Dean's Newsletter April 18, 2005

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Further Discussions with Departmental Leaders and Faculty Regarding the Future

Since my comments in the April 4th Dean's Newsletter regarding the future of academic medicine I have met with the faculty and staff leaders of the Department of Medicine and the faculty of the Departments of Neurology and Neurosurgery. We continued discussions about the future of departments and Institutes at Stanford, and most importantly, I listened to the views, concerns and suggestions of faculty and staff. At both meetings I reiterated my perspective that the future will require greater interdisciplinary and more interdepartmental alignments and collaborations in order to create new and exciting opportunities. I also affirmed that this was an opportunity for Stanford to be a national leader and to set and create new standards and expectations. That said, I also confirmed that we will work to achieve this by sustaining, and wherever possible strengthening, departmental functions and value. However, I added that I will expect that departments will seek to re-invent themselves from within, and, equally importantly, to foster more interactions and collaborations to enhance our missions in education, research and patient care. I further affirmed that we will seek to do this without major reorganizations within or among departments and that we will also look for strong and visionary leaders to help shape our broader institutional agenda for the future.

Based on discussions at and outside of these meetings, I am satisfied that our recent discussions about the future of academic medical centers have heightened interest, awareness and thoughtfulness about how we can work collaboratively to make Stanford an even better role model among research-intensive schools of medicine.

Update on the California Institute for Regenerative Medicine (CIRM)

Progress continues in establishing the California Institute for Regenerative Medicine. While the lay press has frequently commented on the problems and deficits of the CIRM and its Independent Citizens Oversight Committee, on which I serve, I am strongly persuaded that considerable progress is in fact being made. Indeed, the 29 member ICOC has been working quite hard to create the infrastructure that will enable the CIRM to begin funding, at least fellowship training grants, by late summer to early fall, 2005.

In the past couple of months, the ICOC has appointed an Interim President, Dr. Zach Hall, who is also working diligently to develop the infrastructure to support the grant making and policy programs of the CIRM. He is recruiting terrific leaders from around the state and country to help launch this effort and I am encouraged by the progress to date.

In the next months a number of ICOC committees will be completing important activities that will have a further impact on the CIRM. The Search Committee for the permanent president of the CIRM (on which I serve) is working intensely and on a remarkably accelerated timeline. In conjunction with the selected search firm, Spencer Stuart, more than 600 inquiries were sent to leading scientists and institutions across the country. The response has been exceptional and the Search Committee is already developing a short list of candidates for further evaluation. While this process must of course be highly confidential, I can say that I am extremely encouraged by the quality of the candidates who are being considered.

The ICOC is also identifying leading scientists and investigators, almost exclusively outside of California, who will serve on the scientific grant review boards. Again, a remarkable list of individuals has been compiled from recommendations received from both the scientific and public communities. This list has been vetted further and the Grants Committee (on which I also serve) is making contact with individuals to determine their willingness to serve. Once again I can say that the quality of the individuals being considered – and who have in turn expressed interest – is outstanding.

In addition, the ICOC Standards Committee is addressing the policies and procedures that will govern stem cell research. A National Academy of Sciences report due in April or May proposing guidelines for stem cell research will be an important resource for this committee. In addition, the Site Selection Committee will issue its report in early May regarding the headquarters for the CIRM. Clearly these are all positive advances.

At the same time there are a number of challenging issues facing the CIRM. Among these are various law suits and legislative bills challenging the ability of the CIRM to carry out its work on numerous fronts (intellectual property, conflict of interest, ability to fund research, and egg procurement among others). While it is understandable

that different points of view are being expressed, it would be most unfortunate if these activities deterred the CIRM from its mandate to conduct important research in stem cell biology and regenerative medicine.

One of the issues continuing to receive attention is the perceived need for all of CIRM activities to take place in a completely open and public setting. Certainly the Bagley-Keene Act requires that all meetings (including conference calls) occur in an open and public setting. The ICOC supports that. However, some of the public continues to argue (as do editorials in newspapers like the Sacramento Bee) that grant reviews and even the presidential search committee take place in open settings. We have tried to be clear on why this would violate the process of peer review and, in the case of a high level search, almost surely mean that candidates would be unwilling to be considered, but to no real avail. I am fully convinced that successful grant reviews require confidentiality, both for the investigator submitting a proposal and for the scientists carrying out the review. Despite considerable effort to explain why this is so important, including discussions with editorial boards in which I have personally participated, the counter view remains. While I certainly respect the right of individuals – and newspaper editorial boards – to disagree, I have full confidence in the peer review process as carried out by the NIH and virtually every non-profit foundation, and I believe that the CIRM should follow a similar confidential peer review process.

Challenges for the NIH and Academia

I have previously commented on some of the very significant issues impacting the NIH and, as a consequence, our academic medical centers. Of course one of the most disturbing is the deteriorating NIH budget, which, after several years of significant increases, is now facing funding shortfalls. This is due to the need to support multiyear grants and contracts and, most disturbingly, the significant decreases in the NIH budget appropriations during the past two years. The worrisome consequence of this is less funding for new and competing grants. I am very confident that our outstanding faculty will continue to compete well for whatever grant funds are available (Stanford is the topranked school in the nation in competitive NIH dollars per faculty member – see April 4th Dean's Newsletter. However, the difficulty for new young investigators to receive their initial RO1s and similar grants is a source of significant concern. Clearly we will need to monitor this carefully and do all we can to minimize the negative impact.

In tandem with the concerns about NIH funding is the fact that this once hallowed institution is under siege because of the conflict of interest infractions during the past year and, equally importantly, the rather dramatic over-reaction that the NIH imposed in response. I have also addressed this in recent Newsletters (see February 22 2005 edition). There is no question that clearly defined and universally followed conflict of interest regulations are essential to protect the integrity of investigators, institutions and the public trust. And, there is no question that some of the violations at the NIH reported in print media during the past year appear to have been egregious, they required swift and clear action. Indeed, I am quite sensitive to this matter, both because of the many years I spent as an intramural NIH investigator and because of my participation on the Blue

Ribbon Panel that developed new guidelines for conflict of interest for the NIH just a year ago. Unfortunately, while my colleagues and I on the panel felt that we came forward with highly credible and manageable guidelines, the process rapidly become politicized. As a result, the NIH decided to develop more stringent restrictions on outside activities. These were followed just months ago by a one-year ban on all outside activities for NIH scientists.

This ban is creating considerable harm to the NIH, including the decision of a number of senior leaders and investigators to leave – and others not to come. Hopefully the NIH leadership will modify the very stringent restrictions that have been imposed, perhaps to something closer to those of the Blue Ribbon Panel. The possibility that the current total ban might be modified is suggested from recent comments by the NIH leadership in the Washington Post and other public media. While the situation at the NIH is clearly different from that of academic medical centers, the unfolding events serve to remind all of us of the importance of exercising care and scrutiny in the surveillance and management of conflict of interest. I concur with the editorial comments by Drs. Richard Popp and Paul Yock in the April 6th issue of the Stanford Report (see also http://med.stanford.edu/spotlight/index.html). I also wish to underscore that it is incumbent on each faculty member to assure that she or he exercises full and complete disclosure and complies fully with any recommended oversight over potential or real conflicts of interest.

Conflict of interest issues also have relevance to the future organization of the NIH because of the "reauthorization" process slated to take place over the next year. While reauthorization in the past has not had major consequences, in this more politicized environment, and especially with the current shadow over the NIH, it is not beyond the realm of possibility that serious consequences could unfold, either inadvertently or directly. To help prepare for any exigencies that might result, Ryan Adesnik, Director of Federal Relations, and I asked the AAMC (Association of American Medical Colleges) to begin considering how we could work toward the most favorable outcomes of the reauthorization process. As a result, an Ad Hoc Work Group has been established through the AAMC that I am co-chairing with Dr. Bob Kelch from the University of Michigan. Last week we had our first conference call with a number of deans around the country. We alerted them to the risks at hand and the events that might unfold, and we defined steps we might take to do all we can to assure the future integrity of the NIH. I will share more about this with you in the months ahead.

On a more positive note, it appears that several NIH leaders are beginning to speak more openly about the current NIH limitations on funding embryonic stem cell research. Even NIH Director Elias Zerhouni has implied in recent testimony before Senators Harkin and Specter that he may advocate for a more engaged NIH position on stem cell research. I hope this is the beginning of a more enlightened NIH position. While we are fortunate in California to have future funding opportunities through the California Institute for Regenerative Medicine, I worry about the potential erosion of NIH funding if future research investments shift from the federal to the state sector. It is the NIH that has made the United States the unique and worldwide leader in biomedical research, so I

hope it will continue to stand as the dominant supporter and funder of all biomedical research in the future.

Enhancing Clinical Research

I am pleased to report that the Stanford/Packard Clinical and Translational Research in Medicine (SPCTRM) will be formally launched in the near future, thanks to the efforts of Drs. Steve Alexander, Professor of Pediatrics and Director of the ACCESS Program, and Harry Greenberg, Senior Associate Dean for Research & Training, and Acting Co-chair, Department of Medicine. Considerable progress has been made during the past two years in developing the key infrastructure components to help foster a robust clinical and translational program to support our faculty and help Stanford achieve its mission in *Translating Discoveries*. In addition, the innovative programs being developed by the Strategic Center for Clinical Informatics under the leadership of Dr. Henry Lowe, Senior Associate Dean for Information Resources and Technology, and his colleagues will enhance SPCTRM.

Given the emphasis of the NIH Roadmap on translational research, such developments at Stanford are timely. The importance of clinical research and especially of training the next generation of students and postdoctoral trainees to understand and engage in clinical research was a topic for discussion at the recent Council of Dean's meeting that I attended on Sunday April 10th. It was noted that several task forces have addressed the importance of clinical research, including one sponsored by the AAMC (Association of American Medical Colleges) in 1999 as well as one initiated in the Fall of 2004. While the 1999 task force laid out a number of important goals for the education and training of clinical investigators as well as for the development and support of the infrastructure for conducting clinical research, it is not clear how well these recommendations were implemented.

A similar deficit appears to apply to a report produced in 2001 by a diverse group that included Stanford's Dr. Phyllis Gardner. This report offered strong recommendations for educating medical students about the scientific method underpinning traditional and non-traditional therapies and the ethics guiding clinical practice. Further, this committee recommended that students have a working knowledge of seminal clinical research findings and their application to patient care. In addition, they recommended that students be able to assess and critique the research findings published in major medical journals and know how to assess medical information. Although these and related goals are important and should be part of every students learning repertoire, it has been widely acknowledged that most schools fall short of a formal didactic program of these important principles. At Stanford the principles governing clinical research are incorporated in to a number of courses and there is a Scholarly Concentration devoted to clinical research – but it is clear that we can and should do more to foster knowledge and interest in this important area of medicine.

The need for additional emphasis on clinical research is highlighted by two important facts. First, there is a shrinking number of graduates pursuing careers in

clinical research and second, a number of recent events have impacted the public trust regarding clinical research. With regard to the pipeline for clinical research, it has been estimated (albeit based on limited data) that only about 15% of the individuals who receive a K grant in clinical research actually make it to the point where they have two RO1 grants (a reasonable gold standard for career success). At the same time, data presented at the Council of Deans meeting underscored that individuals who enter clinical research have a high satisfaction with a career that combines patient care with the opportunity to generate knowledge that improves that care. However, it was acknowledged that the pressures and demands on such individuals are enormous. Further, in most academic centers, insufficient protected time is made available to carry out the expected clinical research, and there are an inadequate number of truly knowledge mentors to guide the career development of junior faculty who seek a career in clinical research.

Dr. Bernard Schwetz, the Director of the Office for Human Research Protections, underscored to the Council of Deans the importance of learning how to conduct clinical research in a scientifically sound and valid matter. He noted that, particularly recently, the public trust in clinical research has been eroded. Surely a number of tragedies have contributed to this loss of trust (e.g., the gene therapy death at U Penn, the normal volunteer who died in a clinical trial on asthma at Johns Hopkins and, of course, the recent and widely reported cardiac deaths due to NSAIDs). The effects of these events has been compounded by assertions and perceptions of conflict of interest by physicians and investigators involved in carrying out the clinical trials. Of course this underscores the importance of conducting clinical studies with honesty, integrity, transparency and the highest ethical standards. It also underscores the importance of assuring that individuals involved in designing, conducting and reporting clinical trials have been well trained to carry out these tasks. Indeed it is incumbent on institutions to assure that these standards are met – both for investigators and for institutions.

One recent issue that is attracting considerable attention and debate relates to the question of clinical trial registries. The genesis for this comes from the concern by the public, regulatory agencies (including the FDA) and journal editors, that clinical research reports contain selected information and do not offer the full context of data to assure that therapeutic claims are justified. I have commented on this topic previously and have been working with the Institute of Medicine to craft a plan that will better align the various constituents involved in clinical research and that, most importantly will earn the public trust. We are planning a public meeting on this issue at the Health Science Policy Board of the IOM at the end of June to further address this important topic. I will keep you apprised of the outcome of these proceedings.

Progress in Bio-X and Bioengineering

On April 14-15th, the Stanford Advisory Council on Interdisciplinary Biosciences, which is comprised of leading figures from industry (including biotechnology and information technology) as well as venture capitalists, heard updates on the progress being made in Bio-X and Bioengineering. Dr. Scott Delp, Chair of the Department of Bioengineering, noted that some 55 departments and more than 280 faculty from at least

four schools at Stanford participate in BioX. Since its faculty-initiated inception and the opening of the Clark Center in the summer of 2003, a series of themes have emerged that organize faculty into various networks. These include biocomputation, genomics/proteomics, biophysics, chemical biology, brain/behavior, regenerative medicine, imaging and biodesign. The Bio-X Graduate Student Fellowships, Postdoctoral Fellowships, Innovation Awards and a number of educational programs have complemented these efforts. Notably, on March 25th an exciting symposium, "Watching Life" was held in the Fairchild Auditorium (see below) and in tandem, another program entitled "Talks in English" extend the reach of Bio-X to a broad and very interested community.

Important progress is also being made in the new Bioengineering Department, which is unique by its joint placement in the Schools of Engineering and Medicine. The department is now admitting its second class of graduate students. More than 360 highly qualified students applied for less than 20 positions. Equally notable, approximately 80% of the students offered acceptance are choosing Stanford over peer institutions like UC-Berkeley, Cal Tech, MIT, Michigan, etc. This surely reflects the exciting community of excellence that is beginning to emerge in the department – evidenced also by the outstanding faculty recruitments, new core curriculum, and nascent evidence of successful faculty competition for major center grants. The latter include a training grant in regenerative medicine (Dr. Michael Longaker, PI), a training grant in biomedical computation (Dr. Russ Altman, PI) and the successful competition to be a Center for Biomedical Computation (Drs. Russ Altman and Scott Delp, Co-PIs), the latter being one of only four such centers in the nation. These early achievements provide some assurance that the department will achieve its goal of being a "top 5 department in 5 years and the number 1 department of bioengineering in 10 years." With the leadership of Drs Delp and Yock, the excellent faculty joining the department and the superb students and fellows being selected, this goal surely seems achievable.

Dr. Paul Yock, Co-Chair of the Department of Bioengineering, described how the programs in BioX relate to the four Stanford Institutes of Medicine. These relationships provide a unique opportunity to engage a broad array of faculty and students into both thematic areas (see above) and important diseases and medical disciplines. The resulting interactions will further promote innovations, technology development and the opportunity to translate discoveries to improve the health of adults and children locally, nationally and globally.

We are clearly at the early days of interdisciplinary research and education, but there is little doubt that the efforts underway at Stanford will make us the leader in this important field. In addition to our institutional efforts, you may also be interested in reading more about the emerging experiences in interdisciplinary research. I would recommend the recent report published by the National Academy of Sciences entitled, Facilitating Interdisciplinary Research (http://www.nap.edu/catalog/11153.html).

Watching Life

On March 25th and 26th Stanford's Bio-X Program celebrated the culmination of 400 years of imaging at their first large annual symposium, "Watching Life." The Symposium was organized by Drs. Matthew Scott, Professor of Developmental Biology and Genetics and Chair of the BioX Leadership Council and Sam Gambhir, Director, Molecular Imaging Program at Stanford (MIPS) and Professor of Radiology, and was sponsored by the Bio-X Program, the Stanford Molecular Imaging Program, and the Stanford Beckman Center for Molecular and Genetic Medicine.

The symposium, held at Fairchild Auditorium and the James H. Clark Center, brought together nine of the world's leading scientists in the field of imaging to present and discuss imaging at different scales of life. Over 420 attendees listened to presentations ranging from imaging intact cells to imaging cells in small organisms to human clinical studies. The presenters covered new types of microscopy, diagnostic imaging, engineering, chemistry, medical bioethics and clinical imaging of human brain addiction. Learning about all scales of imaging is important in bridging the different ways scientists observe biological processes.

Following the scientific presentations, 49 posters exhibited some of the tremendously exciting research being conducted at Stanford. The poster session provided great opportunity for Stanford students and postdoctoral fellows to meet each other, the symposium's world leading speakers, and the attendees from industry. The workshop on Saturday at the Clark Auditorium was attended by over 120 of Stanford's faculty, students and postdoctoral fellows and concentrated on the technical aspects of imaging.

The symposium, the poster session and the workshop were all open to the public. The events very well attended. The Speakers Dinner was attended by about thirty of Stanford's imaging specialists, and provided a fantastic environment for exchanging ideas. Bio-X will continue to sponsor annual symposia on topics in multi-disciplinary biosciences for the benefit of both the Stanford community and visitors from elsewhere.

Stanford in New York

During the last several months members of the School of Medicine have been participating in major Stanford University events around the country. These have included appearances in San Diego, San Francisco, and London and, on April 16th, New York. Our specific charge was to host a plenary panel on stem cell research and medicine and I was pleased to be joined by an outstanding group of panelists including Drs Paul Berg, Irv Weissman, Mary Lake Polan and Hank Greeley. We had a far-ranging discussion that began with the fundamentals of stem cell biology and regenerative medicine. We addressed the extraordinary opportunities we believe will flow from research in this area and how Stanford will help lead that effort. The discussion included the controversies surrounding stem cell research and egg procurement as well as some of the legal and moral issues that impact this important new area. Our panel had the opportunity to address important and challenging issues. It is incredibly important that we provide as much public information and education about this extremely important area of

bioscience and medicine as possible, and I am very appreciative that the University leadership given us the opportunity to do so.

Stanford Postdoctoral Fellows Meeting

On Thursday April 14th the Stanford University Postdoctoral Fellows Organization, led this year by Drs. Adriana Parra and Joyce Furfaro, met to review areas of progress and challenge. I am pleased to say that Stanford Postdocs have played a key role in helping to foster and develop support programs at Stanford and have taken a leadership role nationally as part of the National Postdoctoral Association. During the past year the SUPD has continued to make progress in working with the university leadership to improve the health and dental benefits for postdoctoral fellows, including access to Stanford faculty physicians. Other advances have been the initiation of the Career Center led by Michael Alvarez and the appointment of Chequeta Allen as the Assistant Dean for Postdoctoral Fellows.

Without question postdoctoral fellows represent one of the most important and significant assets at Stanford, and I am pleased to note the continued progress being made in providing support that improves their Stanford experience.

Call for Nominations

The Albion Walter Hewlett Award was developed by the Department of Medicine as a recurring award to honor an extraordinary physician with ties to Stanford. Nominees are welcome from all departments and are not confined to the Department of Medicine. The award committee invites your nomination for a possible award presentation in 2005. Nominees should be from among those living who have made a substantial investment in Stanford (past or present students, house officers, fellows or faculty) and who have consistently, over decades, demonstrated the exemplary combination of a scientific approach to medicine and sensitivity to patients. They should be consummate physicians and role models for future academicians in medicine. Their work should be well known at least at Stanford and, optimally, nationally. Deadline for nominations is due on May 1st. For more information please check out the website at http://medicine.stanford.edu/hewlett/.

Upcoming Events of Interest

I want to call your attention to two upcoming events that promise to be of great interest to our community.

MEDICINE and the MUSE: An Arts, Humanities and Medicine Symposium, Thursday April 21, 2005, 5 pm Cantor Arts Center Auditorium, Stanford University. All are welcome. This event is free and open to the public and will include presentations, music and an art exhibit by Stanford medical students. The keynote speaker will be David B. Morris, PhD. He will speak on "Pain & Narrative: Where does it hurt?" Dr. Morris is University Professor, University of Virginia, and author of *The Culture of Pain; Illness*

and Culture in the Postmodern Age. A reception will follow at 7 pm. This event is supported by The Osher Foundation, The Vera M. Wall Center at Stanford, and Helen and Peter Bing. Sponsors include the Biomedical Ethics and Medical Humanities Scholarly Concentration Arts, the Humanities and Medicine Program, the Stanford Center for Biomedical Ethics, and the Iris & B. Gerald Cantor Center for Visual Arts at Stanford University

MUSIC & MEDICINE: The Art of Listening, An Interactive Concert and Lecture by Robert Kapilow and the St. Lawrence String Quartet, Monday May 2, 2005, 5pm Fairchild Auditorium. This event is about using music to explore the practice of medicine: communication, teamwork, focus & the human condition. It is free and open to the public, and a reception will follow at 6 p.m. Composer Robert Kapilow is music commentator for NPR and host for Lincoln Center's 'Great Performers' concert series. The St. Lawrence String Quartet is an internationally-renowned ensemble-in-residence at Stanford. This event is supported by The William and Flora Hewlett Foundation; The Office of the Dean, School of Medicine; Office of the Dean, School of Humanities & Sciences; The Office of the President; Stanford Music Department; and The Vera M. Wall Center at Stanford. It is sponsored by the Arts, Humanities and Medicine Program and the Stanford Center for Biomedical Ethics.

If you have questions about these events, please be in touch with Dr. Audrey Shafer at ashafer@stanford.edu.

Events

- Thanks to Dr. Judy Swain: On Tuesday afternoon April 5th, faculty gathered to thank Dr. Judy Swain for her eight years of leadership in the Department of Medicine. During that time important accomplishments were achieved including significant improvements in the quality of residents admitted to the internal medicine residence program and the increased interest of these residents in careers as physician scientists; the recruitment of outstanding junior faculty, a number of whom are already being acknowledged for their accomplishments as physician-scientists; growth in a number of clinical programs; and a dramatic improvement in performance based clinical activity and the financial solvency and success of the department. In addition to her leadership of the department, Dr. Swain assumed a number of important leadership roles in the university including serving as chair of the Advisory Board and most recently a committee on the professoriate.
- Community Lecture Series Continues: Our extremely popular evening series that provides opportunities for faculty leaders to present exciting new areas of Stanford Medicine to our neighboring communities continues. On April 6th, Dr. Gary Glazer, Professor and Chair of the Department of Radiology, spoke about the fascinating changes that have occurred in the field of imaging, from its inception, to its current and future states. It is remarkable to witness the progress that has taken place and to anticipate the further evolution of this field, due to

computer simulation, processing of large data bases, and the burgeoning field of molecular imaging. This has been an area where Stanford has excelled. Thanks to Dr. Glazer's leadership, we have assembled one of the very best faculty in the world, and they are contributing significantly to new discoveries and innovations.

• Nobel Lecture Week: The Stanford community had the unique opportunity to hear presentations by two of the most significant figures in biomedical research, both of whose extraordinary contributions have been recognized by the Nobel Prize. On Thursday April, the Second Edward Rubenstein Lecture was presented by Dr. Sidney Brenner to a standing room audience in the Fairchild Auditorium. And then on Friday April 15th Stanford's own Dr. Arthur Kornberg gave the Annual Robert A. Chase Lecture entitled, "Reflections on Science and Medicine." Quite a week!

Awards and Honors

• *Dr. Stuart Goodman*, Professor of Orthopedic Surgery, along with five others from around the world in the fields of Biology, Medicine and Dentistry, has been named Adjunct Professor at the University of Helsinki, Finland for the year 2005-06. Dr. Goodman will teach and do research there for short periods of time in the fields of Orthopedic Surgery and Bioengineering. Congratulations to Dr. Goodman.

Appointments and Promotions

- *Richard Lewis* has been promoted to Professor of Molecular and Cellular Physiology, effective 4/01/05.
- *Liqun Luo* has been promoted to Professor of Biological Sciences, effective 4/01/05.
- *Julie Parsonnet* has been promoted to Professor of Medicine and of Health Research and Policy, effective 4/01/05.
- *Paul Wise* has been appointed to Professor of Pediatrics, effective 4/01/05.