AFDT enhances Living Organ Donor Network (LODN) insurance coverage for live kidney donors

The American Foundation for Donation and Transplantation (AFDT) announced that it is enhancing coverage for living kidney donors and their families provided by its Living Organ Donor Network (LODN) insurance program.

On October 1, LODN increased the accidental death benefit available to living donors from $250,000 to $500,000 and made available an additional accident insurance policy to cover the life of the companion who travels to and from the donor’s transplant center.

LODN has been insuring living kidney donors since October of 2000 when it was launched by the South-Eastern Organ Procurement Foundation (SEOPF). In 2005 SEOPF changed its name to the American Foundation for Donation and Transplantation.

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The AFDT said the medical coverage provided to living donors will remain at $250,000 but the deductible will be decreased to $5,000. In addition to coverage for medical complications, the coverage also makes $50,000 available for mental health counseling for the living donor. The disability insurance available in the $250,000 to support income during recovery from two years post donation remains unchanged.

In addition to the insurance policy, the LODN provides demographic information on the people who become living kidney donors and tracks their health after the donation takes place.

The price for a transplant center to participate in LODN is a one-time charge of $550. Participating centers include Sentara Norfolk General Hospital, Norfolk, VA; Henrico Doctors Hospital, Richmond, VA; and Baroness Erlanger Medical Center, Chattanooga, TN; the University of Utah Medical Center, Salt Lake City, UT. To date, 517 living donors have been insured at the participating hospitals. In addition, two donors have purchased the insurance policy directly from LODN.

LODN reports only 52% of living donors nationwide have health insurance, 42% have life insurance, and 32% have disability insurance.

“The gift of a kidney from a living person is truly a selfless act,” said Thomas McCune, MD, Medical Director of LODN, “It behooves the medical and transplant community to make sure they are given the finest health care and that they or their families do not suffer financially as a result of their generosity. In addition, we need to encourage more Americans to donate kidneys. LODN hopefully will ease them in making their decision.”

McCune was a speaker at a July 9 audioconference presented by Transplant News on Paired Kidney Donation, and The Living Organ Donor Network Registry (LODN) and Donor Insurance Policy. All the audioconference materials including an audio CD, edited transcript and speakers presentations are available for $267.00 To order, contact Jim Warren at 800-689-4262 or by e-mail: Trannews@Trannews.com.

For information on joining LODN, contact Arlene Skinner at 1-800-543-6399; 1-804-323-9890; or by e-mail: Skinner@sopt.org.
Under the new regulations, all transplant centers currently participating in the Medicare Program must undergo re-approval and all new transplant centers seeking to participate in the Program must undergo initial approval. Re-approval for all transplant centers participating in the Medicare Program is required every three years.

The certification regulations consist of two types of requirements—(1) “process” requirements and (2) requirements related to outcomes, clinical experience (procedure volume), and data submission. The “process” requirements relate to issues such as patient and living donor selection; organ recovery and receipt; patient and living donor management; quality assessment and performance improvement (QAPI); and human resources. Assuring compliance with the process requirements generally requires an on-site survey. Under current CMS protocols, such surveys are conducted either by a state survey agency (generally an agency within the state health department) or by a federal contractor, depending on where the transplant center is located.

The clinical experience, outcomes, and data submission requirement regulations (42 C.F.R. Sections 482.80 and 482.82) are not of the types that necessarily require an on-site survey. While the survey agency is formally responsible for determining compliance with these requirements, it makes its determinations based on a report provided by CMS, the Transplant Center Quarterly Report (TPQR), which is based on information obtained by CMS from the national Scientific Registry of Transplant Recipients (SRTR), the OPTN, and other sources.

Preparing for the Survey

CMS has issued detailed instructions to survey agencies outlining the protocols to be used in conducting the on-site survey. While the instructions suggest that the survey team includes two to three surveyors who are to be on site for at least three days, surveys involving a larger number of surveyors and taking up to a week have been reported.

Survey agencies are instructed to hold an “entrance conference” with the Program Director and all key personnel. It is crucial that all key clinical and administrative personnel attend the conference. If a state survey team fails to hold such a meeting, it may be advisable to request the meeting, in order to ensure that a timetable for interviews and clinical records review is established that minimizes the burden on clinical personnel and on center operations. At a minimum, the

Program Director should meet with the head of the survey team and request a schedule of survey activities. In addition, we recommend that transplant centers obtain a copy of the most recent TPQR report from the surveyors and check it for accuracy. Transplant centers have a right to receive this report and CMS has explicitly stated that surveyors are permitted to provide it.

CMS has also published on its website additional information intended to assist transplant centers to prepare for the survey, including the interview questions to be asked to various transplant center personnel and a list of documents to be reviewed. Centers that have not yet been surveyed should pull together the information that will be subject to review and have it ready since transplant center surveys are unannounced. It is also advisable to conduct an internal review to ensure that the documents meet the requirements set forth in the Interpretive Guidelines.

In conducting this review, and in participating in the on-site survey, transplant centers should be particularly aware that the new regulations did not become effective until June 28, 2007. Outdated policies pre-dating the effective date of the regulations (and subsequently superseded by policies that meet the regulatory requirements), violations of the standards that pre-date the effective date of the regulations, and clinical records of patients documenting care that pre-dated this effective date should not be reviewed by the on-site surveyors. Deficiencies cited in the survey report should not be based on activities, policies, and other occurrences pre-dating the effective date of the regulations with the exception of compliance with the outcomes standard. Medicare surveyors will take into consideration outcomes reflected in the most recent SRTR report which reflects events from the last two and a half years.

Responding to the Survey Findings

Within ten days of an onsite survey, a transplant center should be sent a written Statement of Deficiencies on CMS Form 2567, which will set forth the deficiencies found during the survey. Not every deficiency found by a survey agency is created equal. The regulations establish twelve CoPs, although the number of conditions that apply to any individual center may vary based on the services provided. However, each “condition” consists of one or more “standard(s),” and each “standard” includes a number of “criteria” or “elements.” A transplant center may be out of compliance with a “criteria” or “element” within a

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standard, a “standard” within a “condition” or one or more condition(s). The survey report will (or should) indicate whether a deficiency was found at the “criteria”, the “standard”, or the “condition” level.

While deficiencies at the “criteria” or “standard” level generally may be adequately addressed by the submission and implementation of a plan of correction without a re-survey, a deficiency at the “condition” level is far more serious. Under the applicable regulations, CMS is required to terminate the participation of a center that fails to meet a condition of participation and that does not achieve correction within the period allowed for remediation.

On April 4, 2008, CMS issued guidance to state survey agencies entitled, “Guidance for Citing Condition and Standard-Level Deficiencies For Certain Regulatory Requirements and Allowing Additional Time to Correct the Deficiency”. This document provides specific guidance as to what level of deficiency will result in a condition level versus standard level citation particularly as it relates to the areas of outcomes and clinical experience. For example, a center seeking initial approval must perform 10 transplants over a 12-month period; if it performs 8 or 9 it is cited with a standard-level deficiency; if less than 8 it is cited with a condition-level deficiency which is much more serious.

While the SRTR analyzes outcomes for the purpose of flagging centers whose outcomes deviate substantially from expected outcomes, CMS uses these same outcomes standards for the purpose of determining whether a center should be terminated from participation in the Medicare program.

If a center is cited for deficiencies, it must submit an acceptable plan of correction in order to continue to participate in the Medicare program and the institution is given 10 calendar days in which to respond with a Plan of Correction (PoC) for each cited deficiency, and enters this response on the CMS Form 2567. Assuming an adequate PoC is submitted, a provider is normally given 60 days to achieve compliance. If the provider does not achieve compliance and it has a Condition Level deficiency, termination proceedings can begin. However, if a transplant center has a Condition Level deficiency due to the failure to meet the clinical experience (volume) or outcomes requirements, the transplant center may be given up to 210 days to come into compliance.

If the state survey agency determines that the PoC is inadequate or if, after the period of correction has elapsed, the cited deficiencies have not been corrected, the state survey agency may request the CMS Regional Office to consider termination proceedings. At this point, a transplant center may seek reconsideration from CMS and, if the reconsideration decision is adverse, may request a hearing before an administrative law judge and may appeal that decision to an HHS Departmental Appeals Board.

Public Disclosure

Medicare regulations provide that Statements of Deficiencies as well as the Program’s PoC must be provided to the public upon request.

Requesting Consideration of “Mitigating Factors”

If a transplant center is cited for a Condition Level deficiency, it may request that CMS consider “mitigating factors”, under 42 CFR § 488.61(a)(4), (b)(2), and (c)(4), so long as the survey findings do not indicate that an immediate jeopardy to patient health and safety exists based on the survey deficiencies. The mitigating factors process is intended to allow CMS, in limited circumstances, to extend Medicare approval in cases where a transplant program sufficiently demonstrates that there are exceptional factors present which constitute grounds for Medicare approval in spite of the fact that the program does not meet the data submission, clinical experience, outcome requirements or other CoPs.

Significantly, however, requesting a mitigating factors determination from CMS does not negate or otherwise affect a transplant center’s obligation to submit to the survey agency a plan of correction for cited deficiencies. The plan of correction must be submitted within 10 days of receipt of the Statement of Deficiencies and must specifically state that the transplant center has requested approval from CMS Central Office based on the presence of mitigating factors; however, the transplant center must still submit a PoC addressing all of the issues cited in the Statement of Deficiencies. Further, a request for a finding of mitigating factors does not affect the transplant center’s right of appeal regarding its certification status if the state agency determines that the PoC is unacceptable or otherwise determines that the center’s Medicare participation status should be terminated.

In order for a transplant center to present mitigating factors, specific timelines and requirements must be met. A transplant center seeking approval based on the presence of mitigating factors must first submit a
formal written request for approval to CMS within 10 calendar days of the date of the Statement of Deficiencies (CMS Form 2567). Additional explanatory materials and rationale may be submitted within 30 calendar days of the date of the Statement of Deficiencies.

A review based on mitigating factors includes, but is not limited to, the extent of the failure to meet a CoP, the availability of Medicare-approved transplant centers in the area, and extenuating circumstances that may have a temporary effect on meeting the CoPs.10

**Conclusion**

Transplant centers facing the Medicare certification process for the first time are entering uncharted waters. Careful preparation for the survey can help minimize the possibility of Condition Level deficiencies that, if not corrected, may result in termination proceedings. Transplant Centers whose outcomes deviate significantly from expected outcomes, based on SRTR standards, should institute corrective action as soon as possible. However, because of the “lag time” in SRTR reporting, it is likely that a center that fails to meet outcomes standards during one reporting period will likewise fail to meet the standards in the following reporting period. Since a center with two failing SRTR reports is considered to have a Condition Level deficiency that may jeopardize Medicare participation, transplant center administrators and surgeons are well advised to track the center’s outcomes against the SRTR standards on an ongoing basis.

**Footnotes**

1 Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule, 72 Fed. Reg. 15198 (March 30, 2007).
2 42 C.F.R. § 482.80 and § 482.82.
3 These instructions as well as other Medicare policies can be viewed at [http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp](http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp).
5 42 C.F.R. § 488.61(a)(4)(iv).
7 CMS, April 4, 2008 Letter to State Survey Agency Directors.
8 Process for Requesting Consideration of Mitigating Factors in CMS’ Determination of Medicare Approval of Organ Transplant Centers(Issued September, 2008).
9 Id.
10 Id.
11 42 C.F.R. § 488.61(a)(4).

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**Access to kidney transplant in US, Canada same for African Americans, but health outcomes worse in America**

African American kidney disease patients in both Canada and the US are less likely than Caucasian Americans to have access to a kidney transplant, but only African Americans in the US have worse health outcomes than Caucasians after a transplant is performed, according to a new study appearing in the January 2009 issue of the *Journal of the American Society of Nephrology* (JASN).

The research team, led by Karen Yeates, MD, of Queens University in Kingston, Ontario, said the results could open the debate further about what has driven the disparities seen only in the US.

Health disparities among racial and ethnic groups have been noted for a number of medical conditions, including kidney disease. The new study is the first to look at disparities in health outcomes following kidney transplantation in Canada.

Yeates and her colleagues performed such a study by analyzing data from the Canadian national renal replacement therapy registry, which included information on 20,243 dialysis patients (3% black and 97% white), 5,036 of whom received a kidney transplant during the study.

The investigators found the African Americans in Canada were significantly less likely than Caucasians to receive a kidney transplant from deceased or living donors just like they are in the US. However, unlike in the US, African-American Canadians who underwent a kidney transplant experienced no significant health differences compared with Caucasians after their procedure. The transplanted kidneys survived just as long as kidneys transplanted into Caucasians, and African-American Canadians actually survived longer following the surgery compared to Caucasians.

Yeates said that increased access to medical care after receiving a transplant in Canada may be one of the reasons for the disparity between the two countries.

“The hypothesis behind this difference could be that the better renal transplant outcomes for African-Americans in Canada are due to better access to post-transplant medical care and access to immunosuppressive medications that are more comprehensive than in the United States,” she observed.

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Survival rates for children of different races receiving liver transplants same; black adults long term survival lower

No differences were found in the survival rates for children of different races receiving a liver transplant but long-term survival rates for African-American (AF) adults are not as good as the other groups, according to two new studies.

The two studies which were presented at the annual meeting of the American Association for the Study of Liver Diseases in San Francisco, CA, painted a different picture of survival based on racial group for adult and child recipients of liver transplantation.

Researchers at the Baylor College of Medicine in Houston used a United Network for Organ Sharing (UNOS) dataset of 2,700 pediatric transplant recipients age 17-year and under to see if there were any differences in survival between racial groups—Caucasians, Hispanics, African-Americans and Asians—patient survival for the period between 2002 and 2007. They found that, although there differences in the leading cause for inclusion on the transplant waiting list, age at time of transplant and sex of transplant recipients, there was no difference in either the allograft or patient survival rates between the racial groups.

In addition, the researchers found no differences in PELD/MELD score at the time of transplantation and percentage of patients undergoing multi-organ transplants.

African-American kidney transplants in the US
(Continued from page 5)

Unlike African-Americans in the US, African-American Canadians have free access to pre-dialysis care, kidney transplantation and follow-up care at all kidney transplant centers.

"Although this study is observation and further study is needed, our results raise potentially important questions bout whether access to health services for African-Americans would improve outcomes following kidney transplantation in this population," the researchers concluded in their study.

The article entitled "A Comparison of Outcomes in Renal Transplantation Among Black and White Patients in Canada" is available now online at [http://jasn.asnjournals.org](http://jasn.asnjournals.org).
Hospital patients with CKD are higher risk for adverse events than patients without the disease, study finds

Hospital patients with chronic kidney disease (CKD) are at higher risk for adverse consequences of medical care compared with those without the disease, according to a new study. The researchers said the findings indicate that steps should be taken to reduce potentially preventable complications of medical care for CKD patients, a population they charge that is frequently under-recognized in most health care settings.

According to the study, which appears in the December 2008 issue of the *Journal of the American Society of Nephrology* (JASN), considerable efforts have been made in recent years to reduce medical errors, and the Agency for Healthcare Research and Quality has established a number of “patient safety indicators” to monitor rates of adverse events among hospitalized patients. These safety indicators include complications of anesthesia, post-operative hemorrhage, transfusion reactions, infections due to medical care, and a number of other conditions.

While CKD patients are likely to be at higher risk of experiencing some of these complications compared with other hospitalized patients, few studies have evaluated their risk. To investigate, Jeffrey Fink, MD, of the University of Maryland Medical System in Baltimore, and colleagues analyzed data from approximately 250,000 hospitalized patients in the Veterans’ Health Administration in 2004-2005.

The researchers found that 29% of the hospitalized veterans had CKD, and had a higher risk of several patient safety indicators, particularly infection due to medical care and death during a hospitalization for a condition considered to be a low mortality risk. CKD patients were also more likely to experience complications of anesthesia, post-operative hip fracture, post-operative physiological or metabolic disturbances, and to have post-operative respiratory failure. Patients with low risk pre-admission glomerular filtration rates (an indicator of significant kidney damage) were at particularly high risk of experiencing a combination of patient safety indicators.

The authors concluded that their study links the presence of CKD with a greater risk of patient safety mishaps during hospitalization. “Further investigation is needed to examine this association in other health care systems and to define more specific safety measures, with the goal of improving patient safety in CKD patients,” they wrote. Fink argued that increased recognition of CKD and consideration of the condition when giving medical care may help reduce the frequency of adverse safety events that occur in the health care setting.

The article – "The Influence of Chronic Kidney Disease on Patient Safety Among Hospitalized Veterans" – is available online at [http://jasn.asnjournals.org](http://jasn.asnjournals.org) and will appear in the December JASN.

FDA approves bone marrow product to treat immune-related low platelet counts

The US Food and Drug Administration (FDA) has approved a bone marrow product developed to treat immune-related low platelet counts. Nplate (romiplostim) is the first bone marrow stimulator to produce needed platelets in patients with a rare blood disorder that can lead to serious bleeding.

The condition, which usually develops in adults, is known as chronic immune thrombocytopenic purpura (ITP), a disease that results in a low number of platelets, the blood components that help with clotting. In patients with chronic ITP, the immune system is believed to destroy platelets and the patient’s bone marrow is often unable to compensate for the loss.

The estimated 140,000 people with chronic ITP are prone to bruising and at risk for life-threatening bleeding. Current medical treatment includes corticosteroids and immunoglobulin. Surgery to remove the spleen, a procedure known as a splenectomy, may help some patients. Nplate is approved only for patients with chronic ITP who do not respond sufficiently to current treatments.

During six months of treatment, patients who received Nplate had significantly higher platelet counts and maintained those higher counts compared to those who did not receive the drug. The response to Nplate was higher in those patients who still had their spleen than in those patients who had undergone a splenectomy. In those patients who did not receive Nplate, only one experienced a sustained increase in platelet counts.

The FDA said a Risk Evaluation and Mitigation Strategy (REMS) has been developed to address the risks of Nplate therapy. The FDA has determined that a REMS is necessary for the benefits of Nplate to outweigh the risks of the product. The REMS will include a Medication Guide for patients and requires that all prescribers and patients enroll in a special program to track the long term safety of Nplate therapy.
**Commentary**

**One-year moratorium on implementation of HHS OPTN regulation - who won, who lost may prove to be deceptive**

(Ten years ago this month, the transplant community was engaged in a monumental debate over how the US organ allocation system should work. The fight centered around whether the federal government could mandate organs be allocated according to medical need instead of geographical boundaries. Here is a commentary I wrote in November of 1998. Older readers will be reminded of the turbulent times; younger readers will get a short history lesson on how the current system was shaped by the fight.)

Jim Warren, Editor & Publisher

“This is a fine mess you’ve gotten us into this time, Ollie?” Laurel and Hardy

When congress recently agreed to a one-year moratorium on implementation of federal regulation of the Organ Procurement and Transplantation Network (OPTN), conventional wisdom suggested that the United Network for Organ Sharing (UNOS) had “won.”

UNOS has spearheaded the fight to resist regulation, which would allocate organs on the basis of medical need, rather than geographical location. If UNOS won, then conventional wisdom would also say someone had to lose. Let’s take a look at who the perceived big “winners” and big “losers” just might be in this latest public confrontation over who sets allocation policy in the US.

**Winners**

• UNOS – at least in the short run. In public testimony before congress, the organization professed eagerness to seek rapprochement with the Department of Health and Human Services (HHS), which would regulate the network. UNOS actions tell another story, however. How else can you explain its decision to join the Louisiana lawsuit against HHS seeking to prevent implementation of the regulation? In reality, the moratorium buys UNOS time to seek relief from the regulation through legislation Rep. Bob Livingston (R-LA), the instigator of the moratorium, has said he will introduce in congress next year.

• American Society of Transplant Surgeons – ASTS, and its immediate past president Ron Ferguson, MD, led the transplant community effort to retain the current UNOS system of allocating organs. Ferguson worked tirelessly to defend the status quo and retain the private sector’s authority to develop public policy with little or no oversight by HHS.

• Louisiana, Oklahoma, South Carolina, Wisconsin – The four states have passed laws mandating that organs be offered first to their own citizens regardless of their status on the waiting list. The moratorium also allows these states to lobby congress to block implementation of allocating organs on the basis of medical priority, not geography.

• The Institute of Medicine – The IOM gets money and time to do yet another study of transplantation in the US. No disrespect towards the IOM is intended, but does anyone really believe it will recommend that decisions in setting organ allocation policies be left strictly to the transplant community and that states’ rights supersede federal agencies’ ability to regulate?

• Small transplant centers – Small centers will survive. However, good small centers will survive regardless of the allocation policy. Those with poorer outcomes and an inability to continue to operate on a financially sound basis will fail no matter who controls the policymaking.

**Losers**

• Patients on the waiting list – This is a no-brainer. Forget the rhetoric from both sides of the dispute saying their only interest is in what is best for the people in need of a transplant, or dueling computer models showing which allocation system would result in the most transplants. Patients are losing because the highly publicized nature of the debate has to be dampening the US public’s willingness to donate organs. People do not trust the system and, according to several opinion polls, that is the major reason why people who should donate do not. When newspaper headlines and wire service stories trumpet one organization’s “victory” in organ allocation, every ounce of common sense says it must be hurting donation. Like it or not, perception is reality!

• Organ procurement organizations (OPOs), tissue banks, eye banks – This should be a time of optimism for increasing donation given the recently implemented Medicare Conditions of Participation which require all US hospitals to notify their local OPO of all deaths and imminent deaths. However, OPOs find themselves in the middle of a no-win situation regarding the HHS regulation. They are funded by the government, beholden to local hospitals to sign agreements to provide organs and tissues, and often seen by the public as co-conspirators in the allocation controversy. The Association of Organ Procurement Organizations (AOPO) has wisely declined to take sides during the dispute. That action alone reveals their precarious
position in the policy debate. OPOs have been unfairly used as the scapegoat for the failure to increase the number of organs over the past five years. That seems certain to continue for at least another year.

*The Coalition on Donation and the federal initiative to increase organ and tissue donation –* How can the Coalition possibly wage a successful public education campaign about the importance of being an organ and tissue donor in light of the negative public debate? Incredibly, the FY ’99 $10 million appropriation given to the Health Resources and Services Administration (HRSA) to be used to increase organ and tissue donation could be wasted if the situation is not resolved quickly and amicably.

*Congressional support –* Gaining the backing of congress for other issues extremely important to the transplant community such as increased support for basic research and unlimited insurance coverage of immunosuppressive drugs has been difficult without the current problems. Doing away with the allocation controversy would allow the transplant community to develop the cohesive legislative effort necessary to move transplantation forward in the 21st century. The shortage of organs and tissues will ultimately be eliminated through medical and scientific breakthroughs, not doubling the number of donors.

The sad thing is that it didn’t have to come to this. Both sides had publicly indicated a willingness to compromise in the past few months. HRSA Director Claude Earl Fox, MD, has said the department is not looking for UNOS to develop a policy requiring a national waiting list. “We’ve never said that we want livers to be shipped coast to coast. I think that’s a misconception,” he told *Transplant News* recently. UNOS President William Pfaff, MD, testified before a Senate committee hearing in September that “we’re in collaboration with the department from the get-go. . . The Secretary has oversight responsibilities. I’m a little surprised that we’ve come to this tenor of thought, where we’re not collaborating and it’s time to do that.”

The reality is that the fight over setting organ allocation policy has never been completely about what is best for patients. It is about power and money. It’s about big centers versus little centers. It’s about states’ rights versus federal rights. It’s about who should have the authority to set policy – physicians who treat the patients or the government agency in charge of oversight.

And, it’s going to go on for at least another year, if not longer, unless the transplant community demands that its leadership – individuals and organizations – call a halt to the bitter public fight.

Senator Bill Frist (R-TN), chairing a joint hearing on the allocation controversy of the Senate Labor and Human Resources Committee and the House Subcommittee on Health and Environment in June, observed that new developments in organ preservation techniques “make sharing of organs easier and changes must be made to reflect these changes.” He also expressed his own fear that “the heavy hand of government is going to come down” if UNOS and HHS can’t resolve their differences.

Despite Livingston’s success in gaining a one-year moratorium which will allow time for legislation to be introduced next year – and the Louisiana lawsuit – does anyone really believe that organ allocation policy in the US won’t be set by the federal government in consultation with the private sector?

Until the situation is resolved, there will be no winners.

**Secretary’s Advisory Committee on Organ Transplantation (ACOT) to meet Nov. 13-14**

The Secretary’s Advisory Committee on Organ Transplantation (ACOT) will meet on Thursday, November 13 and Friday, November 14 in Rockville, MD. The meeting will run from approximately 8:30 a.m. to 5 p.m. on Thursday, and 8:30 a.m. to 3 p.m. on Friday.

The meeting agenda will include presentations on the Report on New York State Transplant Council’s Committee on Quality Improvement in Living Kidney Donation; Organ Procurement Organization Quality Assessment/Performance; Status of the Organ Procurement and Transplantation Network (OPTN) Living Donor Follow Up; Risks for Disease Transmission; Factors Affecting Future Donor Potential; Reimbursement and the Changing Nature of the Donor Pool; Projected Growth in End-Stage Renal Disease and Implications for Future Demand for Kidney Transplants; Economic Impact of Transplantation; and Briefing on OPTN White Paper on Charges for Pancreata Recovered for Islet Transplantation.

In addition, three ACOT work groups will update the full committee on their deliberations on living donor advocacy and post-donation complications, sources of funding for additional data collection, and reducing pediatric deaths on the waitlist.

A draft of the meeting agenda will be available on the following Web site: <www.organdonor.gov/acot.html>.
Thoratec issues worldwide medical device correction of its HeartMate II LVAS

Thoratec Corporation, Pleasanton, CA, initiated a worldwide medical device correction on October 24 of all serial numbers of the HeartMate II Left Ventricular Assist Systems (HM II LVAS) having Catalogue No. 1355 or 102139 which have been distributed since the beginning of clinical studies in November 2003. The company said in a press release that over time, wear and fatigue of the percutaneous lead connecting the HM II VAS blood pump with the System Controller may result in damage that could interrupt pump function, require reoperation to replace pump and potentially result in serious injury or death. The estimated probability of the need for pump replacement due to percutaneous lead damage is 1.3% at 12 months, 6.5% at 24 months and 11.4% at 36 months.

The company said it is voluntarily issuing an Urgent Medical Device Correction notice after confirming 27 reports where wear and fatigue to the percutaneous lead necessitated pump replacement. The reports occurred over five years of clinical experience with 1,972 implants. All patients who have undergone a replacement of the HM III LVAS survived the operation and were alive at least 30 days postoperatively. However, in five cases, pump replacement was not feasible and the patients died.

The company is asking patients who are currently being supported by a HeartMate II LVAS to contact their doctors, who can assess the wear and fatigue of the percutaneous lead as well as provide proper instruction on management and care of the lead. The affected systems were distributed at 153 hospitals and distributors throughout the US, Europe, Canada and other countries. The HM II LVAS can be identified by the catalogue number located on the package label.

Thoratec sent an “Urgent Medical Device Correction” letter identifying the probability and symptoms of the problem, and recommending the pump be replaced as soon as possible if damage to the percutaneous lead is confirmed.

Clinicians and patients with questions may contact the company at 1-800-528-2577. The company said it had contacted the US Food and Drug Administration (FDA) but there had been no response as Transplant News went to press.

Berlin Heart’s pediatric VAD given unconditional investigation device exemption approval by FDA

Berlin Heart, Inc., Berlin, Germany, announced its Excor Pediatric ventricular assist device (VAD) has received unconditional approval from the FDA for the ongoing Investigational Device Exemption (IDE) in the US. In 2007, the FDA granted conditional approval for the prospective IDE study to begin initially at 10 centers with 10 patients, while the company addressed some questions the agency had found after reviewing the study design.

The Berlin Heart Excor Pediatric is a mechanical support system for critically ill pediatric patients suffering from severe heart failure. The company says that unlike standard heart-lung machines, their system has been used as a short-term, mid-term, and long-term support system, supporting failing hearts from days up to several months.

The system is designed to bridge patients awaiting heart transplantation until a donor heart becomes available, but it has also been used successfully as a bridge to recovery when a patient’s heart was able to recover and work on its own again. The company also says unlike other VADs, the Excor Pediatric can be used to support children of all age groups, from newborns up to teenagers.

The following US centers are participating in the IDE study: Arkansas Children’s Hospital; Boston Children’s Hospital; Children’s Hospital of Wisconsin; Lucille Packard Children’s Hospital at Stanford; Mott Children’s Hospital; Riley Children’s Hospital; Seattle Children’s Hospital; St. Louis Children’s Hospital; Texas Children’s Hospital; Children’s Hospital at the University of Alabama at Birmingham; and the Children’s Hospital at the University of Minnesota at Fairview.

Contact: Web site – www.berlinheart.com

RTI Biologics launches bovine pericardium membrane implant for dental applications

RTI Biologics, Inc., Alachua, FL, announced the company’s bovine pericardium membrane has been introduced into the world dental market through its distributor, Zimmer Dental, under the trade name CopiOs. RTI says the CopiOs will address the needs of oral surgeons, periodontists and dentists in conjunction with bone grafting and implant procedures.

Contact: Web site – www.rtibio.com

Business Briefs

Contact: Thoratec Corporation – 1-800-528-2577; Web site: www.thoratec.com

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The Berlin Heart Excor Pediatric is a mechanical support system for critically ill pediatric patients suffering from severe heart failure. The company says that unlike standard heart-lung machines, their system has been used as a short-term, mid-term, and long-term support system, supporting failing hearts from days up to several months.

The system is designed to bridge patients awaiting heart transplantation until a donor heart becomes available, but it has also been used successfully as a bridge to recovery when a patient’s heart was able to recover and work on its own again. The company also says unlike other VADs, the Excor Pediatric can be used to support children of all age groups, from newborns up to teenagers.

The following US centers are participating in the IDE study: Arkansas Children’s Hospital; Boston Children’s Hospital; Children’s Hospital of Wisconsin; Lucille Packard Children’s Hospital at Stanford; Mott Children’s Hospital; Riley Children’s Hospital; Seattle Children’s Hospital; St. Louis Children’s Hospital; Texas Children’s Hospital; Children’s Hospital at the University of Alabama at Birmingham; and the Children’s Hospital at the University of Minnesota at Fairview.

Contact: Web site – www.berlinheart.com

RTI Biologics launches bovine pericardium membrane implant for dental applications

RTI Biologics, Inc., Alachua, FL, announced the company’s bovine pericardium membrane has been introduced into the world dental market through its distributor, Zimmer Dental, under the trade name CopiOs. RTI says the CopiOs will address the needs of oral surgeons, periodontists and dentists in conjunction with bone grafting and implant procedures.

Contact: Web site – www.rtibio.com
In the October Transplant eNews

The following are summaries of news transmitted to Transplant eNews subscribers in the October e-News issues. The date of the issue is indicated in parentheses following each item. Weekly e-mail and monthly print issues of Transplant eNews are archived at www.transnews.com. Please call 800-689-4262 or e-mail Trannews@Transnews.com if you require a password to access Transplant eNews subscriber-only Web site or are not receiving weekly e-mail issues of the newsletter.

Mastromarino Gets 25-58 Prison Years for BTS Scandal Three men who conspired to plunder corpses and sell the sometimes diseased body parts were sentenced to prison Oct. 22 in Philadelphia for what victims said was a gruesome, greedy scheme that violated basic principles of trust and human decency, the Associated Press reported. A federal judge ruled against some of the patients who sued after receiving some of the body parts, saying they had failed to establish grounds to sue. The mastermind of the scheme, Michael Mastromarino, prior owner of Biomedical Tissue Services of Fort Lee, N.J., was sentenced to 25 to 58 years in prison. Mastromarino previously was sentenced to 18 to 54 years for running the scam in New York. His two sentences will run concurrently. The parts were sold and used in about 10,000 surgical procedures performed by unsuspecting doctors in the U.S. and Canada. Litigation was assigned to U.S. District Court in Newark, N.J. Link: http://www.washingtonpost.com/wp-dyn/content/article/2008/10/22/AR2008102202623.html. (10/29/08)

Britain Votes to Allow Animal-Human Embryos for Research

Plans to allow scientists to use hybrid animal-human embryos for stem cell research won final approval from British lawmakers last week. The House of Commons also clarified laws that allow the screening of embryos to produce babies with suitable bone marrow or other material for transplant to sick siblings, the Associated Press reported. Legislators voted 355 to 129 to authorize the proposals after months of sometimes bitter debate that pitted Prime Minister Gordon Brown’s government and scientists against religious leaders, anti-abortion campaigners and others anxious about medical advances. Decisions by Britain’s Human Fertilization and Embryology Authority, an independent body which regulates fertility and embryo research in the U.K., to allow the practice have previously been vulnerable to challenges in court. The process involves injecting an empty cow or rabbit egg with human DNA. A burst of electricity is then used to trick the egg into dividing regularly, so that it becomes a very early embryo, from which stem cells can hopefully be extracted. Link: http://www.washingtonpost.com/wdynccontent/article/2008/10/22/AR2008102202195.html. (10/29/08)

Study Outlines Dangers of Transplant Tourism

Having surgery abroad can be a risky proposition for so-called “transplant tourists” from the United States who go overseas to get kidneys, according to new research from the University of California-Los Angeles. Those who leave the country for kidney transplants experience more severe postoperative complications, more serious infections, and a higher incidence of acute rejection than patients treated domestically, WebMD.com reported. It’s estimated that hundreds of U.S. residents go abroad annually for such operations, Jagbir Gill, M.D., lead author of the study and a kidney specialist at the University of British Columbia, told WebMD. He was at UCLA when the research was conducted. Dr. Gill and colleagues compared the conditions of 33 transplant tourists to 66 similar patients who underwent transplantation and follow-up care at UCLA. A year after their operations, kidney rejection occurred in 30% of those who went abroad, compared with 12% of patients operated on at UCLA. Link: http://www.webmd.com/news/20081016/transplant-surgery-abroad-rife-with-risks. (10/22/08)

Australian Scientists Develop Better Tissue-typing Technology

Scientists at the University of New South Wales in Australia have developed a new tissue-typing technology that is faster, cheaper and more accurate than current technology. The new technology could help save lives by broadening the base of available tissue and organ donors, and boosting the speed and accuracy of essential tissue-matching required, thereby avoiding the complications that come with organ rejection. UNSW’s commercialization division, NewSouth Innovations (NSI), has a provisional patent for the technology. If it becomes the new standard it could save lives and reduce suffering for thousands of Australians, UNSW scientist Matthew Clemson, the technology’s co-inventor, said in a prepared statement. “Its speed, accuracy and cost advantages would bring more companies into the tissue-matching market and broaden the base of stem cell and organ donors who could be matched to potential recipients,” Clemson said. If that happens, tissue-typing could become a routine test done whenever an individual donates blood or has a blood sample taken by a health professional. The cost
Artificial Pancreas Just Years Away
Researchers working on an artificial pancreas believe they are just a few years away from a nearly carefree way for people with diabetes to monitor blood and inject insulin as needed. They believe they can link two current technologies — continuous glucose monitoring and insulin pumps — into a seamless package, Reuters reported. “I think we are on the brink of a first-generation artificial pancreas,” said Dr. Roman Hovorka of Britain’s University of Cambridge, who is testing some experimental devices with components by Abbott Laboratories and Medtronic, the No. 1 maker of insulin pumps and continuous monitors. Hovorka’s team has been testing devices in patients with Type 1 diabetes. A continuous glucose sensor is implanted under the skin, and transmits blood sugar readings to a monitor. A computer calculates the right dose of insulin, which is delivered by an insulin pump. Dr. Hovorka’s team is ready to send devices in patients with Type 1 diabetes. A continuous glucose sensor is implanted under the skin, and transmits blood sugar readings to a monitor. A computer calculates the right dose of insulin, which is delivered by an insulin pump. Dr. Hovorka’s team is ready to send

German Man Doing Well After Double Arm Transplant
A German farmer who received the world’s first complete double arm transplant in July said last week at a press conference that incredulity gave way to joy when he woke from surgery to discover he had arms again, the Associated Press reported. Karl Merk, 54, who lost his arms in a farming accident six years ago, said he at first could not believe that the transplant appeared to have been successful: “It was really overwhelming when I saw that I had arms again.” “These are my arms, and I’m not giving them away again,” he told reporters at the Munich University Clinic where he remains nearly three months after the 15-hour operation. Merk is recovering well and can perform simple tasks such as opening doors and turning lights on and off. Doctors said there were good indications of nerve growth in the arms but it could take up to two years before he relearns how to use his hands. Link: http://www.washingtonpost.com/wp-dyn/content/article/2008/10/08/AR2008100801084.html (10/15/08)

Heart Pump Helps Children Awaiting Transplants
A small clinical trial has found that a miniature heart pump already in use in Europe helped U.S. youngsters waiting for heart transplants, HealthDay News reported. The pump, called the Berlin Heart Excor, helps provide children a bridge to transplantation. Results of the study, from St. Louis Children’s Hospital in Missouri, were published in the current Cardiovascular Surgery Supplement of the journal Circulation. Currently, if children awaiting transplant get into trouble, surgeons will place them on the extracorporeal membrane oxygenation (ECMO) machine. The problem with this device, however, is that children have to remain immobile, which furthers physical deterioration. And, the device carries significant risks of complications. The small, biventricular assist device tested in the trial allowed children to be mobile, and even leave the hospital. The research included nine children between the ages of 12 days to 17 years, with an average age of 1.7 years. Most of the children weighed less than 80 pounds. All of the children were placed on the Berlin Heart Excor between April 2005 and July 2007. Link: http://www.washingtonpost.com/wp-dyn/content/article/2008/09/29/AR2008092901859.html (10/01/08)

Some Other Articles in the October eNews
• Washington Supreme Court allows brain procurement lawsuit (10/01/08)
• Older kidneys may have structural dysfunctions – study (10/01/08)
• Scientists find new way to make stem cells (10/01/08)
• Irish government to draft bill on regulation of organ removal (10/01/08)
• HRSA, NMDP launch related donor cord blood program (10/08/08)
• Australian man sells dead body online (10/08/08)
• Brain rewires after hand transplant (10/15/08)
• Gene mutation leads to transplant rejection in children (10/15/08)
• Freezing technique could extend lifespan of donor livers (10/15/08)
• Testes could be source of stem cells (10/15/08)
• Therapy helps “sensitized” kidney patients get transplanted (10/22/08)
• United Nations to reconsider ban on human cloning (10/22/08)
• Kidney donation Web sites raise ethical concerns (10/22/08)
• Cell printing paves the way to artificial organs (10/22/08)
• President Bush unveils new artificial heart (10/29/08)
• French doctor unveils new artificial heart (10/29/08)
• Study: Steroids could be eliminated after transplantation (10/29/08)