Dean's Newsletter
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Table of Contents

Medical Technology Leadership Forum

Thanks to the leadership of Paul Yock, Martha Meier Weiland Professor of Medicine and, by Courtesy of Mechanical Engineering, and Mildred Cho, Senior Research Scholar in the Center for Biomedical Ethics, a forum on conflict of interest related to medical technologies was held at Stanford on Sunday, July 22nd and Monday July 23rd. Leaders from academia, industry, government, ethics and law from around the nation assembled to review the perceptions and realities of the "Risk and Reward in Medical Technology Innovation: Conflict of Interest at the Academic/Industry Interface". This Summit was sponsored by the Medical Technology Leadership Forum (MTLF), a not-for-profit membership organization dedicated to educating its own members, policy makers, the public, and the media about the critical issues affecting or arising from the development and adoption of advanced medical technology. The President of the MTLF is Hon. David Durenberger, who also participated in the Summit. Stanford President Emeritus Donald Kennedy, the Bing Professor of Environmental Science, served as the Chair of the Summit.

Although there is increasing clarity regarding the conflict of interest regulations with regard to clinical trials involving drugs and biological agents, there is less clarity around the role or participation of the inventor of a new medical device (e.g., a new stent) in the initial patient studies. This is the case when the inventor is also the most experienced and best individual to carry out the initial procedures (e.g., surgeon) to determine the feasibility of using the new device or technology. The perceived or real conflict arises when the inventor-surgeon also happens to be a faculty member as well as equity holder of the company that may ultimately market the new device. A governing principle is that research must be performed in a manner in which the conduct, management and oversight are not biased by potential financial gain to the investigator or the institutions. The MTLF considered this scenario and others related to emerging medical technologies and will formulate a report that will be prepared by the MTLF and available from its Washington Office (1001 Pennsylvania Avenue, NW, Suite 850 North, Washington, DC 20004). Given the recent events at Johns Hopkins and the overall

concerns around clinical research as well as conflict of interest, this Summit was timely and its final report is likely to be quite relevant.

Internal Governing Council Update on "Funds Flow"

In the May 29th Dean's Newsletter, I reviewed the funds flow that occurs between the School of Medicine, the University, the Hospitals and Faculty Practice. An area of debate at Stanford as well as every other academic medical center in the nation concerns the funds that flow from the Hospitals to the School or clinical faculty. These have generally been referred to as "strategic support" or AS&T (administration, supervision and teaching). They include support for the role that clinical faculty play as directors of various services that are otherwise un-reimbursed, for the essential services to the Hospital or for new program development. I prefer to refer to these funds as payments for services rendered.

However, in the setting of decreased hospital revenue and negative bottom lines, the approach followed by academic medical centers around the country has been to challenge or reduce these payments from the Hospital to the clinical departments and faculty. This has happened at Stanford during the past year, placing an increased financial burden on the School and Clinical Department Chairs to accommodate the shortfalls, which have in some instances been quite significant. This challenge is made worse when the guidelines and rationale for the flow of these funds has been altered by years of special arrangements (a.k.a. "deals") that advantage one department but may compromise others. Recognizing that these are issues that could challenge the financial and working relationship between clinical leaders, the School and the Hospitals, an effort has been underway during the past four months to address the principles governing funds flows from the Hospital to the School. Notably, this is not the first time there have been attempts to address this issue. The current goal has been to develop principles that are clear and fair, that are agreed to by the School, Clinical Department Chairs and the Hospitals, and that are transparent. Accordingly, during the past months several subcommittees comprised of Hospital and Medical School leaders have been working to develop the guidelines that will be used to support medical direction, essential and nonessential clinical services, program development and new ventures. Ultimately these funds would be "zero-based". However, for the present they would be based on the historical aggregate (which has been reduced by over 20% in FY01), but redistributed using these new guidelines.

Dr. Norm Rizk, Professor of Medicine and soon to be Senior Associate Dean for Clinical Affairs, has led this effort. Dr. Rizk reported the updates from the subcommittees at the July 27th Internal Governing Council. While the initial expectation is that the new distribution of these funds will not occur in FY02, the Clinical Chairs have since agreed to use the new definitions for FY02. That means that even though Departmental budgets are nearly complete and have factored in the distribution of these funds based on prior guidelines (and deals) they will now be redistributed based on the new definitions. The practical implication of this should not go without notice since the funds available to some departments will increase while they will decrease to others. Obviously this has a number of consequences but I applaud the willingness of the

Clinical Chairs in moving forward with the new principles in order to make the overall funds flow process fairer, clearer and more transparent. We should know within the next couple of weeks how the redistribution will be allocated.

In the interim, I thought it would be helpful to remind all faculty and staff about the guiding principles for fund transfers from the Hospitals to the School of Medicine (specifically Clinical Departments) that has helped shape this important effort.

1. Fund transfers should represent payments for services rendered by the faculty to the Hospital or incentive payments from the Hospital to the faculty for services the Hospital wants to encourage and develop.

2. Payments made for specific services should be contingent on task and performance standards mutually understood by the faculty and the Hospital and should be reviewed annually by the standing committees that report to the Executive Funds Flow Committee.

3. Fund transfers should resemble ordinary business practices in other faculty and community practices and be transparent throughout the clinical enterprise.

4. Program development initiatives should be regarded as investment opportunities, with specific standards, risks and rewards for failure or success in meeting the standards. They should be subject to a maximal 3-year term, after which time they should expire, (unless specifically agreed in advance that continued support is needed for an essential service).

5. Ongoing program support should be restricted to specific services that meet productivity standards, are sized appropriately, and are deemed to be essential to the Hospital or School; other forms of program support should be withdrawn and be replaced by incentive payments for those services felt to be strategically or financially important.

6. Incentive payments should be based on overall financial health of the enterprise.

7. Some fraction of the profits from ancillary laboratory services should be returned to departments that direct and interpret the laboratory results, based on similar customs in the community and other academic medical centers. Fractions of the profits may also be apportioned to a pool within the practice, and/or to the Hospital. This should be individualized by the Executive Funds Flow Committee and reflect the normal business practices in comparable practice settings.

8. New medical ventures should be encouraged but governed by a standing committee that describes boundary conditions for their development to avoid transfer of patient care outside of the hospital. The guidelines for the new

medical ventures are being developed by a separate committee and will be presented in a subsequent report.

9. Implementation of this reorganization will require standing committees on medical direction, program development/incentives, essential services, and ancillary laboratories/medical ventures. These committees will report to the Executive Funds Flow Committee comprised of the VP, Dean, Hospital CEOs, CFOs, Senior Associate Dean for Finance & Administration and Senior Associate Dean(s) for Clinical Affairs.

Although the immediate management of the changes in funds flow from the Hospitals to the School of Medicine will be led by the Clinical Chairs, the results of this process will impact a number of faculty either directly or indirectly. Thus it is important to be conversant in these changes and to have them discussed within Clinical Departments and Divisions.

Senior Faculty Luncheon

On Monday July 30th I had the privilege to speak at the "Senior Faculty Luncheon". This title only partially reflects the attendees and audience, where I was asked to address the role of Stanford in transforming American Medicine in the 21st Century. Indeed, this audience included not only the leaders of Stanford Medical School but the basic and clinical faculty who have literally transformed science and medicine during the past several decades. Addressing such an audience was both daunting and awe-inspiring.

My message at the beginning and end of my formal remarks was the hope that these leaders would help the School by being advocates for change and reaffirmation of our mission within the School and University to improve the lives of children and adults through education and research. I highlighted the remarkable incongruity of the exceptional scientific opportunities that stand before us and how they are challenged by the financial and clinical landscape impacting academic medical centers throughout the country and at Stanford specifically.

I pointed out how these challenges require making choices. This includes choices in the nature and scope of our educational programs, in the focus and size of our investments in research, and in the scope and depth of the clinical programs that are provided. Accordingly, it will be necessary to carry out a comprehensive review and renewal of our programs in the medical education curriculum. In doing so, our overriding goal should address educating future thought leaders by focusing on the development of physician-scientists and leaders in academic medicine and biomedical research, as well as related leadership opportunities in the public and private sectors. We need to have creative pathways for interdisciplinary education and individualized career development, including, for example, opportunities in: Basic and clinical sciences, bioengineering, computer sciences, biocomputation, informatics; Public

Health/International Affairs; Advocacy/Public Policy/Government; Education; Law; Arts and Social Sciences; Religion and Ethics; Business/Health Care Financing.

Stanford is special in that we admit an equal number of graduate students as medical students. Indeed, approximately 20% of the incoming medical class have an advanced degree and others pursue joint degree training programs. Thus, we must do everything possible to sustain and enhance the most outstanding Medical School-based Graduate Education Program which attracts the best students and that prepares them for success as leaders in academia or the public and/or private sector. In doing so, we should create opportunities for graduate students to be acquainted with the principles and practice of clinical medicine in order to foster an understanding and interest in translational clinical research. This should be increasingly feasible with the computer based virtual learning programs being pioneered at Stanford as well as with the use of various clinical simulation models.

We also need to move away from the compartmentalized learning that characterizes current medical education and seek to develop more of a continuum for training physician-scientists that extends throughout medical school, graduate medical education and fellowship training. Such a program might be anchored in the M.D./Ph.D. curriculum – this also being a program pathway we should seek to expand. As noted, each of these will require new funding sources, which will mandate that we convey a clear and understandable message about why these investments are necessary to secure the health and well being of future generations.

In addition to our mission in education, research excellence at Stanford is best secured by continuing to develop and enhance excellence in basic and clinical investigation in conjunction with seeking ways to foster interdisciplinary research efforts that are either programmatic or represent areas of opportunity. Wherever possible, there should be an alignment of basic and clinical research opportunities with the "centers of excellence" areas being developed through the Child Health Initiative and Stanford Hospital strategic initiatives.

Choices are also necessary in our clinical programs, focusing on those we can do uniquely and well, and in a manner that complements those services offered by other providers in our community. At this juncture, the primary areas of focus for both the adult and pediatric clinical programs that seem best pursued are in cardiovascular diseases, cancer, brain and behavior and surgical specialties. Again, wherever possible, these clinical centers of excellence will be enhanced by basic and clinical research agendas. Naturally this means that some other important areas of medicine will be de-emphasized at Stanford, largely because they can be offered by other providers or because they are not as prime for new development and innovation. This also means that we will need to work closely with our colleagues at the VA Hospital, Santa Clara Valley Medical Center and with other community partners to develop an integrated and more embracing academic medical center.

During this period of transition, however, one thing is clear. We must sustain the integrity and relationships among our Hospitals & Clinics, our School of Medicine and our University. Not doing so will threaten the very relationship of our missions in clinical care, education and research. Needless to say, this will require sacrifice and commitment by all. It will require rigorous management of hospital and school operations and resources. It will require accommodation to reductions in services that have been previously valued. It will require even more careful investments in program development, recruitment and capital expansion. It will require us to think rigorously about every decision that requires school or hospital resources and to do so with a Medical Center perspective, as well as that of a student, investigator, clinician or staff member.

I also pointed out how pleased I am that both our clinical and basic science faculty leaders have pledged their support to work on behalf of the Medical Center through this difficult period. I underscored how equally pleased I am that our University leadership and Board of Trustees remain supportive. We have no choice but to work together to assure that future generations will benefit from the success of Stanford University School of Medicine and Medical Center.

Although our challenges are significant, they are achievable if we stay true to our principles and focused on our missions. We need to regain the public trust and their value of academic medicine, physicians and the future of health care. I asked each of the leaders present to help secure Stanford's future by being advocates for our continued excellence and for the choices we will need to make to secure an outstanding future as the role model of a research intensive School of Medicine for the 21st Century.

Some Notable Events

Departmental Faculty Meetings: Since the last Newsletter, I have had the pleasure of attending faculty meetings with the Departments of Dermatology, Comparative Medicine, and Urology. These meetings permitted discussions about issues relevant to different groups although some common themes understandably emerge (e.g., financial support, space, program development, physician leadership). I want to thank the respective Department Chairs for inviting me and the faculty for attending.

Visit to Cowell Student Health Center. On Tuesday July 24th, Dr. Peter Gregory and I had the opportunity to visit with Dr. Ira Friedman and his colleagues and staff at Cowell Student Health. Cowell provides care for 7,500 students and sustains a close working relationship with the Medical Center and faculty. We had the opportunity to discuss the programs currently conducted and to preview the plans for the new Center that is currently under construction. I want to thank Dr. Friedman and his staff for the excellent work they perform and for sharing information about their program with Dr. Gregory and me.

Update on the Johnson Center. On Tuesday July 31st, I had the opportunity to be updated on the work of the Johnson Center. Led by Drs. David Stevenson, Harold K. Faber Professor, and Maurice Druzin, Charles B. and Ann L. Johnson

Professor, the Johnson Center represents a joint effort between the Lucile Packard Children's Hospital, SHC and the Departments of Pediatrics, Obstetrics and Anesthesiology. The Johnson Center includes the perinatal, neonatal and obstetric services at LPCH as well as neonatal and perinatal satellites at Washington Hospital in Fremont, Dominican Hospital in Santa Cruz, Salinas Hospital in San Jose, El Camino Hospital in Mountain View, ValleyCare Medical Center in Pleasanton, St. Louise Hospital in Gilroy and Sequoia Hospital in Redwood City. The Johnson Center is an outstanding model of integrated neonatal and perinatal services that represents an important resource to Stanford and LPCH and value to the community.

Congratulations

I am pleased to announce that Dr. Christopher Garcia, Assistant Professor of Microbiology and Immunology and of Structural Biology, has been named a 2001 Pew Scholar. Dr. Garcia represents one of only 20 Scholars nation-wide this year to receive this competitive award. Congratulations to Dr. Garcia.

Appointments and Promotions.

1. **Jan Matthijs van de Rijn** has been promoted to Associate Professor of Pathology at SUMC, effective 7/1/01-6/30/06.

2. **Alex Macario** has been promoted to Associate Professor of Anesthesia and, by courtesy, HRP, at SUMC, effective 7/1/01-6/30/06.

Congratulations to Drs. van de Rijn and Macario.