SPECIAL REPORT ON THE UNIVERSITY OF CALIFORNIA, IRVINE LIVER TRANSPLANT PROGRAM

Submitted to University of California
Chancellor Michael V. Drake
By the UCIMC Liver Transplant Review Committee

February 15, 2006

Final Report

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Executive Summary

In September 2005, the U.S. Centers for Medicare and Medicaid Services (CMS) issued a report detailing a number of deficiencies at the UC Irvine Medical Center (UCIMC) Liver Transplant Program ("Program"). UCIMC responded with a plan of correction dated October 31, 2005. After further communication with CMS, UCIMC was instructed to provide a revised plan by November 14, 2005. On November 10, however, CMS informed UCIMC that it had rescinded Medicare payment approval for liver transplants performed at the center. Chancellor Michael V. Drake closed the Program the same day.

Appointment and Charge to the Review Committee

Immediately following the closure of the Program, Chancellor Drake appointed the UCIMC Liver Transplant Review Committee ("Committee"). The Committee was chaired by Meredith J. Khachigian, former Chair of the Board of Regents of the University of California. Committee members included, Haile Debas, MD, UCSF Chancellor Emeritus and former UCSF Dean of the School of Medicine; Kenneth Janda, PhD, Chair of the UCI Academic Senate and Professor of Chemistry; Kenneth Shine, MD, Executive Vice Chancellor for Health Affairs at the University of Texas System and Past President of the Institute of Medicine of the National Academy of Sciences; and Steven A. Wartman, MD, PhD, President of the Association of Academic Health Centers and formerly Executive Vice President for Academic and Health Affairs and Dean of the Medical School, University of Texas Health Science Center at San Antonio. (A roster of members is included as Appendix A.)

The charge was stated as follows:

> *The committee is asked to provide guidance and consultation to the chancellor concerning the causes that led to the closure of the UCIMC Liver Transplant Program. Specifically, the chancellor would like the committee to review management practices, organizational structure and culture, and communication at the medical center, and to make specific recommendations for actions to be taken to improve oversight of clinical areas at UCIMC.*

In response to this charge, the Committee reviewed an extensive array of written materials, including but not limited to correspondence with CMS, the California Department of Health Services (DHS) and the United Network for Organ Sharing (UNOS), and other written agreements regarding arrangements for professional services. The Committee held two in-person meetings, the first on December 16-17, 2005 and the next on January 15-16, 2006. The group also met twice by conference call. The Committee interviewed witnesses familiar with the UCI Program and national experts in liver transplantation and ethics.

Major Findings and Observations

The Committee believes that the development of the UCI Liver Transplant Program was driven by a desire to meet the needs of the patient community and to provide what was viewed by both the UCI School of Medicine and UCIMC as an important component of the medical center's clinical programs.

The Program was envisioned as a small program to serve the local Orange County patient population. From its inception as a program affiliated with UC Los Angeles (UCLA), and through its existence as a stand-alone program, the UCI Program faced a number of challenges. By January 2002 (shortly after the departure of its founding director and senior surgeon), the Program developed more serious difficulties. These problems were never fully resolved and eventually led to its closure. Between 2002 and 2005, the Program underwent multiple external reviews, including those by several different regulatory agencies. Although UCIMC management developed plans to address numerous problems identified by these audits, these plans frequently failed due to inadequate oversight, insufficient follow-through, and because there was little or no margin for error.

The Committee observed a disappointing lack of leadership and accountability on multiple levels. This in turn eroded the Program's credibility and reputation, both internally and externally. Beyond its challenges in responding effectively to regulatory organizations, the Program struggled to maintain credibility on campus and in the surrounding medical community. Personnel problems that might be only a distraction in larger programs had major negative impacts that kept the Program from advancing. Quality assurance mechanisms were not adequate and follow-through promised to oversight agencies was often incomplete. In an effort to keep the Program open, campus decision-makers were not always open and transparent in their communications. The Committee identified seven major factors contributing to the Program's failure:

(1) The program did not have a clear strategic plan.
(2) Clear reporting structures in the medical school and hospital were lacking.
(3) There was a failure of leadership and accountability.
(4) Responsiveness to external and regulatory agencies was slow and incomplete.
(5) Standards and procedures for quality assurance were not adequate.
(6) Communication with patients was inconsistent, and at times insufficient.
(7) Personnel issues involving transplant surgeons and staff were poorly managed.

Committee Recommendations

Closure of the UCI Liver Transplant Program was necessary and appropriate. The Committee agrees that those directly responsible for events leading to its closure should be held accountable. As UCI leadership responds to specific issues involving the Program, it is also important that the Chancellor, central campus administration, medical school, hospital, and community begin to carefully plan for the future of the health sciences enterprise at UCI. Resumption of a liver transplant program should be considered only if it is determined to be a high institutional priority that would be appropriately managed and funded.

Recommendations to Improve Management of UCI Clinical Programs

This Committee was requested to review management practices, organizational structure and culture, and communication at the medical center, and to make specific recommendations for actions to be taken to improve oversight of clinical areas at UCIMC. Based upon its review, the Committee offers eight major recommendations, which are listed here and described in greater detail in the full report.

(1) Recruit New Health Sciences Executive Leadership Accountable to the Chancellor
(2) Strengthen School of Medicine Oversight
(3) Establish and Maintain Clear Reporting Lines for All Clinical Programs
(4) Develop New Strategic Plan for the Health Sciences
(5) Conduct Campus-wide Review of All Clinical Programs
(6) Ensure Rigorous Quality Assurance Procedures for All Clinical Programs
(7) Ensure that Capital Plans are based on Academic Plans and Goals
(8) Review UCI School of Medicine Faculty Practice Plan

In the course of this review the Committee became deeply concerned that a number of other UCI clinical programs are operating with marginal resources and staffing. The above recommendations regarding campus-wide review of all clinical programs, prioritization of goals, strategic planning and focus are thus critically important as UCI plans for the future and prepares for a new hospital.

Comments Regarding Possible Re-Establishment of a Liver Transplant Program

The Committee also considered factors that should be taken into account if a new liver transplant program were to be re-established at any time in the future. In keeping with the above recommendations, a clear and complete analysis should be required of how any new liver transplant program would meet the strategic goals of the institution. Careful attention should be given to the "size" of a new program and the resource requirements necessary for success. Resumption of a liver transplant program should be considered only if it is a high priority for the medical school and hospital – and only if it is appropriately managed, organized and funded. Perhaps as importantly, the lessons learned from the UCI transplant program should be remembered and applied.

Concluding Comments

The Committee heard a great deal about "small" or "thin" programs with marginal staffing and inadequate resources. It is thus essential that a rigorous institutional review be conducted for all existing UCI programs, and that a new strategic plan be developed. Only after determining that existing clinical programs are meeting appropriate standards for education, research and patient care, should consideration be given to developing any new program. The Committee strongly believes that many of the problems involving the UCI Liver Transplant Program – and other UCI clinical programs – occurred when good intentions and ambitious plans for growth exceeded both the financial and management resources available to assure quality and success.

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The UCI Medical Center Liver Transplant Program

Special Report of the University of California, Irvine Medical Center Liver Transplant Review Committee – February 15, 2006

Introduction

This Report is submitted to UC Irvine Chancellor, Dr. Michael V. Drake by the UC Irvine Medical Center (UCIMC) Liver Transplant Review Committee ("Committee"). The Committee was convened under the direction of the UC General Counsel's Office to ensure that witnesses knowledgeable about liver transplant programs and individuals familiar with the UCI Liver Transplant Program ("Program") would be able to speak candidly with the Committee under the protection of attorney-client privilege.

The Report responds to Chancellor Drake's request that the Committee provide guidance and consultation concerning the causes that led to the closure of the Program. As part of its charge, the Committee was asked to review management practices and to make recommendations to improve oversight of clinical areas at UCIMC.

While the report respects the attorney-client privilege of individual communications, and the notes and deliberations of the Committee remain under the privilege, the findings and recommendations contained in this Report are based directly upon the Committee's in-depth review of written materials, interviews with administrators, faculty, and staff, and consultations with experts in liver transplantation and medical ethics.

The Report is organized in three major sections:

- Section I briefly describes the context for the Committee's review, including an overview of recent events leading to the closure of the Program. The Committee's charge and a description of the scope and timeline of its review are provided.
- Section II reviews the history of the Program, with a focus on the challenges faced and the Committee's findings regarding the causes leading to the closure of the Program. Seven major findings are identified and discussed.
- Section III contains the Committee's eight major recommendations for improving oversight, strategic planning and quality assurance for clinical programs. It also includes general comments and recommendations regarding the possible future re-establishment of a liver transplant program at UCIMC.

I. Background and Context for Committee Review

The UCI Medical Center

Difficulties leading to the closure of the Program are better understood within the broader historical context of the UCI School of Medicine and UCIMC. In the mid-1960s, the assets of an institution known as the California College of Osteopathic Medicine were moved to UCI, where they became the foundation for a new allopathic (MD granting) medical school. In 1976, at the urging of the State, UC assumed operational responsibility for the former Orange County Hospital. The contract between UC and the State called for County support of indigent (un-reimbursed) care. However, unresolved disputes resulted in UC's assumption of significant responsibility for indigent care and the financial burdens of serving as the primary provider of health services to Orange County's lowest income patients.

In 2006, three decades later, the patient community served by UCIMC still includes the largest proportion of Medi-Cal and indigent patients in the UC system and among the largest served by any major U.S. teaching hospital. Orange County funds indigent health care at nearly the minimum rate allowable by State law and it ranks at the bottom of per capita indigent health care spending among California's ten most populous counties. These and other realities have created long-standing financial challenges for UCIMC in building the breadth and depth of academic and clinical programs that are characteristic of high quality academic medical centers.

Although major achievements have been made by the School of Medicine and by UCIMC, the campus has also endured several widely-publicized problems related to patient care and public accountability. In the mid-1990s, three faculty members practicing at the UCI Center for Reproductive Health were discovered to have taken oocytes (eggs) from a number of women and implanted them in other women without their consent. In 1999, UCI fired the director of its "willed body program" after he was discovered to have sold donated body parts for personal financial gain. These criminal acts created intense emotional distress for the patients and families involved, led to extensive litigation, and resulted in an erosion of confidence in the medical center within the UCI community and broader public.

Unlike the problems of the UCI Liver Transplant Program, these previous events involved criminal activities by a small number of individuals who were intent on financial gain. It is important to note, however, that the absence of clear reporting lines and strong management oversight were identified as contributing factors. In these respects, there are similarities to the UCI Liver Transplant Program.

Recent Events involving the UCIMC Liver Transplant Program

In September 2005, the U.S. Centers for Medicare and Medicaid Services (CMS) issued a report detailing a number of deficiencies within the Program and set forth specific procedures for addressing them. UCIMC responded with a plan of correction dated October 31, 2005. After further communication with CMS, UCIMC was instructed to provide a revised plan of correction by November 14, 2005. On November 10, however, CMS informed UCIMC that it had rescinded

Medicare payment approval for liver transplants performed at the medical center. Chancellor Drake closed the Program the same day.

Among the examples of major concerns cited by these agencies over the past three years were those indicating that:

- The UCIMC Liver Transplant Program failed to meet the required annual number of 12 liver transplant procedures [for CMS certification] and the required number of 18 annual transplants [for DHS certification] each year for three consecutive years. In 2002, 2003, and 2004, eight or fewer liver transplants were performed annually.

- According to UNOS and One Legacy (the Organ Procurement Organization for UCIMC, UCLA, Loma Linda, USC and other regional programs), UCIMC's acceptance rate of livers for transplantation was significantly less than national and regional averages for other transplant centers.

- The Program did not have an adequate number of liver transplant surgeons, and there was inadequate evidence of a clear plan for addressing this need. This limited staffing arrangement made it difficult to ensure adequate back-up and surgical coverage for the Program.

- The Program did not have a rigorous and effective quality assurance and performance improvement program. In its September 2005 communication to UCIMC, CMS stated that "...The cumulative effect of these systemic practices resulted in the failure of the hospital to deliver statutorily mandated services and compliance with Federal requirements under quality assessment and performance improvement."

- The Program did not always inform patients of changes in plans for their care, with indications that some patients were not informed about changes in treatment decisions.

These and other allegations are currently under review by external oversight agencies and the University. A number of questions also were raised about the adequacy of oversight and accountability of the UCIMC Liver Transplant Program. In response to these important questions and concerns, as well as and others related to management practices and oversight of UCI clinical programs, UCI Chancellor Drake sought further review and guidance.

Appointment and Charge to the UCIMC Transplant Review Committee

In November 2005, following closure of the UCI Program, Chancellor Drake appointed this UCIMC Liver Transplant Review Committee. The five-member Committee was asked to submit its report by February 15, 2006. Membership included:

Meredith J. Khachigian – Committee Chair
Former Chairman of the Board, The Regents of the University of California
Former Chairman, Regents Committee on Health Services
Former Member of the Board of Directors, UCSF Stanford Health Care System

Haile Debas, MD
Executive Director, UCSF Global Health Sciences Institute
Maurice Galante Distinguished Professor of Surgery
UCSF Chancellor Emeritus and former UCSF Dean of the School of Medicine

Kenneth Janda, PhD
Chair, UCI Academic Senate
Professor of Chemistry, UCI Department of Chemistry

Kenneth Shine, MD
Executive Vice Chancellor for Health Affairs at the University of Texas System
Past President of the Institute of Medicine of the National Academy of Sciences
Professor of Medicine Emeritus, UCLA School of Medicine

Steven A. Wartman, MD, PhD
President, Association of Academic Health Centers
Former Executive Vice President for Academic and Health Affairs and Dean of the Medical School, University of Texas Health Science Center at San Antonio

Chancellor Drake's charge to the group was as follows:

The committee is asked to provide guidance and consultation to the chancellor concerning the causes that led to the closure of the UCIMC Liver Transplant Program. Specifically, the chancellor would like the committee to review management practices, organizational structure and culture, and communication at the medical center, and to make specific recommendations for actions to be taken to improve oversight of clinical areas at UCIMC.

The committee is encouraged to draw upon written materials related to this matter and to interview administrators, faculty, staff and others as appropriate and suggest any follow up actions deemed necessary.

Scope and Timeline for the Committee's Review

The Committee reviewed extensive written materials, including, but not limited to: correspondence with CMS, DHS and UNOS, written agreements regarding staffing and arrangements for professional services, and other records relevant to the Program. The Committee held two in-person meetings, the first on December 16-17, 2005 and the second on January 15-16, 2006. The Committee also met twice by conference call. The Committee interviewed witnesses familiar with the Program and national experts in liver transplantation and medical ethics. Every interview was conducted in the presence of counsel, who advised witnesses that their testimony would remain confidential and privileged to the extent allowed by law.

II. THE UCI LIVER TRANSPLANT PROGRAM

History of the UCIMC Liver Transplant Program

The creation of the UCI Liver Transplant Program was driven by a desire to meet the needs of the patient community and to provide what was viewed by both the UCI School of Medicine and UCIMC as an important component of the academic medical center's comprehensive clinical training and patient care programs. In this respect, the goals of the campus were in keeping with the mission of major academic medical centers, and with those of the University of California in general. While the development and management of clinical programs routinely requires the ability of leadership to resolve unanticipated challenges, the UCI Liver Transplant Program faced challenges that overwhelmed the ability of the leadership to meet its goals.

The UCI Liver Transplant Program opened in 1993 as an affiliated program with UCLA. Two years later, UCI recruited its first transplant surgeon from UCLA, Dr. David Imagawa. In 1997, the UCI Department of Surgery created a Division of Transplantation and in 1999, UCI hired a second transplant surgeon, Dr. Sean Cao. UCI and UCLA ended the affiliation in 2000 and UCI's transplant program began to operate on a stand-alone basis. Dr. Cao was the primary transplant surgeon from 2001 until his departure in July of 2004. At that time, Dr. Marquis Hart, a transplant surgeon at UC San Diego (UCSD), became the Director and he and his UCSD faculty colleague, Dr. Ajai Khanna, performed all of the liver transplants until the Program was closed in November 2005. During its 12-year history, UCI performed an estimated 135 liver transplants. The annual number of transplants varied considerably from year to year, ranging from highs of 17 to 23 transplants in the years 1996 to 1998 (during its affiliation with UCLA), to eight or fewer from 2002 through 2005.

Program Challenges

Program Size: The Program was originally created and envisioned to operate as a small program. (A "small program" was interpreted by the Committee as one performing 35 or fewer transplants per year.) Small programs, by their nature, frequently face unique challenges. The UCI Liver Transplant Program was no exception. Problems included specific difficulties in performing annual minimum numbers of transplants required for certification and funding from DHS (18 per year for Medi-Cal), and CMS (12 per year for Medicare), and the fact that individual patient decisions and outcomes more dramatically influenced acceptance rates and mortality statistics. The UCI Program did not benefit from economical efficiencies of larger programs and the loss of one individual, whether the transplant surgeon or key transplant program staff, put the Program at risk until replacements could be hired.

The UCI Liver Transplant Program suffered substantially because of these size-related challenges. Over the past ten years, the Program met the DHS minimum number of 18 transplants only two times (most recently in 1997), and met the CMS minimum of 12 transplants only five times (most recently in 2001). These data show that the Program was experiencing difficulty for several years before it was closed. The turndown rate was affected by legitimate patient-care related decisions that did not always allow the Program to take marginal organs, or to perform transplants on the

sickest patients because there was not an adequate institutional infrastructure for providing this level of service. Finally, the Program suffered from an inability to recruit and retain a transplant surgeon and Program Director. Ironically, the Program had just recruited a transplant surgeon to take over at the time it was closed.

Leadership and Surgical Staffing: The success of a small transplant program depends on the professional skill, experience and leadership of the chief transplant surgeon. Unfortunately, following the departure of Dr. Imagawa as the senior transplant surgeon, the Program was left without an effective Director and transplant program leader.

With Dr. Imagawa's departure in September 2001, the staffing for the Program began to suffer and turnover among support staff became more frequent. Other problems, including the low number of transplants and poor communication with hospital personnel, contributed to a difficult work environment and to low referral rates from the surrounding medical community. These challenges were partially attributable to the very small number of UCIMC transplant surgeons available to support the Program, and the fact that difficulties between the former Director and his successor (discussed below) went unresolved.

Given that the Program operated almost exclusively with only one available transplant surgeon, surgical staffing was another constant challenge. The difference between having one versus two transplant surgeons on staff is significant for managing back-up, coverage for patient care and referrals from the surrounding professional community. By way of illustration, Dr. Imagawa informed the Committee he had not taken a vacation for over five years while serving as the primary transplant surgeon.

In the late spring of 2004, UCIMC learned that Dr. Cao would be resigning from his position, with an effective date of July 29, 2004. The resignation came at a particularly difficult time because UCI was about to defend the continuation of the Program to UNOS at the July 2004 Membership and Professional Standards Committee (MPSC) meeting in Chicago. Without a transplant surgeon, the Program would have to be suspended or closed, options that UCIMC chose not to pursue. The UCIMC CEO and Medical School Dean contacted senior administrators at UCSD and Dr. Hart to begin discussions about the possibility that Dr. Hart serve as interim transplant surgeon and UCI Program Director, while UCI recruited another full time transplant surgeon to the Program.

Dr. Hart wrote a thoughtful critique of the UCI Program, but to the Committee's knowledge, his recommendations were never acted upon. Discussions did lead, however, to the formation of both an on-call service agreement for the services of Dr. Hart and his UCSD faculty colleague, Dr. Khanna, and a Transplant Director Agreement with Dr. Hart. While the immediate need for transplant surgical coverage was apparently met through these agreements, there were also preliminary discussions about a more formal affiliation between the two transplant programs. These discussions never advanced beyond preliminary stages. From July 2004 until the Program was closed, Dr. Hart and Dr. Khanna traveled to UCIMC to perform transplant surgeries.

Staffing and Work Environment: Dr. Imagawa and Dr. Cao did not get along. In 2001, at the time Dr. Imagawa was giving up his transplantation practice and Dr. Cao was named as Director, their open disagreements spilled over to the staff, creating what some interviewees considered to be a

hostile work environment within the Program. These personnel issues contributed to a variety of difficulties, including high turnover of staff, poor communication between the Program and the UCI School of Medicine's Department of Surgery, and between and among the hospital administration, medical school, and referring physicians in the area. UCIMC attempted to resolve the problem by assigning a highly experienced supervisory nurse within the Program to manage the personality differences and provide some level of mediation between the physicians and the staff. The supervisory nurse and the transplant program coordinator were responsible for the day-to-day management of Program staff, and both reported directly to UCIMC's Director of Nursing, rather than to the Director of the Program.

Although this arrangement addressed the immediate needs of the Program's deteriorating work environment, it created barriers to communication and oversight by reducing contact between the transplant surgeon and the Program's nursing and administrative staff. In the view of the UCIMC administration, many of these difficulties stemmed from the new Director's absence of adequate leadership and administrative skills to run the Program.

Financial Resources: The low volume of liver transplantation contributed to UCI's difficulty in recruiting and maintaining adequate transplant surgical staff. UCIMC attempted to address this by guaranteeing the salary of transplant surgeons despite the financial losses the hospital experienced as a result of the low numbers (and high costs) of the transplant surgeries performed. In fact, the Committee was told by the former CEO that the Program never generated the income needed to cover its costs. This arrangement had limited effectiveness, however, because it neither compelled surgeons to dedicate their fullest efforts to the Program, nor adequately addressed the challenges faced by the ancillary medical services that supported the Program. This became especially problematic after May 2004 when UCI could no longer bill for Medi-Cal patients.

Organ Acceptance and Turndown Rates:

The UCI Liver Transplant Program's organ acceptance rate, when compared with national and regional statistics, was low. The Committee was advised by the Chief Medical Officer that the national and regional organ acceptance rate data were not made available to the hospital until just before the Program was closed.

Over the past five years, there has been a 38 percent national average acceptance rate of liver organs for transplant. OneLegacy, the local Organ Procurement Organization (OPO) for the Los Angeles/Orange County area, of which UCI was a member, had an average regional acceptance rate of about 25 percent over the same five year period. According to UNOS, UCI's acceptance rate was 9.3 percent during the same period.

The Committee was advised by its liver transplant expert consultant that one cannot generalize from such statistics without further study – something well beyond the Committee's charge. The expert consultant noted that turndown rates can be misleading and high organ acceptance rates do not necessarily correspond to good outcomes. As one anecdotal example, the Committee learned of one patient who was approximately 4'8" and 90 lbs. The Program had to turn down approximately 40 organs before a suitable one was found for his patient. This was explained by the fact that this patient, and many others served by UCI, are small in stature and weight, requiring

UCI's Program to compete with pediatric patients awaiting transplants in other hospitals. In a small program such as UCI's, the experience of one individual such as the patient mentioned above will significantly impact UCI's statistical turndown rate for that year; yet, in this example the Program could not be faulted for its medical decisions and judgments.

UCI's waitlist mortality statistics were determined by UNOS to be not significantly different than regional or national averages, and UCI's transplant statistics for its acutely ill patients were found comparable to other regional hospitals.

Demographics of the Patient Population Served: UCI's patient population is predominantly poor and ethnically and racially diverse. Approximately 30% of UCIMC's overall patient population and 32% of those awaiting liver transplantation are of South East Asian origin (primarily Vietnamese). Another significant percentage of the served population is Hispanic. The Committee was told (although did not see specific statistical support) that a significant percentage of the patients suffer from Hepatitis B and/or C, and are suitable candidates for liver transplantation listing. These patient care needs supported the rationale for a small and well-focused program at UCI, but also created unique challenges.

Significantly, UCI's patient population included many patients of smaller than average stature, thereby adding to the difficulty in obtaining suitably sized organs for them. According to UNOS statistics over the past five years, over 30 percent of the UCI turndowns were the result of such a mismatch. By eliminating the organs that were turned down by UCI because of size and weight, UCI's acceptance statistics would increase to nearly 15 percent over the past five years. This suggests that the anecdotal witness evidence that donor size was a key factor in its acceptance statistics should be taken seriously.

Survival Rates Among Patients with End-Stage Liver Disease: In 2002, a more quantitative analysis for donor suitability was established, nationally known as the MELD score (Model End-Stage Liver Disease). A patient's MELD score is based on the measurement of kidney and liver function in patients with liver disease. The more severe the disease and greater immediate need for a transplant, the higher the MELD score. The Southern California area suffers from two independent and related issues that bear on the interpretation of statistics used to judge the UCI Program. First, there is a shortage of organs relative to other regions nationally. Second, and perhaps as a result, the patients qualifying to receive an organ for transplant in the local region have much higher average MELD scores. This means that the patients who receive transplants in the local area are often sicker than in other national regions. The raw UNOS data therefore must be carefully interpreted before conclusions are drawn. As just one such example, the number of patients at UCI with high MELD scores was similar to other institutions. As to that particular patient population, UCI appears to have performed transplantation at the same rate as other centers in the same OPO. While UCI only received "credit" from UNOS for eight transplants performed in 2004, six additional very sick patients from UCI's waitlist received transplants that year after having been referred to other institutions. This means that 14 patients on the UCI Liver Transplant List received transplants in 2004. In 2005, UCI performed seven transplants at UCIMC and transferred an additional five patients to other sites. This means that 12 patients on the UCI Liver Transplant List received transplants in 2005.

Committee Findings and Observations

The Committee believes that UCIMC developed the Liver Transplant Program with the goal of serving the patient community and creating a strong clinical program. Beginning in January 2002, shortly after the departure of its founding director and senior surgeon, the Program developed serious difficulties. Although UCIMC senior management made many efforts to address these problems, their inability to resolve them ultimately led to the closure of the Program. The Committee identified seven major factors contributing to this outcome.

(1) The Program did not have a clear strategic plan.

The foundation of a strong University-based clinical program is a clear and well-articulated strategic plan. The original plan for developing a small, sustainable transplant program serving a specific local patient population appeared to be reasonable. However, the plan for the Program was never integrated with the academic, clinical and research goals of the medical school, particularly after it disaffiliated with UCLA. This failure over time had the effect of leaving the medical school faculty leadership disenfranchised and ultimately disinterested in the success of the Program.

The Committee found the lack of a viable financial plan and a clear research and educational agenda for this University program disappointing and unacceptable. Transplant programs are "high cost" services that are expensive to operate. It appears that UCI did not have an adequate plan to fund the Program in a manner that would have allowed it to fulfill its potential. Dedicated ancillary hospital services such as high quality medical hepatology services and expert transplant anesthesia services were not always available. While this resulted in cost-savings and allowed faculty physicians to engage in other patient care activities that may have generated more income, the failure to invest adequate resources in the Program during all of its phases did not serve the longer-term interests of the Program or UCIMC.

(2) Clear reporting structures in the medical school and hospital were lacking.

The Medical School Dean and Hospital CEO both reported to the Chancellor and Provost and Executive Vice Chancellor (EVC), the campus' most senior administrator reporting to the Chancellor. Hospital decisions were largely left to the Dean and CEO, and between them, there was no clear line of authority. The Dean and the CEO had a very strong working relationship, and often made decisions by consensus. Witnesses repeatedly advised the Committee that the strong personal and professional working relationship between the Dean and the CEO was considered to be a key strength for UCI's health sciences enterprise.

The Committee concluded, however, that this strong relationship was also a weakness. The relationship between the Dean and CEO, while highly productive for many other purposes, was not appropriate for assuring effective communication and oversight at the many levels required to manage the program within the organizational structures of the hospital and the medical school. On multiple occasions the Committee found evidence of breakdowns in communication at various levels between the two organizations. Ironically, the "comfort level" between the Dean and CEO

may have made it more difficult for them to recognize these problems. As one example, a Chair of a major UCI clinical department indicated that the impending closure of the liver transplant program was "not on the radar." He stated that he did not know the chain of reporting lines for the Program and that his own responsibilities with regard to program certification were not clear.

As there were no clear reporting lines from the Program to the UCI central campus, the Program's difficulties and UCIMC's response to them were not fully communicated to the UCI leadership or campus administration, an administration that acted appropriately and closed the Program when it was finally apprised of the seriousness of these difficulties.

(3) There was a failure of leadership and accountability.

The level of disinterest in and lack of knowledge about the Program expressed by the medical school faculty was alarming. The Dean did not take clear or effective responsibility for quickly recruiting a new Chair of Surgery and did not recognize that the Interim Chair (see below) was not fulfilling his responsibilities with respect to oversight of the Program. Other medical school chairs, whose physician services supported the Program, appeared to be similarly uninformed and disinterested.

Throughout its review, the Committee observed a general lack of accountability within the medical school and from an overall campus perspective. No one seemed to be accountable overall for ensuring that essential steps for success occurred. Oversight and corrective action for those who did not perform their jobs was also lacking. The Committee observed a "*laissez faire*" attitude toward many of the red flag issues that ultimately led to the closure of the Program. A major example is the Program's repeated failed efforts to recruit new liver transplant surgeons. This problem was especially pronounced after the former Chair of the Department of Surgery was not reappointed as Chair, but was asked to serve for the next 18 months as Interim Chair. During this time, he withdrew from active involvement in the recruitment processes for a new transplant program director. Although he characterized his role in the liver transplant program as being "out of the loop," he was not held accountable for his lack of leadership during the time he served as the Interim Chair, and there appeared to be no defined mechanisms established by the Dean to ensure that he fulfilled this important responsibility.

To fill the void created by an absentee Chair of Surgery, the Chief Medical Officer (a senior administrator in the hospital, not the medical school) led the search for a new transplant surgeon to be appointed at the medical school with little input from the school's Department of Surgery. While the Chief Medical Officer's search committee identified a candidate for the kidney transplant director position, the Department of Surgery should have been more involved at the outset in the search and the process should have been coordinated with active faculty participation.

(4) Responsiveness to external and regulatory agencies was slow and incomplete.

As a result of the challenges and deficiencies previously described, the Program underwent several external reviews between 2002 and 2005. Among these:

- In July 2003, UNOS conducted a site review of the Program and made recommendations for improvement. Among these were recommendations for a multi-disciplinary process for transplant candidate selection; hiring of a new dedicated surgeon and hepatologist; hiring of an additional transplant surgeon; additional staff training and education; and reassessment of the limited role of an outside back-up surgeon.

- In September 2003, the UCI Transplant Program participated in a benchmarking project sponsored by the University Health System (UHS) Consortium. Methodology included a planned retrospective review of 30 consecutive renal (kidney) transplant cases and 30 consecutive liver transplant cases that met inclusion criteria.

- In July 2005, CMS conducted an audit of UCI transplant programs, and in September 2005, CMS recommended improvements based on the same audit.

Each of these reviews led to similar concerns, criticisms and recommendations. Reviewers repeatedly expressed concern about the low number of transplants performed, the inadequate number of transplant surgeons available for coverage, the inadequate management of patients on the waiting list, and the lack of communication with referring physicians in the community. In its responses to these reviews and in its replies to letters from CMS, DHS and UNOS, UCIMC described various plans for corrective action. These well-intentioned plans often failed, however, due to inadequate follow through, unforeseen personnel changes, and because there was little or no margin for error.

One example is noteworthy. In late 2003, in response to a UNOS review and recommendation, UCI promised to obtain a new patient database, with the expectation that it would be in place by February 2004. But no database was installed until July 2004, and it was subsequently found to be inadequate. In December 2004, UCI announced that a request for proposals would be issued in February 2005 for a replacement database that would be purchased in April 2005 – more than a year after the issue was identified as a problem by UNOS.

A more serious example occurred in 2004 when UNOS informed the UCI Administration that it planned to decertify the Program because of persistent problems. UCIMC's CEO requested and received an opportunity to meet in Chicago with UNOS representatives to discuss the Program. The medical school Dean, Dr. Hart and the Transplant Administrator accompanied him. Based upon representations regarding Dr. Hart's participation as program director and his availability at UCIMC, UNOS did not act on its recommendation to decertify.

It is important to emphasize that a review of the specific findings related to this set of UNOS interactions was not conducted by this Committee because of a separate inquiry. Nevertheless, the Committee did conclude that the documents submitted by UCI representatives to UNOS, in combination with the representations made during the July 2004 meeting, were disappointingly vague when they should have been specific, transparent and open. The Committee could not help but conclude that the desire to maintain the Program led to statements by the UCI leadership that were not wholly accurate and likely misleading.

(5) Standards and procedures for quality assurance were inadequate.

UCI did not have rigorous or effective quality assurance (QA) programs in place to evaluate the transplant program. QA was hampered by two parallel but unrelated quality assurance procedures – one for hospital staff directed by the Chief Medical Officer, and one for the Program's faculty and staff, generally coordinated with departmental mortality and morbidity (M&M) reviews.

With respect to the Program specifically, there was no effective method for evaluating turndown rates for quality assurance. The Chief Medical Officer, who is not a surgeon, held weekly conferences with Dr. Cao to review turndowns. He concluded, however, that he was ultimately forced to accept the surgeon's judgment, and did not engage any outside expert reviewers, even when confronted with evidence that Dr. Cao's turndown rates were higher than expected. Under the former Chair of Surgery, it also appears that efforts were made to down-play the significance of problems and to avoid bringing them to the attention of the administration.

The Program went through multiple external reviews during its last five years, which in turn should have prompted very strong internal QA reviews. Despite these reviews, there appeared to be no concerted effort to improve or ensure the rigor or effectiveness of the Program's QA mechanisms. Internal QA mechanisms at UCI, including the Council of Clinical Chairs and the Medical Executive Committee, failed even to identify problems within the Program independent of issues raised in external reviews. A growing lack of confidence in the quality of the liver transplant program among physicians at UCI hospital was another red flag that limited patient referrals and should have triggered a far stronger QA response.

(6) Communication with patients was inconsistent, and at times insufficient.

UCI attempted to communicate clinical information to its patients in good faith, as exemplified by the well-crafted and easy to read documents geared toward patients of the Program. The Program also appeared to communicate to patients the benefits of multi-listing at other transplant centers. While day-to-day communications were likely acceptable, the Program was at times slow or non-specific in clearly communicating with patients about the actual programmatic changes that occurred. For example, the Committee saw no evidence that UCI sent communication to patients when Dr. Hart became the program Director, or informing patients that Dr. Hart was still affiliated with UCSD and not always available at UCI. Similarly, the Committee saw no evidence that UCI notified patients when there was only one surgeon on the Program's staff (or effectively one, following the UCSD affiliation), which might also affect surgeon availability.

(7) Personnel issues involving transplant surgeons and staff were poorly managed.

The Program suffered substantially as a result of the personality differences between Drs. Cao and Imagawa, and the UCI response was ultimately not effective. The hostile and contentious interactions between surgeons were clearly detrimental to the Program at the same time UCI was attempting to create a stand-alone program. The Chair of Surgery appeared overly concerned with keeping the matter internal to the Department, so as not to alarm the administration or affect physician referrals.

While there is no direct evidence that patient care or quality was adversely affected, the Committee cannot imagine the Program was able to function at its true potential during this time. The two surgeons sometimes worked at cross-purposes, fracturing the staff and harming morale. Personnel issues of this magnitude present difficult challenges in any context, yet UCI's intervention efforts did not help in the long term. It is worth noting that this personnel issue in a larger well-established program might have resulted in a limited distraction, for UCI it was a significant detriment.

III. COMMITTEE RECOMMENDATIONS

Closure of the UCI Liver Transplant Program was necessary and appropriate. The Committee agrees that those directly responsible for events leading to its closure should be held accountable. As UCI leadership responds to specific issues involving the program, it is also important that the Chancellor, central campus administration, medical school, hospital, and community collectively plan for the future of the health sciences enterprise at UCI. Resumption of a liver transplant program should be considered only if it is determined to be a strong institutional priority, and even then, only with a clear commitment that it be adequately organized, funded and staffed.

Recommendations to Improve Management of UCI Clinical Programs

The UCI Chancellor requested that this Committee review management practices, organizational structure and culture, and communication at the medical center, and that it make specific recommendations for actions to be taken to improve oversight of clinical areas at UCIMC. Based upon its review, the Committee offers the following eight recommendations.

(1) Recruit New Health Sciences Executive Leadership Accountable to the Chancellor

The organizational structure of the health sciences at UCI should be modified to provide enhanced institutional oversight and to create clear lines of reporting and accountability. A national search should be undertaken to recruit a new senior executive as Vice Chancellor for Health Affairs (or Health Sciences) who will oversee the medical school, medical center and other health sciences programs on campus. In light of the major issues involving a number of clinical programs at UCI, the Committee recommends that this new position report directly to the Chancellor. This recommendation was communicated by the Committee to the Chancellor prior to his announcement of the creation of this position. The Committee strongly supports its rapid implementation.

As one of his/her initial tasks, the new Vice Chancellor for Health Affairs should lead the development and implementation of a joint medical school/medical center strategic planning process to comprehensively review all existing clinical services and programs, and to identify and select those areas in which UCI should develop well-resourced, sustainable programs of clinical excellence (see recommendation 4 for more detail).

(2) Strengthen School of Medicine Oversight

The role of the Senior Associate Dean for Clinical Affairs should be strengthened and given adequate authority and resources to represent faculty interests in their interactions with the hospital. The authority and resources of the UCIMC Council of Clinical Chairs, chaired by the Senior Associate Dean for Clinical Affairs, should also be strengthened. The Senior Associate Dean should be directly and closely involved in the initial review of clinical programs, and in the strategic planning process for the medical school and hospital. This should include participation in decision making about clinical programs to be conducted by the faculty and the hospital, and in recruiting faculty for these programs in coordination with the academic departments and the hospital. The Senior Associate Dean should assure that clinical programs have appropriate educational and research content that is consistent with the academic mission. He or she should participate in the ongoing review of all clinical programs and participate in the review of clinical Chairs when their Departmental stewardship is assessed.

(3) Establish and Maintain Clear Reporting Lines for All Clinical Programs

The Senior Associate Dean should be accountable to the Dean for assuring that regular reviews of clinical programs occur and that for all UCI programs, clear reporting lines are established and maintained. The Dean should be accountable for ensuring that these oversight structures are in place and that they are working effectively. For all clinical programs, these reporting lines should be clear and transparent within the medical school and hospital organizational structures. The Committee agrees that these reporting relationships should, within the medical school, generally track from the level of individual faculty, to the program director, to the chair of the department, to the Dean. Within the hospital, similar reporting clarity should be ensured.

(4) Develop a New Strategic Plan for the Health Sciences

Following the recruitment of a new Vice Chancellor for Health Affairs, a strategic planning process should be initiated to address academic, clinical, research, and business priorities for the medical school and hospital. As part of this process, the mission statement and core values of the enterprise should be reviewed and clearly articulated. Elements of the plan should include: an in-depth discussion and analysis of the programmatic priorities and goals of the School of Medicine and UCIMC; an analysis of the financial and clinical resources needed to meet those goals; an assessment of the feasibility of securing those resources; a timeline for meeting the goals in the plan; and a set of performance objectives by which the campus can measure progress in the future. The Committee wishes to note that these are five of the eight elements identified by another committee that recommended a strategic planning process for the UCI medical school and hospital in 1998. The Committee believes that these are as relevant today as they were at that time. The Chancellor and the new Vice Chancellor for Health Affairs should ensure that this strategic planning process occurs as soon as possible.

In view of the crucial role which the Medical Center plays in the community, and the extraordinary potential value which it could have for improving health, supporting research, training and economic development, the strategic planning process should include efforts to obtain much more

participation of the County in its activities and to obtain equitable support for the patients who are cared for at UCIMC.

(5) Conduct Campus-wide Review of All Clinical Programs

Regular review of all clinical programs should occur to ensure that proper governance and oversight mechanisms are in place, and to assure accountability of programs in meeting both programmatic and institutional goals. As part of this process, a regular cycle of review for all academic departments within the medical school, including a review of all chairs should be planned. Where inconsistencies exist in program descriptions and/or in the position description of individuals serving as program directors, clarification and correction should be made. For example, although the liver transplant program is a surgical department, the faculty in the Department of Surgery tended to view the program as more of a surgery service belonging to the hospital.

These internal program reviews should be conducted at regular intervals to assist programs in identifying difficulties or vulnerabilities, and to repair or correct them before they become crises. The results of these reviews should be communicated directly to the Dean and hospital CEO, and in turn to the new Vice Chancellor for Health Affairs. This regular review process is intended to assist leadership in identifying programs that might be at risk for future problems. These plans should be regularly reviewed and periodically updated.

(6) Ensure Rigorous Quality Assurance Procedures for All Clinical Programs

The Committee recommends that all clinical programs create and maintain individualized and rigorous quality assurance programs. Components of this should include measurement and monitoring of clinical outcomes as well as routine review of complications (e.g., at morbidity and mortality or "M & M" conferences) with reporting to (and integration with) the hospital's quality assurance program. The QA process for individual programs should periodically draw on the expertise of experts from outside campus programs. This is a particular area in need of attention across all clinical areas because quality problems from within a program should never be first identified by an external source.

(7) Ensure that Capital Plans are based on Academic Plans and Goals

The construction of the new hospital is an important strategy for attracting a broader patient base and developing the type of facilities that support state-of-the-art clinical care. To meet this goal, and to assure that new facilities provide the space and structure for meeting the strategic goals of the campus, medical school and hospital, the hospital's capital and infrastructure plans should be based upon the academic, clinical, and research goals of the medical school and hospital. These should be integrated to the fullest extent possible with the strategic planning process recommended above. Based upon the information it received, the Committee has concerns about the strategic programs and focus for the new hospital, including the adequacy of facilities and operating rooms that appear to be planned. It was beyond the Committee's charge, however, to examine this in further detail.

(8) Review UCI School of Medicine Faculty Practice Plan

Careful review of the faculty practice plans should occur as part of the strategic planning process to ensure that these plans support the mission and goals of the institution and that they are adaptable for these purposes. With the development of new clinical programs, careful attention to faculty salaries and program funding within departments should attempt to ensure that these arrangements are aligned to support the goals of the program and the mission of the institution.

Comments Regarding Possible Re-Establishment of a Liver Transplant Program

If, at some future time, the liver transplant program is reopened, UCI should first require a clear analysis of its link to the strategic goals of the institution and a careful assessment of the size needed to ensure the critical mass for success. This planning should also take into account the particular needs of the UCIMC patient population. Resumption of a liver transplant program should be considered only if this is a high priority of the leaders and faculty of the medical school and hospital and with the assurance that it will be adequately organized and funded.

At a minimum, if UCIMC was to reopen a new program, the Committee believes that at least two transplant surgeons and one medical hepatologist experienced in transplantation (and dedicated to the program) will be required. An affiliation with another program may be advisable, but should be pursued only if there is evidence that this will add quality and stability.

If a new liver transplant program is resumed, the leadership of the campus, medical school and hospital must ensure that ongoing efforts are made to address ethical issues and to integrate these values in all aspects of planning and management. The Committee recognizes that this could be achieved in a variety of ways, but explicitly recommends that focused attention to ethical issues be central to all deliberations and decision making. One approach to addressing these issues might involve formation of an advisory committee to oversee all transplantation programs, with one or more members representing ethical perspectives. As importantly, the lessons learned from the UCI transplant program should be remembered and applied.

Concluding Comments

The Committee heard a great deal about "small" or "thin" programs with marginal staffing and inadequate resources. It is thus essential that a rigorous institutional review occur for all existing UCI programs, and that a comprehensive strategic plan be developed. Only after a clear determination that existing clinical programs are meeting appropriate institutional standards for education, research and patient care, should consideration be given to the development of any new program. The Committee recognizes that although the hospital remained profitable this year, the commitment to the new hospital realistically limits choices about what else can be funded. The Committee strongly believes that many of the problems involving the UCI Liver Transplant Program – and other UCI clinical programs – occurred when good intentions and ambitious plans for growth exceeded both the financial and management resources available to assure quality and success.

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APPENDIX A: UCI LIVER TRANSPLANT REVIEW COMMITTEE

Meredith J. Khachigian – Chair of Committee
Former Chairman of the Board, The Regents of the University of California
Former Chairman Regents Committee on Health Services
Former Member of Board of Directors, UCSF Stanford Health Care System

Haile Debas, MD
Executive Director, University of California, San Francisco Global Health Sciences
Maurice Galante Distinguished Professor of Surgery
Chancellor Emeritus, UCSF
Former Dean of Medicine, UCSF
Former Vice Chancellor of Medical Affairs, UCSF

Kenneth C. Janda, PhD
Chair, University of California, Irvine Academic Senate
Professor of Chemistry, UCI Department of Chemistry

Kenneth Shine, MD
Executive Vice Chancellor for Health Affairs, University of Texas System
Former President of the Institute of Medicine of the National Academy of Sciences
Professor of Medicine Emeritus, University of California, Los Angeles School of Medicine

Steven A. Wartman, MD, PhD
President, Association of Academic Health Centers
Former Executive Vice President for Academic and Health Affairs and Dean of the Medical School, University of Texas Health Science Center at San Antonio

APPENDIX B: CHRONOLOGY OF UCI TRANSPLANT CENTER EVENTS

August 1993	UCI Liver Transplant Program begins affiliation with UCLA
July 1995	Dr. David Imagawa joins full-time staff at UCI
July 1997	Department of Surgery creates Division of Transplantation Dr. Imagawa named Division Chief
1999-2004	Dr. Sean Cao joins staff focusing on liver and pancreas transplantation
Sept. 2001	Dr. Imagawa's develops health condition requiring that he no longer perform liver transplants
Oct. 2001	Dr. Cao named Director of Transplant Services
Jan. 2002	Recruitment begins for transplant surgeon to join Dr. Cao
Nov. 2002	Confidential external peer review of transplant program conducted
July 2003	United Network for Organ Sharing (UNOS) conducts site review of the Program
Sept. 2003	Transplant program participats in a transplant benchmarking project sponsored by the University Health System Consortium (UHC)
Nov. 2003	UCI formally responds to UNOS with a detailed plan outlining the actions being taken to address each of their recommendations
April 2004	In response to a request from UNOS for an updated action plan, UCI provides a detailed report describing progress in addressing their recommendations
May 2004	California Department of Health Services rescinds the Center of Excellence designation for Medi-Cal due to annual liver transplant volumes falling below required levels (18 per year)
May 2004	UNOS recommends inactivation of liver transplant program citing inadequate progress on action plan
June 2004	UCI requests interview with UNOS to present additional information about progress and to appeal recommendation for inactivation
June 2004	Dr. Cao submits resignation effective July 29, 2004

June 2004	Discussion begins with leadership at UCSD and Dr. Marquis Hart regarding program leadership for UCI, transplant physician coverage and possible long-term program affiliation
June 2004	Discussions with UCSD and Dr. Hart continue with development of joint vision statement and agreement to have Dr. Hart assume transplant director role at UCI and for provision of transplant surgeon coverage
July 2004	Dr. Marquis Hart named Director of UCI Transplant Program
July 2004	Dr. Ralph Cygan, Hospital CEO, Dr. Thomas Cesario, medical school Dean, Dr. Hart, and Gail McGory, RN and Program Administrator, meet with UNOS Membership and Professional Standards Committee in Chicago
Sept. 2004	UNOS agrees to suspend its decertification recommendation and requests an updated action plan and progress report from Dr. Hart
Dec. 2004	Dr. Hart provides written progress report and action plan to UNOS
Feb. 2005	UNOS letter acknowledges significant improvements in patient survival and releases Program from further review
July 2005	CMS reviews liver and kidney transplant programs
Sept. 2005	CMS recommends improvements based on July review
Oct. 2005	UCI provides written response to CMS containing detailed action plans
Nov. 4, 2005	CMS requests clarification of corrective action plan and requests response by November 14, 2005
Nov. 10, 2005	LA Times prints article regarding the Program
Nov. 10, 2005	CMS rescinds Medicare payment approval for liver transplantation program
Nov. 10, 2005	UCI Chancellor closes the Program
Nov. 11, 2005	UNOS notified of inactivation of transplant program