Gryphes Technology: A Discussion with Randal Miller, CTO, Gryphes Inc.

Every day, 18 people die while waiting for a transplant of a vital organ. More than 85,000 U.S. patients are currently on the waiting lists for a donor kidney and 4,000 new patients are added to this list every month. The demand for paired donor kidney exchange is a growing entity which provides lifesaving donor organs for families with loved ones with end stage renal disease. Once a compatible donor is located, logistics, accountability and FDA temperature compliance are key issues in maintaining organ integrity during transport.

Gryphes is a secure, continuously monitored transport solution for moving controlled medical support products outside a controlled environment anywhere in the world. The accountability and integrity of the controlled medical support products are proven by recording the payload temperature and location in real time while broadcasting and making that data accessible to all responsible parties. By providing this data, decision-making will be enhanced, delays or losses of critical payloads prevented and positive patient outcomes improved.

Jim Warren: I think it is fair to say a majority of my subscribers do not know about Gryphes technology and how it works.

Randal Miller, Chief Technology Officer at Gryphes Inc: The technology was developed more than 10 years ago and evolved from input and testing by blood and tissue bankers. The current patent pending version is the third generation. Gryphes technology solutions are in use on over 100 medical facilities including hospitals, medical center and medical helicopter services. Gryphes is a real time location and temperature monitoring transport solution for maintaining accountability along with steady, stable temperatures compliance between 2 and 6 degrees Centigrade for 48+ hours without wet ice or gel packs with customizable text message reporting which provides a virtual chain of custody for critical payloads such as donor organs.

Warren: Is it true Gryphes technology supports global transport of donor kidneys and significantly increases the odds of finding donor matches for patients suffering from ESRD?

Miller: Yes, because time and temperature are the leading factors leading to degradation and loss of integrity for donor organs during their transportation. The greater the distances between donors compromises the playing field for paired donor matching. With documented temperature compliance and total accountability, the integrity of the donor organ is maintained for up to 48 hours.

Warren: How long has the technology been available?

Miller: More than 7 years and has been in development for more than a decade. It is currently in use in over 100 medical facilities for donor distribution and medical helicopter services.

“...The technology was developed more than 10 years ago and evolved from input and testing by blood and tissue bankers. Gryphes is a secure, continuously monitored solution for moving controlled medical support products outside a controlled environment anywhere in the world.”

Randal Miller, Gryphes Chief Technology Officer

(Continued on page 2)
Miller Interview (continued from page 1)

**Warren:** What is needed to increase awareness of the Gryphes technology?

**Miller:** What we really need is exposure of this technology to both those giving and receiving a donor organ to make them aware of the extensive benefits to accountability and integrity and to transportation companies that currently transport donor organs.

**Warren:** Does Gryphes technology justify its cost?

**Miller:** Absolutely! Because the cost of a compromised compatibly donor organ transported to a patient in need due to loss, delay or temperature issues is priceless.

**Warren:** When was the first time Gryphes technology was used for a real donor kidney transplant?

**Miller:** In May 2008 Johns Hopkins Medical Center in Baltimore, MD in a successful paired kidney donor event with the California Pacific Medical Center in San Francisco, CA (3,000 miles apart). It was a first and was stated as a "hat trick" after the transplanted donor kidney produced urine. The event was documented on "Hopkins," a TV documentary type prime time network show in July 2008.

**Warren:** What was the reasoning for its use and outcome?

**Miller:** A need existed for transcontinental transport of a live donor kidney with real time security, accountability and integrity with temperature compliance. A donor kidney was successfully transported and saved a woman's life from a successful paired kidney exchange event 3,000 miles away.

**Warren:** Has Gryphes proven technology been used in other areas?

**Miller:** Yes. Gryphes technology is in use to maintain FDA storage compliance of cross-matched blood for supporting surgeries in many major hospitals across the US and it is on-board on several medical helicopter units saving lives.

**Warren:** Is Gryphes technology used routinely for donor organ transport?

**Miller:** No it is not because it is not widely known to people who may need to transport a compatible life-saving donor organ over great distances or acquiring a match from donors living far away.

**Warren:** What is needed to increase awareness of Gryphes?

**Miller:** Exposure is needed to those both giving and receiving a donor organ to make them aware of extensive benefits to accountability and integrity as well as transportation companies that currently transport donor organs for compliance and integrity. Gryphes increases the global playing field for paired kidney donor programs increasing the organ donor pool so it needs to be promoted in donor programs, journals and clinical newsletters.

**Warren:** How can readers find more information about Gryphes technology?

**Miller:** Visit the web site at http://gryphes.net or e-mail gryphesus@gmail.com

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**CMS says transplant immunosuppressant drugs will remain a benefit of Medicare Part D**

The US Centers for Medicare and Medicaid Services (CMS) has announced that it will retain the existing "protected class" status of immunosuppressant medications available as a benefit under Medicare Part D coverage. The action will allow transplant recipients covered by Medicare to continue to receive these medications without having to pay substantially more for them or possibly forego taking them because of an inability to afford them.

Virtually all transplant recipients take daily medication to prevent organ rejection by suppresing the body's immune system response to cells from the transplanted organ.

CMS issued a proposed rule in January 2014, which included provisions to possibly remove the protected class status of certain groups of medications as part of a broader review of Medicare prescription coverage. The United Network for Organ Sharing (UNOS), along with a number of other transplant professional and patient advocate organizations, responded to the proposed rule and asked CMS to keep the current status of these medications for the continued health and survival of transplant recipi-

(Continued on page 4)
UNOS board of directors actions in June

In yet another example of transplantation justifying its claim to be the "space program of medicine," the first national policies and standards for the transplantation of limbs, faces and other structures collectively known as vascularized composite allografts (VCAs) were unanimously approved by the OPTN/UNOS Board of Directors at its meeting June 23 and 24th in Richmond, VA.

VCAs involve the transplantation of multiple structures that may include skin, bone, muscles, blood vessels, nerves and connective tissue. The requirements will be in effect for 15 months, allowing the transplant network during that time to seek public comment regarding potential improvements.

"These policies establish the framework for further development of this groundbreaking therapy, which returns vital function and identify to people who have a devastating injury or illness," Kenneth Andreoni, MD, president of the OPTN/UNOS, said in a press release. "We want to make this treatment more widely available while recognizing the unique medical and ethical issues involved."

The items approved by the Board, to be effective beginning July 3, include: *criteria for defining VCAs to be covered in OPTN policy; *OPTN membership requirements for VCA transplant programs; *initial policies for VCA allocation; and *guidance for gaining specific consent for the donation of VCAs.

In addition to seeking public comment on the initial requirements, the OPTN/UNOS Vascularized Composite Allograft Transplantation Committee will continue the development of other aspects of VCA policy, data requirements and data collection procedures for VCAs.

Other Board Actions

In a separate action, the Board approved amendments to heart allocation for pediatric candidates (those listed for a transplant before their 18th birthday), with the goals of reducing waitlist deaths and providing better access to available organ offers.

The revised pediatric heart policy includes a re-definition of medical criteria for the two highest urgency statuses (Status 1A and 1B) to lessen the effect of waiting time among candidates in these status groups. Infants with high medical urgency will also have greater access to hearts from donors of incompatible blood types. These hearts can be transplanted safely for some infant candidates because their immune system has not developed enough to reject such organs. In addition, to better reflect current clinical practice, the policy eliminates a rarely used provision that allowed candidates to be listed for a transplant shortly before birth.

In other developments included:

- the Board adopted a recommendation to the Health Resources and Services Administration (HRSA) that the OPTN/UNOS Kidney Paired Donation Pilot Program should become a permanent function of the OPTN, thus ending the pilot phase of its development. Since the program became operational in December 2010, it has coordinated 97 kidney transplants at 45 hospitals across the US.

- the Board approved minimum requirements for living liver donor transplant programs to report post-operative outcome data on those donors at intervals up to two years from the donation. Similar to standards enacted previously for reporting data on living kidney donors, living donor transplant programs must report accurate, complete and timely donor status information for at least 80 percent of donors who donate on or after September 1, 2014. They must also report accurate, complete and timely laboratory data on living donors for at least 70 percent of donors one year from donation.

- finally, the Board approved on a permanent basis a policy change allowing transplant programs to request additional, exceptional priority for adolescent or adult donor lung offers for transplant candidates age 11 or younger. The action followed additional review of a temporary exception adopted in 2013.

Transplant Games to Cleveland in 2016

Cleveland, OH, has been awarded to host the Donate Life Transplant Games scheduled to be held in July 2016. Under the auspices of the Transplant Games, the 2016 event will be managed by the Greater Cleveland Sports Commission. Donate Life said two dates are under consideration and a final decision will be made later.

Since 2000, the Sports Commission responsible for attracting more than 150 sporting events in Cleveland, which contributed more than $400 million in economic activity, Transplant Games of America said in a press release.

Lifebanc, Northeast Ohio’s Organ Procurement Organization, University Hospital Systems, and the Cleveland Clinic will partner with the Greater Cleveland Sports Commission.
World Transplant Congress to be held in July in San Francisco

The 2014 World Transplant Congress (WTC) is being held July 26-31 at the Moscone West Convention Center in San Francisco, CA. The pre-meeting symposia featuring a variety of courses for clinicians, scientists, and allied health professionals will be held on Saturday, July 26 and Sunday, July 27 and focus on current topics of major interest in the science and clinical practice of transplantation.

The event is the joint meeting of the American Society of Transplant Surgeons (ASTS), The Transplantation Society (TTS), and the American Society of Transplantation (AST). Congress planners expect the number of attendees will be between 7,000 and 8,000 with 55-60% traveling from around the world.

Some of the featured programs at the WTC will feature:

- More than 700 invited speakers and moderators, including Stae-of-the-Art speakers Eric Schadt, MD, Chair and Professor of the Department of Genetic and Genomic Sciences and Director of the Genomics and Multiscale Biology at Mount Sinai Medical School, and Nobel Laureates Alvin Roth, PhD, and Shinya Yamanaka, MD, PhD.
- Specific tracks designed to cater to professionals focused on basic science, pediatric transplantation, immunology, tissue injury/preservation, xenotransplantation, pathology, nephrology, organ donation, infectious diseases, heart transplantation, immunosuppression, liver transplantation, and allied health.
- Nearly 3,500 abstracts, 100 concurrent oral sessions, and 2,000 poster presentations, all delivered in a way that will encourage the exchange of new clinical and scientific information and support an interchange of opinions regarding care management as well as socioeconomic, ethical and regulatory issues relevant to organ and tissue transplantation.

"The 2014 World Transplant Congress offers professionals in the field the opportunity to discover and exchange new scientific and clinical information relevant to solid organ and tissue transplantation with world-renowned speakers," said Kathryn Wood, D.Phil., Congress Chair. "The meeting gives attendees an opportunity like no other -- to network and collaborate with peers and identify future opportunities in the transplant field.'

"This year's congress is only the second time that these three associations have come together to host an event of this magnitude," Wood pointed out. "The first World Transplant Congress was held in Boston in 2006 and we're looking forward to building upon the success of that event."

Additional program information can be found at www.wtc214.org.

Medicare Part D (Continued from page 2)

Under the statute, one of the three criteria that are used to target beneficiaries for MTM services is whether a Part D beneficiary has multiple chronic diseases such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. CMS previously interpreted this language to allow sponsors to define "multiple chronic diseases" with three chronic diseases being the maximum number a plan sponsor may require for targeted enrollment.

Further, sponsors are allowed to target beneficiaries with select chronic diseases, but must include at least five of the nine core chronic diseases in their criteria.

This list of core chronic diseases, as updated in the 2013 Call Letter (available at http://www.cms.gov/Medicare/HealthPlans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf) includes hypertension, congestive heart failure, diabetes, dyslipidemia, respiratory disease, bone disease--arthritis, mental health, Alzheimer's disease, and end stage renal disease.

"We proposed to revise our interpretation of 'multiple chronic diseases' to require that at least one of the chronic diseases that a beneficiary has in order to satisfy the eligibility criteria must be one of the list of core chronic diseases. In addition, we proposed to redefine the core diseases by combining hypertension and congestive heart failure under the umbrella of 'cardiovascular disease,' which would also encompass congestive heart failure, acute myocardial infarction, cerebral hemorrhage and effects of stroke, vascular disease, specified heart arrhythmias, and hypertensive heart disease. The proposed list of core chronic diseases became cardiovascular disease, diabetes, dyslipidemia, respiratory disease, bone disease--arthritis, mental health, Alzheimer's disease, and end stage renal disease.
Thoratec announces the first HeartMate III and beginning of its CE Mark Clinical Trial

Thoratec Corporation, Pleasanton, CA, announced in late June that its CE Mark Clinical Trial for HeartMate III commenced with its first patient implanted with its new device. HeartMate III is a centrifugal-flow chronic left ventricular assist system. The company said the fully magnetically levitated technology foundation of HeartMate III is designed to lower adverse event rates through improved hemocompatibility while enhancing ease of surgical placement through a compact size.

The Hannover Medical School in Hannover, Germany performed the first human implant of HeartMate III under the direction of surgeon Jan Schmitto, MD, PhD, and Professor Axel Haverich, MD, chief of the Cardiothoracic, Transplantation and Vascular Surgery Department of the Hannover Medical School. "I am enthusiastic about the potential for HeartMate III based on its elegant implant technique and the promise of improved clinical outcomes," Dr. Schmitto commented. The implant marked the first patient enrolled in the HeartMate III CE Mark Clinical Trial, which will enroll up to 50 patients at nine sites in Europe, Australia, and Canada. The study includes a primary endpoint of six-month survival compared with estimated mortality based on the Seattle Heart Failure Model.

In addition to the first implant performed by Dr. Schmitto in Hannover, enrollment of the HeartMate III CE Mark Trial has also commenced at the Vienna Medical University of Vienna, Austria with an implant under the direction of Daniel Zimpfer, MD, Director of Mechanical Circulatory Support and Professor Gunther Laufer, MD, Head of the Department of Cardiac Surgery.

Thoratec's products include the HeartMate II and HeartMate III LVAS (Left Ventricular Assist Systems) and Thoratec VAD (Ventricular Assist Device) with more than 20,000 devices implanted in patients suffering from heart failure. Thoratec also manufactures and distributes the CentriMag and PediMag, PediVAS product lines.

For more information contact Neil Meyer, Director of Investor Relations, Thoratec Corporation - (925) 738-0029 or visit the company's web site at http://www.thoratec.com

Veloxis says Envarsus XR outperforms Prograf's tacrolimus in treating adult kidney rejection in African Americans

Veloxis Pharmaceuticals, A/S, Horsholm, Denmark, announced that one-daily Envarsus XR (tacrolimus extended-release tablets), an investigational new drug under review by the US Food and Drug Administration (FDA) for the review for the prevention of organ rejection in adult kidney transplant patients, demonstrated a lower treatment failure rate in African-Americans compared with twice-daily tacrolimus (Prograf).

The company said:

* Envarsus XR is an extended release formulation of tacrolimus being designed for once-daily dosing, flatter pharmacokinetics and greater bioavailability compared to twice-daily Prograf. Data from two Phase III trials were pooled (Envarsus XR n=428; Prograf n=433) and several pre-specified subgroup analyses were conducted;

* African-American subgroup demonstrated significantly less efficacy failure in favor of Envarsus XR (-13.82%, CI= -27.22%, -0.31%)

* A second subgroup, older patients greater than 65 years of age demonstrated a similar significant result. Other pre-specified subgroups trended toward improved in efficacy with Envarsus XR.

For investor and media contact: John Weinberg, MD or Johnny Stilou, EVP & COO EVP & CFO - Phone: 1 908-304-3389 or + 45 21 227 227

For further information, visit Veloxis Web site: www.veloxis.com

Ampersand sells ViraCor-IBT to Eurofins for $255 million

Ampersand Capital Partners, Wellesley, MA, announced it has completed the sale of majority owned portfolio company ViraCor-IBT Laboratories (ViraCor) to Eurofins Scientific for $255 million. VIBT is a premier specialty testing laboratory providing complex, high-value diagnostic tests to 550 institutional clients and more than 4,000 affiliated clinicians across the US with an emphasis on the transplant market. The company says it will continue to be known as ViraCor-IBT, operating from its large, state-of-the-art facility in the Kansas City area and its satellite laboratory in California.

Ampersand created VIBT in 2009 through a merger of two independent laboratories in the Kansas City area. In addition to specialty testing, the company provides industry-leading turn-around times for its most time-sensitive tests, which assists physicians in making quicker treatment decisions of critically-ill patients, particularly transplant patients.

For further information, contact Herb Cooper, at
**58 Senators urge President Bush to change stem cell research policy**

Pressure on President Bush to change his current stance on stem cell research increased significantly this past week when a majority of the US Senate, including 14 Republicans, sent him a letter urging him to loosen current restrictions on federal funding.

The letter was signed by 58 Senators including the presumed Democratic candidate for president John Kerry (D-MA), John McCain (R-AZ), Trent Lott (R-MS), and John Warner (R-VA). The organizers of the letter included Senators Dianne Feinstein (D-CA), Tom Harkin (D-IA), Orrin Hatch (R-UT), Edward Kennedy (D-MA), and Arlen Spector (R-PA).

Ironically, the death of former president Ronald Reagan, who banned research on fetal tissue and was a strong opponent of abortion, may invigorate the debate even further. Nancy Reagan has been an outspoken supporter of embryonic stem cell research and just last month made an impassioned plea to President Bush to take the funding of stem cell research out of the political arena.

"Ronnie's long journey has finally taken him to a distant place where I can no longer reach him," Mrs. Reagan said on May 9th. "Because of this, I'm determined to do whatever I can to save other families from this pain. I just don't see how we can turn our backs on this."

The letter from 58 Senators was sent to the president a day before Reagan died and made no mention on the former president.

"This issue is especially poignant given President Reagan's passing," said Senator Feinstein. "Embryonic stem cell research might hold the key to a cure for Alzheimer’s and other terrible diseases. This is why we must do everything in our power to support this research and give hope to millions of Americans who suffer today."

Senator Hatch, a staunch conservative and leading sponsor of legislation to federal fund embryonic stem cell research, said "we should not close the door on a form of scientific research--nuclear transplantation--that has the potential of curing millions of debilitating and life-threatening diseases."

"As a right-to-life Senator, I believe that a critical part of pro-life, pro-family philosophy is helping the living," Hatch concluded.

The Senators' request is similar to one issued by a bi-partisan group of 206 House members last month asking the president to expand stem cell research.

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**HHS: Organ Procurement-Tissue Recovery fight may affect supply of organs, tissue**

Tensions exist between organ procurement and tissue recovery if intensified could have "adverse consequence for the supply of organs and tissues," according to the findings of a national survey conducted by the US Department of Health and Human Services Office of the Inspector General (OIG).

The dire assessment is one of a variety of findings and recommendations contained in the OIG study - "Organ Procurement Organs and Tissue Recovery - released early this month.

The purpose of the study was to "describe and assess the role of organ procurement organizations in procuring tissue for transplantation, and to identify vulnerabilities associated with that involvement."

The reason for the tensions, according to the OIG was "inherent differences between organ procurement and issue recovery (in urgency, prestige, and organization) can limit OPOs and tissue banks' willingness to work together."

Among the differences outlined in the report include:

- the higher prestige often afforded organ procurement over tissue recovery; organs viewed as life saving while tissues are merely life enhancing;
- renowned transplant surgeons operate at prestigious hospitals while tissue transplants are part of routine surgery practiced at community hospitals;
- competition for donors among multiple tissue banks could threaten hospitals' eagerness to work with OPOs and tissue banks;
- OPOs generally operate in specifically defined areas while tissue banks are free to roam - about half of the OPOs reported that more than one tissue bank operates in their area.

"Where multiple banks operate, the competition for donors can become intense," the report notes. "The fear from the OPO perspective, is that competition among multiple tissue banks can damage the OPO's relationships with hospitals, which many OPO staff believe are already tenuous."

The OIG found that 34 OPOs refer potential donors to tissue banks while 28 OPOs recover tissue themselves. The report breaks down OPO participation into three performance categories: "Organ donors referred to tissue banks - Assessing the degree to which an OPO actually refers its organ donors for tissue donation found: "Three of the 34 OPOs reported that they referred all of their organ donors for tissue recovery. at the other extreme, two OPOs reported that they referred fewer than 20% of organ donors for tissue donation."
In Memoriam

Karl Nolph, MD, a pioneer in the field of dialysis and a longtime leader of the University of Missouri School of Medicine's Division of Nephrology, passed away on June 18 at his home in Columbia, MA. He was 77. Throughout is nearly 45 years of service to the University of Missouri Health System, Nolph held many roles, including serving as director of the Division of Nephrology from 1974 to 1999. He was the recipient of the Loren E. Broaddus Distinguished Professorship in 1984 and the University of Missouri Board of Curators' Professorship in 1988. To hear Dr. Nolph and his historical recollections in dialysis go to: http://voiceexpeditions.com

Barbara Lee Receives UNOS Award

Barbara Lee, of Greenville, NC, has been named the 2014 recipient of the National Donor Memorial Award for Excellence presented annually by the United Network for Organ Sharing. Lee was nominated in recognition of her work as a donation champion for more than two decades. UNOS established the award in 2010 to recognize exceptional advocates for organ and tissue donation. UNOS solicits nominations for the award from the 58 organ procurement organizations in the US. Lee was nominated for the award by Carolina Donor Services. The effort that had the most far-reaching impact was the result being awarded a $100,000 grant in 2012 from the North Carolina "License to Give" Trust Fund Commission. After the award, Lee assembled a team of 12 donation advocates and created a nonprofit organization called the Eastern North Carolina Donor Impact Project (ENCDIP). ENCDIP's purpose is dispel myths and educate the African American and Latino communities about the need for minority donors, and since its creation has been highly visible at local festivals, health fairs and churches, schools and colleges.

Marty Golden Named Astellas VP


AATB Announces Rose Bowl Participants

The American Association of Tissue Banks has announced the tissue recipients who will ride on the Donate Life Float in the January 1, 2015 Rose Parade. The float rider is Adam Teller was nominated and the floragraph honoree is Andy Hendel. Both riders were nominated by OneLegacy in Los Angeles, CA. The theme of the 2015 Rose Parade is "Inspiring Stories."

Business Briefs (Continued from page 5)

Ampersand Capital Partners, Phone: (781) 239-0700.

Cell Source announces acquisition and $3.6 million private placement to Advance Novel Cancer Therapies

Cell Source, Inc., Tel Aviv, Israel and New York, announced the successful acquisition through a share exchange agreement, of all the outstanding shares of Cell Source, Inc. a pre-clinical cell therapy company with a focus on the facilitation of safer more accessible bone marrow and organ transplants and effective treatment of blood cell cancers (e.g., leukemia, lymphoma).

Cell Source said it is planning to commence a Phase I/II clinical trial with a cell therapy treatment that aspires to significantly reduce the need for immune suppression treatment for both donor-matched and "mismatched" bone marrow transplant patients. The treatment could potentially lead to a substantial increase in patient survival rate, Cell Source said in a press release.

Contact: Cell Source Web site: http://www.cellsource.com