk in either model. Some private institutions did eliminate the dean of the graduate school--but have largely gone back to it because it provided many unrecognized services, services that were recognized as soon as the position was eliminated.

Professor Balas thanked Dr. Maziar for joining the meeting. Dr. Maziar advised the Committee not to take an entrenched position because the new president might have ideas. She said this is not something anyone needs to work up a lot of passion about because the system works both ways. She said she would ask any presidential candidate about the PROCESS that he or she would use to think about the decisions; the answer to that question could be more illuminating than the answer to the question about the structure.

Following Dr. Maziar's departure from the meeting, Dr. Hamilton commented that the technical aspects of the job of Vice President for Research are completely different from anything that a faculty member in the humanities would ever encounter; such an individual would have a very long learning process. He recalled that he started in 1994 on a committee to look at grants management redesign, a subject that still occupies a large percentage of his time. He has a 100%-time appointment as vice president and is working harder than he has at any time in his life; he said he was amazed that Dr. Maziar could also handle the decanal responsibilities.

He said the institutional differences are illustrated by the fact that at one institution in the Big Ten the Chief Information Officer is also the Vice President for Research--it works at that institution but would not work at Minnesota.

Is the job more complex because there are more issues in the research arena than there were five years ago, Professor Orf asked? That may be, Dr. Hamilton said. He noted that he has been asked to talk with this Committee about the impact of the events of September 11, 2001, on research at the University; the impact is extensive. New regulatory language creates new compliance issues and affect the status of the University's research enterprise. And there are things the University needs to be wary about, he said.

Some types of research could limit graduate student participation, Professor Orf said; having the two positions together could bring the perspective of both positions. One can argue that way, Dr. Hamilton agreed; the University must insist that the dean and the vice president work together because there are things that are part of the common good that the institution must deal with.

Are there metrics that the vice president is held to that would put him or her in an adversary position with the dean, Professor Balas asked? They would not put them in adversary positions, Dr. Hamilton said, but there are many things the vice president looks at that are not directly related to productivity such as research statistics, number of awards and proposals, number of patents, etc., that he would like to discuss with the Committee.

Professor Balas said that at the Council of Research Associate Deans meeting the discussion came to the issue of supporting graduate students versus postdocs; the latter are getting cheaper. The metric of the Vice President for Research office would argue in favor of hiring postdocs. Dr. Hamilton promptly and vigorously disagreed. He noted that he has been a faculty member at the University for 35 years; becoming vice president did not take away that experience. At the same time, people must understand that to renew grants one must be very productive--and one gets more productivity from

postdocs (who do not need to be trained) than from graduate students (who do). The institution must think about this. They provide program training for labs so the student can step right in; the faculty member can teach the student to think. The University needs to consider ways to provide training to graduate students so they can be productive.

Professor Seybold asked Dr. Hamilton if he saw any change in priorities as vice president. Dr. Hamilton recalled that he came into the office on August 5; the priorities are still evolving. He inherited a number of things he will carry through. He and Winifred Schumi have talked to department heads and set priorities that be accomplished in a short period of time. (1) All the units that report to him are service units; they will look at whether those units are performing support well and if not how to improve them. (2) The University is obligated under federal law, as an institution that interacts with federal agencies, to set up electronic interaction; it has joined the Federal Demonstration Partnership to work on streamlining research life. (3) He is very supportive of patenting activities and wants to discuss them with the Committee. (4) As a land-grant institution, it is important that the University let the people of the state know what it is doing and why, and to listen to what they want, so he supports the civic engagement initiative.

One question that arose at the Faculty Consultative Committee was the location of Sponsored Financial Reporting, Professor Balas reported. SFR reports to the Controller's Office, SPA reports to the Vice President for Research; PIs are responsible to both and have to go to two different offices to get information they need for contract monitoring. Will they ever be together, he asked? When he started working on these matters in 1994, both offices, along with patents, were under the old ORTTA, Dr. Hamilton said. He and a colleague who worked on grants management persuaded the administration that SFR--an accounting function--needed oversight and belonged in the Controller's Office. The administration agreed, without discussion. Now, Dr. Hamilton said, he believes that was the wrong decision without discussion. He said he still believes the accounting oversight function is important but they have to make sure PIs are not bounced back and forth between offices. The problem is the accountability of SFR, Professor Seybold said; who is responsible for holding it up to appropriate standards? SFR gets money but it does not provide the reports that are needed.

All that has been said points to the uniqueness of institutions, Dr. VanDrasek said, and they must be sure that the Dean of the Graduate School is not orphaned. Dr. Hamilton agreed and said the new president would need advice on the matter.

4. University Intellectual Property Interests and Essential Medicine

Professor Balas now welcomed Ms. Greta Bauer, a Ph.D. candidate in the School of Public Health, to lead a discussion of intellectual property and essential medicine. Ms. Bauer introduced associates who were working with her on the issue and she provided a binder with a number of articles and pieces of information.

She said she wished to talk about the ethical conflicts with respect to intellectual property and essential medicines. The issue arose with passage of the law (the Bayh-Dole act) that allows universities to hold patents and grant exclusive licensing rights. That was a change for universities and it helps get useful products out to the public. There are ethical dilemmas, however, and the University ended up facing one that it probably did not expect because of its licensing agreement with Glaxo for Ziagen, the anti-AIDS drug.

The World Health Organization (WHO) keeps a list of essential medicines, those that are necessary to operate a basic health care system, the basic pharmaceutical arsenal that a country needs to take care of its people. Many on the list are no longer under patents but some are; all of the AIDS drugs are still patented and companies do enforce the patents in Africa and other countries in need. The University is tied into this enforcement through its licensing agreement with Glaxo and must cooperate.

If a disease affects only under-developed or poor countries, cure or treatment will likely not be discovered, Ms. Bauer commented, and that is another issue by itself. If a disease afflicts a wealthy country, a cure or treatment will be discovered and brought to market, and the market will function relatively well. If a disease exists in both kinds of countries, there is a conflict between ethics and the demands of the market. Companies with patents fight production of generic versions of drugs that would be much cheaper for poor countries. Here, the market fails to deliver a life-saving product to the people who need it, despite demand.

There is a long link between products and delivery, Ms. Bauer observed, but her request is that the University not be part of a chain that blocks delivery of essential medicines to poor countries. These discussions are taking place around the country. Last year the administration said the University would not get in front on this issue because it would be non-competitive and the University would get "shot down." Since that time there have been conferences on the issue of intellectual property and essential medicines and the University should follow best practices. Intellectual property rights have in practice been more protective of companies holding the rights, to the detriment of human rights. It is that situation she is against, Ms. Bauer told the Committee--she is not against intellectual property rights. Her arguments here apply only to patents and licensing agreements on essential medicines or potential essential medicines.

Ms. Bauer noted that a discussion at Yale had identified several possibilities, such as not patenting essential medicines or not enforcing the patent in developing countries or not enforcing it in countries with a certain level of a disease. Some universities have ethics clauses in their intellectual property policies; the University of Minnesota, like most, does not. She asked that the Senate Research Committee acknowledge that essential medicines differ ethically from other patentable inventions. She asked that the Committee study the issue quickly; she also said she would prefer that the University deal with Glaxo through the existing agreement on Ziagen. Yale, she reported, had renegotiated a similar agreement. She also said she hoped the Committee would consider recommending changes to the intellectual property policy so it addresses this issue--which will arise in the future.

Dr. Paller said that he supported making essential medicines available to those in need. The Bayh-Dole act allows universities to patent discoveries and also allows the federal government to take the patent if public health requires it. Part of the burden should be on the federal government; universities cannot predict if something will be a big success and only the federal government can say that Glaxo is not serving the public good and take back the patent rights.

Ms. Bauer said she was aware of these provisions. Few believe the Bush administration will enforce them, however; ideally, it would do so. But the University's policy has played a role in the obstruction of access to essential medicines.

Dr. Susan Craddock said it is not an either/or situation; it is both. A lot of organizations are pressing the federal government (so far unsuccessfully) to act. Pressure must be leveled internationally, nationally, and locally. It is also not possible to predict when a product would fall into the essential

medicine category; all agreements should say that the product will meet market need wherever the markets are. Ms. Bauer agreed; the University would not know if something will be brought to market or put on the WHO list of essential medicines but language can be written to cover that eventuality.

The flaw is in the University policy, Professor Balas said, but there is no way to reach agreement at the University on the provision of essential medicines where they are needed at low cost. The market should be opened up to competition, Ms. Bauer said; the University and pharmaceutical companies would not lose a lot of money in royalties because under-developed countries produce only a tiny minority of revenues for these products. The World Health Organization has a "rule of five," she said, where it has found that it obtains the best prices with at least five providers competing in a market. With generic production, companies can also combine drugs for more effective treatment and provide them more cheaply, something they cannot do if patents are held by different companies.

What do drug companies say when they are approached on this issue, Professor Johnson asked? Ms. Bauer said that pharmaceutical associations have generally taken the position that any movement to change patents would be bad for everyone and would affect profitability. At the same time, several drug companies have been working with the United Nations, although they have not thus far gotten a lot of drugs to places they are needed. Are they afraid of opening a Pandora's box, Professor Johnson asked? The big fear is the loss of revenues because drugs provided to under-developed countries will be re-imported into developed countries, Ms. Bauer said. Glaxo is working on getting approval for different packaging for under-developed countries, a common practice with other medicines.

Dr. Joel Albers said the drug companies also want to make sure that African countries do not develop their own generic drug programs. They are willing to offer price cuts of up to 90% but they are NOT willing to change patent policy or have compulsory licensing for generic drugs. They do not want local self-sufficient companies. Ironically, the companies have manufacturing facilities in South Africa but the people in Africa cannot get the drugs. Overall intellectual property policy must change; as with Ziagen, the University should be careful when it enters into agreements. Bayh-Dole allows exclusive licensing when it is in the public interest not to have it. In reduced pricing, Ms. Bauer reported, drug companies have cut the cost of a three-drug regimen to \$1000-1500 a year--a drastic reduction--but generic companies can offer three-drug combinations for approximately \$300 a year, and that price should decline further if they are allowed increased production.

Professor Orf commented that in terms of production of generic drugs, there must be a basic cost to manufacture them that someone must pay. Even that cost is perhaps beyond the ability of many to pay. Does the WHO address this problem? Yes and no, Ms. Bauer said. There is a global fund to which both countries and companies contribute to get drugs to people who need them. People are trying to pull that money together. And the larger the market, the cheaper the drug can be manufactured.

Dr. Craddock said the latest TRIPs (Trade Related Intellectual Property Rights) agreements of the World Trade Organization allow compulsory licensing for least developed countries (LDCs) until 2016, ten years later than previous TRIPs provisions. The countries that are left out are those without manufacturing facilities. Parallel importing, that is importing generic antiretrovirals, is allowed only under narrow circumstances. The next step is for the TRIPs council to work out better terms for parallel importing, enabling those countries without pharmaceutical manufacturing capacity to gain better access to essential medicines at lower prices.

Professor Balas asked Dr. Hamilton for his perspective. Dr. Hamilton said he is listening and wants to understand the issue and said he hoped there is some way to address the problem. He said he has been a consultant for the WHO and has seen the terrible conditions in Kenya, for example, and the dichotomy between the wealthy and the poor. Unfortunately, he also knows that Daniel Arap Moy has made an enormous amount of money from re-selling drugs intended for people in need. He said he worries that what people want will not be what they get because Moy's successors will be among the wealthiest people in the world from the drug re-importation business. But he said he is willing to listen to the discussion.

Countries have a provision within the TRIPs agreement wherein the government can declare a state emergency and thus allow access to generic drugs. However, Ms. Bauer said, that puts the responsibility on one government leader, and there may be economic and social implications to declaring such a state of emergency. Also, one leader may or may not share the goals of the populace. South African President Thabo Mbeki, for example, has denied that HIV causes AIDS. She added that they do not expect the University to solve the whole problem, they only want to see that the University does not obstruct the process if a country does want to get drugs to its people. That is one part the University can play. Dr. Hamilton said he supports that goal.

Dr. Albers said that even though companies lower AIDS drug costs by 90%, ever since then the costs in the United States has risen a lot. Ziagen started at \$300 per month and is now over \$400; this is a problem in Minnesota as well. It is one of several problems one encounters with the exclusive licensing arrangement with Glaxo.

What do they wish the University to do, Professor Johnson inquired? Alter the intellectual property policy, Ms. Bauer said, so that others have a right to license in order to get drugs to people in need. Professor Johnson followed up: What would they like the Committee to recommend? They have left that open, Ms. Bauer replied. She said she would like to see an ethics clause in intellectual property agreements specific to essential medicines, providing that there would not be impediments to providing drugs to people in need.

Professor Orf said the Committee should look at all sides; presumably there is a counter-argument to what has been said today and the Committee should hear those other arguments. Perhaps there are ways to get to get drugs to countries in need. Ms. Bauer said their goal was simply that the University not block the process.

Professor Balas said the Committee would return to this issue at a future meeting, and adjourned the meeting at 3:05.

-- Gary Engstrand