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Deals roundup

Medtronic's $370M ATS buy is 2nd largest deal of 2010

By LYNN YOFFEE
***Medical Device Daily* Staff Writer**

Less than three months after **Medtronic**'s (Minneapolis) $500 million acquisition of **Invatec** (Roncadelle, Italy), the powerhouse firm continues its growth spurt via another big-ticket purchase. This time it's the cardiac surgery device maker and Minneapolis neighbor **ATS Medical** for $370 million, making it the second largest med-tech deal of 2010.

It's the fourth transaction for Medtronic in the last 18 months. Scott Ward, senior vice president of Medtronic, told *Medical Device Daily* that, "These four transaction comprise a deliberate strategy to increase the strength of our products." Last year Medtronic acquired **Ventor Technologies** (Netanya, Israel), a developer of percutaneous, catheter-based transapical aortic valve replacement products, for

See Deals, Page 5

New egg 'flash freezing' beats earlier techniques

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Advances in oocyte cryopreservation, or egg freezing, is making it possible for a healthy woman to put her biological clock on hold until years later when she is ready to conceive.

The procedure also gives women at risk of losing their fertility due to medical circumstances the chance to circumvent sterility brought on by cancer treatment or other medical maladies that damage childbearing potential. But until recently, fertility doctors had not had much luck with egg cryopreservation because older methods of "slow freezing" yielded unpredictable results and lower pregnancy rates.

The new, more successful egg freezing technique, known as vitrification, is a flash freezing technique

See Cryopreservation, Page 6

Washington roundup

Supreme Court may hear Pfizer appeal on Nigerian Trovan suit

A *Medical Device Daily* Staff Report

The increasing use of clinical trials in other nations has introduced a lot of interesting dilemmas to drug and device makers, including the lawsuit against drugmaker **Pfizer** (New York) by a group in the African nation of Nigeria over a trial conducted there for an antibiotic in 1996. According to an April 27 white paper by the law firm of **Hogan & Hartson** (H&H; Washington), Pfizer has appealed to the U.S. Supreme Court for a writ of *certiorari* to hear the case of *Abdullahi v. Pfizer*, the outcome of which the authors of the paper assert could signal a "changing landscape" for legal liability of drug and device makers who conduct clinical trials in other nations, "especially in resource-poor countries."

The *Abdullahi* case turns in part on the fact that Pfizer

See Washington, Page 7

BSX launches new resource to help treat pelvic injuries

By OMAR FORD
***Medical Device Daily* Staff Writer**

A new resource is set to give physicians and surgeons new insight on how to treat women who suffer from a damaged pelvis, a condition that sometimes occurs when the muscles of the pelvic floor are injured or become weak and one or more of the pelvic or abdominal organs begin to drop (prolapse) below their normal positions.

Boston Scientific (Natick Massachusetts) reported launching the Pelvic Floor Institute – an online guide that gives instruction and tips on how physicians and surgeons can treat the condition.

"We've had a tremendous amount of interest in the [institute]," Abby Fischer, a market development manager for Boston Scientific, told *Medical Device Daily*. "So far we've

See BSX, Page 8

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Report from Europe

Zoll establishes a LifeVest direct sales force in Germany

A *Medical Device Daily* Staff Report

Zoll Medical (Chelmsford, Massachusetts) reported that it has established a direct sales force in Germany, as of April 1, dedicated to the LifeVest wearable defibrillator business in that country.

Germany represents the most significant market opportunity in Europe for the LifeVest based on both size and overall healthcare policy. The reimbursement system in Germany is comprised of a mix of payers and is similar to the system in the U.S. The LifeVest is currently fully reimbursed for most patients in Germany.

The LifeVest was first used in Germany as part of the nearly 300 patient multi-center WEARIT/BIROAD trial that proved the efficacy of this therapy for patients at risk of sudden cardiac arrest. Since that time, the LifeVest has experienced significant growth. The LifeVest currently generates revenue in excess of $2 million annually in Germany.

"The United States has experienced rapid growth over the last four years, exceeding a 55 percent compounded annual growth rate," said Richard Packer, chairman/CEO of Zoll. "In fiscal 2009, we generated almost $45 million in LifeVest revenue in the U.S. By the end of the year, we had approximately 2,500 patients wearing the device at a time. Given the similarities between the United States and the German markets, we are confident that the lessons learned in the United States will enable rapid growth of the German LifeVest business."

"We believe the long-term annual U.S. market for the LifeVest approximates $2 billion. Although currently in its infancy, we see no reason the long-term international opportunity should not be at least as big," Packer added.

"As the LifeVest business matures, we will become more aggressive with our international efforts," Packer continued. "In addition to our German initiative, the LifeVest is also marketed in Europe via distribution partners located in the UK, Italy, France, and The Netherlands. Furthermore, we have begun work on the multi-year effort to gain LifeVest approval in Japan."

Zoll also operates direct sales operations for conventional defibrillators, AEDs, and mechanical CPR devices in Germany.

The LifeVest is worn by patients at risk for sudden cardiac arrest, providing protection during their changing condition and while permanent SCA risk has not been established. The LifeVest allows patients' physicians time to assess their long-term arrhythmic risk and make appropriate plans. It is used for a wide range of patient conditions or situations, including following a heart attack, before or after bypass surgery or stent placement, as well as for those with cardiomyopathy or congestive heart failure that places them at particular risk. ■

Today's MDD food for med-tech thought

"I would say in another year or two [the technique will be producing higher pregnancy rates], it's not that far away."

— Nina Desai, PhD, of the Women's Health Institute at the Cleveland Clinic, on the rising utility of a new egg freezing technique known as vitrification, a flash freezing technique which protects eggs from injury during the freezing and subsequent thawing process, "New egg 'flash freezing' beats earlier techniques," pp. 1, 6.

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Agreements/contracts

Philips, Orion Health partner to deliver on interoperability

A *Medical Device Daily* Staff Report

Royal Philips Electronics (Amsterdam, the Netherlands) reported an agreement with **Orion Health** (Andover, Massachusetts), a provider of integration solutions in healthcare, to deploy the Orion Health Rhapsody Integration Engine across Philips' portfolio of healthcare informatics solutions.

Healthcare requirements around meaningful use demand a strong focus on enterprise interoperability, with a detailed understanding of standards, privacy, security and scalability. Currently, integrating systems across the healthcare enterprise is a daunting task for healthcare organizations. By partnering with Orion Health and automating the delivery of clinical data in a standardized, secure and efficient manner, Philips is pursuing its goals of healthcare transformation and interoperability.

The Orion Health Rhapsody Integration Engine enables high-performance, standards-based healthcare integration. This technology provides Philips with the interoperability required in today's complex healthcare environments, making it a perfect choice for Philips' diverse product portfolio, the company said. Standardizing on the Rhapsody platform will allow Philips to deploy technology faster and pass cost savings and benefits on to the customer.

Paul Viskovich, president of Orion Health North America, said he anticipates this new partnership will help health providers of all sizes take advantage of technology to streamline patient data. "Making data from Philips' solutions more accessible to physicians can improve patient outcomes by presenting a more complete clinical record. The electronic exchange of patient data is a critical component of advancing health reform and we're proud to partner with an organization of Philips' caliber."

In other agreements/contracts news, **NewCardio** (Santa Clara, California) reported that an undisclosed global biopharmaceutical services provider has signed an agreement, licensing NewCardio's QTinno software solution to enhance its delivery of fully automated cardiac safety analyses for early phase QT studies. The CRO is expected to deploy QTinno in several clinical unit locations worldwide.

In addition, the CRO has signed a services work order related to the first study using QTinno, which is scheduled to be initiated this June. ■

Court report

Houston medical equipment firm owner pleads to fraud scheme

A *Medical Device Daily* Staff Report

Houston-area residents Doris Vinitski and John Lachman pleaded guilty in connection with their roles in a durable medical equipment Medicare fraud scheme, the Departments of Justice and Health and Human Services (HHS) reported.

Vinitski was the owner of **Onward Medical Supply** (Houston). Lachman operated the day-to-day business for several years, and Vicki Phillips was a patient recruiter for Onward. Vinitski and Lachman each pleaded guilty before U.S. District Court Judge Nancy Atlas of the Southern District of Texas to one count of conspiracy to commit healthcare fraud. Phillips pleaded guilty on April 21, 2010, to one count of conspiracy to defraud the U.S. and to paying healthcare kickbacks.

Onward began billing Medicare for fraudulent durable medical equipment in 2003, according to court documents. Vinitski and Lachman admitted they paid kickbacks, sometimes $1,000 per patient, to recruiters who brought patients to Onward. Lachman and Vinitski then would bill Medicare for durable medical equipment that these patients did not need or never received.

Phillips admitted that she recruited Medicare beneficiaries for the purpose of allowing Onward to submit claims to Medicare for durable medical equipment, including power wheelchairs and orthotic devices. Phillips also admitted she received kickbacks from Onward for each patient she recruited whose claims were reimbursed by Medicare.

Lachman and Phillips are scheduled to be sentenced on Aug. 16, 2010. Vinitski is scheduled to be sentenced on Aug. 17, 2010. Lachman and Vinitski face a maximum penalty of 10 years in prison and a $250,000 fine. Phillips faces a maximum penalty of five years in prison and a $250,000 fine.

In other legal news, **Edwards Lifesciences** (Irvine, California) reported that the Federal Patent Court in Munich, Germany, has ruled in Edwards' favor, finding **Cook Medical**'s (Bloomington, Indiana) German transcatheter heart valve patent invalid. This follows a favorable ruling by the District Court of Düsseldorf in March 2009 that determined Edwards did not infringe the Cook patent, and victories on both validity and infringement in the courts of the UK in June 2009.

"We are pleased with the court's finding, which reinforces the strength and foundational work of the Andersen invention," said Larry Wood, Edwards' corporate vice president, transcatheter valve replacement. "While we remain committed to protecting our comprehensive intellectual property in transcatheter heart valves, this represents only one important element of our broader leadership strategy to benefit patients."

Cook filed suit in Germany in February 2008 claiming that the Edwards Sapien transcatheter heart valve infringes the Cook patent. ■

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Financing roundup

Realton closes 'B' round led by OrbiMed and CHP

A *Medical Device Daily* Staff Report

Realton Corporation (Beijing), a developer of diode-pumped laser systems initially targeted to treat an enlarged prostate, reported the closing of its Series B financing co-led by OrbiMed Advisors and China Healthcare Partnership (CHP). The company did not disclose the amount raised in the round.

Existing investor CSV Capital Partners will also participate in the round. Realton said it would use the funds primarily to enhance its marketing and distribution networks, expand its manufacturing capabilities and pursue new technology development.

According to the company, surgery for an enlarged prostate, also known as benign prostatic hyperplasia (BPH), is the second most common operation for men over 60 years of age worldwide. Realton's laser system is an alternative to traditional TURP surgery, delivering comparable results with reduced bleeding, shorter hospital stays, and fewer complications, the company said. As China and other developing countries' populations are aging, an increasing number of elderly men are suffering from BPH, Realton said. The prevalence of BPH in China has already exceeded 30 million people, with nearly 300,000 surgically treated annually and growing, the company noted.

Realton laser BPH treatment utilizes a 100-watt second generation green light laser allowing procedures to be easily performed on larger prostates, providing physicians with more freedom in clinical decision making. Lower upfront and operating costs allow Realton's systems and fiber optic delivery devices to be affordable at all levels of Chinese hospitals and urologist offices, the company said. The Realton laser products also have potential surgical applications in other urologic diseases.

"Realton's 100W green surgical laser has demonstrated great advantages in the treatment of BPH. Its high power reduces operation time and allows surgeons to treat large prostates. With the Realton laser, we are usually able to finish a minimally invasive procedure within 30 minutes to 60 minutes," said Xunbo Jin, MD, director of Minimally Invasive Center in **Shandong Provincial Hospital**. "Having successfully completed hundreds of these green laser procedures in our center, its clinical outcomes have proven effective and safe. With its advantages in both cost and service, the Realton surgical laser and fiber optic delivery device are well-suited to Chinese hospitals."

In other financing activity, **PositiveID** (Delray Beach, Florida) said that Socius Technology Capital Group has agreed to purchase up to $4.2 million in non-convertible Series B preferred stock from PositiveID. Socius has also agreed to buy shares of the company's common stock equal to 100% of the value of the preferred stock priced at the average of the individual daily volume weighted average price calculated over the 10 trading days preceding the applicable investment price.

Socius will also receive 35% warrant coverage, which warrants will also be priced at the investment price. Socius may pay the investment price for the common stock and the exercise price of the warrants, at Socius' option, in cash or a secured promissory note. Proceeds from any sales of the preferred stock will be used to fund additional development of the company's HealthID product portfolio, including its Easy Check system for non-invasive glucose monitoring through breath analysis, its iGlucose system for real-time diabetes management, and other diabetes and healthcare products, as well as to provide working capital. ■

Grants roundup

Align provides $75K for study of new orthodontic treatments

A *Medical Device Daily* Staff report

Align Technology (Santa Clara, California) reported that it is awarding $75,000 in scientific research funding to two universities with projects seeking to further the understanding of orthodontic treatment with clear aligners. The two recipients selected to receive research funding in 2010 as part of Align's Clear Aligner Research Award Program are Dr. Maria Orellana, assistant professor at the **University of California**, **San Francisco School of Dentistry**, and Dr. Robyn Silberstein, clinical associate professor at the **University of Illinois at Chicago College of Dentistry**.

Orellana will receive a $25,000 award with an option to renew for an additional $25,000 in 2011 for the project "Awareness, Acceptance and Use of the Invisalign System," which seeks to conduct a cross-sectional, epidemiological study examining awareness, acceptance, and use of clear aligners in the adolescent Latino population. Silberstein will receive a $25,000 award for the project "Adherence Predictability to Invisalign Treatment," which seeks to design and test effective tools to predict patient compliance.

All proposals received were reviewed and prioritized by an independent academic committee.

The review committee chair for 2010 was Timothy Wheeler,PhD, professor and chairman of the Department of Orthodontics at the **University of Florida** (Gainsville), who noted, "We received some very interesting and creative proposals that could produce data that would help practitioners in the near future. Using a peer-review process, our independent academic committee based its recommendations for funding on the scientific merit of the proposals." ■

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Deals

Continued from Page 1

$325 million; and $700 million, plus additional milestone payments, was the bid for **CoreValve** (Irvine, California) (*MDD*, Feb. 24, 2009).

With nearly $2 billion spent to expand the business, Ward said Medtronic is, "focused on creating a cardiovascular franchise that will be a market leader in this $15 billion global marketplace."

Medtronic will pay $4 per share in cash for each share of ATS Medical stock. The acquisition of this company, which is best known for its heart valves and cryoblation technology, includes the assumption of $20 million of debt.

Many analysts have predicted heightened mergers and acquisitions as a result of the poor economic climate and the resulting lack of available capital. But Ward said that really hasn't come into play as part of the company's acquisitive moves.

"ATS Medical is a very strong and successful company in the cardiac surgical segment. However, for them to really be successful with their innovative products, they need to leverage the strength of Medtronic competencies to take their technology and rapidly bring them to market around the world," Ward said. "That's the driving factor behind the ATS transaction more so than any economic factors."

He pointed to the value of four ATS products in particular that will compliment Medtronic's portfolio:

• The company's Open-Pivot bileaflet mechanical valve has been approved in 80 countries. "This mechanical valve is important because as we look at the standard of care in emerging markets such as China, Latin America and India, we know that physicians there choose mechanical valves for aortic valve disease," Ward said. "We really see the ATS Open-Pivot Valve as creating important opportunity in these emerging markets."

• 3f Aortic Bioprosthesis, an aortic valve designed to function just like a native valve, was just launched in 2009.

• 3f Enable Bioprosthesis, recently CE marked, is the first surgical aortic valve replacement approved for commercial use that is implanted using a sutureless technique. "It enables minimally invasive cardiac surgery and it's an exciting new addition," he said.

• ATS' CryoMaze Surgical Ablation System is whole line of products that Ward said was a particularly appealing aspect of the acquisition.

"Medtronic has a product in each of these segments and these compliment our portfolio, but are differentiated," he said.

ATS will become part of the Medtronic structural heart business. Its two locations, one in Minnesota and the other in Orange County, California, will be maintained for now, although Ward said "Over time those facilities will become consolidated, but for now will remain separate."

"It's going to be a win-win for both sides," Guy Nohra, **Alta Partners'** (San Francisco) co-founder and managing director, who serves on ATS Medical's board, told *MDD*. Nohra led Alta's private placement of shares of ATS common stock and warrants in 2007. "Our management team did a great job managing the company and that's probably what attracted Medtronic. Medtronic, being a savvy and experienced acquirer, will take their time and then decide what kind of integration will follow," he said in response to a query about whether or not ATS will undergo eventual consolidation.

"We were the largest ATS shareholder for last three years with an investment done as a PIPE [private investment in a public company] in June 2007," he said. "We definitely expect this to bring venture-level returns for us. It's a nice quick turnaround for the fund being in the company for less than three years."

After the two big Medtronic acquisitions of 2010, the largest deals of the year so far have included:

• **Merge Healthcare** (Milwaukee) and **Amicas** (Boston) just this week closed a merger agreement (*MDD*, April 27, 2010). Merge reported earlier this month that it was set to acquire Amicas for $6.05 a share – $248 million – putting an end to a back-and-forth acquisition dance involving Merge, Amicas and an affiliate of private equity firm **Thoma Bravo** (Chicago), that began months ago.

• **CareFusion** (San Diego) acquired **Medegen** (Ontario, California), a developer of needleless access valves and administration sets that deliver intravenous medication to patients, for $225 million in cash (*MDD*, April 6, 2010).

• **Nipro** (Osaka, Japan) launched a cash tender offer to purchase all outstanding shares of **Home Diagnostics** (Fort. Lauderdale, Florida) for about $215 million (*MDD*, Feb. 12, 2010).

• **Quidel** (San Diego), a provider of rapid diagnostic tests, completed its acquisition of **Diagnostic Hybrids** (Athens, Ohio) for roughly $130 million in cash in February (*MDD*, Feb. 23, 2010).

• **Inverness Medical Innovations** (Waltham, Massachusetts) continued its acquisition spree that started several years ago by entering into a binding agreement with **Kroll** (Gretna, Louisiana), a subsidiary of **Marsh and McLennan** (New York), to purchase its Substance Abuse Testing division called Kroll Laboratory Specialists for $110 million in cash (*MDD*, Feb. 5, 2010).

In other dealmaking news, **Skilled Healthcare Group** (Foothill Ranch, California) reported that its board has authorized the acquisition of substantially all the assets of five Medicare-certified hospice companies and three Medicare-certified home health companies. In addition, the company will enter into a fee-based management agreement for another home health company and be granted an option to acquire substantially all of the assets of such other company. The hospice and home health companies collectively have operations in Idaho, Montana, Nevada and Arizona.

See Deals, Page 8

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Cryopreservation

Continued from Page 1

which protects eggs from injury during the freezing and subsequent thawing process.

Because vitrification is becoming so widely used in the fertility world, the technology landed at the number 5 spot on the **Cleveland Clinic**'s Top 10 list of medical innovations expected to have a big impact on healthcare in 2010 (*Medical Device Daily*, Oct. 9, 2010).

Nina Desai, PhD, of the Women's Health Institute at the Cleveland Clinic, told *Medical Device Daily* that traditional methods of freezing embryos and eggs has always been to use a slow freezing technology, during which the laboratory essentially removes the water content from a cell and replaces it with a cryoprotectant. That method, she says, usually takes close to two hours. While clinics have had a lot of success with embryo freezing since about 1985, egg freezing has not been very successful and did not gain a lot of popularity until the early part of the last decade, Desai said. With the new technique, the freezing process is much faster, almost instantaneous, she said.

Desai noted that the **American Society of Reproductive Medicine** (Birmingham) still considers egg freezing to be experimental, as the number of births that have resulted from this procedure is still well under 1,500. The Cleveland Clinic just had its first two births using this method last year, she said.

In order for a lab to freeze eggs using the vitrification method they have to first know how to freeze embryos the same way, Desai said. "If they don't do it for embryos they are less likely to do it for eggs," she said. The Cleveland Clinic had been using the vitrification method on embryos since 2005 and therefore were "in the right position to start freezing eggs," she added.

Shady Grove Fertility (Rockville, Maryland) reported this week that it has opened a new center for fertility preservation offering the flash freezing technology.

"A woman's ability to conceive is largely dependant on the age of her eggs," said Robert Stillman, MD, the medical director of Shady Grove. "Fertility is naturally declining with age, but the chances of getting pregnant drop off sharply after age 35. By the time she reaches her early 40's there is only a very small chance of achieving a healthy, natural pregnancy and delivery."

While not a guarantee, Stillman says the ability to proactively freeze eggs at a younger age can greatly increase a woman's chances of becoming pregnant with her own biological children well past the age of natural peak fertility.

In a way, this new technique of egg freezing has leveled the playing field between men and women's ability to preserve their fertility.

"Sperm has been cryopreservable for decades now, it is more resistant to the effects of freezing and there are millions and millions of them," Stillman told *MDD*. He said many fertility clinics, until recently, only offered egg freezing to women who were about to begin chemotherapy for cancer and wanted to preserve their fertility. But because of the slower freezing technique that was previously used, "many of those women, unfortunately, will not have good eggs once they are thawed," Stillman said.

As the new technique has proven to be much more successful, clinics are beginning to offer it to women who want to delay fertility for a variety of reasons. "Why not be able to provide and empower women with the opportunity to delay their fertility as men have had for years," Stillman said.

Another fertility clinic, **Advanced Fertility Center of Chicago** (Gurnee, Illinois), also notes on its web site that it, along with many other clinics, are getting away from traditional slow freezing and adopting the vitrification technology of egg freezing.

There could be any number of reasons a woman would want to take advantage of this new ability to freeze their eggs — professional, personal, social, economic, or otherwise. Shady Grove estimates that there are roughly 6 million unmarried women in the U.S. between 30 and 39, many of whom are faced with the dilemma of either having children before they are ready, conceiving through the use of donor eggs, or not having biological children at all.

While the technology for egg freezing has come along way to offer women the opportunity to delay childbearing, Stillman acknowledges that it is "not for everybody."

"It's sort of a catch 22 in that the older you are and want to delay fertility, the more you need it but the less likely it is to [work]," Stillman said.

On the other hand, women who are younger still have several years before their fertility begins to decline so egg freezing might not be a good option for them either. Stillman says the ideal age for a woman to have her eggs frozen is between 30 and 40 when they may face an eminent or near-eminent risk of infertility. A 26-year-old still has plenty of time before she has to worry about a significant decline in fertility, he said, while a 42-year-old may not have enough good eggs left to freeze.

Desai says that when it comes to a woman's fertility, "the age of the egg is the only thing that's important."

Stillman says he hopes women who look into this option use it as an educational opportunity to make an informed decision about whether or not egg cryopreservation is right for them.

While more fertility clinics, like Shady Grove, have begun to offer egg cryopreservation, Desai says the technique is still resulting in pregnancy rates of just 35% or so, and that ideally the rate should be higher than that. Still, the technology is headed in the right direction — and fast.

"It's moving really fast and many labs are starting to get, especially in young patients, very high results," Desai said. "I would say in another year or two [the technique will be producing higher pregnancy rates], it's not that far away." ■

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Washington

Continued from Page 1

allegedly did not acquire informed consent from guardians of the 200 children who were randomized 1:1 in a trial testing Trovan (trovafloxacin) against Rocephin (ceftriaxone) as a treatment for bacterial meningitis. Northern Nigeria was the site of an outbreak of bacterial meningitis in 1996, and the government gave Pfizer permission to test Trovan in the city of Kano, located in the Nigerian state of the same name. Six children in the control arm passed away as did five in the study arm, and the litigants, who filed suit in 2001, claim further that Pfizer deliberately used a sub-optimal dose of Rocephin to enhance the results for the Trovan patients.

According to the web site for the Centers for Disease Control and Prevention, "appropriate antibiotic treatment of most common types of bacterial meningitis should reduce the risk of dying from meningitis to below 15%," although the geographic scope of that reference is not described.

The lawsuit against Pfizer was filed under the Alien Tort Statute of 1789, passed by Congress two years after the year the U.S. Constitution was adopted and hence is a law of long standing. According to the H&H paper, the original intent of the law is thought to have been to ensure that U.S. citizens living abroad would be afforded the same legal protections against breaches of customary law by U.S. business entities as citizens living in the U.S.

A district court judged in favor of Pfizer, which argued in part that the deaths were due to the meningitis, but the legal argument was at least in part that the suit had no jurisdictional standing, although Pfizer is said to have settled a parallel lawsuit with the state of Kano for $75 million.

The H&H paper notes that the Court of Appeals for the Second Circuit, located in New York, reversed the district court opinion, stating that non-consensual drug trials violate customary international law and that the involvement of Nigerian governmental authorities was sufficient to extend the applicability of the Alien Tort Statute to this case. The majority opinion (two judges on a three-judge panel) was rebutted by a minority opinion stating that the Nigerian government had to be directly involved in the purportedly violative action, which the complaint did not indicate was the case.

The paper states that Pfizer's appeal for *certiorari* seeks to argue whether the statute does indeed cover a situation involving a foreign governmental entity "where there is no allegation that the foreign government knew of, or participated in, specific acts claimed," and whether the lack of informed consent in this circumstance qualifies as actionable under the statute.

Prospects for a Supreme Court hearing seem positive, although the signals are mixed. The court is said to have asked the Solicitor General of the United States to file a briefing on the executive branch's views on the issue, hinting that the court may hear the case, although the court will have to win a writ based on four of only seven justices because Justice Sotomayor and Chief Justice Roberts have both recused themselves from the case.

NIH offers knockout mice genes

The National Institutes of Health (NIH) routinely offers its technological developments for licensing by industry, but some offerings have more punch than others.

According to the April 26 edition of the *Federal Register*, NIH has offered a knockout for the SMAD7 gene in mice species. SMAD7, the *FR* entry notes, can be displaced "by breeding with CRE-recombinase transgenic mice with a variety of promoters to yield tissue or cell type-specific deletions" of the gene, which is thought to play a role in several disease states, including cardiovascular disease. A recombinase is an enzyme capable of unwinding genetic material, and this capability is said to offer the potential to model the progression of scleroderma, which in its systemic form can cause disease of the heart.

Interested parties should contact Elizabeth Denholm, PhD, at denholme@niehs.nih.gov for collaborative research opportunities. Those interested in licensing opportunities are advised to call Steve Sandley, PhD, at 301-435-4074 or e-mail him at sstand@od.nih.gov.

Nurse pleads guilty to theft of equipment

The Swiss healthcare economist Gerhard Kocher is credited with having said that "nursing would be a dream job if there were no doctors," but a recent FDA statement indicates that at least one nurse believes that helping oneself to the hospital's inventory – presumably a different kind of gainsharing – would also improve working conditions.

According to an April 27 statement on the FDA web site, Angela DeVarso, 33, of Garfield, New Jersey, has entered a guilty plea for stealing more than $300,000 in supplies and medical equipment from **Passaic County Hospital** (Weehawken, New Jersey). According to the statement, authored by the U.S. Attorney's Office, DeVarso made her money by selling the pilfered items over the Internet and conducted a similar operation at **St. Joseph's Regional Medical Center** (Paterson, New Jersey) between July 2008 and October 2009. That inventory, the statement says, included surgical instruments and supplies valued at almost $303,000 and was sold on the online action marketplace eBay. DeVarso's bail is set at $100,000 and she could face fines of $250,000 or more as well as 10 years in prison. ■

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BSX

Continued from Page 1

had 1,000 people to register for the site."

Fischer said that plans to develop the Pelvic Institute started brewing back in late 2008 and early 2009, when the company did extensive physician research and took surveys on the issue.

She added that out of the surveys that were taken, there was a clear need for an institute that could give surgeons extra resources and experience in treating this condition.

It has already been estimated that this market is set to increase.

According to statistics provided by Boston Scientific, by 2050, the number of women in the U.S. with urinary incontinence, a symptom of a damaged pelvic floor is expected to increase 55% to 28.4 million, while women with pelvic organ prolapse will rise 46% to 4.9 million.

The Pelvic Floor Institute can be helpful treating this need because it is designed to provide physicians with practical training in a hands-on laboratory setting to address the growing need for treatment of these conditions.

The company said that in its first year, the Pelvic Floor Institute plans to host lab training sessions featuring expert anatomical instruction using an innovative hemi-pelvis cadaver that offers improved detail of internal structures and organs. The company said that the institute will also offer an online resource to facilitate peer-to-peer support and communication beyond the clinical setting.

"Today's pelvic floor procedures require a more in-depth understanding of female pelvic anatomy and the specific techniques critical to successful outcomes," said Dennis Miller, MD, medical director of **Wheaton Franciscan Hospita**l (Milwaukee). "Use of the hemi-pelvis cadaver offers a major advance in training for pelvic floor reconstruction, allowing unprecedented visualization of internal structures not available in other lab settings."

According to the company, the Pelvic Floor Institute web site complements the hands-on lab experience by offering online tutorials, case studies, coursework and editorials on contemporary topics. Physicians can customize their online learning experience with specific training modules that match their educational needs and prepare them for cadaver lab instruction. The web site also enables physicians to connect with leading experts in the field.

"So far, we've found that physicians really see it as a positive tool they can use," Fischer said.

She added that physicians can review a study shortly before they take on a new case and have a 3-D model that helps bolster instruction.

The company said that registering on the site was free and that the primary market for the institute was directed toward surgeons.

"We are pleased to introduce and support this innovative training forum that will benefit physicians and their patients," said John Pedersen, president of Urology and Women's Health Division at Boston Scientific. "The Pelvic Floor Institute facilitates a continuum of physician training that will broaden the understanding of treatment methods for pelvic floor disorders, ultimately advancing the quality of patient care."

For or additional information and to review the 2010 Pelvic Floor Institute hands-on cadaveric lab schedule and available online educational materials, visit http://www.pelvic-floor-institute.com/. ■

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Deals

Continued from Page 5

Boyd Hendrickson, chairman and CEO, noted, "We are very excited about this transaction which comes with strong cash flow, a successful operating platform, a solid management team and higher than company average EBITDA margins. Additionally, it expands our business lines into home healthcare and further expands our hospice platform. This lateral diversification expands our footprint to three additional states; thereby, diversifying our revenue stream both geographically and by sector." ■

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Patent watch

DFine expands portfolio with StabiliT approval

A *Medical Device Daily* Staff Report

DFine (San Jose, California), a maker of minimally invasive solutions for treating vertebral compression fractures, said that the U.S. Patent & Trademark Office has issued Patent 7,678,116 relating to the StabiliT Vertebral Augmentation System.

"I am pleased with our expanding patent portfolio," said Kevin Mosher, CEO of DFine. "DFine has a number of innovative technologies and concepts that will provide the basis for future pipeline products and further enhance the value of our patent portfolio. Combined with our global commercialization efforts, our underlying intellectual property uniquely positions DFine as the technology leader in the treatment of vertebral compression fractures and other vertebral pathologies."

DFine claims the RF kyphoplasty procedure with the StabiliT vertebral augmentation system provides physicians greater control in the treatment of vertebral compression fractures through site and size specific cavity creation and an ultra high viscosity bone cement over an extended working time using a remotely controlled delivery system to stabilize the fracture, relieve pain and improve patient quality of life. ■

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Product Briefs

• **Bioject Medical Technologies** (Portland, Oregon) said the Centers for Disease Control and Prevention and its collaborating institutions presented the latest results of its clinical trial of the Biojector 2000 at the 13th Annual Conference on Vaccine Research. The study involved administering influenza vaccine intradermally in reduced "dose-sparing" amounts into the skin by jet injection, increasing the speed and avoiding the risks and discomfort of the traditional "Mantoux" needle method commonly used for tuberculosis skin testing. Bioject says the intradermal route takes advantage of the high immune responsiveness of the skin to reduce the amount of vaccine needed for influenza and some other vaccines. Intradermal delivery may extend protection to larger numbers than would full doses of expensive or scarce vaccines. The traditional intradermal method by needle-syringe is difficult and tedious. Jet injectors can vaccinate into the skin more quickly and also eliminate many of the dangers and drawbacks of using needle-syringe delivery, such as intentional or inadvertent unsterile reuse, needle-stick injuries to healthcare workers, and improper disposal of sharps waste.

• **Calypso Medical Technologies** (Seattle), a maker of non-ionizing real-time localization technology used for the precise tracking of tumor targets, and **Cancer Treatment Centers of America** (CTCA; Tulsa, Oklahoma), a national network of hospitals providing cancer treatment, said that with the installation of the Calypso System at the CTCA at Southwestern Regional Medical Center in Tulsa, Calypso's real-time tumor tracking technology is now available at all CTCA centers nationwide. The Calypso System, with its GPS for the Body technology, uses miniature implanted Beacon transponders to provide precise, continuous information on the location of the tumor during external beam radiation therapy. Any movement by the patient, including internal movement of the tumor, may cause the therapeutic radiation to miss its intended target and hit adjacent healthy tissue. In contrast to ionizing tumor targeting methods which cannot track a target in real-time, the Calypso System's non-ionizing solution provides real-time tumor position information, thereby allowing physicians to deliver radiation directly to the tumor while sparing the surrounding healthy organs from radiation exposure.

• **DR Systems** (San Diego) said it will be exhibiting its cloud-based, virtualized image-sharing technology, eMix, at upcoming conferences of the Radiology Business Management Association and Medical Users Software Exchange. eMix, which stands for Electronic Medical Information Exchange, enables secure sharing of images and reports among disparate institutions and physicians via the Internet. It also facilitates associating patient images with electronic medical records (EMRs) and patients' personal health records (PHRs). eMix is based on cloud-based technology which allows sharing medical imaging studies and reports between disparate healthcare facilities and physicians with the speed and simplicity of email.

• **Hansen Medical** (Mountain View, California) reported results from three independent clinical studies showing that use of the Sensei system in procedures for atrial fibrillation (AF) and other abnormal heart rhythms reduced patients' exposure to harmful cancer causing radiation by 63%, and provided stable, precise catheter control with equivalent safety to non-robotic (manual) procedures. The studies were designed to compare use of the Sensei system in patients with AF to manual technique in terms of success, complication rates, procedure time, and radiation exposure to patient and physician. All of these studies reported substantial reduction in X-ray exposure to the patient and physician, as well as similar safety and success relative to manual technique. One single center study showed substantial decrease in radiation dose during complex cardiac procedures using the Sensei system.

People in the News

• **Analogic** (Peabody, Massachusetts) said that Mervat Faltas will assume the role of senior VP/GM of the newly combined OEM Medical businesses. Mervat was previously president of Analogic's ANRAD subsidiary. Analogic makes medical imaging and aviation security technology.

• The board of **Awarepoint** (San Diego) reported a series of senior executive changes to the company.

Jason Howe has stepped down as CEO. Effective immediately, the board has named Brad Weinert as the company's president/COO. Weinert most recently served as president and acting CEO for Novatel Wireless.

Ben Sperling, former director of strategic business development for McKesson Automation, has been named as the company's VP of business development.

Thomas Hamelin, former associate administrator for University of California San Diego Medical Center, has been named senior VP of business process improvement.

Awarepoint's Real-time Awareness Solutions include Awarenet, its networked awareness platform, real-time location system applications and an open application programming interface for use with partner technologies.

• **California Healthcare Institute** (CHI; La Jolla) said that Paul Hastings, president/CEO of OncoMed Pharmaceuticals, and Ken Berger, president of the Specialty Diagnostics business for Thermo Fisher Scientific, have been elected to its board of directors. CHI is a non-profit public policy research organization, representing California academic institutions, biotechnology, medical device, diagnostics and pharmaceutical firms.

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MDD's Diagnostic Extra

Additional Developments in One of Med-Tech's Key Sectors

Friday, April 30, 2010

Keeping you up to date on recent headlines in diagnostics

Imaging agents provide clear runway to spot tumors . . . A series of novel imaging agents could light up tumors as they begin to form – before they turn deadly – and signal their transition to aggressive cancers. The compounds – fluorescent inhibitors of the enzyme cyclooxygenase-2 (COX-2) – could have broad applications for detecting tumors earlier, monitoring a tumor's transition from pre-malignancy to more aggressive growth, and defining tumor margins during surgical removal. "We're very excited about these new agents and are moving forward to develop them for human clinical trials," said Lawrence Marnett, PhD, the leader of the **Vanderbilt University** (Nashville Tennessee) team that developed the compounds, which are described in the May 1 issue of *Cancer Research*. COX-2 is an attractive target for molecular imaging. It's not found in most normal tissues, and then it is "turned on" in inflammatory lesions and tumors, Marnett explained. "COX-2 is expressed at the earliest stages of pre-malignancy – in pre-malignant lesions, but not in surrounding normal tissue – and as a tumor grows and becomes increasingly malignant, COX-2 levels go up," Marnett said. Compounds that bind selectively to COX-2 – and carry a fluorescent marker – should act as "beacons" for tumor cells and for inflammation. Marnett and his colleagues previously demonstrated that fluorescent COX-2 inhibitors – which they have now dubbed "fluorocoxibs" – were useful probes for protein binding, but their early molecules were not appropriate for cellular or *in vivo* imaging. "It was a real challenge to make a compound that is COX-2 selective (doesn't bind to the related COX-1 enzyme), has desirable fluorescence properties, and gets to the tissue *in vivo*," Marnett said. To develop such compounds, Jashim Uddin, PhD, research assistant professor of Biochemistry, started with the "core" chemical structure of the anti-inflammatory medicines indomethacin and celecoxib. He then tethered various fluorescent parts to the core structure, ultimately synthesizing more than 200 compounds. The group tested each compound for its interaction with purified COX-2 and COX-1 proteins and then assessed promising compounds for COX-2 selectivity and fluorescence in cultured cells and in animals. Two compounds made the cut. In studies led by senior research specialist Brenda Crews, the investigators evaluated the potential of these compounds for *in vivo* imaging using three different animal models: irritant-induced inflammation in the mouse foot pad; human tumors grafted into mice; and spontaneous tumors in mice. In each case, the two fluorocoxibs – injected intravenously or into the abdominal cavity – accumulated in the inflamed or tumor tissue, giving it a fluorescent "glow." To move the agents toward human clinical trials, the team will conduct additional toxicology and pharmacology testing and develop the tools for particular settings that are amenable to fluorescence imaging, such as skin or sites accessible by endoscope (e.g., esophagus and colon).

Researchers find new camera helps diagnose colorectal cancer . . . Colorectal cancer is the third most frequently diagnosed cancer worldwide, accounting for more than a million cases and around 600,000 deaths every year. Beating the disease is strongly linked to how early it is detected, with survival rates of around 90% for cancers that are found early and have not spread. Many developed countries have introduced screening programs using a fecal occult blood test, which can detect early cases and reduce death rates by around 15%. But Wendy Atkin from **Imperial College London** and Jane Wardle from **University College London** said their study showed more lives, and money, could be saved if screening used sigmoidoscopy – a small, flexible camera that is inserted into the rectum. "Economic analyses suggest . . . a once-only flexible sigmoidoscopy screen at age 55 or 60 years would be cost saving, largely because of the avoided costs of treatment," they wrote. Some of the newest drugs in colon cancer – such as **Roche**'s (Basil, Switzerland) Avastin, Vectibix from **Amgen** (Thousand Oaks, California) and Erbitux from **Merck** (Whitehouse Station, New Jersey) KGaA – can cost thousands of dollars a month. Atkin said that sigmoidoscopy screening would save money was based on previous studies showing it was cost effective in preventing the need to treat so many patients with such expensive medicines. "There's a real problem about the affordability of these drugs," she said. "But one way to make them more available is to reduce the numbers who develop these cancers with screening."Cancer screening programs in devel-

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oped nations have come under close scrutiny in recent months with some European studies suggesting national breast cancer screening programs do little to reduce death rates and research in the U.S. showing that prostate cancer screens lead to widespread overdiagnosis.

CMT gains approval for Down Syndrome Screening kit . . . **China Medical Technologies** (Bejing) an *in vitro* diagnostic company, reported that it received approval for its Automaglia 90 fully-automated ECLIA analyzer as well as Down Syndrome screening kit (Down Syndrome Screening) from the State Food and Drug Administration of China (the SFDA). Automaglia 90 Analyzer is a fully-automated analyzer for immunoassay analysis in various types of diseases and disorders. Major clinical diagnostic applications include thyroid disorders, fertility and infertility disorders, diabetes, infectious diseases and tumor markers. The company expects Automaglia 90 Analyzer to enter a new customer segment of its ECLIA business by targeting large hospitals in China which have the highest patient volume and consumable usage. The company will leverage its own direct sales force to cross sell Automaglia 90 Analyzer to existing FISH customers which comprise more than 400 large hospitals in China. Down Syndrome Screening is used for prenatal screening tests for trisomy 21, a chromosomal disorder caused by the presence of all or part of an extra 21st chromosome. The company plans to bundle Down Syndrome Screening with its Prenatal FISH Probe, a molecular diagnostic test for the detection of various prenatal disorders with a view of serving a huge group of pregnant women in China at an estimated size of more than 16 million each year. "We are pleased to receive SFDA approval for both Automaglia 90 Analyzer and Down Syndrome Screening," said Xiaodong Wu, Chairman/CEO of the company. "We expect the approved products to broaden our customers and increase usage of our consumables. We look forward to receive SFDA approval for our HPV DNA Chip which is also expected to broaden our customers and increase our consumable usage."

Iris submits 510K for approval of prostate cancer diagnostics test . . .

Iris International (Chatsworth, California), an *in vitro* diagnostics systems and consumables for use in hospitals and commercial laboratories worldwide, reported that its **Iris Molecular Diagnostics** (IMD) subsidiary has submitted a 510(k) pre-market notification application to the FDA requesting regulatory clearance for NADiA ProsVue, a prostate cancer prognostic test. The test is designed to help physicians identify patients at low risk of cancer recurrence post radical prostatectomy. The NADiA ProsVue 510(k) filing contains the results of a 300 patient retrospective study using retained patient samples. The company believes that the study data meets the pre-established primary and secondary endpoints of the study. The results of the NADiA ProsVue prognostic test were compared to clinical endpoints of stable and recurring disease for at least eight years following radical prostatectomy. The clinical files of 25,000 patients were reviewed to select 611 qualified patients. Three hundred ninety two patients having retained serum samples meeting the study protocol's requirements were statistically selected to generate the 300 patients involved in the study. Two hundred twenty eight patients were classified by the sites as stable and 72 patients were classified as recurring. The specimens used were collected for more than an 18 month period following radical prostatectomy. The clinical trial sites included **Duke University** (Durham, North Carolina), **Memorial Sloan-Kettering Cancer Center** (New York), **Eastern Virginia Medical Center** (Norfolk, Virginia) and the **University of Washington** (Seattle). The data generated from the retrospective clinical study will be presented at upcoming scientific meetings by the clinical investigators. The study was designed based on the results of a previous 85 patient study (involving 42 and 43 stable and recurrent disease patients, respectively) from **Mt. Sinai Hospital** (Toronto) and a 31 patient pilot study (involving 16 and 15 stable and recurrent disease patients, respectively) from Duke University. The results of these two previous studies were used, at the suggestion of the FDA following previous submissions, to establish the prognostic indicator algorithm tested in the new study. According to the **American Cancer Society** (Atlanta) in the U.S. there were an estimated 192,280 new cases of prostate cancer in 2009 with 27,360 deaths, making it the second leading cause of cancer death in men. One in six men will be diagnosed with prostate cancer during his lifetime. Currently, there are more than 2 million men in the U.S. who have undergone radical prostatectomy with another 85,000 new procedures performed each year. NADiA ProsVue is the first diagnostic test developed by IMD. The company's platform technology, NADiA (Nucleic Acid Detection Immunoassay), is used for the ultra sensitive detection of proteins.

– Compiled by Omar Ford, *MDD* Staff Writer
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