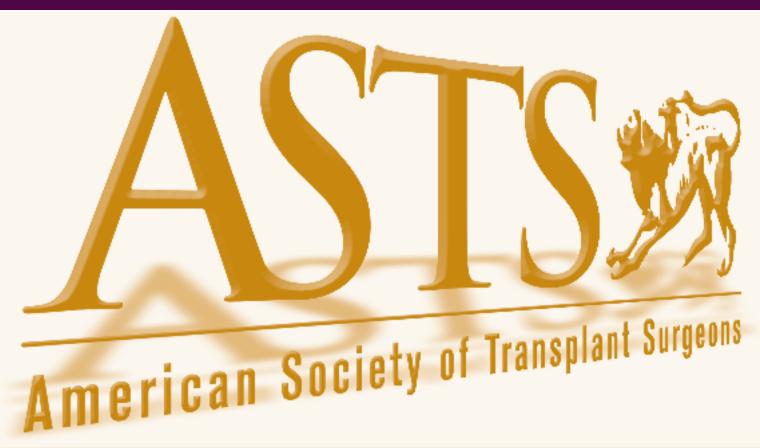
Vol. XV No. 2 Winter 2004

# CHIMERA

Published Quarterly for Members of the American Society of Transplant Surgeons



### CHIMERA

**American Transplant Congress** 

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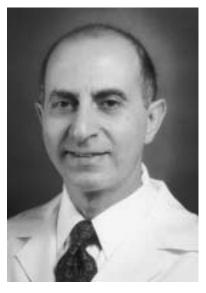
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### president



Dear Friends,

Holidays are always good to have, specifically when they are associated with the exchanging of gifts. As hard as it is to believe, the Government may present the transplant community with a unique one, an amendment to the Public Health Service Act cited as the "Organ Donation and Recovery Improvement Act". Admittedly, I never bothered reading those Congress bills and Government regulations, and always thought that they are written for lawyers, politicians, administrators, insurance companies, etc. However, when reading the document it occurred to me that it provides similar opportunities like those that are often announced by the NIH. In fact, it may be easier to look at the document as an RFA published by the Government, in which the lawmakers recognize future directions, define where they want the resources to be invested, and provide

plenty of opportunities for the transplant community to experiment and develop means to improve organ donation.

The Act recognizes that the federal government should support programs which are aimed to educate the public with respect to organ donation, and emphasize the potentials associated with living donation. The Congress allocates funds for reimbursement of expenses incurred by individuals making living donation of their organs, and provides specific guidelines for the use of these funds. Moreover, it encourages the exploration of joint OPO/Hospital projects that have the potential to increase donation.

The transplant community should applaud the efforts of many elected officials who are sensitive to the needs of our patients. It tells me that there are good people in Congress who understand that the government must support the transplant community in its efforts to increase donation. We have to wait for the Congress to vote on the final version of this Act, and our Washington friends assure us that it will happen. When it becomes a reality, the ASTS must seize the opportunity and support this important mission.

Best Regards,

Abraham Shaked, MD, PhD President

### Call-For-Nominations

# Call For Nominations Deadline is March 1, 2004

The American Society of Transplant Surgeons' Nominating Committee requests nominations from the Membership for the 2004/2005 offices of President-elect, and two Councilors-at-Large. Candidates must be Regular Members in good standing and be willing to serve, if nominated.

To nominate an ASTS Member for a position on the 2004/2005 Council, please send a letter of nomination by March 1, 2004 to the attention of:

Abraham Shaked, M.D., President and Nominating Committee Chairman ASTS 1020 North Fairfax St., #200 Alexandria, VA 22314 Fax: 703-684-6303

ASTS members interested in serving on an ASTS Committee for a 3-year term to begin immediately following the May 2004 Annual Meeting may submit a letter to the ASTS office (address above) indicating which committee they would like to serve on and outlining their proposed contribution to the committee. Letters must be received no later than March 1, 2004.



### Legislative Committee:

The newly formed ASTS Legislative Committee, Chaired by John Roberts, had sent a survey to ASTS Members to ask what they felt were legislative priorities for transplant surgeons and their programs. The Committee then met in December with the ASTS Executive Committee and legislative counsel to discuss these priorities and action the Society will take,

### **Thoracic Organ Committee:**

The following is information regarding the joint Society of Thoracic Surgeons and ASTS Thoracic Organ Committee program:

# ASTS/STS Fourth Joint Program January 25, 2004 5:15-6:45pm San Antonio, Texas

### **Moderators:**

Joren C. Madsen, Co-Chair, ASTS Thoracic Organ Committee, Massachusetts General Hospital Marc L. Barr, Co-Chair, ASTS Thoracic Organ Committee, University of Southern California

### Speakers:

"Current Strategies for the Optimal Utilization of Cardiac Assist Devices"
Robert L. Kormos, MD
Director Thoracic Transplantation and Artificial Heart Program
Medical Director McGowan Institute for Regenerative Medicine
University of Pittsburgh School of Medicine

"Technical Consideration in Lung Transplantation"
G. Alexander Patterson, MD
Joseph C. Bancroft Professor of Surgery
Chief, Section of General Thoracic Surgery
Washington University School of Medicine

"Immunosuppression in the 21st Century"

James S. Allen, MD

Assistant Professor of Surgery, Harvard Medical School

Division of Thoracic Surgery, Massachusetts General Hospital

### Vanguard Committee:

The ASTS Vanguard Committee will be conducting a Career Development Workshop at the 4th Annual State of the Art ASTS Winter Symposium.

The workshop will be held on Saturday, January 24, 2004 at the Marriott Mountain Shadows Resort and Golf Club in Scottsdale, AZ. The topic of the workshop is "Time Management: Strategies for Success."



### Sweeping Medicare Reforms Enacted; Organ Donation Bill Set for Passage

uring the fall of 2003, major legislation affecting transplantation moved through Congress, including the final enactment of a Medicare reform and prescription drug bill and Senate passage of ASTS-supported organ donation legislation. The Congressional appropriations process, which funds federal agencies, including the Division of Transplantation, appears to have stalled going into the holiday break, and should be resolved when Congress returns in January. Other significant transplant-related initiatives, such as regulations issued by CMS on transplant centers and organ procurement organizations, are expected in 2004. In addition, the Health and Human Service Office of Inspector General has placed on their agenda for 2004 a review of transplant centers.

Shortly before press time, on December 8, 2003, President Bush signed into law the Medicare reform and prescription drug legislation. The legislation cleared the House on November 22 by a vote of 220-215 and the Senate on November 25 by a vote of 54-44. This article features a general summary of the legislation with emphasis on the major provisions expected to affect transplant surgeons, but this landmark legislation will generate new and unexpected challenges to Medicare generally and to coverage of transplant patients and providers for years to come.

### Medicare Reform and Prescription Drugs

The 680-page Medicare reform and prescription drug bill will add a longsought prescription drug benefit, place a greater reliance on private, managed care health plans to provide Medicare benefits, make many changes to provider payments and regulatory processes under fee-forservice (FFS) Medicare, and allow all Americans, not just Medicare beneficiaries, to contribute to tax-free "Health Savings Accounts." These reforms, taken as a whole, constitute the largest reform of the Medicare program since its inception in 1965 and will markedly change how Medicare beneficiaries receive and health care providers Medicare benefits.

The following is a brief summary of the key provisions as they relate to

transplant patients and providers of transplant services:

Medicare Drug Benefit—Beginning in 2006, all Medicare beneficiaries (including beneficiaries with End Stage Renal Disease) will have the option to purchase private, "stand alone" drug coverage at the following benefit levels:

- Approximately \$35 monthly premium.
- · \$250 annual deductible.
- 75% coverage from \$251 to \$2,250 in combined total drug costs.
- \$3,600 out-of-pocket catastrophic coverage.
- "Gap" in coverage—\$750 in out-ofpocket costs up to \$2,250 benefit limit, must spend an additional \$2,850 on drugs before reaching out-of-pocket limit
- 5% coinsurance on all drug costs after the \$3,600 limit is reached.

Low Income Subsidies—Low-income beneficiaries would have access to a subsidized premium, deductible, and copayments. For beneficiaries below 135% of the federal poverty line ("FPL"), including those "dually eligible" for Medicare and Medicaid, the full premium would be subsidized, with \$2 copayments for generics drugs and \$5 for brand name drugs, no "gap" in coverage, and no coinsurance above the catastrophic limit. Eligibility would be subject to an asset test of \$6,000/\$9,000 (single/couple), which measures a person's/family's resources to ensure they are low enough to qualify for federal subsidies. For beneficiaries between 135% and below 150% of the FPL, there will be a sliding scale premium based on income, a \$50 deductible, 15% coinsurance up to the catastrophic limit during the "gap" in coverage, and \$2/\$5 copayments thereafter. The

asset test would be set higher, at levels of \$10,000/\$20,000 (single/couple).

Transitional Drug Discount Card—Medicare will administer a drug discount card program that will be available by approximately mid-next year to provide transitional assistance to beneficiaries. It will end when the prescription drug benefit becomes available in 2006.

- Beneficiaries will have a choice of at least two Medicare-endorsed discount cards for a \$30 enrollment fee.
- The card will enable beneficiaries to receive negotiated prices and discounts, expected to be as much as 20% off current prices.
- Medicaid beneficiaries are not eligible for the discount cards as these beneficiaries are covered under state plans until Medicare plans cover drugs in 2006.
- Subsidies up to \$600 per year are available for beneficiaries under 135% of FPL with no asset test, but coinsurance of 5-10% depending on income.

New Medicare Managed Care-Under the Medicare bill, private, managed care insurance companies are encouraged to offer Medicare benefits similar to the existing Medicare+Choice sys-Although Medicare+Choice plans have had limited success since their creation in 1997, the new plans will receive greater federal subsidies to participate in Medicare and are expected to proliferate throughout the country when they are scheduled to begin in 2006. These new managed care plans will offer combined Medicare Part A and B coverage in addition to prescription drug coverage similar to that which could be purchased separately though "stand alone" Medicare drug plans.

Two types of Medicare managed care models would be available to beneficiaries. The first, entitled "Medicare Advantage," would incorporate benefits similar to Medicare+Choice (i.e. enhanced bene-

fits within a managed care model, a restrictive network of providers, capitation arrangements, formularies, etc.). The second option, "Enhanced Fee-for-Service," would rely less on HMO-style managed care and instead provide the standard set of Medicare benefits in privately-administered "Preferred Provider Organizations." This model would use negotiated discounts from a restricted network of providers to lower coinsurance and deductibles while still allowing the freedom for patients to seek care from providers without traditional HMO "gatekeeper" restrictions.

Impact on Transplant-Transplant surgeons should expect that implementation of new Medicare managed care health plans will entail entering into contracts with private entities to provide Medicare benefits, either individually or at the hospital level. Often these arrangements will discount reimbursement in exchange for being included in a particular health plan's "network" with a defined set of patients. However, many patients who eventually require transplantation have a compromised health status for years prior to receiving a new organ. These beneficiaries are more likely to eschew managed care and stay in feefor-service Medicare. In this respect, transplant surgeons may be less impacted by the shift to Medicare managed care that other physicians and providers.

There are likely to be many new regulations are expected to be promulgated by CMS as a result of the Medicare bill. It is very likely that many will impact transplantation. ASTS will continue to monitor and anticipate potential regulatory issues and respond appropriately through comments and meetings with CMS as the implementation of the new law progresses.

Immunosuppressive Drug Coverage— The final Medicare bill did not include an ASTS-supported provision relating to expanded coverage of immunosuppressive drugs in Part B of Medicare. This was not a surprise considering that neither the House nor the Senate bills included this provision going into final negotiations. The proposal, which was included in previous versions of Medicare reform in years past, would have provided full benefits for beneficiaries requiring use of high-cost immunosuppressive drugs through the current Medicare Part B system, which covers all costs, minus 20% coinsurance paid by the beneficiary. Current immunosuppressive drug coverage continue under Part unchanged, but this coverage is subject to a 36-month time limit and is specific to only certain Medicare-covered transplants.

As a result of passage of the new Medicare drug benefit, beneficiaries not qualifying for immunosuppressive coverage under Part B could receive coverage in one of three new ways: through one of the new drug-only plans, through an enhanced fee-forservice option, or through a Medicare Advantage plan. Coverage levels under these plans, assuming these private plans include immunosuppressive drugs in their benefit packages, would require greater cost-sharing by benefiunder Part ciaries than Furthermore, under all of the proposed drug coverage options, issues relating to therapeutic classification, formularies, and potentially tiered copayments (which the new drug plans have the option of employing) could complicate the ability for patients seeking a specific immunosuppressive drug therapy to receive the appropriate course of treatment, or to access immunosuppressive drugs at all.

Although the immunosuppressive drug coverage expansion issue was spearheaded by the National Kidney Foundation, ASTS actively supported its adoption in the House and Senate on inclusion Medicare bills as a Part B benefit. Now that a prescription drug benefit has been enacted, ASTS will moni-

# ASTS worked extensively with key Senate leaders, including Senate Majority Leader and transplant surgeon, Bill Frist (R-TN), to finalize legislation aimed at increasing organ donation rates.

tor access to immunosuppressive drugs under the new program in order to build the case in the future for expanded access under Part B of the program.

**Premium Support**—The final Medicare bill includes a controversial provision that will require a "demonstration" beginning in 2010 that requires traditional, fee-for-service (FFS) Medicare and private, managed care plans to compete directly for Medicare beneficiaries. The provision is known as "premium support" because the federal government would contribute a defined, percentage subsidy toward a beneficiary's premium to health plans and Medicare FFS rather than direct Medicare payment for services. Based on the subsidy, plans would compete for beneficiaries based on premium (by lowering the beneficiary portion of the premium) and lower deductibles/ copayments.

Proponents (mostly Republicans) maintain the provision will hold down Medicare costs and provide beneficiaries with "choice." Opponents (mostly Democrats) generally believe that it would effectively "privatize" the Medicare program and cause Part B premiums to move higher for beneficiaries who remain in traditional FFS Medicare, who would more likely be those with complex, chronic, or expensive conditions.

Physician Fee Schedule Update—Although the final physician fee schedule rule, published on November 7, 2003, proposed to cut physician payments by 4.5 percent in 2004, the

Medicare bill contains a provision that will increase Medicare payments to physicians by at least 1.5 percent per year in 2004 and 2005 (over 2003 levels). The bill also permanently corrects the sustainable growth rate (SGR) formula, which was viewed by many as a flawed method of updating physician payments. The new formula, pending regulations by CMS, is expected to ameliorate large fluctuations in physician payments over time. This constitutes a major legislative victory for ASTS and organized medicine and should be viewed as a very positive outcome to a multiple-year effort.

### Organ Donation Legislation Passes Senate, Close to Enactment

ASTS-supported organ donation legislation appears to be very near to enactment. ASTS worked extensively with key Senate leaders, including Senate Majority Leader and transplant surgeon, Bill Frist (R-TN), to finalize legislation aimed at increasing organ donation rates. The bill passed the full Senate by "unanimous consent" on November 25 and is expected to pass the House shortly. Following House passage, most likely in January, it will go to President Bush for his signature. (The House passed an organ donation bill earlier this year, but in order to avoid the necessity for a House/Senate conference committee, the House will likely pass the Senate bill so the bill can go straight to the President for his signature.

The bill will authorize many key ASTS priorities in organ donation, including travel and subsistence reimbursement for living donation, grants for transplant coordinators, studies and demonstrations relating to increasing organ donation, and authorization of mechanisms to study the long-term effects of living donation.

Upon enactment, ASTS will actively monitor implementation of these programs and work to secure adequate funding for these programs in the FY 2005 appropriations cycle.

### **Appropriations Update**

The FY 2004 appropriations levels for key ASTS programs have not been finalized due to a Congressional dispute over FY 2004 appropriations legislation. Congress is likely to push approval of a final conference report of the Labor-HHS-Education appropriations bill into late January. The following is a summary of where priority programs currently stand in the House and Senate bills.

- HRSA's Division of Transplantation received level-funding of \$24.8 million for FY 2004 in the House and Senate bills. Although ASTS has recommended \$30 million, the proposed level of \$24.8 million is still significant considering the fact that DOT's budget has increased \$10 million over the past three years, a 66 percent increase.
- The National Institutes of Health received an overall increase of 2.3 percent increase in FY 2004 in the House bill and 3.5 percent in the Senate. The President had requested a 2 percent increase.

• The Agency for Healthcare Research and Quality was level funded at \$303.7 million in the House and Senate bills. The President's budget had proposed a \$24 million cut in the budget for the Agency.

Affected agencies, which include all of Health and Human Services, will operate at current funding levels until enactment of the final appropriations bills early next year.

### Advisory Committee on Transplantation

The HHS Advisory Committee on Transplantation (ACOT) met in Washington, DC, on November 6-7, 2003 to discuss a wide-range of transplant-related topics. At the meeting, ASTS released a joint statement that reaffirmed the importance of donor rights in conjunction with the United Network on Organ Sharing (UNOS) and the Association of Organ Procurement Organizations (AOPO). The concept of this approach was to affirm that the wishes of the decedent donor may not be overruled by family members after death and, thereby, bring this donor rights approach to greater national attention. At its May 2003 meeting, the ASTS Council adopted and reaffirmed ASTS's commitment to this policy. ASTS will continue efforts to work with ACOT, HHS, and other transplant-related organizations on donor rights and other organ donation policy.

### Regulatory Update

The Department of Health and Human Services is currently in the final drafting stages of the long-awaited transplant center and organ procurement organization regulations. The process to publish these regulations began in 1999. The latest report on their status was given by CMS at the ACOT meeting. CMS stated that both rules would likely be released in late winter or early spring. CMS has indicated, however, that the OPO regulations would likely be issued first, followed shortly by the transplant center regulations. ASTS will closely monitor

In addition, the HHS Office of Inspector General ("OIG") has placed a review of transplant centers on its 2004 enforcement work plan. This indicates a stepped up monitoring and potential enforcement actions on transplant centers. ASTS will continue

to monitor this situation closely so that the OIG's efforts are conducted in a manner not disruptive to legitimate transplant-related services.

### Conclusion

While the recently enacted Medicare reform and prescription drug bill is likely to offer some benefit to Medicare beneficiaries by assisting them with coverage for prescription drugs, it is also likely to have many unintended consequences. ASTS will continue to monitor developments as they relate to transplantation and be actively involved in the issuance of Medicare regulations and new legislation as the overall Medicare debate continues. ASTS will also continue to be active in shepherding the organ donation bill toward enactment early in 2004 and for its proper implementation and funding over the coming years. 💆

Prepared by Peter W. Thomas, Esq., ASTS Legislative Counsel; and Dustin W.C. May, Legislative Director, Powers, Pyles, Sutter, and Verville, PC.

### **ASTS**

"THANKS"

**Benefactor's Circle** Fujisawa Healthcare, Inc.

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Novartis Pharmaceuticals Corporation Roche Laboratories, Inc. Wyeth Pharmaceuticals

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### Regulatory and Reimbursement Update

ASTS has recently launched a number of initiatives related to Medicare coverage of and payment for transplant services. These initiatives seek improvements in Medicare payment and policy related to both transplant surgeons' professional fees and hospital payment for transplant and related services.

### Medicare Coverage

### VADs as Destination Therapy

CMS issued its final coverage determination on ventricular assist devices (VADs) in October of this year. ASTS, represented by Robert Kormos, MD, had testified in March of this year before the Medicare Coverage Advisory Committee in support of extending VAD coverage to destination therapy. CMS has agreed and effective October 1, VADs as destination therapy will be covered by Medicare. However, the VAD must be implanted in a facility that meets certain Medicare requirements. Specifically, the facility must be a Medicare approved heart transplant facility that implanted at least 15 VADs as a bridge-to-transplant or destination therapy between January 1, 2001 and September 30, 2003. CMS has already approved several facilities. CMS has requested the JCAHO to provide additional guidance regarding the eligibility of hospitals to perform VAD procedures, and ASTS plans to offer its assistance to JCAHO to ensure that the final guidelines are clinically appropriate.

### Pancreatic Islet Cell Transplants for Medicare Beneficiaries in a Clinical Trial

The Medicare prescription drug legislation recently enacted by Congress includes a provision that authorizes the National Institute of Diabetes and Digestive and Kidney Disorders at NIH to conduct a clinical trial of pancreatic islet cell transplantation which includes Medicare beneficiaries. The trial will start no earlier than October 1, 2004, and Medicare will pay for the routine costs as well as transplantation and appropriate items and services for Medicare beneficiaries participating in the clinical trial, as though those services were covered by Medicare. Routine costs include reasonable and necessary routine patient care costs, including immunosuppressive drugs. Other costs related to islet transplantation, such as acquisition of the pancreas and delivery of the islet cell transplant, would also be covered. Under the provision, payment will be made only for islet cell transplant services provided to Medicare patients; however, it is hoped that the trial will pave the way for more extensive payment by Medicare and private payers in the future.

### **Medicare Payment**

### Physician Payment

The Physician Fee Schedule that will go into effect on January 1, 2004 not only includes a 1.5% increase in the conversion factor applicable to all physicians' services, but also includes significant improvements in payment for a number of transplant-related services. In particular, the CY 2004 Physician Fee Schedule includes three new living donor hepatectomy codes supported by ASTS. The CY 2004 Physician Fee Schedule likewise incorporates the Relative Value Units (RVUs) for these codes that were recommended by ASTS and approved by the Relative Value Update Committee of the AMA. Thus, effective January 1, 2004, Medicare will pay for living donor hepatectomies under the three new CPT Codes approved by the CPT Editorial Committee last spring and reimbursement for this service will increase.

In addition, in response to ASTS's request, CMS agreed to mitigate cuts that had been proposed for a number of other transplant services. The reductions initially were proposed a result of standardization of certain

clinical labor times and staff mix. ASTS was successful in convincing CMS that the standardized labor time was not appropriate for transplant services and that increased staff time was necessary because of the special needs of transplant patients. In addition, CMS also agreed with the ASTS position that the appropriate physician clinical staff to deliver services to transplant patients was an RN, which also resulted in restoration of some of the cuts in payment that were proposed earlier in the year. As the result of this initiative, CMS requested that ASTS seek review by the Practice Expense Advisory Committee of the RUC of the practice expense inputs for transplant codes, and ASTS is hopeful that this reevaluation will result in increases in future years.

### **Hospital Payment**

### Medicare Payment for Certain Immunosuppressive Drugs

ASTS submitted comments to CMS urging that proposed reductions in hospital outpatient reimbursement for certain immunosuppressive drugs be rescinded. Last year ASTS was successful in restoring some of the proposed payment reductions for a number of immunosuppressive drugs furnished on an outpatient basis. This year, the proposed cuts affected primarily two drugs used for the treatment of transplant patients: OKT3 and Thymoglobulin. Although the final rule published in November does implement the proposed payment reductions for these two drugs, the agency did make some favorable changes to its policies on drug reimbursement in the hospital outpatient setting. Specifically, the agency has lowered the threshold for separate payment of drugs from \$150 to \$50. As a result, drugs costing more than \$50 will be separately paid and not bundled into hospital APC payment.

### New Standards for Rehabilitation Hospitals

Currently, CMS rules require that 75% of a facility's patients have one of ten conditions or diagnoses in order for the facility to be considered a rehabilitation facility for Medicare payment purposes. Post-transplant rehabilitation is not among those conditions or diagnoses. In comments on a proposed rule on this policy, ASTS expressed concern that the policy was too narrow and did not reflect changes in clinical care over the last decade. ASTS also urged that CMS include rehabilitation of transplant patients as a qualifying condition for purposes of being a Medicare-approved rehabilitation facility. In the Medicare prescription drug legislation enacted earlier this week, Congress echoed this concern and has urged CMS to delay publication of a final rule until the GAO has completed a report and made recommendations. In the meantime, as a result of intensive lobbying by the rehabilitation community, CMS has announced its intent to soften the proposed rule by expanding the list of qualifying diagnoses and lower the 75% threshold.

### **Coding Issues**

ASTS recently submitted applications for several new CPT codes to describe backbench or back table dissection of donor organs prior to transplantation. The applications also propose modifications to existing codes to create consistency among the entire transplant code family. The CPT Editorial Panel will consider the applications in February. If approved, the new codes should be available for use in 2005. ASTS is in discussions with CMS regarding the extent to which backbench services should be considered part of hospital organ acquisition costs.

ASTS, together with the American College of Surgeons, is also providing input on the correct coding initiative (CCI) edits that will apply to the new living donor hepatectomy codes.

### Other Issues

### Generic Substitution of Immunosuppressive Drugs

ASTS signed on to a letter from a number of medical specialties to pharmacy organizations calling for the two professions to work together to develop a protocol for pharmacists' substitution of generic drugs which would include the provision of appropriate information to physicians and patients and final physician approval.

### OIG 2004 Work Plan to Include Audits of Hospital Organ Acquisition Cost Centers

The OIG's recently released 2004 Work Plan announces that the OIG will be auditing hospitals to determine whether they are correctly reporting organ acquisition costs. The audits will focus, in particular, on hospital relationships with physicians and on whether the hospital is inappropriately classifying post-transplant services as organ acquisition costs. ASTS plans to begin a project pulling together cost reporting guidelines for transplant centers, since the governing regulations are extremely vague and, in some cases, nonexistent.

Prepared by Diane Millman, Esq.; and Rebecca Burke, Esq., Powers, Pyles, Sutter, and Verville, PC.

### **Transplant Reimbursement: Frequently Asked Questions**

- Q: What is the DRG for allograft rejection and how is it reimbursed?
- A: There is no DRG that is specific to rejection, for each organ. Various DRG's can be used, such as: Kidney: DRG 331 (other kidney and urinary tract diagnosis with complications) Liver: DRG 305 (disorders of liver except malignancy, cirrhosis and alcoholic hepatitis with complications) Pancreas: DRG 204 (disorders of pancreas except malignancy) Intestine: DRG 452 (complications of treatment with complications) Also, there is an ICD-9 code for complications/rejection of transplanted organ to support the DRG: Kidney is 996.81, Liver is 996.82m and so forth. In general reimbursement for these DRG's, (although variable by geographic region, institutional type, etc) is approximately \$5,000.
- **Q:** Can you provide any information about the use of plasmapheresis for highly sensitized or abo incompatible kidney transplantation?
- A: The regulations have been changed to approve the use of plasmapheresis for highly sensitized or abo incompatible kidney transplantation. The changes went into effect on April 1, 2002. However, some Medicare intermediaries have decided not to adopt these regulations. Thus, you can contact your local contractor about coverage.



### ASTS 2004 Winter Symposium

"Surgical Challenges in Transplantation"

STS will be conducting its 4<sup>th</sup> Annual State of the Art Winter Symposium on January 23-25, 2004 at the Marriott Mountain Shadows Resort and Golf Club in Scottsdale, Arizona.

The program will be on "Surgical Challenges in Transplantation." The members of the planning committee are Sandy Feng, Osama Gaber, Elizabeth Pomfret, Thomas Fishbein and Abhinay Humar.

The Marriott Mountain Shadow Resort and Golf Club is set on seventy acres of desert paradise, with picturesque gardens, lush fairways, and endless variety. Tucked away in the pastel-tinted shadows of Arizona's Camelback Mountain, you'll discover a relaxed elegance and unparalleled convenience. Luxurious guest rooms with spectacular views, and unlimited recreation. Extraordinary options for indoor and outdoor dining, and so much more - all just minutes from Phoenix, and less than 12 miles from Sky Harbor International Airport. You can view the Marriott Mountain Shadow Resort and Golf Club at www.mountainshadow.com

More detailed information and registration materials will appear on the ASTS website at www.asts.org \$\mathbb{M}\$

### **ASTS 2004 Winter Symposium**

4th Annual State of the Art Winter Symposium Program



### FRIDAY | january 23

12:30 - 2:10pm OPTIMIZING DONOR SAFETY: **TECHNICAL APPROACHES IN LIVING** KIDNEY AND LIVER DONORS

- · The Kidney Donor with Co-Morbid Conditions
- Operative Techniques to Maximize Safety of the Kidney Donor
- Operative Techniques to Maximize Safety of the Liver Donor
- · The Live Kidney Donor: Clinical Management and Outcomes
- . The Live Liver Donor: Clinical Management and Outcomes

2:10 - 2:30

2:30 - 4:00

THE CHALLENGING RECIPIENT

- Obesity: A Correctable Contraindication to Transplantation?
- Hemostatic Failure: New Options
- · Splanchnic Thrombosis: Liver and Intestinal Transplantation
- · Liver Retransplantation: **Ethics and Outcomes**
- · Pancreas Retransplantation: Surgical Options and Outcomes

4:00 - 6:00

POSTER SESSION

· Mini-Oral Poster & Video Presentations

6:30

COCKTAILS

7:00

ASTS 30TH ANNIVERSARY **CELEBRATION DINNER** 

### **SUNDAY** january 25

7:00 - 7:30am

BREAKFAST

7:30 - 9:00

**SURGICAL VIDEOS** 

- Pediatric Urologic Reconstruction Prior to Transplantation
- Laparoscopic Left Lateral Donor Segmentectomy
- · Inflow Outflow Reconstruction in Living **Donor Liver Transplantation**
- · Porto Enteric Pancreas Transplantation
- · Small Bowel / Multi-Visceral Transplantation

9:00 - 9:20

9:20 - 10:00

KEYNOTE SPEAKER: JOHN NAJARIAN, M.D.

10:00 - 11:30

· Surgical Innovation in Transplantation **CONTROVERSIES IN TRANSPLANTATION** 

· Pancreas: PTA for Non-Uremic Diabetic Recipients

- · Liver: Difficult Cases
- · Kidney: Donor Incentives

### SATURDAY | january 24

7:00 - 7:30am

7:30 - 8:30

THE CHALLENGE OF VASCULAR INSUFFICIENCY

- The Recipient with Peripheral Vascular Disease
- · Early Peripheral Vascular Complications after Organ Transplantation
- · The Lack of Access!

8:30 - 9:30

**PLENARY SESSION OF SELECTED ABSTRACTS** 

9:30 - 10:00

**BREAK** 

10:00 - 12:00

- **ORGANS IN AN IMPERFECT WORLD**
- · Unexpected Donor Circumstances at St. Elsewhere
- The Injured Organ
- · Progress in the Use of Organs from Non-Heart Beating Donors
- Unusual Kidneys
- Fatty Livers

LUNCH

· Split Liver Transplantation for Two Adults

12:00 - 1:00

6:30

**FAMILY BAR-B-QUE/ACTIVITIES** 

### SPECIAL EVENTS

FRIDAY, JANUARY 23, 2004 6:30 - 10:00 PM

ASTS 30TH ANNIVERSARY CELEBRATION DINNER

Cocktails by the Pool **Elegant Dinner** 

**Black-Tie Optional** Separate Special Children's Event Planned

SATURDAY, JANUARY 24, 2004 5:30 - 6:30 PM

ASTS VANGUARD COMMITTEE CAREER DEVELOPMENT MINI-SYMPOSIUM

COME CELEBRATE!

ASTS • 30TH ANNIVERSARY

### **SPEAKERS**

### WINTER SYMPOSIUM SPEAKERS

J. Wesley Alexander, M.D., Sc.D. Professor of Surgery University of Cincinnati

Stephen Bartlett, M.D.
Professor of Surgery & Medicine
Head, Division of Transplantation
Vice Chairman of Surgery
University of Maryland School of Medicine

Kenneth Chavin, M.D., Ph.D. Assistant Professor of Surgery, Microbiology & Immunology

Medical University of South Carolina

Daniel Cherqui, M.D.

Professor of Surgery Director of Hepatobiliary Surgery & Liver Transplantation

Hopital Henri Mondor-Universite Paris 12

Anthony D'Alessandro, M.D. Professor of Surgery Executive Director, Organ Procurement Organization University of Wisconsin

Francis Delmonico, M.D.
Professor of Surgery
Harvard Medical School
Director, Renal Transplantation
Massachusetts General Hospital
Medical Director
New England Organ Bank

Alan Farney, M.D., Ph.D. Associate Professor of Surgery Wake Forest University

Thomas Fishbein, M.D.
Associate Professor of Surgery
Director, Small Bowel & Pediatric Liver
Transplantation
Georgetown University Hospital

A. Osama Gaber, M.D.
Professor of Surgery
Chief, Division of Transplantation
University of Tennessee Health Science
Center

R. Mark Ghobrial, M.D., Ph.D. Associate Professor of Surgery The Dumont-UCLA Transplant Center

Abhinav Humar, M.D.
Associate Professor, General & Transplant
Surgery
Director, Living Donor Program
University of Minnesota

Goran Klintmalm, M.D., Ph.D. Professor of Surgery Chief, Baylor Regional Transplant Institute Baylor University Medical Center

Dicken Ko, M.D.

Assistant Professor of Surgery and Urology
Harvard Medical School

Paul Kuo, M.D., M.B.A. Professor of Surgery Chief, Section of Transplantation Surgery Duke University Medical Center Elvira Lang, M.D.
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Arthur Matas, M.D. Professor of Surgery Director, Renal Transplant Program University of Minnesota School of Medicine

John Najarian, M.D. Clinical Professor of Surgery University of Minnesota

William Payne, M.D.
Professor of Surgery
Director, Liver Transplant Program
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Elizabeth Pomfret, M.D., Ph.D. Assistant Professor of Surgery Tufts Medical School Director, Living Donor Liver Transplantation Lahey Clinic Medical Center

Mikel Prieto, M.D. Assistant Professor of Surgery Mayo Clinic

James Pomposelli, M.D., Ph.D. Assistant Professor of Surgery Tufts Medical School Senior Staff Surgeon Lahey Clinic Medical Center

Margaret Ragni, M.D., M.P.H. Professor of Medicine University of Pittsburgh Director, Hemophilia Center of Western

Pennsylvania
Lloyd Ratner, M.D.
Professor of Surgery
Chief, Solid Organ Transplantation
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Abraham Shaked, M.D., Ph.D. Professor of Surgery Chief of Transplantation University of Pennsylvania

Ron Shapiro, M.D.
Professor of Surgery
Director, Kidney, Pancreas, and Islet
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University of Pittsburgh

James Schulak, M.D., Ph.D. Professor and Chief of Surgery Case Western Reserve University

M. Hosein Shokouh-Amiri, M.D. Professor of Surgery University of Tennessee Health Science Center

Hans Sollinger, M.D., Ph.D. Folkert O. Belzer Professor of Surgery Chairman, Division of Transplantation University of Wisconsin-Madison

Andreas Tzakis, M.D., Ph.D.
Professor of Surgery
Chief, Division of Liver and
Gastrointestinal Surgery
Co-Director, Division of Transplantation
University of Miami School of Medicine

Michael Wachs, M.D. Associate Professor of Surgery University of Colorado Health Sciences Center

### CLINICAL RESEARCH COURSE SPEAKERS

Nancy Ascher, M.D., Ph.D. Professor and Chair of Surgery University of California San Francisco

Nancy Bridges, M.D.
Chief, Clinical Transplantation Section
National Institute of Allergy & Infectious
Diseases
National Institutes of Health

Ronald Ferguson, M.D., Ph.D. Professor of Surgery Chief, Division of Transplantation Ohio State University College of Medicine

Thomas Fishbein, M.D.
Associate Professor of Surgery
Director, Small Bowel & Pediatric Liver
Transplantation
Georgetown University Hospital

A. Osama Gaber, M.D.
Professor of Surgery
Chief, Division of Transplantation
University of Tennessee Health Science Center

David Gerber, M.D. Assistant Professor of Surgery University of North Carolina

Barry Kahan, M.D., Ph.D. Professor of Surgery Director of Organ Transplantation The University of Texas-Houston

Allan Kirk, M.D., Ph.D.
Chief, Transplant Surgery Section
Transplantation and Autoimmunity Branch
National Institute of Diabetes & Digestive &
Kidney Diseases
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Robert Merion, M.D.
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University of Michigan Medical Center
Clinical Transplant Director
Scientific Registry of Transplant Recipients

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Microbiology/Immunology
Indiana University-Purdue University
Indianapolis

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Professor of Surgery in Residence
Chief, Division of Transplantation
University of California San Francisco

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Raymond Tesi, M.D. Senior Vice President Clinical Development & Medical Affairs Sangstat Medical Corporation

J.Richard Thistlethwaite, Jr., M.D., Ph.D. Professor of Surgery University of Chicago esigned by TumStyle Solutions www.turnstylesolutions.com

### **ASTS 2004 Winter Symposium**

### SPECIAL FEATURE: ASTS COURSE ON

### Fundamentals of Clinical Research in Transplantation

### COURSE description

This course aims to teach fundamental methodology of designing and conducting clinical research/trials in transplantation. Instruction and interaction will focus on how to:

- Develop concepts and skills to design and implement clinical research/clinical trials in transplantation.
- 2. Assemble the appropriate components to complete clinical research/clinical trials in transplantation.
- 3. Identify possible and appropriate funding mechanisms.
- 4. Disseminate research results through publications and identify issues such as patents and proprietary rights.

**Target Audience:** Transplant Physicians, Surgeons, Transplant Coordinators, and Nurses, particularly those interested in clinical research in the area of solid organ transplantation.

### **COURSE** objectives

The participant will be able to:

- 1. Discuss the concepts necessary to develop a protocol for clinical research/trials that are fundable by a peer-reviewed agency.
- 2. State the design and implementation issues unique to performing clinical research/trials in transplantation.
- 3. Develop collaborative elements necessary to conduct a clinical trial.

### COURSE sessions

### THURSDAY | january 22

1:00 PM - 5:45 PM

Why Do Clinical Research?

Overview of Study Design: Strengths and Weaknesses

Advancing Surgical Techniques

Registry-Based Data Analysis: Pros and Cons

Clinical Trial Design

Selecting Endpoints: Critical Choices

Regulatory Alphabet Soup: IRB, FDA, HIPAA

Who Might Fund My Study?

The NIH

The Pharma Interaction

Investigator-Initiated Pharma-Sponsored Research

### FRIDAY | january 23

7:30 AM - 11:30 AM

The Anatomy of Funding Proposals

Breakout Sessions and Proposal Reviews

- Phase 1 & 2 Trials
- Retrospective/ Registry-Based Trials
- Multi-Center Randomized Prospective Trials

**JANUARY 22-23** 

The Fundamentals of Clinical Research in Transplantation

MARRIOTT MOUNTAIN SHADOWS

Publication / Patents / Proprietary Rights

Successful Trial Administration: From Budget to Personnel

**Ethics of Clinical Research** 

### CME/continuing education

The American Society of Transplant Surgeons (ASTS) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

AMA PRA: The ASTS designates this educational activity for a maximum of 7.8 category 1 credits towards the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Transplant Coordinators: Category 1 Continuing Education Points for Transplant Coordinators (CEPTCs) have been applied for through the American Board of Transplant Coordinators (ABTC).

Nursing Credit: This program is co-sponsored by Amedco and American Society of Transplant Surgeons. Amedco, St Paul, MN, is approved as a provider of continuing education in nursing by the Wisconsin Nurses Association Continuing Education Approval Program Committee, which is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Maximum of 9.1 contact hours.

### **ASTS**

wishes to THANK the following sponsors of the 2004 ASTS Winter Symposium and the Clinical Research Course:

Sangstat

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### Come Celebrate

**ASTS's** 

30th Anniversary
to take place at the
American Society of Transplant Surgeons'
4th Annual Winter Symposium
"Surgical Challenges in Transplantation"

January 23-25, 2004

Marriott Mountain Shadow Resort and Golf Club

Scottsdale, AZ



## American rans

### May 14 - 19, 2004 • Hynes Auditorium • Boston, MA

### Tentative Schedule at a Glance

### Saturday, May 15

### **Pre Meeting Symposia**

Symposium #1: Complications of Transplantation and Infections

Session II: Strategies to Minimize Complications of Immunosuppression

Session III: Infection in Transplantation: State-of-the-Art and Future Challenges

Symposium #2: Immunology Update 2004

Session I: The Basics of Transplant Immunology for the Clinicia

Session II: Update in Transplantation Biology

Symposium #3: Tissue Typing Laboratory and Its Clinical Applications

Cosponsored by the American Transplant Congress and the American Society for Histocompatibility & Immunogenetics

Session 1: Antibodies and Crossmatch: Past, Present and Future

Session II: Clinical Desensitization Protocols

Symposium #4: Pediatric Symposium

Cosponsored by the American Transplant Congress and the International Pediatric Transplant Society

Session 1: Transplantation of the Adolescent

Session II: Use of Newer Immunosuppressive Drugs in Pediatric Recipients

Symposium #5: Transplant Nurses and Coordinators Program

Cosponsored by the American Transplant Congress, International Transplant Nurses and National Association for

**Transplant Coordinators** 

5:00 pm - 7:00 pm Opening Reception with Exhibits

### Sunday, May 16

### **Annual Meeting**

7:00 am - 8:15 am Sunrise Symposia

8:30 am - 9:30 am Joint Plenary

9:45 am - 11:15 am Basic Science Symposium

Genomics and Proteomics in Transplantation

9:45 am - 11:15 am Clinical Science Symposium

An Overview of the UNOS and SRTR

11:30 am - 12:00 pm Awards

12:00 pm - 12:30 pm State of the Art Address:

"Advances in Drug Delivery and Tissue Engineering"

Robert Langer

12:30 pm - 2:00 pm Poster Session I and Mini-Oral Sessions

2:00 pm - 5:30 pm Concurrent Sessions

# plantCongress

### Monday, May 17

7:00 am - 8:15 am	Sunrise Symposia
8:30 am - 9:30 am	Dual Plenaries
9:45 am - 11:15 am	Basic Science Symposium The Science of Complex Systems as it Relates to Transplantation
9:45 am -11:15 am	Clinical Science Symposium Pre-transplant Risk Factors and Effect on Post-transplantation Outcomes
11:30 am - 12:30 pm	In-depth Reviews: Clinical: Use of Registery-Based Evidence for Clinicians and Policy Makers
12:30 pm – 2:00 pm	Poster Session II and Mini-Oral Sessions
2:00 pm - 5:30 pm	Concurrent Sessions

### Tuesday, May 18

7:00 am - 8:15 am	Sunrise Symposia
8:30 am - 10:00 am	Basic Science Symposium Regulatory T Cells in Their Role in the Control of Counter-adaptive Immunity
8:30 am -10:00 am	Clinical Science Symposium Campath
10:15 am - 12:00	Presidential Addresses
12:30 pm - 2:00 pm	Poster Session II and Mini-oral Sessions
2:00 pm - 5:30 pm	Concurrent Sessions

### Wednesday, May 19

### A S T S N E W m e m b e r s

Jonathan M. Chen, MD Children's Hospital of New York

Alan M. Hawxby, MD Johns Hopkins Hospital

Harish D. Mahanty, MD University of California - San Francisco

Yoshifumi Naka, MD PhD New York Presbyterian Hospital

Nicholas Onaca, MD Baylor University Medical Center

Philip G. Thomas, MD University of Pittsburgh

Paul L. Tso, MD Emory University

Takehisa Ueno, MD Baylor University Medical Center JANUARY 2004

January 22-23, 2004

AMERICAN SOCIETY OF TRANSPLANT SURGEONS

Clinical Research in

Transplantation: Getting Started

Marriott Mountain Shadow Resort and Golf Club

Scottsdale, AZ

Contact Website: www.asts.org

Contact Phone: 1-800-736-6261

January 23-25, 2004

ASTS 4TH ANNUAL WINTER

**SYMPOSIUM** 

Surgical Challenges in

Transplantation

Marriott Mountain Shadow Resort

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Scottsdale, AZ

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Contact Phone: 1-800-736-6261

**FEBRUARY 2004** 

February 5-8, 2004

**6TH INTERNATIONAL CONFER-**

ENCE ON NEW TRENDS IN

**IMMUNOSUPPRESSION** 

Salzburg, Austria

Contact Website:

www.kenes.com/immuno

Contact Email: immuno6@kenes.com

Contact Phone: +41 22 908 0488

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**MAY 2004** 

May 15-19, 2004

AMERICAN TRANSPLANT

**CONGRESS** 

John B. Hynes Convention Center

Boston, MA

Contact Phone: 856-439-0880

Contact Website:

www.atcmeeting.org

SEPTEMBER 2004

September 5-10, 2004

XX INTERNATIONAL CON-GRESS OF THE TRANSPLANTA-

TION SOCIETY

Vienna, Austria

www.transplantation2004.at

**JANUARY 2005** 

January 21-23, 2005

AST 5TH ANNUAL STATE OF

THE ART WINTER SYMPOSIUM

Eden Roc Resort and Spa

Miami Beach, FL



# TS Research Bulletin Board

ASTS has developed a "research bulletin board" to enable you to post information about research projects in which you would like additional participants or other input.

The purpose of this bulletin board is to allow investigators to solicit participation from other centers for their clinical trial. It is hoped that this bulletin board will attract enrollment of a sufficient number of patients to statistically power clinical trials.

Please go to **www.asts.org** and click on to "Members Only" section and then click "ASTS Research Bulletin Board."

Click into the specific organ where your study better belongs or to see any proposal that has been posted.

We encourage you to utilize this site and refer to it on a regular basis to see what has been added and to post studies for which you are seeking input. We hope this tool will help in developing research studies for which Members would like to find collaborators or receive input and advice from other investigators. Both clinical and basic projects are welcomed.

It should be noted that posting of studies on the trials bulletin board does not in any way denote support or sponsorship of the principal investigator or clinical trial by the American Society of Transplant Surgeons. In addition, the American Society of Transplant Surgeons does not vouch for the scientific validity, clinical efficacy, and/or

The site was developed by the ASTS Scientific Studies Committee.

### JOB BOARD

The ASTS Job Board is enhanced further by the addition to the ASTS website, **www.asts.org**, of CV's of ASTS Candidate Members. This is in an effort to facilitate the interactions between graduating fellows and transplant programs with junior position openings. To access the CVs go to the **www.asts.org**, log into the Members Only section and click on Upload/download files.

**TRANSPLANT SURGEON** The Section of Transplantation, Division of General Surgery, at the Albany Medical Center Hospital is recruiting for a position in Transplant Surgery at the Assistant or Associate Professor level. Duties involve clinical responsibilities in all aspects of kidney and pancreas transplantation, as well as multi-organ donor procurement. Interested parties should forward a CV to David Conti, M.D., Chief of General Surgery, Director-Abdominal Organ Transplant Program. Fax: (518) 262-5571, email: contid@mail.amc.edu, mail: Albany Medical College, MC 61GE, 43 New Scotland Avenue, Albany, NY 12208 \$\mathrew{M}\$

MULTI-ORGAN TRANSPLANT FELLOWSHIP University of Minnesota Medical School Department of Surgery. Applications are now being accepted for two positions for a two-year advanced ASTS-approved training program in multi-organ transplantation at Fairview University Medical Center. Must be board certified, eligible, or equivalent in general surgery, and hold or be eligible to obtain a State of Minnesota medical license. Responsibilities include 24 months of specialty training in kidney, pancreas, and liver transplantation. Successful candidates will be appointed as full-time yearly renewable non-tenure track Instructors in the Department of Surgery. The start dates are January 2005 and July 2005. Candidates are immediately needed and encouraged to apply for the January 2005 opening. The positions will remain open until filled. Applications for future years will also be accepted. To apply, please submit curriculum vitae and bibliography to: Arthur J. Matas, M.D., Professor of Surgery, Director, Transplant Fellowship Program, University of Minnesota Dept. of Surgery, 420 Delaware St. SE, MMC 280, Minneapolis, MN 55455, matas001@umn.edu, The University of Minnesota is an equal opportunity educator and employer.

MULTI-ORGAN TRANSPLANT FELLOWSHIP The Division of Organ Transplantation, Northwestern University Feinberg School of Medicine is seeking highly motivated individuals for its ASTS-approved transplant fellowship beginning July 1, 2004. The fellowship is a two-year program with training in kidney, pancreas, and liver transplantation and multi-organ cadaver procurement. Comprehensive training in adult and pediatric renal and liver transplantation will be provided. Training will also be provided in laparoscopic living-donor nephrectomy, living donor liver transplantation, and dialysis access. Participation in ongoing clinical research projects and translational projects within the Division of Transplantation is encouraged. Fellows should be board eligible or board-certified in general surgery. Interested individuals should contact: Joseph R. Leventhal, MD, PhD, Division of Transplantation, Department of Surgery, 675 N. St. Clair Street, Suite 17-200, Chicago, IL 60611, 312-695-1703 - Phone, 312-695-9194 - Fax, Email: jleventh@nmh.org

THE CENTER FOR SCIENTIFIC REVIEW (CSR) at the NIH is expanding and reorganizing its scientific review structure into four Divisions, including a Division of Clinical and Population-based Studies. CSR is seeking a Director for this division with experience and knowledge in clinical research and/or behavioral and social science, who can serve as an effective liaison with these research communities. This is a senior executive level position. For more information, please see ad at <a href="http://www.csr.nih.gov/employment">http://www.csr.nih.gov/employment</a>, or contact Ms. Pam Sullivan, SullivanP@csr.nih.gov

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