MEDICAL DEVICE DAILY™

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Implantable chip could hold promise for paralyzed patients

By Omar Ford, Staff Writer

Spinal cord injuries can at times be traumatic and ultimately lead to patients being paralyzed. One company is working on a technology that could see movement restored in patients suffering from these types of injuries, with a system that almost sounds like something out of a science fiction movie.

Battelle (Columbus, Ohio), a firm that has its hands in arenas ranging from biotechnology to medical devices, is developing the Neurobridge, a system that consists of an implantable chip to help patients to regain lost movement.

"We've been working on various elements of the technology and there are actually three pieces to it," Chad Bouton, research leader for neurotechnology with Battelle, told *Medical Device*

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WASHINGTON ROUNDUP

CMS offers more jingle for TAVR in 2015 IPPS draft; MitraClip iffy

By Mark McCarty, Washington Editor

The Centers for Medicare & Medicaid Services released a proposed payment rubric for hospital inpatient services for fiscal 2015 and as always, there are winners and losers. Among the winners are patients in need of transcatheter aortic valves and the makers of those valves, who will benefit by the proposed creation of two new Medicare severity diagnostic related group (MS-DRG) codes that should boost payment and make the procedure/device more economically practicable for a wider range of centers. The bid by **Abbott Vascular** (Santa Clara, California) to shift the MitraClip into an alternative DRG code

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NEW CO ON THE GO

Versicor aims to help bring new medical device ideas to life

By Amanda Pedersen, Senior Staff Writer

Taking an idea for a new medical device from concept to commercialization is never easy. The pathway to market in the medical technology industry is almost always long, complicated, and expensive. For new companies with fewer resources, going it alone isn't necessarily an option.

One newcomer to the medical device space, a firm called **Versicor** (Royal Oak, Michigan), said it wants to help technology entrepreneurs bring those ideas to life. Versicor also works with businesses in the clean-tech and transportation industries to accelerate product development.

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LATIN AMERICA

Venezuela's Ministry of Health finally addressing medical supply crisis

By Sergio Held, Contributing Writer

After months of reports and complaints of a shortage of hospital supplies and obstacles to importing and distributing medical devices, Venezuelan health minister Francisco Alejandro Armada finally acknowledged that the country is experiencing serious difficulty in supplying the country's hospitals and clinics.

"We have very significant failures at the level of hospital care," Armada said on a nationally televised talk show on April 27. "We have a group of more than 20 hospitals that have been established over the past 15 years and have functioning infrastructure and pretty good equipment and then we have

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INSIDE

DIAGNOSTICS EXTRA

Staff Writer Omar Ford on one of med-tech's key sectors

Read this week's Friday Special

FINANCINGS

Enterome Bioscience raises €13.87M in Series B round for Metagenotyping

Staff Report

Enterome Bioscience (Paris), a company that makes disease management solutions based on an understanding of the gut microbiome, said that it has raised €13.87 million ($19.32 million) in the first tranche of a Series B fund raising. The funding has been led by the company's existing investors, Seventure (including from its new Health for Life Capital fund, which is dedicated to companies focused on health, nutrition and the microbiome) and Lundbeckfond Ventures, and is supported by Omnes Capital.

The funds raised will be used by Enterome to undertake the R&D and business development activities needed for its Metagenotyping process, which is designed for the quantitative and functional analysis of the gut microbiome in relation to health and disease.

The company said this platform will allow it to develop new disease management solutions including biomarkers, companion diagnostics and, in time, therapeutics, for inflammatory bowel and metabolic disorders, two important disease areas where the gut microbiome plays a key role. //

BRIEFLY NOTED

MELA SCIENCE SECURES CLINICAL STUDY SITES

MELA Sciences (Irvington, New York), maker of the MelaFind system, an optical diagnostic device that assists dermatologists in the diagnosis of melanoma, has concluded an agreement with the sixth and final investigative site participating in the company's post-approval study (PAS) of the MelaFind system for the diagnosis of melanoma. More than 100 patients have been enrolled in the study to date.

The three-year PAS is required in connection with the MelaFind system's premarket approval (PMA) in November 2011 by the FDA. The study will report on the safety and effectiveness of the system's non-invasive optical imaging and data analysis capabilities in a real-world setting. In April 2014 the FDA approved a revised study timeline to address the slower than anticipated pace of patient recruitment. The study is now identified as "Progress Adequate" according to the current FDA status report.

The PAS protocol anticipates the enrollment of at least 720 patients to accrue the requirement of 78 patients diagnosed with a melanoma or a high-grade lesion. The study involves a two-year follow-up period for each lesion enrolled but not undergoing biopsy. The study is designed to observe dermatologists' clinical decision-making behavior in a real world setting under conditions where the MelaFind system is and is not available to them. This design will test the primary endpoint hypothesis that the incorporation of the additional MelaFind system information into dermatologists' clinical assessment results in the identification of more than 110% of the melanomas or high-grade lesions than are identified without data from the MelaFind system.

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WORLD IN REVIEW

Boston Sci launches Promus stent in Japanese market

Staff Report

Boston Scientific (Natick, Massachusetts) has launched the Promus Premier Everolimus-Eluting Platinum Chromium Coronary Stent System in Japan. This DES system recently received Japan Ministry of Health, Labor and Welfare (MHLW) approval.

Coronary artery disease is a narrowing of blood vessels that supply blood and oxygen to the heart. Patients with coronary artery disease may experience pain, shortness of breath and fatigue. They may also be at risk for a heart attack. One treatment option is the placement of a stent in the artery to help keep it open and allow the blood to flow more freely.

Boston Scientific says the Promus Premier Stent System was developed with extensive input from interventional cardiologists and is designed to provide best-in-class acute performance and clinical outcomes. It features visibility and low recoil, and radial strength and fracture resistance. A low-profile delivery system is designed to facilitate precise stent delivery across challenging lesions.

The Promus Premier Stent System received CE mark and FDA approvals in February and November of 2013, respectively.

Boston Scientific makes medical devices. //

BRIEFLY NOTED

SANUWAVE ENROLLS 90TH PATIENT IN STUDY

Sanuwave Health (Alpharetta, Georgia) has enrolled its 90th patient in the Phase III supplemental clinical trial using dermaPACE for treating diabetic foot ulcers (DFU's), which represents the minimum number of patients the company must enroll for the first interim analysis.

The goal of the trial is to demonstrate that the healing rate of dermaPACE is statistically superior to that of sham at 12 weeks post initial device application. Patients enrolled in the study receive four non-invasive procedures (dermaPACE or sham) during the first two weeks. In addition, up to four additional non-invasive procedures (dermaPACE or control) are delivered bi-weekly between weeks 4 and 10. After the 12-week efficacy evaluation, patients are followed for an additional 12 weeks for safety. The study will continue to enroll new patients while 12-week efficacy data are collected on the first 90 patients.

Sanuwave is a shock wave technology company that makes noninvasive, biological response activating devices for the repair and regeneration of skin, musculoskeletal tissue and vascular structures.

INSPIREMD INITIATES VFA FOLLOWING DISLODGEMENT REPORTS

InspireMD (Boston), a maker of embolic protection systems (EPS), has initiated a voluntary field action (VFA) following recent reports of MGuard Prime EPS stent dislodgements. These reports have primarily occurred during the preparation of the MGuard Prime EPS, upon removal of the protective sleeve, or during withdrawal of the MGuard Prime EPS into the guide catheter. To date, there have been no reports of any patients being harmed in these recent reports reviewed by the company.

The company said it has identified the root cause of these dislodgements and, upon approval from the European regulatory agency, intends to modify all existing units of the MGuard Prime EPS in order to improve stent retention and performance. InspireMD began notifying its clinical and commercial partners worldwide of its VFA for the MGuard and intends to modify all units in the field once regulatory approval is received.

The VFA will have a short term impact on both the commercial and clinical activities relating to the MGuard. The company said regulatory review should be completed by the end of the current (second) quarter and then it will resume shipping the MGuard back to the marketplace.

IDANT GETS AABB ACCREDITATION

Daxor (New York), an investment company with medical instrumentation and biotechnology operations, said its Idant Laboratories subsidiary has once again been granted accreditation by the American Association of Blood Banks (AABB) for the collection, freezing and storage of a patient's own blood.

Idant specializes in blood banking. It can store an individual's frozen red blood cells for up to ten years. The frozen blood is then available for future use, such as during a scheduled elective surgery or in an emergency.

HIT BITS

Plexus IS offers meaningful use product for anesthesiologists

Staff Report

Plexus Information Systems (Plexus IS; Boston), an anesthesia information management systems company, reported that its technology for anesthesiologists is certified as a complete EHR for meaningful use. Plexus IS said it shares insighs from anesthesia practitioners about attesting for meaningful use wiht a certified EHR system in order to qualify for incentive payments through the incentive program administered by the Centers for Medicare and Medicaid Services (CMS).

The company offers a product called Anesthesia Touch that is designed to support both of the first two stages of meaningful use under the American Recovery and Reinvestment Act. Anestesia Touch is designed to collect and collate data for submission to CMS for the meaningful use incentive program. According to the company, the device offers users the ability to monitor progress and provide real-time feedback of a physician's compliance and participation in the meaningful use program. //

Battelle

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Daily. "One of the key pieces is that there is a chip in the brain and that picks up signals for the part of the brain that is responsible for movement. Once you have those signals how do you make sense out of them? How do you decode or decipher those? That's the second piece of this technology and the one piece we have been working on for almost 10 years and that is to basically understand or be able to recognize that brain activity when someone who's paralyzed thinks about a movement that they would like to make. That's a big piece. In more recent years we've been working on recoding how you can translate from the language of the brain to the language of the muscles. With someone who is paralyzed, now that you've recognized that they want to make a move, how do you recode and translate that language so that the muscles understand it and send it to our stimulator, the third piece of the technology actually targets muscle segments."

Earlier this week, media outlets reported on a patient that was implanted with the system, which was built off a decade's worth of research. The goal was to do what no one else has been able to thus far, and that is to allow paralyzed patients to control their own limbs with their own thoughts.

"We're actually creating virtual spinal cord algorithms or software that can basically emulate the spinal cord," Bouton said. "Not only does it decode the spinal code activity, but then it tries to serve as an artificial spinal cord. Why is that so important, well it revolves around reflexes. If you touch something hot and you jerk back and you know that your spinal cord is very involved in that because there's not enough time to have the signal travel all the way up the brain, in fact the pathway is fairly slow. It turns out it goes a lot further than that. Even your movements are coordinated and controlled with not only the brain but your spinal cord as well. Your spinal cord really helps with these coordinating moves such as walking. Our future goal is to bring it all together and have the subject think about a movement and then take control of their own limb and attempt to make their own movements, with their own thoughts."

Eventually Bouton said that the company would seek approval to commercialize the Neurobridge, but that's probably about 10 years away.

"We're still in the very early stages of development so it is very difficult to predict when we could bring such technology to the market," Bouton told, *MDD*. "But we are certainly taking it step by step and taking it through each phase of development. But we hope in the next five to 10 years that we want to see this type of technology make it into the market place."

If the device does gain approval, then spinal cord injuries are just the beginning of what it has the potential to treat, Bouton noted.

"We are absolutely looking at spinal cord injury but translating and adapting this technology to stroke patients and stroke rehabilitation," he said. "So possibly a little further out in the future, we could treat traumatic brain injury and potentially more movement disorders as well."

In the meantime, Bouton acknowledged that the role of the engineer in the healthcare setting is growing, and moving at a faster rate because of recent technological advances.

"I think we're seeing more people that are developing a multi-disciplinary background, we're seeing more multi-disciplinary teams being formed," he told *MDD*. "This idea has been around where you've seen engineers working with doctors, but I think it's growing at an exponential pace. I think the growth rate is just climbing faster and faster." //

AGREEMENTS/CONTRACTS

Gateway signs Medicare contract with U. of Penn

Staff Report

Gateway Health and the **University of Pennsylvania Health System** (both Philadelphia) reported a three-year contract agreement that they claim will improve the quality of healthcare and increase access and affordability of services for Gateway Health Medicare Assured members who live in eastern Pennsylvania. The network includes around 1,600 physicians that will now be part of the Gateway Health network that incorporates both primary care and multi-specialty providers. The new agreement is a first for Gateway Health and goes into effect immediately.

The new contract includes access to three Penn hospitals comprised of: The Hospital of the University of Pennsylvania, Penn Presbyterian Medical Center, and Pennsylvania Hospital. Ancillary services include ambulance, home care, home infusion, sleep centers, ambulatory surgery centers, skilled nursing rehab facilities and free standing radiology.

"This collaborative agreement will help support strong patient care coordination to help deliver better quality outcomes for our Medicare members and improve overall health by having access to local doctors and specialists," said Austin Ifedirah, VP Medicare and Strategic Planning, Gateway Health.

Gateway Health offers four Medicare Advantage Special Needs Plans that includes programs for those living with diabetes, cardiovascular disease or chronic heart failure, including those who are low income.

Gateway Health is a managed care organization that focuses on providing the best possible healthcare to a growing number of Medical Assistance (Medicaid) and Medicare members.

In other agreements/contracts news, The **U.S. Veteran's Administration** (Washington) chose **Nonin Medical**'s (Plymouth, Minnesota) PalmSAT 2500A Handheld Pulse Oximeter for use in its V.A. Hospitals.

Nonin's PalmSAT Model 2500A is a portable handheld pulse oximetry system with alarms that measures a patient's arterial oxygen saturation (SpO2) level and pulse rate. It can be used for spot checking or continuous monitoring. Pulse oximetry measurements can provide clinicians an early warning of hypoxemia. //

Washington

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did not fare so well, however, putting the company in a holding pattern for the device's access to market.

The IPPS proposal would slot endovascular cardiac valve replacement with major complications/comorbidities (MCC) into the novel MS-DRG 266, which CMS proposes to reimburse at nearly $62,000. MS-DRG 267, another new code, would cover the procedure without MCCs for slightly more than $46,000. Providers at some clinics had complained that practice of transcatheter aortic valve replacement (TAVR) in many centers was an economic absurdity, a message the agency seems to have heard. The two obvious winners here are **Edwards Lifesciences** (Irvine, California) for its Sapien series of TAVR entries, and **Medtronic** (Minneapolis) for the CoreValve. These two firms are locked in a transcontinental intellectual property struggle over their respective devices.

Abbott had the backing of the **Society for Cardiovascular Angiography and Interventions** (SCAI; Washington) in its effort to persuade CMS to reassign the MS-DRG for the company's MitraClip mitral valve repair device. CMS indicated that its advisers felt that MS-DRGs 250 and 251 are "reasonable" because the MitraClip uses resources at a rate similar to other procedures billed under those codes. The agency added that MS-DRGs 216-221 invoke a "post-operative resource utilization rate [that] is significantly higher" than is typically required for percutaneous procedures/device placements.

Boston Scientific (BSX; Natick, Massachusetts) still has a lot of work on its hands if it wants to get the Watchman left atrial appendage closure device to market. CMS noted in the IPPS draft that BSX anticipates FDA approval in the next month or two, but CMS indicated it is uncertain that the data are strongly suggestive of a substantial clinical improvement over warfarin therapy. The draft IPPS document says that the primary endpoint in the Prevail AF trial "was not significantly improved in the conventional hypothesis testing statistical analysis at any time point." CMS added that long-term data "remain sparse," although the agency acknowledged that the numbers do trend toward improved safety and efficacy outcomes for the study article compared to warfarin.

CMS said that the new technology add-on payment application for the CardioMEMS implant recommended the service be mapped to MS-DRG 264 and that the sponsor's analysis of claims rendered a set of 138 claims from the pivotal trial. The analysis of this claims set yielded an average case-weighted standardized charge of nearly $80,000, sufficiently in excess of the standard payment of $60,000 to qualify for an add-on application.

The sponsor, which by now is reasonably counted as **St. Jude Medical** (St. Paul, Minnesota) thanks to the impending completion of its acquisition of **CardioMEMS** (Atlanta), made note of the 28% rate of reduction in hospitalization for the device compared to controls, along with a 33% reduction at 18 months.

The sticking point where CMS is concerned is that the trial missed the lower confidence limit for one of the primary safety endpoints, freedom from device/system-related complications, although the agency acknowledged that the overall metric of 98.6% easily met the target of 90%. CMS remarked that the sponsor "did not discuss long-term outcomes, specifically death," and hinted at reluctance to offer a new-tech add-on by asking for comment on the substantial clinical improvement question.

CMS published a fact sheet for the IPPS draft, which said that the proposal includes a net payment update for acute care hospitals of 1.3%, a figure arrived at by three subtractions from the 2.7% market basket update. The subtractions include a 0.8% reduction for recoup of charges via documentation and coding adjustments, and a 0.4% cut for "multi-factor productivity." Vendors of EHR software will note that CMS would pocket 25% of the 2015 market basket update for providers that do not meet the metric for the meaningful use program. That clawback increases to 50% in fiscal 2016 and 75% the following fiscal year.

Medtronic e-mailed a statement to *Medical Device Daily* saying that the company is "pleased to see that CMS accepted the proposal to create two new separate MS-DRGs for these cardiac valve replacements." Medtronic said the new DRGs "are intended to more appropriately recognize the distinct clinical and resource differences between TAVR and surgical valve replacements." The statement observed that "appropriate" reimbursement levels "will allow Medicare beneficiaries better access to this lifesaving therapy."

Edwards also responded with a statement e-mailed to *MDD*, which like the Medtronic statement made reference to "the significant clinical differences between TAVR patients and those treated with traditional surgical aortic valve replacement" (SAVR). Edwards pointed to the higher costs associated with TAVR compared to SAVR as well. The company remarked that while payment policies "are complex, we are encouraged that if this proposal is finalized, it should benefit many hospitals performing TAVR, including those in rural areas, by ensuring future payments more accurately reflect the costs associated with TAVR."

Abbott said in a statement e-mailed to *MDD* that it is "committed to supporting more favorable CMS reimbursement" for the MitraClip, "including the new technology add-on payment." The company cited "widespread clinical support of the MitraClip," which aided the FDA approval of the device for patients "at prohibitive risk for surgery." Abbott vowed to "continue to work with CMS during the public comment period to ensure that this data is incorporated into the review process and to address any remaining questions."

Aptus Endosystems (Sunnyvale, California) filed an application for a new-technology add-on payment for the Heli-FX anchor system for fixation of aortic grafts, which FDA cleared in 2011 via application K102333, a *de novo* filing rather than a 510(k) filing. The add-on application was for abdominal and thoracic aortic grafts, which invoked MS-DRGs 236 and 237

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Versicor

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Recently the company launched a contest, dubbed Ideas to Action, through which it will provide $250,000 worth of electronics, controls and software development services to select winners. The first of two application rounds opened today and applications will be accepted through Aug. 15. Selected winners will gain access to Versicor's team of engineers as well as its platform. Christie Coplen, president of Versicor, told *Medical Device Daily* the company has been in business working with medical entrepreneurs for about two years. From a very broad perspective, the firm works with any device that requires electronics on the inside, she said.

"Effectively we're providing controlled electronics to small to mid-size companies," Coplen said. "Some companies we work with are very early in the infancy phase, but we work with other companies that are making $50 million to $100 million a year and have a clear path forward."

In addition to helping engineer hardware and software for medical devices, the company's services also include developing application interfaces or website development. The company also helps with data management and mobile design and development.

Data management is a growing need in the medical industry because there are an abundance of technologies available to collect data but not as many solutions to help the right people access and understand that data. According to Versicor, its software can not only transmit data from a medical device or mobile application but also help clients use that data and optimize the information to outcomes.

As for mobile design, Versicor said it is not a question of if but of when a medical device company will go mobile. The firm said it can develop a company's application to drive its medical device, engage customers, and accelerate product adoption.

Often, early stage medical device companies do not have a clear understanding of the regulatory pathway their products will need to take, and Versicor offers support in the way of ensuring that all the regulatory requirements are met, and offering guidance on that process from inception.

Coplen said that based on client feedback, Versicor's services can help clients bring a new product to market six times faster and can replace somewhere between four and six of the company's engineers. The way Versicor is able to do this, she explained, is by using building blocks it has developed, taking that off-the-shelf hardware and software and integrating it into the device in a plug-and-play fashion.

"It's kind of like building with Legos," she said. Versicor can build a prototype of the product which the client can then use to secure venture capital, which in turn helps move the device that much closer to the commercialization phase.

Versicor's Ideas to Action contest is expected to be an ongoing program that will include application rounds about twice a year. There will be one award recipient each round and applicants will be pooled together rather than separated by which industry they operate in.

"Through this award, our goal is to recognize product ideas in their infancy so we can better assess and deliver tangible products that embody their full potential," Coplen said. She added that the goal of the contest is also to identify companies that have the potential to make a social impact in the U.S. but need support to make that happen.

"We want to help them get out of the gate faster" and ensure that an idea isn't just an idea, it's a product, Coplen said.

But what happens after the product is out of the gate? Coplen said her firm's partnerships with clients, including medical device companies, does not end after the product is through the FDA process. "Versicor is really a design distribution service provider," she said. "We're kind of a one-stop shop: Not only can we design it, we can also distribute the product that we touch." //

Washington

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(aortic) and MS-DRGs 219-221 (thoracic).

Aptus asserted that the device's availability date for the aortic indication was June 2012, rather than the approval date because uncertainty over the *de novo* channel impeded acquisition of the capital needed to go to market. CMS did not follow this line of reasoning due to the fact that "four implantations were performed on Medicare beneficiaries" between November 2011 and June 2012. Consequently, the newness of the device for CMS's purposes expires in November 2014, thus depriving the firm of having met the newness criterion.

CMS said that FDA had approved the Heli-FX for the thoracic indication Aug. 14, 2012, however, putting the three-year anniversary at "the second half of FY 2015," giving the device/indication at least the upcoming fiscal year for eligibility. CMS indicated that Aptus had pegged the case-weighted standard charge for the device at slightly less than $159,000 whereas the metric for DRGs 219-221 came in at slightly less than $142,000. CMS indicated it would seek comment on the cost criterion "particularly with regard to the assumptions and methodology" used by Aptus in its calculations.

CMS also indicated it has concerns about the quality of the evidence behind the Heli-FX for the thoracic indication, which was provided by the Staple-2 study, a single-arm study, and the Anchor study, said to be a registry study.

The **American College of Cardiology** (Washington) declined to comment pending further review. SCAI and Boston Scientific did not respond to contacts for comment. CMS says that it will accept comment for 60 days after the appearance of the document in the *Federal Register*. According to the *FR* website, the official publication date will be May 15. //

Latin America

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a group of hospitals that already require some technological intervention and quite significant infrastructure upgrades."

The main problem Armada said he hopes to avoid is the closure of Venezuelan hospitals. A shortage of U.S. dollars in Venezuela has closed international credit lines for importers and distributors since July 2013, while exporters have halted their shipments to Venezuela fearing an increase in the overdue debt (*Medical Device Daily*, Feb. 26, 2014).

Armada's confirmation of this crisis followed a widely distributed April 23 statement by the Venezuelan Association of Clinics and Hospitals (AVCH in Spanish) that 194 out of 239 crucial items were out of stock since March 26.

"[Everything] from drugs and gloves to surgical heart valves, from injection machines to probes, catheters and sutures are out of stock," AVCH said.

"This is an extremely serious situation because of the implications for patient care in both the public and private systems. The clinics do not import directly, we acquire our supplies in the domestic market at the price established by the market. We are the final link that provides services and we suffer, along with our patients, the consequences of the progressive exhaustion of inventories."

Although Armada admitted the supply problem affecting hospitals and clinics nationwide, he also said that many complaints are politically motivated.

"We do not share those doomsday estimates made by actors performing with political intentions to generate anxiety about a situation," the health minister said. "There have been problems with some categories in particular but they are not always the same."

Armada said that the government is currently importing medicine and supplies through international agreements with Argentina, China, Cuba and Uruguay.

"Initial supplies have started to arrive through direct imports made by the government, which have allowed us to strengthen supplies," he said.

Armada added that a new vaccine plant will be built and two new medical technology corporations would be founded with the support of China, Cuba and Portugal. No further details of these projects were given.

Imports from Argentina, China, Cuba and Uruguay mentioned by Armada follow a February decision by the government to create the "Corporación Nacional de Insumos para la Salud" (CONSALUD), a public corporation designed to buy, import, export, store, promote and distribute healthcare-related products such as medical and lab devices and supplies. (*MDD*, Mar 10, 2014.)

Venezuela produces very little of the medical and surgical supplies it uses, the majority of which are imported. It appears that importing via international agreements has not been enough to address the serious shortage of supplies that the country is facing.

"A month and a half ago we had a meeting at the Ministry of Health, where we presented all these realities and both parties committed to promote a joint agenda to promote the mechanisms that would allow to solve this juncture with the urgency needed," AVCH said. "Today, six weeks later, we have not received any concrete answers to our proposals, which forces us to alert the community of this critical situation and the uncertainty that the health sector is facing in our country. Health has no ideology!"

Meanwhile, Armada announced that in the midst of the conferences that are being held between the Venezuelan government and different domestic economic sectors, the government has vowed to overcome the obstacles to access to foreign currency for medical technology importers so that they can purchase much-needed supplies. AVCH is not participating in these talks. The importers and distributors were represented by the **Venezuelan Association of Distributors of Medical, Odontological and Lab devices**, which declined to comment on Armada's statement or the crisis. //

PATENT WATCH

LabStyle Innovations gets patent for Dario Diabetes management solution

Staff Report

LabStyle Innovations (Caesarea, Israel), maker of the Dario Diabetes management solution, has received a notice of allowance from the U.S. Patent and Trademark Office for core patent claims covering the company's personalized blood glucose monitoring device.

LabStyle's patent specifically relates to how the Dario blood glucose monitor draws power from and transmits data to a smart phone via the audio jack port. This device is designed to work in tandem with LabStyle's Dario software application to form the overall Dario Diabetes management solution.

The company says the issuance of the notice of allowance is the critical milestone that will allow LabStyle to obtain formal U.S. patent protection in the coming months for this invention while LabStyle continues to seek similar patent protection in non-U.S. jurisdictions. LabStyle also believes that the claims of this invention could potentially be expanded to cover the measurement of parameters to help manage additional chronic diseases. //

PRODUCT BRIEFS

• **HeartWare International** (Framingham, Massachusetts) has issued a voluntary Urgent Medical Device Correction related to all HeartWare Ventricular Assist System batteries, product codes 1650 and 1650-DE. In letters to clinicians and patients, the company reports an observed increase in complaints related to earlier-than-expected battery depletion and routine battery handling. HeartWare is providing information to assist patients and clinicians in monitoring battery performance, recognizing abnormal behaviors and reinforcing proper power management. Premature or unrecognized deterioration of battery capacity or lapses in recommended power management pose a risk to the patient and, although rare, may result in serious injury or death. If a battery shows abnormal behavior, patients are instructed to stop using that battery and contact their VAD Coordinator for a replacement. Similar to the battery in a mobile cell phone, HeartWare batteries will begin to lose charge over time. If a fully-charged battery lasts less than two hours or if the controller switches back-and-forth between batteries, patients are asked to take the affected battery out of service and replace it with a new one. No deaths have been reported to HeartWare that were directly related to a faulty battery.

• At the Heart Rhythm Society's 35th Annual Scientific Session in San Francisco, **The Spectranetics Corporation** (Colorado Springs, Colorado), says it will focus on management of cardiac device infections and debut of the company's first mechanical lead extraction devices. The new TightRail Rotating Mechanical Dilator Sheath and SightRail Manual Mechanical Dilator Sheath Set represent Spectranetics' entry into the mechanical extraction device market. TightRail combines shaft flexibility and a forward-facing dilating blade that remains shielded until activated by the physician. The SightRail manual dilator sheath features visual indicators that show bevel orientation and tip alignment, supplementing fluoroscopy as a means to determine position and orientation.

PEOPLE IN BRIEF

• **Abingdon Health** (London) reported the appointment of Marsha Leeman as quality and regulatory assurance manager with immediate effect. Leeman joins Abingdon from Alere Toxicology plc, a subsidiary company of Alere. Abingdon Health is a specialist medical diagnostics company.

• As reported in October 2013, Niklas Savander will assume the role as **Elekta**'s (Stockholm, Sweden) president/CEO, succeeding Tomas Puusepp who will continue as member of the company's board. Elekta is a human care company pioneering significant innovations and clinical solutions for treating cancer and brain disorders. Elekta makes solutions in oncology and neurosurgery .

• **EndoGastric Solutions** (EGS; San Mateo, California) has named Skip Baldino as president/CEO. The past four years, Baldino was president, Americas for Given Imaging. EndoGastric Solutions specializes in endoluminal reconstructive treatment for gastroesophageal reflux disease.

J&J suspends sale of device used in fibroid surgery

Staff Report

Johnson & Johnson (J&J; New Brunswick, New Jersey) suspended worldwide sale of its device used in fibroid surgery amid concerns over its potential to spread undetected cancer beyond the uterus, according to *Reuters*.

Medical Device Daily reported that the FDA held an April 17 press briefing reported it wants to "discourage" the use of power morcellation to remove uterine fibroids, and the patient reaction might be expected to reflect that concern. However, a surgeon told *MDD* that some hospitals "are clamping down on the use of the morcellator," suggestive of an overreaction to the FDA statement that will not only needlessly hinder sales of the affected devices, but also deprive some patients of a legitimate option to open surgical access.

Bill Maisel, MD, the chief science officer at the Center for Devices and Radiological Health, said in the briefing that one in 350 women "is found to have an unsuspected uterine sarcoma," and that there is a risk that morcellation "will spread the cancer to the abdomen and the pelvis." However, Jessica Shepherd, MD, of the **University of Illinois College of Medicine** (Chicago), said in an interview with MDD that the discrepancy in FDA's statement "is just what really is the risk. I think that's the unknown number right now."

The company said it is suspending the sale of its power morcellators until their role in fibroid treatment is better understood and redefined by the medical community.

The action follows an FDA advisory on April 17 that discouraged doctors from using laparoscopic power morcellators to remove fibroids because of a risk of worsening an often-hidden cancer.

"Ethicon morcellation devices have always included cautions in their instructions for use about the potential spread of malignant tissue," J&J wrote in a letter to customers, a copy of which is available with *Reuters*.

J&J said the step was not a product removal as the FDA maintained that power morcellation may still be the best option for some patients after risk evaluation and informed consent.

Laparoscopic power morcellation is one of several available treatments for fibroids. It is a procedure that uses a medical device to divide the uterine tissue into smaller pieces or fragments so it can be removed through a small incision in the abdomen.

Uterine fibroids are non-cancerous growths that originate from the smooth muscle tissue in the wall of the uterus.

DIAGNOSTICS EXTRA

Keeping you up to date on recent developments in diagnostics

By Omar Ford, Staff Writer

Diagnosis Of Childhood TB Could Be Improved By Genetic Discovery

A distinctive genetic 'signature' found in the blood of children with tuberculosis (TB) offers new hope for improved diagnosis of the disease. TB is very difficult to diagnose in children and is often recognized late when the child is already critically ill and the disease has spread from the lungs to the brain or other organs. Now an international team of researchers has shown that the disease can be identified in more than 80% of cases by looking at 51 specific genes in the blood of affected children.

The researchers hope the findings – published on 30 April in the *New England Journal of Medicine* – could be used to develop a cheap, quick and effective diagnostic test. Lead researcher, Michael Levin, director of the **Welcome Centre for Clinical Tropical Medicine at Imperial College** (London), said, "We urgently need better methods to diagnose TB in children, so treatment can be started earlier and to avoid unnecessary treatment of children who are wrongly diagnosed. The symptoms of TB in children are common to many other childhood diseases, and the standard tests used on adults are not effective in children. Although the disease is treatable, thousands of children still die each year due to late diagnosis and many more are left with damage to their brain, bones and lungs."

The study – funded through the EU and carried out at Welcome Trust-supported units in Africa – looked at more than 2,800 children admitted to hospitals in South Africa, Malawi and Kenya with symptoms of TB. The researchers identified those who had proven TB and those in whom TB was excluded as the cause of the child's illness.

Blood samples from the South African and Malawian children were examined to see which genes were activated or suppressed in those with the disease. The researchers found that TB could be distinguished from other diseases by looking at just 51 genes from over 30,000 in the human genome and seeing whether they were activated or suppressed. This information was used to give a single TB risk score for each child which, when tested in the Kenyan patients, accurately diagnosed over 80% of the children with TB.

Levin said: "It has taken seven years and the combined efforts of clinicians and scientists in the UK, Africa and Singapore to identify this gene signature of childhood TB. What we now need is collaboration from biotechnology and industrial partners to turn these findings into a simple, rapid and affordable test for TB that can be used in hospitals worldwide."

Depression detectable in the blood: Platelet serotonin transporter function

Researchers at the **MedUni Vienna** (Vienna, Austria) have demonstrated the possibility of using a blood test to detect depression. While blood tests for mental illnesses have until recently been regarded as impossible, a recent study clearly indicates that, in principle, depression can in fact be diagnosed in this way and this could become reality in the not too distant future.

Serotonin transporter is a protein in the cell membrane that facilitates the transport of the neurotransmitter serotonin (popularly known as the "happiness hormone") into the cell. In the brain, serotonin transporter regulates neural depression networks. Depressive conditions can frequently be caused by a lack of serotonin. As a result, the serotonin transporter is also the point of action for the major antidepressant drugs.

The serotonin transporter, however, also occurs in large quantities in numerous other organs such as the intestines or blood. Recent studies have shown that the serotonin transporter in the blood works in exactly the same way as in the brain. In the blood, it ensures that blood platelets maintain the appropriate concentration of serotonin in the blood plasma.

Researchers at the MedUni Vienna have now used functional magnetic resonance imaging of the brain and pharmacological investigations to demonstrate that there is a close relationship between the speed of the serotonin uptake in blood platelets and the function of a depression network in the brain.

This network is termed the "default mode network" because it is primarily active at rest and processes content with strong self-reference. Findings from recent years have also demonstrated that it is actively suppressed during complex thought processes, which is essential for adequate levels of concentration. Interestingly, patients with depression find it difficult to suppress this network during thought processes, leading to negative thoughts and ruminations as well as poor concentration.

MRI-Guided Biopsy tehcnology For Brain Cancer Improves Diagnosis

Neurosurgeons at **UC San Diego Heath System** have combined real-time magnetic resonance imaging (MRI) technology with novel non-invasive cellular mapping techniques to develop a new biopsy approach that increases the accuracy of diagnosis for patients with brain cancer.

"There are many different types of brain cancer. Making an accurate diagnosis is paramount because the diagnosis dictates the subsequent course of treatment," said Clark Chen, MD, PhD, vice-chairman of research, division of neurosurgery, UC San Diego School of Medicine. "For instance, the treatment of glioblastoma is fundamentally different than the treatment for oligodendroglioma, another type of brain tumor." Chen said that

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as many as one third of brain tumor biopsies performed in the traditional manner can result in misdiagnosis.

Chen's team applied an MRI technique called restriction spectrum imaging (RSI) to visualize the parts of the brain tumor that contain different cell densities. "RSI allows us to identify the regions of the cell that are most representative of the entire tumor," said Chen. "By targeting biopsies to these areas, we minimize the number of biopsies needed but still achieve a sampling that best characterizes the entire tumor."

To ensure a targeted biopsy, Chen performs the procedure in the MRI suite while the patient is under general anesthesia. Because conventional biopsy equipment cannot be used in the MRI, Chen uses a special MRI-compatible system called ClearPoint. This system utilizes an integrated set of hardware, software and surgical equipment to allow the surgeon to target and visualize the path of the biopsy as well as the actual biopsy site, intraoperatively.

"Surgeons have been performing brain biopsies in a near blind manner for the past fifty years. The ability to see where the biopsy needle is located and where the biopsy is being performed in real time is groundbreaking," said Chen. "This combination of technologies gives me an opportunity to immediately adjust my surgical approach while minimizing risk."

MRI Shows Disrupted Connections In The Brains Of Young People With ADHD

A new study has found that children and adolescents with attention deficit hyperactivity disorder (ADHD) have disrupted connections between different areas of the brain that are evident on resting-state functional magnetic resonance imaging (rfMRI). The results of this research are published online in the journal *Radiology*.

The findings point to the potential of rfMRI to help provide objectively accurate, early diagnosis of a disorder that affects about 5% of children and adolescents worldwide.

ADHD is a disorder characterized by age-inappropriate degrees of inattention, hyperactivity and impulsivity. Functional MRI studies, which measure brain activity when a person is focused on a particular task, have implicated the brain's frontostriatal circuit, a collection of neural pathways in the frontal lobe of the brain that helps control behavior. However, the specific brain physiology underlying ADHD remains poorly understood.

For the new study, researchers used rfMRI, a relatively new technique that assesses neural function when the brain is not focused on a specific task. The technique is useful for exploring the brain's functional organization independent of task performance.

The researchers compared rfMRI results in 33 boys with ADHD, ages 6 to 16, with those of 32 similarly aged, healthy controls. They correlated the MRI findings with results from tests of executive function, a term for the set of mental processes involved in planning, organizing, time management and regulating emotions, among other things. People with ADHD often have abnormal executive function.

The results showed that the patients with ADHD had altered structure and function located in areas of the brain like the orbitofrontal cortex, which is primarily involved in the cognitive processing of strategic planning, and the globus pallidus, which is involved in executive inhibitory control.

"Our study suggests that the structural and functional abnormalities in these brain regions might cause the inattention and hyperactivity of the patients with ADHD, and we are doing further analysis on their correlation with the clinical symptoms," said Qiyong Gong, MD, PhD, a neuroradiologist from the Department of Radiology at **West China Hospital of Sichuan University** (Sichuan, China). "Our preliminary results show the association between imaging findings and symptoms."

The researchers also found abnormalities in the connections between resting-state brain networks associated with executive dysfunction. These abnormalities indicate more widespread brain alterations in ADHD than previously had been shown, Gong said.