MEDICAL DEVICE DAILY™

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ESC Backers See Gains Despite Looming Veto Of Senate Bill

By AARON LORENZO
***Medical Device Daily* Staff Writer**

WASHINGTON — A bill to ease federal funding restrictions on embryonic stem cell research seems destined to die from an all-but-certain presidential veto, but supporters of the measure are envisioning alternate routes forward while lauding the progress they've made.

"This shows how far we've really come," said Michael Werner, president of a Washington-based consulting firm called the Werner Group and a long-time advocate on the issue. In contrast, he recalled worries that the science might face an outright ban. But these days, he told *Medical Device Daily's* sister publication *BioWorld Today*, supporters have reached "a point where we're talking about whether there's a veto-proof majority."

In short, there's no futility in pushing the agenda.

So the Senate late Wednesday passed the "Stem Cell

See Stem Cell, Page 6

NAS presenter says nanoprobes will soon detect brain waves

By MARK McCARTY
***Medical Device Daily* Washington Editor**

WASHINGTON — The second day of the conference on nanotechnology hosted by the **National Academy of Sciences** (Washington) included discussions of a number of healthcare applications of nanomaterials, including cancer and heart disease.

Among the presentations was one that described the work going toward exploration of the most exotic and delicate organ of all, the human brain.

Herc Neves, PhD, principal scientist for biomedical systems for **IMEC** (Leuven, Belgium), gave an overview of the dilemmas faced in the effort to use nanotechnology to deal with neurological conditions. He said that IMEC is the largest research center in Europe for micro- and nano-electronics that operate on a scale of 45 nanometers or smaller.

Science has a fairly successful history of electrically

See NAS, Page 7

World Health Care Congres

Biobank is Euro pacesetter with genomic data/health record link

By JOHN BROSKY
***Medical Device Daily* Contributing Writer**

BARCELONA — April 16 is opening day for the UK's Biobank, a project of the **National Health Service**, in the hunt for 500,000 middle-aged volunteers to contribute blood and urine specimens for what will become the world's largest database linking individual genomic data to patient medical records.

More than 5 million UK citizens will receive an invitation to join the project by contributing the biomaterials, completing a 90-minute physical examination and interview during which they are asked to respond by touchscreen to 200 questions about health, lifestyle and family.

Biobank will progressively build a database toward the goal of connecting in late 2007 for the first time with individual medical records from the NHS, including both hospital and primary care documents.

A genomic analysis of each patient sample will then be

See Biobank, Page 8

Medtronic set to combine its Vascular, Cardiac Surgery units

By HOLLAND JOHNSON
***Medical Device Daily* Managing Editor**

Medtronic (Minneapolis) reported the formation of Medtronic CardioVascular, a new, global business combining its existing Vascular and Cardiac Surgery businesses.

The company said the new CardioVascular business will bring together people, technology and worldwide operations focused on delivering products, treatments and therapies for coronary artery, vascular and structural heart disease. It will have combined revenues of about $1.9 billion (FY07) and will consist of four major divisions: Coronary and Peripheral — minimally-invasive catheter and stent-based technologies for the treatment of atherosclerosis; Endovascular Innovations — stent grafts for the treatment of aortic abdominal and thoracic aneurysms; Structural Heart Disease — products for the treatment of heart valve disease and atrial fibrillation; and Revascularization and Surgical Therapies — open heart and coronary bypass grafting surgical products.

See Medtronic, Page 9

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Deals roundup

Teleflex buys HDJ/SMD assets; Biotel receives offer from ART

A *Medical Device Daily* Staff Report

Teleflex (Limerick, Pennsylvania) reported that it has acquired the assets of **HDJ** (Lancaster, Pennsylvania) and its wholly owned subsidiary, **Specialized Medical Devices** (SMD), a provider of engineering and manufacturing services to medical device manufacturers. Terms of the agreement were not disclosed.

Teleflex said that the purchase adds another line of medical components, devices, implants and instruments used in orthopedic procedures to the Teleflex Medical portfolio.

In 2006, HDJ's annual revenues for these product lines were about $14 million.

"Combining the SMD brand with our Beere and KMedic lines strengthens and extends our product offerings for the orthopedic and spine markets and creates the opportunity to provide medical device manufacturers worldwide with a more complete range of products and services," said Ernest Waaser, president of Teleflex.

Founded more than 40 years ago, HDJ/SMD is a provider of engineering and manufacturing services for medical device manufacturers. SMD provides prototyping, engineering and testing services along with production machining, assembly and contract packaging.

Teleflex Medical, a division of Teleflex, is a supplier of disposable medical products, surgical instruments and medical devices, supporting health providers in three main areas: Devices for sleep therapy, respiratory care, anesthesia and urology instruments, medical devices and specialty suture used in surgery

Teleflex Medical markets its products under the HudsonRCI and Rüsch brand names, and its surgical instruments and medical devices under the Beere, Deknatel, KMedic, Pilling, Taut and Weck brands.

Biotel (Minneapolis) reported receiving a proposal from **Arrhythmia Research Technology** (ART; Fitchburg, Massachusetts) to acquire all of its outstanding shares through a conversion, at each Biotel shareholder's election, of one share of Biotel common stock into $4 in cash or 0.154 shares of ART's common stock.

The election is subject to a limitation that no more than 50% of Biotel's shares convert into cash consideration. The closing price for ART's common stock on April 11 was $24.63. ART indicated that the transaction was conditioned on negotiation and execution of a definitive merger agreement and reaching satisfactory employment agreements with Biotel personnel ART deemed key to the combined operations.

Biotel said that a special meeting of its board willbe called to consider the proposal prior to the expiration date for the proposal which ART said is April 24.

Biotel, through its wholly owned subsidiaries, offers analog and digital Holter recorders, as well as tape playback systems for analog devices. Holter recorders enable physicians to monitor and analyze a patient's heart activity over a continuous period without the need for hospitalization.

The company also manufactures digital cardiac event recorder products, which record heart functions over a month or longer time period to record infrequent events, such as arrhythmia.

In other dealmaking news:

• **LHC Group** (Lafayette, Louisiana), a provider of post-acute healthcare services primarily in rural markets, reported signing an agreement with **Munroe Regional**

See Teleflex, Page 9

Today's* MDD *food for med-tech thought

"It's important not to understate how important this development is. Personalized medicine can significantly increase a patient's chances of survival. The only argument is, can we afford it?"

— ***Charles Scatchard, VP of the EMEA Health Sector business of Oracle. "UK's Biobank is pacesetter in European Info Rx effort, pp. 1, 8, 10.***

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Financings roundup

Cord Blood America adds new funds for 'potential acquisition'

A *Medical Device Daily* Staff Report

Cord Blood America (CBAI; Los Ageless), an umbilical cord blood stem cell preservation company, reported securing $200,000 in capital that it said it will use to complete a potential acquisition, not yet named, for which a letter of intent has been issued.

It said that the funds are being provided by "a leading institutional investment firm from New York City."

Matthew Schissler, CEO of Cord Blood America, said that the funding is a debt placement, "which we chose for similar reasons to our previous debt placements. Most importantly, it minimizes dilution, protecting our current shareholders."

He said the debt will be serviced primarily with cash flow from the acquisition.

Schissler said completion of the debt placement prior to completing the acquisition is "extremely important to principals of selling companies." He said that CBAI can continue to attract new acquisitions because of its ability to secure capital prior to closing.

CBAI is the parent company of **CorCell** (Philadelphia), which facilitates umbilical cord blood stem cell preservation for expectant parents and their children. Collected through a non-invasive process, cord blood stem cells offer a resource for treating a growing number of ailments.

In other financing activity:

• **BioWizard** (Philadelphia), an online information portal specifically designed for the biomedical research community, announced today that it has closed a first-round of financing of $675,000. BioWizard will use the funding to further enhance its web-based portal and to initiate marketing.

BioWizard secured the funds through Series A Preferred Stock from MentorTech Ventures, an early-stage venture capital fund that invests in information technology, marketing technology and medical device companies with a focus on companies originating at the **University of Pennsylvania** (Philadelphia).

"MentorTech Ventures brings much more than the financial capital. The team's substantial intellectual and social capital is a valuable asset that we plan to leverage as we continue to build the company," said Jeffrey Boily, chairman of BioWizard.

"There is a significant demand in the biomedical research community for an interactive web community like BioWizard," said Michael Aronson, managing director of MentorTech Ventures and a member of the BioWizard board. "Founded by a team of current University of Pennsylvania graduate students, BioWizard is a perfect fit for our portfolio."

BioWizard is a free, web-based community for life scientists and physicians. BioWizard says it is "leveraging . . . more than one million unique visitors a day to build the BioWizard user community." Access to the portal is free for life scientists and is funded by the site's advertisers.

• **Health Care REIT** (Toledo, Ohio) said that it intends to offer 5 million shares of its common stock and will grant to underwriters a 30-day option to purchase up to an additional 750,000 shares to cover any over-allotments.

The shares of common stock will be registered under Health Care REIT's existing shelf registration statement on file with the **Securities and Exchange Commission**.

Health Care REIT said it will use the proceeds to invest in additional senior housing and healthcare properties. Pending that use, proceeds will primarily be used to repay borrowings under the company's unsecured line of credit arrangements.

Health Care REIT is a self-administered, equity real estate investment trust that invests across the full spectrum of senior housing and healthcare real estate. ■

Contract news

U.S. Army group selects Cogon for handheld solution project

A *Medical Device Daily* Staff Report

Cogon Systems (Pensacola, Florida) reported receiving a Research, Development, Test and Evaluation contract by the **U.S. Army's Telemedicine & Advanced Technology Research Center** (TATRC; Frederick, Maryland) to develop clinical decision support tools for handheld computer use.

The project is intended to determine if a mobile technology in an inpatient setting can deliver clinical decision support through rapid retrieval of clinical data, intelligently filtered clinical knowledge, and appropriately generated alerts and reminders, while also improving care and achieving physician acceptance and efficiency.

The project will use Mobile Moment of Care software from Cogon, utilizing data residing within a hospital's inpatient information system, thus using existing infrastructure investment and serving as the foundation to which advanced clinical decision support modules will be added. The project's objective is applicable to all Medical Treatment Facility or Combat Support Hospitals.

The project's beta site will be **DeWitt Army Community Hospital** (Fort Belvoir, Virginia) and will run for 15 months.

TATRC is an element of the U.S. Army Research and Materiel Command charged with managing core Research Development Test and Evaluation and congressionally mandated projects in telemedicine and advanced medical technologies.

Siemens Medical Solutions Diagnostics (Tarrytown, New York) reported being selected by **Premier** (San

See Army, Page 10

Around the Beltway

Grassley seeks GAO look at not-for-profit hospital service

A *Medical Device Daily* Staff Report

Sen. Chuck Grassley (R-Iowa) reportedly has sent a letter to the Government Accountability Office requesting an investigation of how not-for-profit hospitals comply with laws that require them to provide community benefits in exchange for tax-exempt status and other tax breaks.

Grassley asked GAO to investigate what community benefit standards states have established, as well as those established by the Internal Revenue Service, and what guidelines hospitals use to interpret the community benefit standard. In addition, Grassley requested that GAO examine hospital executives' and board members' compensation and the extent to which they are involved with for-profit business ventures with the not-for-profit hospitals.

The investigation is part of a series of hearings on charities and the breaks they receive under the tax code.

Grassley said that because of the "generous" tax breaks that non-profit hospitals received, there was a need to better understand how these hospitals are fulfilling the mandate for providing public service. He said that this is especially important with increasing discussion of medical care to the uninsured.

Blunt-tip needle use urged

The U.S. Department of Labor's **Occupational Safety and Health Administration** (OSHA) and the **National Institute for Occupational Safety and Health** (NIOSH) in the **Centers for Disease Control and Prevention** (Atlanta) have published a Safety and Health Information Bulletin (SHIB) recommending broad use of blunt-tip needles designed to protect surgical personnel from needle stick injuries while using suture needles.

The SHIB is available on the OSHA Web site at:

http://www.osha.gov/dts/shib/shib032307.html and on the NIOSH Web site at:

http://www.cdc.gov/niosh/docs/2007-132.

The sites present evidence of the effectiveness of blunt-tip needles in decreasing injuries and emphasize OSHA's requirement to use appropriate, available and effective safer medical devices.

Sharp-tip suture needles are the leading source of penetrating injuries to surgical personnel, causing 51%-71% of these incidents.

Edwin Foulke Jr., assistant secretary of labor for OSHA, said in a statement, "We strongly encourage the use of blunt-tip suture needles when feasible and appropriate to reduce this risk."

"The effectiveness of blunt-tip suture needles for preventing needle stick injuries has been widely reported," said John Howard, MD, director of NIOSH. "We are pleased to partner with OSHA in offering guidance to protect the safety and health of medical professionals."

The **American College of Surgeons** (ACS) issued a statement in 2005 supporting the use of blunt-tip suture needles where clinically appropriate. This statement has been endorsed by the six organizations that, along with the ACS, make up the Council on Surgical and Perioperative Safety.

CMS revises clinical trial coverage rules

The Centers for Medicare & Medicaid Services (CMS) has reported proposed revisions to the Clinical Trial Policy national coverage determination (NCD) related to certain items and services for Medicare beneficiaries involved in clinical trials.

"This new decision will signal our continued support to provide access to services for beneficiaries by facilitating participation in the full range of qualified, scientifically sound research projects," said CMS Acting Administrator Leslie Norwalk.

In developing the revised clinical trial policy, CMS convened the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) last December. The MedCAC proposed several recommendations, subsequently reviewed by a federal panel led by the Agency for Healthcare Research and Quality (AHRQ). In addition to AHRQ, the federal panel included representatives from CMS, FDA, CDC, HRSA and the NIH.

The new rules include:

- Renaming the policy as the Clinical Research Policy;
- Adding FDA post-approval studies and coverage with evidence development (CED) to studies that would qualify under this policy;
- Requiring all studies to be registered on the NIH ClinicalTrials.gov website before enrollment begins;
- Requiring studies to publish their results;
- Paying for investigational clinical services if they are covered by Medicare outside the trial or required under a CED through the NCD process;
- and expanding the "deeming" agencies to all Department of Health and Human Services agencies, the Veterans Administration, or the Department of Defense. Deeming agencies are agencies that can "deem" whether a trial has met the general standards outlined in the policy.

"This proposed Clinical Research Policy exemplifies the Agency's commitment to providing access to services for beneficiaries by encouraging the conduct of research studies that add to the knowledge base about the efficient, appropriate, effective, and cost-effective use of products and technologies in the Medicare population, thus improving the quality of care that Medicare beneficiaries receive," Norwalk said.

The proposed NCD opens a 30-day comment period. CMS will review all the public comments and suggestions received and incorporate them into a final NCD. CMS will publish the final NCD no later than sixty days after the end of the comment period. The revised policy will be effective with the publication of the final NCD.

Details of the policy are available at the CMS website: www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186. ■

Agreements roundup

EDAP TMS reports conclusion of pact with HealthTronics

A *Medical Device Daily* Staff Report

EDAP TMS (Lyon, France), a developer of minimally-invasive devices for the treatment of urological diseases, released supplemental details on the conclusion of a distribution agreement with **HealthTronics** (Austin, Texas).

EDAP TMS said that it has entered into an agreement with **HealthTronics Surgical Services** to terminate its 2004 distribution agreement with HealthTronics originally entered into in 2004 to pursue FDA approval of EDAP's Ablatherm-HIFU device for use in the U.S.

In accordance with the termination, on April 4, HealthTronics exercised 200,000 warrants granted under the distribution agreement to acquire an equal number of EDAP's shares, paying an aggregate exercise price of $300,000. The 600,000 remaining warrants granted under the distribution agreement were cancelled.

EDAP also agreed to file a registration statement under the Securities Act of 1933 to enable HealthTronics to resell its shares in transactions that are registered under the Securities Act.

HealthTronics agreed to pay EDAP $600,000 after the resale registration statement has been effective for 60 days. EDAP may also receive additional cash compensation based on a formula related to the price at which HealthTronics resells the EDAP's shares in the future.

HealthTronics agreed to transfer to EDAP one Ablatherm device and six lithotripters previously acquired by HealthTronics, and to return two Ablatherm devices already owned by EDAP. The transfer of these devices is part of the overall termination transaction and their value is included in the estimated transaction value.

The EDAP parties and HealthTronics parties released each other from liabilities arising under the terminated agreement, and agreed to indemnify each other for breaches of the termination agreement and certain liabilities arising from any claims related to the use of the Ablatherm-HIFU device and the conduct of the clinical study evaluating the Ablatherm-HIFU device.

In other agreements:

• **Transgenomic** (Omaha, Nebraska) said it will provide **Spectrumedix** (State College, Pennsylvania) instrument service and consumables support in the U.S. and other areas as well as continue the offering to European customers of Spectrumedix.

Transgenomic has been the exclusive Spectrumedix systems European distributor since 2003, and Spectrumedix customers were affected by the SpectruMedix decision to discontinue operations after March 9.

Spectrumedix systems are high-throughput capillary electrophoresis (CE) instruments designed for various applications including comparative genome scanning, SNP genotyping, heterozygote identification, fragment sizing, PCR quality testing, and custom assay development.

Transgenomic also reported acquiring certain assets from the SpectruMedix court-appointed receiver and a license from the gel patent holder necessary to manufacture consumables for Spectrumedix systems.

Financial terms of these transactions were not disclosed.

Craif Tuttle, president/CEO of Transgenomics, said, "We are pleased to announce this series of transactions which clarifies this situation for Transgenomic and its European customers subject to the limitations of no longer being supported by Spectrumedix itself. Additionally, we intend to service and support other Spectrumedix customers as well, subject again to the same limitations."

• **Accuray** (Sunnyvale, California), focused on the field of radiosurgery, signed a co-marketing and distribution agreement with **Siemens Medical Solutions USA** (Malvern, Pennsylvania), enabling Accuray to integrate its CyberKnife Robotic Radiosurgery System and RoboCouch Patient Positioning System with a Siemens SOMATOM computed tomography (CT) scanner with a sliding gantry configuration. The combination enhances visibility of internal structures at the time of treatment, according to the companies.

The companies said that the clinical benefits of the in-room diagnostic CT system are realized "mainly in the treatment of tumors that move with respiration, such as lung, liver and pancreas, as well as prostate tumors, which are impacted by bowel and bladder function."

Unlike cone beam CT, diagnostic CT provides higher resolution imaging and allows for differentiation of soft tissue structures. ■

Patent Watch

SRU Biosystems reports eight new patents for its BIND tech

A *Medical Device Daily* Staff Report

SRU Biosystems (Woburn, Massachusetts) reported the receipt of several U.S. patents related to label-free biomolecular detection methods, saying that it now has 16 issued patents.

Owen Dempsey, president/CEO of SRU Biosystems, said, "SRU has been granted eight additional U.S. patents in the last few months that cover important aspects of our BIND technology, further strengthening our leading position in label-free detection for drug discovery and diagnostics."

The eight awarded patents are: No. 7,162,125 Optimized grating-based biosensor and substrate combination; No. 7,158,230 Method and apparatus for detecting biomolecular interactions; No. 7,153,702 Label-free methods for performing assays using a colorimetric resonant

See SRU, Page 9

Stem Cell

Continued from Page 1

Research Enhancement Act of 2007" by a margin of 63-34 after two full days of debate, an expected outcome that demonstrated the issue's bipartisan support. Majority Leader Harry Reid (D-Nevada) introduced the bill earlier this year.

Of the total yeas, 44 Democrats voted in favor of the measure, designated S. 5, along with 17 Republicans. Three absent supporters will cast their lots to turn back a veto from a firmly entrenched President Bush, who reiterated his intentions earlier in the week, signaling a repeat of last summer's veto of an almost bill.

But those aggregate 66 supporters remain one vote shy of an override. In the House of Representatives, where companion legislation passed 253-174 early this year, the requisite two-thirds majority to overrule a veto appears further out of reach. A full 290 votes are needed in the lower chamber. So it would seem that supporters would have to wait until another congressional session, or another White House administration, to again try to move the needle further and overturn Bush's five-and-a-half-year-old executive order.

But Werner hinted at the possibility of a nearer-term alternative: affixing the legislative language to another bill, such as a must-pass appropriations measure. Given S. 5's support among congressional leaders, as well as the issue's popularity among the general public in various polls, it's not a far-fetched scenario. Still, it's yet to bubble up in the open.

"There have been no conversations about that yet," he said, "and nobody is really even talking about that yet. But that's clearly the next discussion that would happen." S. 5 is written to extend federal financing to cell lines created from embryos slated for discard by fertilization clinics. In addition, donors must give written consent and would not receive any monetary compensation. Those provisions mirror the House version, H.R. 3, which is sponsored by Reps. Diana DeGette (D-Colorado) and Mike Castle (R-Delaware).

But the Senate bill is slightly revised, adding language to support alternate methods of acquiring embryonic stem cells. That difference means the House must approve this final version before the legislation moves to the president. Castle is urging his colleagues, who return to town next week after their spring recess, to act quickly.

Though Bush will certainly veto S. 5, he has expressed support for another bill, S. 30, the "Hope Offered through Principled and Ethical Stem Cell Research (HOPE) Act." Sponsored by Sens. Norm Coleman (R-Minnesota) and Johnny Isakson (R-Georgia.), the so-called compromise legislation is written to expand federal funding to pluripotent stem cell lines derived from embryos incapable of surviving in the womb or that died during fertility treatments but still contain viable stem cells. Though some critics called it a cover for S. 5 opponents, and rooted in science fiction, it nonetheless passed 70-28 in the Senate.

But there are uncertainties around the science supporting such research, Werner said, calling the notion of a naturally dead embryo unclear, as well as determining such an embryo's viability. In addition, he pointed to language in S. 30 contradictory to Bush's existing restrictions. Of note, companion legislation has not arisen in the House.

This week's Senate activity evoked similar debates last summer, when a compromise bill was included in the debate on legislation to curb federal funding restrictions on embryonic stem cells. Written to authorize federal funds for research into obtaining pluripotent stem cells without destroying embryos through methods such as altered nuclear transfer, the bill passed in the Senate but not the House. That's the new language incorporated into S. 5 relative to H.R. 3. A third stem cell-related bill passed unanimously in both chambers to prohibit research on embryos from fetal farms where they could be created specifically for research, and was signed into law.

Whether or not S. 30 reaches the president's desk, it doesn't seem like the kind of legislation that's going to prompt significantly more research or drive investors to back further commercialization efforts in the embryonic stem cell field. At present, only a dozen or so companies operate in this space, which remains many years from generating a marketable product. The first clinical trials of an embryonic stem cell therapy are scheduled to begin next year. But S. 5, which Werner labeled "the bill that advances the science that's going to make a difference," sends a good signal to the financial community.

"You have to be pleased with the progress we've made over the long term," he said, "and I think that we will continue to see progress until we ultimately reach our objective, and we will. I don't think there's any doubt about that." ■

BRIEFLY NOTED

Manor Care retains JPMorgan

Manor Care (Toledo, Ohio) has retained JPMorgan as its exclusive financial advisor to assist the company in reviewing strategic financial and related business alternatives to enhance shareholder value. The company said there can be no assurance that its review of strategic alternatives will result in it pursuing any particular financial or business transaction.

The company also said it does not expect to make further announcements regarding the review until completion and "unless and until" its board has approved a specific transaction or course of action.

Manor Care provides short-term post-acute and long-term care.

NAS

Continued from Page 1

interacting with biological tissues, Neves said, but he noted that monitoring chemical activity on such a small scale is a different task, especially over extended periods of time. Such uses of nanotechnology open up what he called "a Pandora's box, because you have a lot of new problems to tackle."

When attempting to record any kind of synaptic activity, the rule is the same as that for real estate: location, location, location. Ideally, the signal from a single synapse is all that an electrode will pick up, but the electrode "can pick up data from nearby neurons" as well if the placement is imprecise, he said.

Neves worked on sensor tip arrays for peripheral nervous system use while at the **University of California at Los Angeles**, and while he said that work was on a larger scale than his current endeavor, the electrodes he and others engineered at that time provided a better signal-to-noise ratio. This then enabled researchers to move into the central nervous system (CNS).

He said, "The justification for doing brain recordings is that the techniques that we use today, such as functional MRI," do not allow researchers to map brain cell activities.

Management of movement disorders, such as Parkinson's, is a huge opportunity, as is localization of pathological activity to aid surgical excision in intractable epilepsy.

Neves said that signals recorded from the motor cortex could lead to an intervention that might facilitate motor control in neurologically damaged patients, but such neural interface systems are several years away.

One of the practical considerations in neurological implants is fairly simple: Such devices can be fixed in place reliably, but "the brain moves over time," Neves said, and any effort to zero in on single-nerve action potentials demands that electrodes be set no farther away than 150 nanometers of the target synapse.

Neves noted that the late John C. Lilly, MD, had described other well-known hurdles in this area of research in 1940. Among these are the need to manufacture electrodes that are sufficiently small to pick up synaptic signals without damaging adjacent tissue.

The other side of the size dilemma is that too small an electrode is subject to impedance that will distort the signal. Hence the probe's size must be closely matched to the size of the target synapse.

Other difficulties include the need to ensure the long-term stability of the probe, and the tendency of foreign matter to damage brain tissue, which can result in signal impedance. For some purposes, single-electrode probes do not draw in sufficient data, but as might be expected, researchers have found that multi-electrode probes are more damaging.

Biocompatibility is a much bigger issue in an organ as sensitive as the brain than it is for other organs, according to Neves. "As soon as you insert something into the brain, you start a reaction," he said, including absorption of proteins onto the implant.

"Your best chances are to reduce cell adhesion" by using materials such as dextran, a polysaccharide, to coat the probe and reduce interaction. "If this process [of adhesion] persists, there is encapsulation of the probe," which will fend off any signals, Neves noted.

On the other hand, "when you stimulate the brain, you lose electrode material to the brain," a fact of which researchers were unaware until recently.

"The brain is just as chemical as it is electrical," Neves said, and researchers are interested in acetylcholine and glutamate because of their relationships to several conditions, including Alzheimer's and schizophrenia.

At present, one must use cholinesterase inhibitors to examine levels of acetylcholine, which creates problems because of the tendency of cholinesterase inhibitors to suppress cardiac and respiratory function. The neurotransmitter glutamate's role in schizophrenia is well known, but the locations of interest include the limbic system, which is located deep in the brain, creating a new set of dilemmas in terms of access and device stability.

The shapes of probes are also problematic in that "[i]n the first seconds of use, you need a needle," but Neves said that he wished "I had something that ceases to be a needle and acquires a more flexile form" after insertion, which is the kind of thinking "we desperately need" where electrode design is concerned.

Despite the long list of headaches, medical science is "at a very good time for this," Neves said, partly because Moore's law should start kicking in for miniaturization of electrodes.

Described in 1965 by **Intel** (Santa Clara, California) co-founder Gordon Moore, this principal states that scientists should be able to double the number of transistors on an integrated circuit every 12 to 24 months. (A web search suggests, however, that the period of doubling referred to by Moore is the subject of debate).

"The problem we see more and more now, no pun intended, is that Moore's law deals with only about 10% of the system," Neves said, namely the sensors in the electrodes and not the other elements required to detect synaptic function. A similar law regarding systems integration is said to lag behind Moore's law, but it "is catching up very quickly," according to Neves.

As for alternate shapes and materials, Neves said that IMEC is "very interested in using diatoms as building materials" for probes.

Diatoms are marine flora as small as 10 nanometers that leave behind a skeleton of silicon dioxide in a stunning array of shapes, featuring scales and spikes with potential uses in this area. And Neves pointed to the possibility of genetically engineering their shapes to grow diatoms in large numbers with features that are uniquely suited to this kind of research. ■

Biobank

Continued from Page 1

added. The cross-referenced datasets are expected to yield 30 years of research into causes of diseases, individual patients' interactions with the British medical system and the effectiveness of therapeutics by pathology and genetic disposition.

"Half a million people is a pragmatic number because it is what we can afford," said Andy Harris, system architect with Biobank, at a press briefing during the World Health Care Congress Europe, late last month.

The only criterion is age, and the volunteers give their consent at six stages of the interview for a broad use of the data.

In exchange for the broad consent, the Biobank agrees to inform any patient if a significant disease association is found within his or her data. A detailed process will reverse the anonymity of records to make the patient aware of the problem.

For the recruitment campaign, Biobank is subject to strict constraints of the British Data Protection Act and has followed guidance of the Office of the Information Commissioner. The recruitment was given a green light after a review of procedures by the Patient Information Advisory Group.

See Biobank, Page 10

'Info' scrips are lauded as good medicine for e-health

By JOHN BROSKY
***Medical Device Daily* Contributing Writer**

BARCELONA — An emerging practice for keeping patients in the loop and capable of making decisions about their health is the information prescription, presented at the World Healthcare Congress by Petra Wilson, director of public sector healthcare in the UK for **Cisco Systems** (San Jose, California). "People respond well to being guided," she said, "and here is an opportunity to build on the trust in the medical relationship."

A former deputy director of the **European Health Management Association** who created e-health road map for the European Commission, Wilson said capabilities for data management and communication created by e-health systems provide caregivers with new tools for dispensing information to individuals.

"Sending a patient to the Internet is like asking them to drink from a fire hydrant," she said. E-mails, direct television, interactive training and text messages to mobile phones are now readily available, along with the expected web references and printed brochures.

An info-prescription program should be based on the same principles as pharmacy prescriptions, using a formulary, an issuing service and an access service, Wilson said.

An evolution of the "bibliotherapy" program pioneered by the **German National Library Association**, the electronic tools for pushing information to a patient are coordinated with patient care, she added.

The **UK Department of Health** has called for information prescriptions to be issued routinely by 2008 at different stages in the care pathway as a routine part of the consultation that patients can expect.

The quality of the prescription information plan depends entirely on the quality of information the patient is given or directed to review, Wilson said.

"Is the information usable?" she asked, citing a study by Roy Kessels, PhD, of **Utrecht University** (Utrecht, the Netherlands), published in the *Journal of the Royal Society of Medicine*, that showed 40%-80% of medical information is forgotten immediately by a patient "and what is remembered is wrong."

According to Kessels, "patients tend to focus on diagnosis-related information and fail to register instructions on treatment."

Patient compliance to an info-prescription is also as problematic as for other therapies, she said, citing results from a pilot program conducted by the **National Library of Medicine** (Washington) that showed 65% of patients used a designated Internet link that was prescribed during a consultation, but that with an e-mail reminder, almost half of the remaining patients subsequently checked the link.

The NLM's Health Information Rx program issued customized prescription pads to doctors to point patients to health information in the library's MEDLINEplus online database.

While patients today seek out information on the Internet, patients should not be left unguided to wander the web, argued Célia Boyer, executive director of the **Health On the Net Foundation** (HON; Geneva, Switzerland).

"There is no overview for information on the Internet, none, and no regulation at all," she said. The ease of putting information online is exactly the problem. "The patient is not skeptical enough."

An evaluation by HON of 5,941 websites and 1,329 web pages found one-third contained inaccurate information. Closer analysis showed the inaccuracy levels highest for lifestyle conditions, with 89% of nutrition information and 45% of diet advice being wrong. Web-sourced information for prostate or breast cancer, on the other hand, was found 95% reliable.

Boyer said the HONcode is considered the *de facto* standard for accreditation of websites offering medical information. Over 5,000 websites have received the HONcode endorsement, and the foundation offers a browser plug-in as an online search tool for pathology-specific information available on accredited sites.

Medtronic

Continued from Page 1

The four core divisions will remain in their current locations but will leverage common business processes and specific functional infrastructure while expanding scientific knowledge and engineering capabilities to advance cardiovascular care.

According to Medtronic spokesperson Rob Clark, the company decided to merge the divisions because of the ever increasing trend towards performing minimally-invasive procedures in the vascular space coupled with the more recent push towards performing MIS procedures by cardiac surgeons.

"You just see that trend of physicians moving more and more towards those types of procedures," Clark told *Medical Device Daily*. "From our vantage point, it made a lot of sense to bring these two units together."

Clark noted that the company also gains some other efficiencies internally by merging these divisions. "You can eliminate some duplication in some areas and then take some of those efficiencies and reinvest them in clinical trials and other future technologies."

He stressed that this new combination would not result in any "substantive" employee layoffs or facility closings. This unit merger, he added is "not really a cost-savings move," it's more about "focusing existing resources."

Scott Ward will serve as the new head of the CardioVascular business unit. Ward currently serves as senior VP and president of the company's Vascular business. Ward joined Medtronic in 1981 and has been president of the Vascular business since May 2004. Prior to his current position, Ward served as president of the company's Neurological and Diabetes businesses.

"The new CardioVascular business will assemble an exceptional collection of people, technology and global operations that will be focused on collaborating with physicians to improve the quality of care for people with cardiovascular disease," said Ward. "Medtronic will continue to be a powerful innovative force supporting the convergence of cardiovascular specialties focused on applying both surgical and minimally invasive approaches to patient care."

After the merger, Scott said the company will, for now, have six primary business units: CardioVascular; Cardiac Rhythm and Disease Management; Spinal; Neurological; Diabetes; and Physio-Control.

The company said back in December that it planned to spin-off its Physio-Control (Redmond, Washington) unit, which makes automated external defibrillators, to focus on opportunities that it said "align better with its strategic aims" (*Medical Device Daily*, Dec. 5, 2006). ■

SRU

Continued from Page 5

reflectance optical biosensor; No. 7,148,964 Method and apparatus for detecting biomolecular interactions; No. 7,142,296 Method and apparatus for detecting biomolecular interactions; No. 7,170,599 Method and instrument for detecting biomolecular interactions; No. 7,175,980 Method of making a plastic colorimetric resonant biosensor device with liquid handling capabilities; No. 7,197,198 Biosensor substrate structure for reducing the effect of optical interference.

BIND from SRU Biosystems enables label-free detection of biomolecular interactions. The commercially available system is comprised of the BIND Reader and 96- or 384-well microplate biosensors.

The BIND system takes advantage of a novel optical effect to provide very sensitive measurement of binding on the biosensor surface.

The biosensor incorporates a proprietary nanostructured optical grating, which is incorporated in microwell plates in industry standard formats.

SRU develops sensing and molecular biology technologies used to screen the interactions of large genomic, protein, peptide, or antibody libraries against a range of biochemical targets. ■

Teleflex

Continued from Page 2

Health System (MRHS; Ocala, Florida) to create a partnership relating to the home health services business owned by MRHS in Ocala, Florida. LHC will acquire a controlling interest in the assets of **Munroe Regional Home Health Services** (MRHS) and will oversee the day-to-day operations.

MRHS operates Munroe Regional Medical Center in Ocala, which includes Munroe Regional Home Health Services. The Munroe Regional Medical Center is a 421-bed community hospital.

The service area covered by this joint-venture includes seven counties with a population of about 1,043,000.

· **Montecito Medical** (Santa Barbara, California) reported the acquisition and re-development of two medical office buildings, Knoll I and II, in Columbia, Maryland.

Along with 155,314 square feet of medical office space, the acquisition of these properties also includes 19 acres of undeveloped land zoned to allow other developments.

Montecito acquires and develops medical-related real estate. ■

Biobank

Continued from Page 8

Anything less than extreme security for the system is "not negotiable," said Steve Walker, chief information officer for UK Biobank. "We are not building an open multi-user system."

The briefing was sponsored by **Oracle** (Redwood Shores, California), which in 2005 won the task of building the data storage and communication systems using the Oracle Healthcare Transaction Base application. Up to 10 assessment centers will gather patient specimens and data for transmision to distributed regional centers, with central storage of the massively parallel datasets at both Oxford and Manchester. More than 20 universities are collaborating on the program.

The physical specimens will be stored in automated archives kept at -112 degrees Fahrenheit in a center in Manchester that is expected to use some 70 liters of liquid nitrogen a week.

Dr. Michael Thick, chief clinical officer for NHS's Connecting for Health IT program, told *Medical Device Daily*, "The promise of genetic prediction for health has been with us a long time. We are going forward to enter the world of 'omic' data with the goal of getting tighter, specific definitions from our patient population."

He added, "Pilots have shown that technologies can be deployed within a primary care setting, and that an enormously detailed profile of the patient can be produced very quickly." This capability, he said, "coupled with the clinical data, has great predictive and therapeutic power. It is not difficult to see that this could have a great impact on the overall health of the population and the costs of healthcare for the NHS."

Thick said the NHS team was inspired and convinced of the viability of the Biobank project after a visit to the **Marshfield Clinic Research Foundation** (Marshfield, Wisconsin). After breaking new ground in genetic research, in 2004 the Wisconsin group practice affiliated with the foundation began tracking 18,000 patients for a personalized medicine program that is America's largest population-based genetic research project

Personalized medicine creates the ability to deploy highly sophisticated testing to an individual and produce a specific list of probabilities of disease, drug susceptibilities and how both the disease and the drugs will react in that individual, Thick said.

The payoff of savings for the NHS, he said, includes patients being referred to appropriate specialties much earlier, delaying or avoiding progress into chronic disease, and avoiding the morbidity and cost of inappropriate drug treatment.

"It's important not to understate how important this development is," said Charles Scatchard, vice president of Oracle's EMEA Health Sector business. "Personalized medicine can significantly increase a patient's chances of survival. The only argument is, can we afford it?"

The personalization of medicine is the inevitable outcome of an e-health system where the use of services by an individual can be tracked both clinically and financially.

The UK Biobank extends the logic of e-health to an advance state beyond preventive programs to the ultimate application of predictive medicine.

Like the NHS's Connecting for Health effort, the German healthcare reform signed into law at the end of March also shifts responsibility for health toward the patient, not only recognizing the patient as the end-user of health services but enabling the patient to act as a direct consumer.

Dr. Hans Jürgen Ahrens, chairman of **AOK-Bundesverband** (Bonn, Germany), Germany's largest group of regional health insurance funds, said, "Responsibility is often only considered as financial involvement of the patient, but it means more. It means taking on a personal responsibility for your actions and behaviors."

For this to work, "people need to be better informed in order to make their choice," Ahrens said. "We've seen that the personal situation of the patient improves if the patient feels better informed. We help promote their responsibility and the training we do is positive. Patients feel that they are being given something."

Cor Spreeuwenberg, dean of health sciences at the **University of Maastricht** (Masstricht, the Netherlands), agreed, saying, "the background assumption is that better-informed patients have better outcomes."

But he cautioned that the readiness of patients for self-management "is critical for success. An informed, activated patient supported by the health system and the community implies interaction at all levels." ■

Army

Continued from Page 3

Diego), to provide a line of immunoassay, chemistry, automation and urinalysis solutions, as part of Premier's recently issued "Core Lab" segment which sought solution providers in six separate bid categories.

Siemens was selected to provide the integrated and urinalysis solutions.

Hospitals in Premier's alliance will utilize the ADVIA Chemistry Systems, ADVIA 2400, 1800, and 1200. The line of Immunoassay Systems; ADVIA Centaur XP, ADVIA Centaur CP, IMMULITE 1000, 2000, 2500 and Automation Solutions such as ADVIA WorkCell and ADVIA LabCell.

The ADVIA 1800 Chemistry System will enable labs to perform 1,800 tests per hour and work more efficiently through its high-resolution touch screen which delivers push-button operation. The ADVIA Centaur XP Immunoassay System features a data archive which reduces time spent on administrative tasks.

Premier also will offer Siemens' urinalysis solutions to its network including the ADVIA Urinalysis WorkCell which minimizes sample handling and maximizes throughput. The solution integrates urine chemistry and urine sediment analyzers. ■

PRODUCT BRIEFS

• **Cardica** (Redwood City, California) reported that it has received clearance from the FDA to market its C-Port flex A anastomosis system in the U.S. The Flex A is a variation of Cardica's C-Port xA distal anastomosis system product line and further facilitates the automated anastomosis, or attachment of blood vessels and grafts, during less invasive coronary artery bypass graft (CABG) procedures. The C-Port flex A system has a flexible, rather than rigid, shaft; is effective in creating compliant anastomoses in vessels as small as one millimeter in internal diameter; and, can be used in either on- or off-pump CABG procedures. The flexible shaft allows surgeons to position the device to create a secure connection even in the most difficult to reach areas of the heart. Cardica makes automated anastomosis systems for CABG surgery.

• **MedicalCV** (Minneapolis) reported that Allen Raczkowski, MD, the director of robotic cardiac surgery at **Banner Baywood Health Systems** (Mesa, Arizona), performed a closed-chest, robotic, lone cardiac ablation procedure on an arrested heart using the Atrilaze surgical ablation system. The system is a laser-based technology platform to provide cardiac tissue ablation in both open and endoscopic surgeries. MedicalCV makes surgical ablation systems that utilize a laser energy technology platform to create precise lesions, or scars, on soft and cardiac tissue.

• **MIV Therapeutics** (Atlanta) reported the addition of a portfolio of new cardiovascular stents and related products, which have already been CE-marked for commercialization in several multibillion dollar markets, including Europe, Asia and India. The new products include the GenX CrCo thin-strut coronary stent system, which was recently combined with MIVT's biocompatible stent coatings in a milestone bench test showing that together, the technologies pass critical FDA fatigue test guidelines. Other products acquired by MIVT include the GenX stainless steel coronary stent system, the X-ACT Inflation Device, a haemostatic y-connector adaptor kit, an insertion tool, a guide wire torquer and a high-pressure 3-way stopcock. Some credit for this new portfolio of products can be traced to MIVT's purchase of cardiovascular device company Biosync Scientific this February (*Medical Device Daily*, Feb. 21, 2007). MIVT makes biocompatible coatings and advanced drug delivery systems for cardiovascular stents and other implantable medical devices.

• **Polymedco** (Cortlandt Manor, New York) reported the introduction of the BTA stat test — a point of care technology for the early detection of recurrent bladder cancer. This method uses monoclonal antibodies to detect the presence of bladder tumor associated antigen in urine. It is a single-step, rapid immunochromatographic assay for bladder tumor-associated antigen in voided urine. The specificity of the BTA stat test was 93-95% in patients with non-genitourinary diseases and cancers and healthy individuals tested as part of a multi-center study. The test has a sensitivity that is considerably higher than voided urine cytology, enabling detection of recurrent early stage and grade cancers that cytology often misses. Requiring five drops of urine, the result is delivered in five minutes. The appearance of a line in the patient window indicates a positive result. Polymedco describes itself as one of the leading marketing and distribution companies in the clinical laboratory marketplace.

• **Possis Medical** (Minneapolis) reported that its AngioJet Spiroflex VG rapid exchange catheter has been approved by FDA for blood clot (thrombus) removal in coronary conduits. The catheter was first introduced to remove thrombus in larger peripheral arteries, and the recent approval allows the catheter to be used in saphenous vein bypass grafts in the heart and larger native coronary vessels. The catheter offers performance benefits, including: increased trackability inside the vessel; improved crossing in difficult anatomy; and 360-degree thrombus removal. Possis makes products for endovascular procedures.

• **PuriCore** (Malvern, Pennsylvania) said that it has received FDA clearance allowing it to market its proprietary Sterilox endoscopy high-level disinfectant system as a medical device in the U.S. The Sterilox system produces a high-level disinfectant solution that is indicated for use in reprocessing and disinfecting heat-sensitive medical instruments, including endoscopes, between patient procedures. Sterilox solutions are completely non-toxic and are of no risk to patients, healthcare professionals, or the environment. Puricore focuses on antimicrobial technology.

PEOPLE IN PLACES

• Melissa Fitzpatrick, RN, MSN, has been named VP and chief clinical officer of **Hill-Rom** (Batesville, Indiana). Most recently, Fitzpatrick was the chief healthcare strategist for the health and life sciences organization of SAS. Also, Richard Mussmann has been named VP of global product development and chief technology officer. Mussmann was most recently VP of global infusion systems R&D at Baxter Healthcare. Hill-Rom is the healthcare unit of **Hillenbrand Industries**.

• Andrew Miclot has resigned his position as senior VP of sales, marketing and business development and investor relations officer for **Symmetry Medical** (Warsaw, Indiana). Miclot said that these sales and marketing responsibilities will be decentralized with a significant portion transferred to Michael Curtis, recently appointed senior VP and general manager of medical products. Symmetry is a provider of orthopedic devices.