

Uncertainty plagues panel in Repel CV trial discussions

By MARK McCARTY

Medical Device Daily Washington Editor

GAITHERSBURG, Maryland – Thursday's meeting of the circulatory systems advisory committee made clear again how much detail FDA seeks in its regulation of high-risk medical devices. FDA convened the panel for ideas about what should be required for a clinical trial for a cardiac anti-adhesion device in adult populations, but the feedback was not as extensive as the agency may have hoped.

Perhaps the only take-away message FDA heard, however, is that the panel was flatly unable to tell FDA whether there was any legitimate difference between pediatric and adult populations where adhesions and a device's efficacy are concerned.

At present, the only anti-adhesion device available in the U.S., the Repel CV, is indicated only for pediatric use. The product's sponsor, **SyntheMed** (Iselin, New Jersey),
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NIH launches \$30M project to map 'wiring diagram' of brain

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

It comes as no big surprise that "no two brains are wired up exactly the same," Michael Huerta, PhD, associate director of the National Institute of Mental Health (NIMH) told *Medical Device Daily*.

But with the help of a new \$30 million project scientists will now have an opportunity to learn more about how the brain is wired, and how many similarities and differences exist between different brains.

Huerta is the lead NIH contact for the Human Connectome Project (HCP) being launched by the National Institutes of Health Blueprint for Neuroscience Research. The HCP will use "cutting-edge" brain imaging technologies to map the circuitry of the healthy adult human brain. According to the NIH, by systematically collecting brain imaging data from hundreds of subjects, the HCP will yield insight into how brain connections underlie brain function, and will open up new lines of inquiry for human neuroscience.

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AACC 2009

Rapid tests for dengue virus, tuberculosis launched at AACC

By LYNN YOFFEE

Medical Device Daily Staff Writer

CHICAGO – **MP Biomedicals** (Singapore) has launched rapid tests for two highly contagious and rapidly spreading diseases. Dengue virus and tuberculosis (TB) infect literally millions of people each year and result in millions of deaths.

"FastSure TB DNA molecular rapid test is the first ever rapid test," Samson Chen, MD director of sales and marketing, MP Biomedicals Asia Pacific, said at the **American Association for Clinical Chemistry's** (AACC; Washington) annual meeting.

"With Assure Dengue IgA Rapid test, we seek to fill the gap that definitely exists in the current dengue diagnosis," said Bijon Kumar Sil, R&D director, MP Biomedical Asia Pacific and lead inventor of the test. "This is a significant
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Consulting firm head sees opportunity in reform effort

By JIM STOMMEN

Medical Device Daily Contributing Writer

Ask Harry Glorikian to look into the future of medical technology companies and the founder and managing partner of consulting firm **Scientia Advisors** (Cambridge, Massachusetts) sees opportunity. Make that opportunities – and some threats as well.

The opportunity part of the equation comes from the broader base of covered lives anticipated under whatever final form is taken by healthcare reform, along with, he said, "opportunities to sell products differentiated by cost-effectiveness, faster adoption due to faster standardization, and the opportunity to leverage things like EMR [electronic medical record] data to speed time to market and reduce clinical trial costs."

Add to that the anticipated commercialization of innovative products such as cell therapies, Glorikian said, and you have ready examples of opportunity knocking.

"The threats are where companies are not ready for
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AHC Media LLC

*Report from Europe***Biotronics3D in collaboration to develop oncology software****A Medical Device Daily Staff Report**

Biotronics3D (London) has worked with **The Institute of Cancer Research** (ICR; London) to develop and launch new software to significantly improve the accuracy of MRI scan analysis. Called 3D Net Perfusion, the system extracts data from images of tumors and transforms it into usable information.

A powerful analytical tool, 3D Net Perfusion enables clinicians to gain clearer comprehension of MRI scans, improving the accuracy of diagnosis and assessment of treatment efficacy. It is also a way of visualizing and measuring the blood supply to cancers – a crucial factor in tumor growth.

The software is the result of pioneering trials at the ICR led by Professor Martin Leach, David Collins and James d'Arcy, and is currently used in 10 research centers. Scientists from the ICR continue to work with Biotronics3D software developers to further enhance the product.

Paul Carnochan, Senior Business Development Manager at the ICR, believes the partnership could have broader implications and says: "London has an abundance of research capabilities and commercial expertise in the field of medical imaging and we believe that collaborations like this one can be the key to raising London's profile as a major biotech hub."

"Innovation carries risks and in fast moving markets such as global diagnostics it is important to leverage skills that exist outside the company through partnerships such as ours with the ICR," said Harry Hatzakis, CEO of Biotronics 3D.

The project has attracted significant investment from

Today's MDD food for med-tech thought

"What we're going to see is manufacturers and payers embracing not technology for its own sake, but technology that truly improves the cost-effectiveness of health-care."

– Harry Glorikian, founder and managing partner of consulting firm Scientia Advisors, on what should drive innovation in the future of med-tech innovation, "Consulting firm head sees opportunity in reform effort," pp. 1, 8.

London-based venture specialist Longbow Capital.

Biotronics3D develops software applications for the diagnostic imaging industry.

Hyperbranch gets CE mark for NuSeal 100

HyperBranch Medical Technology (Durham, North Carolina) reported that it has received a CE mark for its NuSeal 100 dural sealant product. NuSeal 100 is used in cranial neurosurgical procedures where a water tight seal is required on the dura. NuSeal 100 is intended for direct application on the dural surfaces to provide a positive seal after suturing thereby minimizing risks associated with post-surgical CSF leaks.

The unique, single use device is terminally sterilized and sets on contact after a spray application. The synthetic, biocompatible composition is stored at room temperature and is delivered through the custom applicator to meet the specific needs of the procedure. The intended users of NuSeal 100 are Neurosurgeons in a surgical environment.

The company has also been developing advanced surgical sealants for pleural (lung), cardiovascular and hernia mesh fixation. These products are at various stages of clinical and pre-clinical development. The company also has licensed its ophthalmic sealant to **BD Medical** (Waltham, Massachusetts) for sale outside the U.S. ■

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*Deals roundup***Cardium sells InnerCool unit to Philips for \$11.25 million****A Medical Device Daily Staff Report**

Cardium Therapeutics (San Diego) said it has completed the previously disclosed asset sale of its **InnerCool Therapies** (San Diego) business to **Royal Philips Electronics** (Best, the Netherlands) for \$11.25 million, as well as the transfer of roughly \$1.5 million in trade payables (*Medical Device Daily*, July 17, 2009).

Cardium's initial investment portfolio includes InnerCool Therapies, the Tissue Repair Company, and Cardium Biologics, medical technology companies primarily focused on the development of therapeutic products and devices for cardiovascular, ischemic and related indications.

In other dealmaking activity, **JAG Media Holdings** (Boca Raton, Florida) reported a further update of the status

of its acquisition of **CardioGenics** (Mississauga, Ontario). The closing date for the acquisition, currently scheduled for a date on or before July 24, has been rescheduled to a date on or before July 31, 2009 to allow the parties sufficient time to attend to the final closing matters.

The closing of the deal remains subject to: CardioGenics closing on private placements of not less than \$1,500,000; the completion of the pro forma financial statements for the transaction based on CardioGenics' and JAG Media's relevant financial statements; the CardioGenics shareholders and debenture holders making certain deliveries, prior to the closing, as set forth in the share purchase agreement; and the satisfaction of various customary conditions to closing.

JAG Media is a provider of Internet-based equities research and financial information that offers its subscribers a variety of stock market research, news and analysis.

CardioGenics develops technology and products targeting the immunoassay segment of the *in-vitro* diagnostic testing market. ■

*Patent watch***USPTO validates 3 KCI patents licensed from Wake Forest****A Medical Device Daily Staff Report**

Kinetic Concepts (KCI; San Antonio) reported that the U.S. Patent and Trademark Office (USPTO) issued office actions confirming the validity of three separate patents licensed to KCI by **Wake Forest University Health Sciences** (Winston-Salem, North Carolina) in re-examination proceedings.

"The advanced wound care market represents a very competitive environment," said Stephen Seidel, KCI executive VP, CAO and general counsel. "In a competitive market, patents remain important and are a protection due any

company that truly innovates. KCI's patents reflect thorough research undertaken with an eye towards patient care, meaningful clinical outcomes and reduced costs to the healthcare system. That's what competition and innovation are all about."

The patents associated with this decision include U.S. Patent Nos. 5,636,643 (the '643 Patent), 5,645,081 (the '081 Patent), and 7,216,651 (the '651 Patent), which all relate to KCI's negative pressure wound therapy technologies. The USPTO has provided public notice of its intent to issue certificates of re-examination affirming the validity of key claims in the '643 Patent and the '081 Patent. The USPTO also issued a formal office action confirming the validity of all claims in the '651 Patent.

KCI develops therapies and products for the wound care, tissue regeneration and therapeutic support system markets. ■

*New ventures***Agilis Systems establishes Mobile Health Tech div.****A Medical Device Daily Staff Report**

Agilis Systems, (St. Louis), developer of comprehensive work order and workflow management solutions that transform mobile devices into wireless business platforms, has reported the establishment of its latest division: Mobile Health Technologies. Mobile Health Technologies will cater specifically to professionals in home healthcare, durable medical equipment companies, pharmaceutical distributors and patient transport providers.

The new entity will combine the power of Agilis' software with an expert team that has more than 30 years of combined experience in the healthcare technology field.

Mobile Health Technologies employs traditional GPS location-based tracking tools to generate increased organizational efficiency and cost savings.

Time and location stamps, electronic signature capture, bar code scanning and extending back office forms and policies to the field staff can promote regulatory compliance and create essential auditable trails for healthcare employees and their companies. In addition, the solution software supports features such as picture capture for wound management, payment processing at the point of delivery and visit documentation at the point of care.

Customers can choose a mobile device (and blue tooth enabled peripherals) to pair with Mobile Health Technologies' modular software components and create the complete set of indispensable healthcare tools specific for their needs. ■

Agreements/contracts

Calypso, Varian partner for tumor therapy technologies

A Medical Device Daily Staff Report

Calypso Medical Technologies (Seattle), a developer of real-time localization technology used for the precise tracking of tumor targets, reported that it has entered into a strategic development agreement with **Varian Medical Systems** (Palo Alto, California) to jointly develop products integrating its Calypso System with Varian's radiotherapy treatment technologies.

The two companies will jointly develop products that integrate the Calypso System with Varian's technologies. Further terms of the agreement were not disclosed.

Calypso Medical's technology uses miniature implanted transponders to provide precise, continuous, real-time information about the location of the tumor target during external beam radiation therapy. Any movement by the patient, including internal movement of the tumor, has the potential to compromise treatment accuracy. In contrast to other tumor targeting solutions, Calypso's technology provides continuous tumor position information, objectively, thereby enabling the correct radiation dose to be delivered to the tumor while minimizing the amount of radiation misapplied to normal tissue.

The Calypso technology is complementary to Varian's technology for delivering intensity-modulated radiotherapy, including RapidArc radiotherapy.

"This strategic development agreement will facilitate advanced treatment capabilities through the integration of the Calypso System with Varian's market-leading radiotherapy technologies," said Eric Meier, president/CEO of Calypso. "We believe these efforts may prove beneficial for prostate patients as well as some of the more difficult radiation therapy targets such as pancreas and lung. In the near term, two exciting joint development efforts will integrate the motion management capabilities of our Calypso System with Varian's state-of-the-art treatment platform. This agreement will provide the framework for the joint development of Real-Time MLC Tracking, a future capability demonstrated by both companies last year, which causes the radiation beam to move in concert with the tumor target based on real-time tracking data provided by the Calypso System."

"It can augment the image-guidance tools that are integral to Varian's technology, and enable us to better follow both normal respiratory motion and to react to unanticipated shifts in the target position – for example, when a patient coughs or moves. These capabilities could lead to entirely new treatment approaches for hard-to-treat tumors. We look forward to working with Calypso Medical to integrate our technologies," said Dow Wilson, president of Varian's Oncology Systems business. ■

Financings roundup

SafeStitch in stock purchase pacts for nearly \$2 million

A Medical Device Daily Staff report

SafeStitch Medical (Miami) reported that it has entered into two stock purchase agreements with private investors, pursuant to which SafeStitch may issue an aggregate of up to four million shares of the company's newly-designated 10% Series A cumulative convertible preferred stock, par value \$0.01, at a price of \$1 per share.

The company closed on the sale of two million shares in a private transaction for aggregate proceeds of \$2 million on July 22, 2009, and SafeStitch may elect, in its sole discretion, to issue an additional two million shares on or before June 30, 2010. Shares issued pursuant to the agreements, including the shares of the company's common stock into which the preferred shares may be converted, are restricted securities, and no registration rights have been granted.

In other financings: **St. Jude Medical** (St. Paul, Minnesota) reported that it has priced an offering to sell \$700 million of senior notes due 2014 (the 2014 notes) and \$500 million of senior notes due 2019 (the 2019 notes). The 2014 notes will bear interest at 3.750% per year and, unless previously redeemed, will mature on July 15, 2014. The 2019 notes will bear interest at 4.875% per year and, unless previously redeemed, will mature on July 15, 2019.

The company said it intends to use the net proceeds from the offering for general corporate purposes, which may include the repayment of certain of its indebtedness and the repurchase of its outstanding common stock pursuant to its \$500 million authorized share repurchase program, as separately reported.

As previously reported, BofA Merrill Lynch is acting as active booking-running manager for the offering. ■

Med-tech Notes

Biopure delisted from Nasdaq

Biopure (Cambridge, Massachusetts) said that it has received notice from The Nasdaq stock market that its common stock would be delisted from Nasdaq. The notice stated that because of concerns raised by the company's filing for protection under Chapter 11 of the Bankruptcy Code, trading would be suspended at the opening of business on July 28.

Biopure makes pharmaceuticals, called oxygen therapeutics, that are intravenously administered to deliver oxygen to the body's tissues.

Panel

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won a vote of approvability from the panel in 2007 (*Medical Device Daily*, Sept. 21, 2007), only to have to wait for another year and a half before the agency finally gave the product the nod (*MDD*, March 12, 2009).

SyntheMed obtained a CE mark for the Repel CV's use in all patients in 2006 and regulatory approval in Australia for all patients earlier this year. The company got the nod from Health Canada in July 2008 for pediatric patients only.

SyntheMed's original application was for patients of all ages undergoing open heart surgery, but the data presented at the 2007 advisory committee hearing was for pediatric patients and the panel was averse to extrapolating to adult patients, hence the agency's approval for only the study population. In FDA's documents for Thursday's hearing, the agency acknowledges, however, that "the formation and pathophysiology of adhesions is generally the same in pediatric and adult populations."

One of the peculiarities that arose in the pivotal trial for the original PMA submission was that while controls did indeed experience more adhesions (42.7% vs. 21.3% of subjects on the study article) upon re-operation at an average of 150 days, overall rates of adverse events were similar.

Among the adverse events that were more common in the study group was mediastinitis, an inflammation of any one or more of several organs and blood vessels of the thorax. The study group also experienced a higher rate of deaths, although the difference was not deemed statistically significant. Also problematic for the pivotal trial was that blinding of the physician was not possible inasmuch as the surgeon who performed the second procedure on the subjects was usually the same surgeon who implanted the device in the first operation on the patient.

The first question FDA posed to the panel was essentially a request that the panel discuss the similarities between adults and infants regarding the physiology of adhesion formation and whether the duration of the efficacy of the device was age-dependent. After some discussion, panel chairman Jeffrey Borer, MD, of **Weill Cornell Medical College** (New York), summarized, "the panel's overall opinion is that we don't have any evidence that there is any fundamental difference . . . because there aren't many data relevant to this point." Borer observed that the paucity of data means that physicians "don't know how to pick out which patients will develop" adhesions. As for whether data from the from the pivotal trial's neonatal population can be extrapolated to adults, Borer summarized, "the general consensus is that the pediatric population" is a reasonable surrogate.

One panelist said it would be reasonable to assume the device would work in patients other than those who received ventricular assist devices (VADs) if the device showed efficacy in VAD patients. On the other hand, Borer observed that a device's failure to cut down on adhesions in a VAD population would not rule out its efficacy in other populations.

Because neonatal patients typically are re-operated on relatively quickly because of the severity of their heart defects, FDA sought opinions as to whether the longer stretch between surgeries in the typical adult candidate was meaningful. Once again, however, the panel more or less shrugged. "The shorter interval [for pediatric patients] may indeed be meaningful," Borer summarized, "but we can't know in any rigorous way."

As to a method for evaluating device efficacy over time, Borer opened the discussion saying, "the best candidate procedure for this is MRI," but added, "it hasn't been validated for this use yet, thought it could be." Tagged echocardiography is another candidate, he said.

Panelist Michael Domanski, MD, of the National Heart, Lung and Blood Institute made the case that "some real effort should be bent around developing the non-invasive imaging" to evaluate adhesions, which he said is "not necessarily an extraordinarily difficult" task and which he characterized as "relatively inexpensive."

As for what the benefit of the Repel CV might be in patients with ventricular assist devices (VADs), the panel concluded that the current generation of VADs do present a risk of adhesion, but one panelist noted that the next generation of VADs will present a smaller surface area and hence will soon render such considerations obsolete. "Within two years, you're not going to see pulsatile devices" serving to augment the function of the ventricle, said Brett Sheridan, MD, of the **University of North Carolina** (Chapel Hill, North Carolina). After further discussion, Borer said the gist of conversation was that "there are situations in which a study of the device . . . could be very useful in a VAD population" but that "there are concerns about the extrapolability" of such a study.

Regarding FDA's questions about a trial's safety endpoints, the committee drew few definite conclusions, but among those discussed were mediastinitis, cardiac tamponade (fluid buildup within the pericardial membrane) and mortality.

Panelist Eugene Blackstone, MD, of the **Cleveland Clinic** (Cleveland), remarked, "I find it difficult to believe that mortality as an endpoint would be more than noise" to no dissent. Domanski opined, "I think myocardial infarction as an endpoint" may be useful because of contact between the barrier and the coronary arteries in some instances. He recommended a year or so to follow up.

Taking up efficacy endpoints, Domanski restated an earlier position: "I want to put in a pitch again for imaging" to validate the device. "I think a reasonable endpoint is in fact having someone who is blinded to the treatment [to] grade the severity" of adhesions.

In the context of non-inferiority safety margins, Borer summarized the panel's view with the observation that it is "very difficult to infer efficacy in a rigorous way" because of lack of quantitative links. "Given that we can't measure the benefit" directly, he said, "it's hard to conceive of allowing" the device into the market with a risk "that is substantially greater than none at all." ■

AACC

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step in dengue diagnostics, more so when you consider the scenario. Dengue treatment is merely supportive; there are no signs of preventive vaccination in the immediate future.”

The **Centers for Disease Control and Prevention** (CDC; Atlanta) reports that nearly nine million people around the world become sick with highly contagious TB each year with two million TB-related deaths. And it's estimated by the **World Health Organization** (Geneva) that dengue, which is spread via mosquitos, infects 50 million people annually.

“PCR shows good results when testing for TB, but there's a high cost associated and you need highly trained lab technicians,” Chen said. “FastSure TB DNA is more economical and more accurate.”

AFB smear and culture test is the current gold standard to diagnose TB. When FastSure TB DNA was compared in tests, it produced 96% sensitivity and 98.8% specificity.

For the user, the test requires a very small sample to be placed in a cartridge, which is then inserted in the handheld device. Results are observed with either a line or not, similar to a pregnancy test. Chen said this ease of use is critical in places of the world where trained lab technicians aren't available. Results are available within two hours.

“Relatively newer technologies such as PCR are promising but they can have their own challenges in terms of higher capital expenditure, need of specialized manpower and they're not easily available in underdeveloped and developing countries,” Chen said.

The dengue test, the company reports, is the very first of its kind.

The Assure Dengue IgA Rapid Test is a reverse flow immuno-chromatographic rapid test for qualitative detection of anti-dengue IgA antibody in whole blood, serum or plasma.

The dengue test produces results with an indicator line similar to the TB test and results are available in 20 minutes.

In other news from the conference:

- **Abbott** (Abbott Park, Illinois) reported that a diagnostic marker, human epididymal protein 4 or HE4, combined with other tests, can be used to more effectively monitor for early stage ovarian cancer (EOC), improving treatment options for many of the 22,000 women in the U.S. who develop the deadly disease each year.

New research on HE4 presented by Richard Moore, MD, associate professor in the Program for Women's Oncology at **Women and Infants' Hospital/Brown University**, at a scientific workshop hosted by Abbott, provided validation for the use of the HE4 test in combination with CA125, the current standard for monitoring ovarian cancer, in estimating EOC risk in women presenting with pelvic masses.

The HE4 test was developed through research efforts

aimed at identifying combinations of biomarkers to add sensitivity to the CA125 test, which is limited in its sensitivity and specificity, as well as its ability to monitor early EOC.

“Our results show that the dual marker combination of HE4 and CA125 can aid in the differentiation of benign pelvic masses from ovarian malignancies in women diagnosed with a pelvic mass,” said Moore. “This is exciting as it will help us improve the care we give to the many women who are afflicted by this deadly disease.”

- **Fujirebio Diagnostics** (Malvern, Pennsylvania) and Abbott have signed a license agreement to develop this new ovarian cancer marker for use on Abbott's automated Architect diagnostic analyzers. A manual form of the HE4 test has been approved by the FDA as an aid in monitoring recurrence or progressive disease in patients with EOC and is CE marked for use within the European Union.

- **AMDL Diagnostics** (Tustin, California) introduced AMDL's FDA-approved non-invasive Onko-Sure *in vitro* diagnostic (IVD) blood test that enables physicians and their patients to effectively monitor and/or detect solid tumor cancers, including colorectal cancer, by measuring the accumulation of specific breakdown products in the blood called fibrin and fibrinogen degradation products.

AMDL Chairman/CEO Douglas MacLellan said, “Since AMDL Diagnostics began commercializing its Onko-Sure IVD cancer test we've seen substantive market demand both as a CRC monitoring test and a pan tumor cancer screen. This is positive news for the company in that selling Onko-Sure in the U.S. as a CRC monitoring test and expanding the application of the test as a pan tumor marker internationally offers greater market penetration and revenue upside. On tests sold to IVD distributors ranging from \$50 per test per patient for CRC and up to \$150-\$250 per test per patient as a pan tumor screen we expect a gross profit margin above 90%. Our top priority is to continue signing strategic distributor partners that will enable us to achieve our market share targets.” ■

Med-tech Notes

Fire fighters, Masimo head CO safety program

The **International Association of Fire Fighters** (IAFF; Washington) and **Masimo** (Irvine, California) jointly reported the launch of a new international health and safety initiative aimed at educating fire fighters about the duty-related dangers of carbon monoxide (CO) and reducing known risk factors that unnecessarily kill and injure hundreds of fire fighters each year.

“We are pleased to team with Masimo and with Randolph Mantooth in this important effort,” said IAFF General President Harold Schaitberger. “This is a critical educational endeavor that we hope will help contribute to the protection of our members.”

NIH

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"A major feature of the brain that underlies how it works – or how it doesn't work, very often – is the connectivity of one part of the brain to another part of the brain," Huerta said.

He said scientists have been studying brain connectivity since the 1800s, but until recently it has always required invasive approaches or post-mortem tissue so researchers haven't been able to look at connectivity in healthy, intact human brains because they haven't had the right tools. Within the last five to 10 years, however, Huerta said several different imaging modalities have been developed which the NIMH thinks could be used to start studying the relationship between the structure and function of the human brain.

"These tools are just kind of on the cusp of being able to be used for this so the initiative is bold in that we're asking these people to take these cutting-edge tools and in the first year or two [of the project] to optimize them for this purpose," Huerta said. He added that the organization is asking researchers to use tools that provide complimentary types of data.

Investigators have been invited to submit detailed proposals to carry out the HCP, which will be funded at up to \$6 million a year for five years, according to the NIH. The HCP is the first of three Blueprint Grand Challenges, projects that address major questions and issues in neuroscience research, the organization noted.

Unlike a typical NIH grant program that provides a certain amount of money to individual researchers working on separate projects, the HCP will be a "very highly-coordinated, very objective approach," Huerta told *MDD*. He said the field of human connectomics hasn't really gotten the kickstart that it needs, so that is what the project will hopefully accomplish.

After all the applications are in, only one award will be made, Huerta said. It will probably involve several labs, but they are going to have to work together as a unified team, he added. Rather than being considered a grant program, the HCP is a cooperative agreement, Huerta said, which allows the NIH to be more involved in an ongoing way with the program.

The Blueprint Grand Challenges are intended to promote major leaps in the understanding of brain function, and in approaches for treating brain disorders. The three Blueprint Grand Challenges to be launched in 2009 and 2010 address: the connectivity of the adult, human brain; targeted drug development for neurological diseases; the neural basis of chronic pain disorders.

"The HCP is truly a grand and critical challenge: to map the wiring diagram of the entire, living human brain. Mapping the circuits and linking these circuits to the full spectrum of brain function in health and disease is an old challenge but one that can finally be addressed rigorously by combining powerful, emerging technologies," said Thomas

Insel, MD, director of the NIMH, which is part of the NIH Blueprint.

Some parts of the brain serve basic functions such as movement, sensation, emotion, learning and memory. Others are more important for uniquely human functions such as abstract thinking. The connections between brain regions are important for shaping and coordinating these functions, but scientists know little about how different parts of the human brain connect, the NIH says.

"Neuroscientists have only a piecemeal understanding of brain connectivity. If we knew more about the connections within the brain – and especially their susceptibility to change – we would know more about brain dysfunction in aging, mental health disorders, addiction and neurological disease," said Story Landis, PhD, director of the National Institute of Neurological Disorders and Stroke (NINDS), also part of the NIH Blueprint.

For example, there is evidence that the growth of abnormal brain connections during early life contributes to autism and schizophrenia, according to the NIH. Changes in connectivity also appear to occur when neurons degenerate, either as a consequence of normal aging or of diseases such as Alzheimer's.

In addition to brain imaging, the HCP will involve collection of DNA samples, demographic information and behavioral data from the subjects. Together, these data could hint at how brain connectivity is influenced by genetics and the environment, and in turn, how individual differences in brain connectivity relate to individual differences in behavior. Primarily, however, the data will serve as a baseline for future studies. These data will be freely available to the research community.

According to the NIH, the brain is estimated to contain more than 100 billion neurons that form trillions of connections with each other. Neurons can connect across distant regions of the brain by extending long, slender projections called axons – but the trajectories that axons take within the human brain are almost entirely uncharted.

In the HCP, researchers will optimize and combine brain imaging technologies to probe axonal pathways and other brain connections. In recent years, sophisticated versions of MRI have emerged that are capable of looking beyond the brain's gross anatomy to find functional connections. Functional MRI (fMRI), for example, uses changes in blood flow and oxygen consumption within the brain as markers for neuronal activity, and can highlight the brain circuits that become active during different behaviors.

Three imaging techniques are suggested, but are not required, for carrying out the HCP: high angular resolution diffusion imaging with magnetic resonance (HARDI), which detects the diffusion of water along fibrous tissue, and can be used to visualize axon bundles; resting state fMRI (R-fMRI), which detects fluctuations in brain activity while a person is at rest, and can be used to look for coordinated

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Glorikian

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this, or not willing to make a change," he said, citing in particular "threats to products that are deemed to be not cost-effective, or accelerated penetration of more cost-effective products into an incumbent's market."

Glorikian's comments came during a wide-ranging question-and-answer session, the full version of which will appear as the BB&T Interview in the September issue of *Medical Device Daily's* sister publication, *Biomedical Business & Technology*.

He noted that, despite the gloomy economic outlook and the strong potential for regulatory change, "the opportunity for companies is to actively manage their products as portfolios and retool to support a long-term value equation." He added that those companies "can't neglect the sub-segment opportunities, because those are the ones that are going to drive growth and profitability."

Glorikian said that companies "need to dramatically increase their focus on the management of cost and quality/improvement of this healthcare equation, and that's a paradigm shift for most organizations."

He added, "Only the firms that take advantage of this current situation to reposition themselves for the future are actually going to emerge from this crisis with what I would consider a healthy bottom line or a clean bill of health."

Glorikian said that, "given healthcare reform and other forces at work in this environment, companies really need to follow an analytically driven, experience-influenced strategy to meet the specific needs of the market when developing new products."

He cited focused product development efforts to address a specific pain point in the patient care cycle as an example. "We see a lot of companies that don't go through the details of understanding the care cycle. It's a matter of finding an unmet need that is responsible for high costs or poor outcomes."

By truly understanding the need, Glorikian said, "these companies are more likely to be successful in developing a winning solution. To do that, you have to work closely with the customers and caregivers to understand the care cycle, the problem and how well your solution may fit it. Every detail counts when you're looking at this."

He said he would urge companies to be "technology agnostic" whenever possible. "Understand the problem first and then start thinking about the solution."

Glorikian added that firms should ensure that the pain point of what they're looking at isn't just specific to the U.S. healthcare system, because the solution may be relevant to many geographic markets, and will give them access to other emerging high-growth markets.

But he reiterated that the main points for the U.S. are going to be cost-effectiveness and reimbursement. "Kill a project if it's not going to be value-added or will not secure

reimbursement," Glorikian emphasized.

Understanding the care cycle is one piece of the health economics puzzle, he said, "but understanding your sales and marketing strategy also is important. What we're seeing is that the good sales and marketing people are those who understand the care cycle and can have a real discussion with providers and the reimbursement system about the treatment paradigms."

A good example of that from a diagnostic perspective, Glorikian said, is **Genomic Health** (Redwood City, California). "What they found was that salespeople from oncology therapeutic companies like **Genentech** [South San Francisco, California], who have experience in working with oncologists, were better-suited to selling their Oncotype DX breast cancer test than a typical *in vitro* diagnostics salesperson."

Saying that companies have to look carefully for opportunities, he noted a recent study done by Scientia Advisors in the area of peripheral vascular disease. "There's a big market in compression stockings," Glorikian said, "but with those, you're not solving the problem – you're essentially putting a Band-Aid on it, and you're creating a long-term chronic problem."

Conversely, "we're seeing the ablation market not only driven by the docs providing the procedure, but also by educated consumers who are saying, 'I don't want you to just put a Band-Aid on it; I want you to get rid of this problem.' When you go in there and ablate, you eliminate the problem and essentially, you become a more cost-effective solution because now that person is not chronically in the system and developing more problems as time goes on."

That's a good example, Glorikian said, of the direction healthcare clearly is taking. "What we're going to see is manufacturers and payers embracing not technology for its own sake, but technology that truly improves the cost-effectiveness of healthcare." ■

NIH

Continued from Page 7

networks within the brain; and electrophysiology and magnetoencephalography (MEG) combined with fMRI (E/M fMRI), which adds information about the brain's electrical activity to the fMRI signal. In this last procedure, the person performs a task so that the brain regions associated with that task become active.

Since this is the first time that researchers will combine these brain imaging technologies to systematically map the brain's connections, the HCP will support development of new data models, informatics and analytic tools to help researchers make the most of the data, the NIH said. Funds will be provided for building an on-line platform to disseminate HCP data and tools, and for engaging and educating the research community about how to use these data and tools. ■

Product Briefs

- **Applied NeuroSolutions** (Vernon Hills, Illinois) said that it has achieved promising results in its development of a blood-based test related to the diagnosis of patients with Alzheimer's disease (AD). The results of two studies, which provided data from blinded serum samples, showed the ability of this tau-based test to differentiate between patients with AD and normal controls with a sensitivity greater than 80% and a specificity greater than 70%. Applied NeuroSolutions is in collaboration with Eli Lilly to develop therapeutic compounds to treat the progression of AD. For its diagnostic pipeline, Applied NeuroSolutions is focused on both cerebrospinal fluid (CSF) and serum tests to detect AD at a very early stage. The CSF based P-Tau 231 test now being offered for use in clinical trials can effectively differentiate AD patients from those with other neurological diseases that have similar symptoms.

- **Wonderbox Technologies** (Mequon, Wisconsin) has released version 4.5 of the Enterprise System. Central to Enterprise System 4.5 is a Care Management Module designed for managed care benefit administration and case management. The Care Management Module provides care teams with customizable tools for scheduling, managing, and monitoring day-to-day care tasks and case assignments. Wonderbox Technologies provides information technology solutions for the dental benefits management industry.

- **WellAWARE Systems** (Charlottesville, Virginia) reported the commercial availability of its monitoring products, which gathers and reports behavioral and wellness information of a cared-for individual, in their home or at a senior living facility. "As the population of the elderly in the U.S. continues to increase exponentially, we saw an opportunity to help empower families and profes-

FDA: Medtronic's Intrepid Fusion recall now Class II

A Medical Device Daily Staff Report

Medtronic (Minneapolis) said the FDA has classified its voluntary recall action of the Intrepid Intervertebral Body Fusion device as a Class II recall. Medtronic initiated a voluntary recall of the product in February 2009, and communicated the risk to physicians and hospitals. Medtronic confirms that all unused product has been retrieved and the company has received confirmation of notification from all affected physicians and hospitals.

The Intrepid Intervertebral Body Fusion device is intended to provide stabilization of the vertebral bodies and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine.

The device was recalled because, upon review of the clinical experience, Medtronic had determined that there was a need to revise the labeling and modify the device design.

Medical assessment indicates that use of the device without adherence to the revised labeling criteria or without a cover plate creates a risk that the implant could become unstable which could, in turn, possibly lead to the need for revision surgery. Given the close proximity of major blood vessels in the lumbar spine region, such revision surgery has the potential for serious complications.

sional care givers by providing solutions that increase the quality of life for our aging population," said Jeff Noce, president/CEO of WellAWARE Systems. "By offering a passive, unobtrusive monitoring system, seniors are able to maintain privacy and dignity but allow caregivers to make better-informed decisions about the care they provide their residents based on the wellness and behavioral information collected, processed and analyzed with our technology."

People in the News

- John Bluford was named chair-elect of the **American Hospital Association** (AHA; Washington). Bluford is president/CEO of Truman Medical Centers in Kansas City. Bluford will assume the chairmanship in 2011. The AHA is a not-for-profit association of health care provider organizations that are committed to health improvement in their communities.

- **AmSurg** (Nashville, Tennessee) said that Steven Geringer, who has been an AmSurg director since 1997, has succeeded Thomas Cigarran as chairman of the board. Geringer is the former president/CEO of PCS Health Sys-

tems. AmSurg acquires, develops and operates ambulatory surgery centers in partnership with physician practice groups throughout the U.S.

- Patricia Morrison was named chief information officer of **Cardinal Health** (Dublin, Ohio). Previously, Morrison was CIO at Motorola. Cardinal Health makes various products to assist the hospital, physician, and pharmaceutical fields.

- **Tenet Healthcare** (Dallas) said that Deborah Keel has been named CEO for North Fulton Hospital, a 202-bed hospital located in Roswell, Georgia, effective Sept. 1, 2009. Keel most recently was CEO for Fountain Valley Regional Hospital and Medical Center. Tenant Healthcare owns and operates acute care hospitals and related ancillary health care businesses.

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