

Dean's Newsletter

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Some Brief Reflections at the Conclusion of 2004

While a more complete accounting of this past year's performance and plans for 2005 will be offered in the January 10 2005 Newsletter, I thought I would offer a few high level reflections in this last Dean's Newsletter of 2004. When framed against the larger challenges that dominate our attention – the war in Iraq, tides of terrorism, the fragile economy, the rise of fundamentalism and theocracy, along with so many other important issues – the concerns we face at Stanford can sometimes seem small by comparison. And yet we are undertaking some truly important issues that have national and global impact.

Recently, I offered some comments on the deficiencies of our health care system, many of which continue to erode the public trust in medicine and its aligned disciplines. The recent debacle surrounding the availability of the flu vaccine, which revealed how tenuous our supply line for vaccines can be, along with the increasing fears about the possibility of an influenza pandemic surely have an impact on the public trust in medicine and the pharmaceutical industry. So too do the revelations regarding disclosures of potential health hazards related to drugs the public counts on (e.g., Cox-2 inhibitors like Vioxx). The rising price of drugs, a major driver of health care costs, further challenges the public's confidence in insurers, doctors and health care providers, as well as in the pharmaceutical industry and its regulatory oversight by the FDA.

Paradoxically, these public concerns arise at a time of remarkable scientific promise and opportunity. Yet, worries abound here as well. For many years the NIH, our nation's largest funder of biomedical research, has enjoyed a high level of bi-partisan respect and confidence, especially by the Congress. This featured prominently in the extraordinary efforts to double the NIH budget in 5 years, which was accomplished but which also ended in 2004. Fiscal constraints in discretionary spending, coupled with last

year's conflict of interest scandals, which significantly tarnished the image of the NIH, likely contributed to an FY05 budget increase of only 2.1%. While this is certainly higher than nearly all other federal agencies, it will not sustain the prior strength of the NIH budget. In particular, it will reduce the amount of support available for new and competing RO1 grants, which are, in many ways, the true heart and soul of our biomedical research enterprise. The potentially devastating impact of this reduction on new young faculty has extremely important implications that could, if unchecked, stifle the development of the next generation of bioscience investigators.

These issues are hardly trivial and, even when balanced against serious global matters, propel us to act assertively and with as much care, precision and advocacy as we can. They provide yet another reason why our prior strategic planning efforts at Stanford School of Medicine loom so importantly as we seek to define our future against a backdrop of potentially declining resources. Our efforts to educate the next generation of physicians who are also scholars and leaders may prove essential in filling a potential national void as well as in seizing important opportunities for discovery and progress. These will surely be aided by the important curriculum revisions that have come on line during the past 18 months. Our commitment to training our graduate students in interdisciplinary ventures as well as in offering opportunities to connect basic research to patient care by "*Translating Discoveries*" will almost surely be increasingly important as the pipeline of young investigators becomes more difficult to sustain. Stanford's role will surely be important in this vital area and I believe we will be successful.

Assuring connections between basic and clinical research will also be essential as the NIH Roadmap assumes an increasingly important place in the eyes of the Congress. Here our Stanford Institutes of Medicine and our new department of Bioengineering, as well as the entire BioX initiative, should permit us to assume leadership in key strategic areas. Proposition 71 and the new California Institute for Regenerative Medicine will certainly prime the pipeline of stem cell research. With our Stanford Institute of Cancer/Stem Cell Biology in place we should be well positioned to assume a leadership role here as well (see below for additional information). In addition, the interconnections of stem cell research among each of our four Institutes – which in addition to Cancer/Stem Cell Biology, include Neuroscience, Cardiovascular and Immunity/Transplant/Immunity – are notable and important.

Of course, bringing discovery to improvements in the health of adults and children must remain among our highest priorities. To do this, additional improvements in our clinical research infrastructure will be critically important. To this end, early next year we will launch SPCTRM (Stanford/Packard Clinical And Translational Research). This broad based infrastructure support organization for clinical and translational research will surely play an important enabling role for *Translating Discoveries* (see our Strategic Plan Website <http://medstrategicplan.stanford.edu/>). Further, we must accomplish these improvements in health in ways the public – our most important constituency – can recognize, understand and support. This need underscores the reason for embracing communication and advocacy as an important part of our strategic efforts, through our community events, mini-med schools, writing and communication.

As we end 2004 and begin 2005 I certainly see the obstacles that lie before us. But more importantly, I am confident that we have the opportunity to continue to do extraordinary work: to educate future leaders, conduct groundbreaking research, and initiate new innovations in patient care. Moreover, I continue to believe that we can pave new paths and open new vistas – making Stanford the role model it must be for the future.

Best wishes for the Holidays and, of course, for the New Year!

Stem Cell Research: Proposition 71, the California Institute on Regenerative Medicine and Stanford University

The next decade will offer significant opportunities to advance knowledge in stem cell biology and regenerative medicine, especially in California, thanks to the passage of Proposition 71 on November 2nd. During the next couple of months the research landscape will be more clearly delineated, since there is every expectation that Prop 71 (now known as the California Institute for Regenerative Medicine) will begin funding proposals as soon as the Spring of 2005. Obviously this will create an enormous pressure on the various oversight and review committees, which will need to be up and running in the next weeks to months. The Independent Citizens Oversight Committee (ICOC), which will oversee the whole effort, will hold its first meeting on Friday December 17th. As you likely know I was asked to serve on the ICOC by State Controller Steve Westly. While I recognize the importance of this effort, I am also cognizant of the enormous responsibility and accountability it will bring, both for me personally and for Stanford. I will give you periodic reports on the progress of the ICOC and the overall efforts of the California Institute for Regenerative Medicine.

At Stanford we have been putting into place an organizational structure to help bring together our own community of faculty interested in stem cell research. Our Stanford Institute for Cancer/Stem Cell Biology will oversee this effort. As part of this initiative, Dr. Irv Weissman, Director of CSCI, has appointed Dr. Linda Giudice, Stanley McCormick Memorial Professor, to chair a retreat focused on Stem Cell Research. This retreat, scheduled for January 15th, will bring the Stanford community together to share ideas and plan for the future. The specific goals are to identify all who are interested in regenerative medicine research at Stanford, to begin discussion, and to coordinate strategic planning regarding research programs, research collaborations, infrastructure, training opportunities, and organizational structure. In addition, we hope that the retreat will lead to planning for Stanford University proposals for Proposition 71 funds.

Per Dr. Giudice, “regenerative medicine research has extraordinary potential in basic research as well as translational medicine.” She and her colleagues have been in the planning phases of a Human Embryonic Stem Cell Center in the Stem Cell Institute. They hope to facilitate a broader effort to develop existing NIH cell lines, derive new cell lines, elucidate stem cell biology, stem cell renewal and differentiation, and develop new applications for treating chronic diseases. Dr. Giudice points out that “regenerative

medicine research takes place in the context of ethical and legal guidelines, and it is likely that new technologies will be developed for therapeutic applications. These are all important issues, and we hope to discuss their integration at the retreat.”

Further details will soon be available about the January 15th Retreat but I wanted to let you know about this event now so that you can mark it on your calendar. If you are interested, please contact Dr. Giudice for additional details (giudice@stanford.edu).

Addressing the Challenges Facing the NIH

At the December 3rd Executive Committee, Ryan Adesnik, Director of Federal Government Relations, provided an update on issues the NIH will face in the next Congress. The discussion focused on two topics: the current and projected level of NIH funding and the upcoming NIH Reauthorization Bill—which is basically a policy review of the agency.

These are challenging budgetary times for research funding and support as the federal government confronts the costs of the Iraq War, a growing deficit and the ongoing effort to fund tax cuts. Last week, in this budgetary environment, Congress passed an NIH budget that constituted a 2.2% increase over last year’s funding. Studies show that, because of the costs associated with biomedical research, annual increases of at least 6% are needed to keep grants at existing levels. Unfortunately as we look to the future, the President’s last budget through 2009 projects continuing declines in non-defense R&D including NIH, where the funding level in 2009 is projected to be 5% less than its 2005 level (in constant dollars). This is obviously very challenging news to biomedical research, and it has many implications for academic medical centers, including Stanford.

In addition to this difficult legislative environment, the NIH faces a number of important policy (and public perception) challenges, including: the communications dilemma of explaining the need for continued funding increases following the historic doubling, questions related to the recent conflict of interest inquiry that has plagued the NIH since this matter arose a year ago, and recent challenges to the peer review process.

This is the context in which the 109th Congress is planning to take up an NIH Reauthorization Bill. By way of background, a reauthorization bill is a policy review of a federal agency or program conducted through the legislative process. However it can result in a number of important financial impacts. Importantly, a reauthorization bill can be as broad or narrow as the committee of jurisdiction chooses. For example, the most recent NIH Reauthorization Bill was passed in 1993 and made significant changes, including:

- Establishment of the Office of Research Integrity at HHS
- Mandating the inclusion of women and minorities in clinical research trials
- Creation of the Office of Alternative Medicine, the Office of Research on Women’s Health, the Office of Research on Minority Health, the Office of

Behavioral and Social Science Research, and the National Center for Human Genomic Research

In 1996 Congress attempted another NIH Reauthorization Bill. Although it passed the Senate it was not acted upon in the House. Nonetheless, many of its provisions later became law, including:

- Increased Parkinson's funding
- The Pediatric Research Initiative in the Office of the Director
- Increased funding for Type 1 diabetes
- Establishment of the Office of Rare Diseases

In response to the plans for a new NIH Reauthorization Bill, I have worked with the American Association of Medical Colleges (AAMC) to establish an NIH Reauthorization Task Force to develop ideas that will inform the process. I am co-chairing this Task Force along with Bob Kelch, Vice President for Medical Affairs and CEO of the University of Michigan Health System. This group's goal will be to work in a cooperative way with Capitol Hill in an effort to educate Members of Congress and their staff and to develop ideas that will benefit the research mission. Ryan Adesnik will staff this group and will also serve on an analogous committee of the American Association of Universities (AAU). Time permitting, we maybe calling on members of the School of Medicine community to assist in reviewing draft legislation, and possibly giving testimony at one of the numerous hearings that will no doubt occur.

In addition, your input is needed as we address critical questions. For instance, what structural or organizational changes, if any, would benefit the NIH and biomedical research? How can the NIH demonstrate accountability it is oversight (e.g. the peer review process) without having a negative impact on the research mission? How can the NIH better communicate its successes, especially given the increasing desire of the Congress to show results from the recent NIH doubling? What are some ideas for arguments to defend peer review?

Your ideas are welcome. Please direct them to Ryan Adesnik at radesnik@stanford.edu. Thanks to Ryan for a very helpful primer on this critically important topic. We will keep you apprised of further developments about this extremely important issue.

School of Medicine and Hospital Leaders Explore Model for Interactions at the University of Michigan

On December 7th, a joint School of Medicine-Stanford Hospital & Clinics team visited the leadership of the School of Medicine and Hospital at University of Michigan. The purpose of the visit was to compare approaches to crafting joint ventures or business relationships between the school, faculty and hospital. The University of Michigan has successfully launched an innovative program that supports their Cancer Center. Based on

information I had gathered during an earlier visit to U Michigan, we felt we could learn from their experience and perhaps emulate aspects of it at Stanford. The methodology was published in an article entitled “New Organizational and Fund Flow Models for an Academic Cancer Center” by David Spalinger (who coordinated our visit) in *Academic Medicine* 2004;79:623-627).

Our School-SHC Funds Flow Team comprised of Norm Rizk, Jerry Shefrin, Mike Hindery, Marcia Cohen, David Keane and Rob Jackler has been evaluating a number of methodologies to address funds flow and will now be exploring how the Michigan experience might apply. We anticipate having more updates about this topic in the early part of 2005.

Roundtable Discussion with the Governor

On Thursday December 9th I and other members of the Board of Directors of the California Healthcare Institute (CHI) met with Governor Schwarzenegger at the State Capitol Building in Sacramento. We had the opportunity to discuss a number of important issues with the Governor, including the importance of innovation in improving the health and well being of our communities. The consortium of academic institutions, biotech and related industries which comprises the CHI has played a major role in stimulating the discovery of new drugs and medical devices that have impacted the health of adults and children. In addition, academia-industry collaborations have also fueled the job market –over 230,000 Californians are working in the 2600 biomedical companies located in the state. Moreover, there are hundreds of thousands of Californians who are employed at state or private universities or research institutions and who also contribute significantly to innovation and discovery. As you know, Stanford has played a major role in these efforts. There is little question that the passage of Prop 71 will further stimulate the process of innovation and, as a result, stimulate the state economy as well. At the same time, we also spoke with the Governor about the important challenges of health care access, the uninsured and underinsured and the costs for care, including the cost of pharmaceuticals. I made the point of how broken our health care system is and emphasized that major efforts are necessary to address its underlying problems. This meeting was introductory. I am hopeful that it will lead to continued dialogue that will seek solutions as well as opportunities.

Introducing the New Executive Assistant to the Dean

I am very pleased to announce that Ms. Noel Beauchamp has accepted my offer to come to Stanford as my Executive Assistant. Noel replaces Sharon Olsen, with whom I had the pleasure of working for many years in Boston and at Stanford.

Noel comes to Stanford from a varied career in government and the private sector. Most recently she served as Executive Assistant to the Vice President for Research and Clinical Development at Avigen, Inc. Her previous positions have included Executive Assistant to a CEO and to a Senior Vice President for Scientific Affairs in other biotech companies. In addition, Noel spent a year as a volunteer in with the United Nations

Volunteer Program, which she spent as a Civil Affairs Officer with the UN Interim Mission in Kosovo. There she was a team member of the first UN-led municipality and was involved in a wide range of administrative, coordination, reporting, program oversight, and public relations activities. I am pleased that Noel will bring this wide range of experience and expertise to bear in working with me and others in the School and University.

Update on Administrative Restructuring

At the December 3rd Executive Committee meeting, Mike Hindery, Senior Associate Dean for Finance and Administration, provided an update on administrative restructuring in the School. Work in this area has been underway for well over a year. Earlier stages in the project included an assessment of the School's current structure and units and the development of principles to guide a revised administrative structure. A model for this revised administrative structure was introduced at the January 2004 Strategic Planning Retreat and was further discussed and evaluated by the Executive Committee. The purpose of this update was to describe the progress to date in the implementation of this model.

The fundamental reason for undertaking administrative restructuring was the fact that changes in the School's environment in recent years has significantly complicated delivery of the School's administrative functions. These changes include the breaking down of boundaries between disciplines and the corresponding rise in non-departmental program units, the development and implementation of new University-wide information systems, continued increases in regulatory compliance requirements, a constrained economic environment, and staff burnout.

Departments continue to be an organizing priority, but non-departmental units (NDUs) – such as our Stanford Institutes of Medicine or Strategic Centers - are recognized as the important administrative units they are increasingly becoming. This model allows for effective support of both, through such mechanisms as shared DFAs (Departmental Finance Administrators) and the clustering of some functions. An Administrative Steering Committee made up of DFAs and other members of the School's administrative staff has the responsibility of implementing the model. Key elements of the model are currently being implemented in pilot projects. They are:

- ***The clustering of the Human Resource functions of PeopleSoft and Kronos.*** The basic science departments created a cluster in 2002-03 covering data management and other HR services. Three clusters of clinical departments were formed in 2004. Currently 23 departments participate in clusters. The expected improvements from the new structure include greater data integrity in PeopleSoft and more expert and faster service.
- ***IT Support service clusters.*** Bob Burkhardt of our Information Resources and Technology Office is directing the development of a "hub and spoke" model for desktop support that is intended to allow departmental users to get problems

resolved more quickly by enabling remote desktop service and to allow higher desk top performance standards. It is hoped that this new model will significantly improve turnaround time on desktop assistance, provide more cost effective service, and lead to the development of consistent standards for desktop systems.

Mike Hindery concluded by noting several challenges, including the need to design funding models for implementing new administrative structures, finding space for clustered services, and managing organizational change issues. The next steps include the continuation of implementation projects, documentation and communication of lessons learned with each implementation, and the creation of methods and metrics for evaluating success on a regular basis.

This set of projects is obviously of great importance to the School. A great deal of progress has already been made, and I look forward to seeing more positive change in the months ahead.

In Memoriam

- The Stanford community lost one of its most revered and respected colleagues when Professor Emeritus Byron “Bill” Brown died unexpectedly (see December 8th Stanford Report <http://news-service.stanford.edu/news/2004/december8/med-brown-1208.html>). His personal and professional contributions and collegiality are legion and he will be missed by generations of Stanford faculty, students and staff. A memorial service is planned for a later date and I will do my best to let you know when that is planned. The family suggests contributions to the Nature Conservancy in Professor Bill Brown’s memory.
- I am also very sorry to report that Steve Aldrich, the son of Rick and Mary Aldrich died in late November. His loss is deeply felt. Our condolences to Dr. Aldrich, Professor of Molecular and Cellular Physiology and his family for this tragic loss. The family has indicated that contributions can be made to the National Alliance for the Mentally Ill, 1111 Howe Avenue, Suite 475, Sacramento CA 95825.