

Washington roundup

Expert panel says national HIT network will cost \$156 billion

By CHRIS DELPORTE

Medical Device Daily Washington Editor

A panel of healthcare and technology experts said a \$156 billion capital investment would be needed for a national health information network and the five-year cost would represent almost 2% of annual U.S. healthcare spending.

In addition to the \$156 billion price tag, achieving a “desirable, workable” network also could add up to \$48 billion in annual operating costs, according to a new study released by healthcare research firm **The Commonwealth Fund** (New York).

The estimates were developed by a panel of experts, including David Brailer, MD, national coordinator for health information technology at the U.S. Department of Health and Human Services and Janet Corrigan, formerly of the Institute of Medicine, and now president of the National
See Washington, Page 9

Report from Europe

Medtronic planning 40-country launch of Endeavor DES device

A Medical Device Daily Staff Report

Medtronic (Minneapolis) reported receiving CE-marking for its Endeavor Drug-Eluting Coronary Stent with the Rapid Exchange Delivery System in European Union member countries. The company said it plans to launch this drug-eluting stent (DES) system simultaneously in 40 countries, outside the U.S.

The Endeavor system – which Medtronic bills as the first cobalt alloy platform on the (DES) market – features “best-in-class deliverability, excellent clinical results and a strong patient safety profile,” according to the company.

Scott Ward, president of Medtronic Vascular, said, “We believe the Endeavor system offers a powerful combination of deliverability, efficacy and safety that is unmatched by any other commercially available stent.”

Ward said Medtronic sales representatives and customer support staffs are fully trained, and that it has an ample supply of Endeavor systems to support the global rollout.

See Europe, Page 8

Viking bringing affordable 3-D capability to MIS procedures

By HOLLAND JOHNSON

Medical Device Daily Associate Managing Editor

While many are familiar with the concept of 3-D imaging, not everyone is aware that the 3-D concept also is being applied to real-time surgical procedures, particularly in performing an increasing array of minimally invasive techniques in which the surgeon needs the added depth perception to do the job properly.

One company at the forefront of developing 3-D minimally invasive surgical (MIS) products is **Viking Systems** (La Jolla, California), with the focus of providing digital solutions to the surgical suite.

MIS is rapidly gaining popularity with both patients and physicians due to improved outcomes, faster recovery times and lower post-operative care costs. These procedures are now being performed in many specialty areas, including bariatric, pediatric, cardiac, urologic, ENT
See Viking, Page 6

American Association for Clinical Chemistry

More individualized patient care drives new paths in diagnostics

By KAREN YOUNG

Medical Device Daily Staff Writer

ORLANDO – Diagnostics is both growing broader – through new techniques and systems – and at the same time narrower – through more individualized assessment.

These were just two conclusions that could be drawn from the session titled “Experiences with an Active Therapeutic Drug Management Practice,” during a **Mayo Clinic Reference Services** (Rochester, Minnesota) conference held just prior to last week’s joint conference of the **International Federation of Clinical Chemistry and Laboratory Medicine** (IFCC; Milan, Italy) and the **American Association for Clinical Chemistry** (AACC; Washington).

Loralie Langman, PhD, and a consultant in clinical biochemistry and immunology for the **Mayo Clinic College of Medicine**, said that the “old” definition of therapeutic drug monitoring is “quantitative measurement of drugs in plasma in order to assist a care provider to ensure that a
See AACC, Page 7

INSIDE: GUIDANT GETS RELAUNCH OKAY FOR CONTAK ICD	2	THOMSON ★
INSIDE: VASCULAR IN \$50M SHELF FILING (FINANCINGS ROUNDUP)	3	

Guidant gets relaunch okay for Contak ICD; to offer more info

A Medical Device Daily Staff Report

Though still pummeled by the legal and public relations effects of a rash of recalls for its implantable cardioverter defibrillators (ICDs), **Guidant** (Indianapolis) had good news to report this week, saying that it has received FDA approval to re-launch its Contak Renewal 3 family of cardiac resynchronization therapy (CRT) defibrillators in the U.S.

The company said in a statement that it expects to resume worldwide distribution and implants of its CRT defibrillators by mid-week and that it expects "full product supply within this month."

Additionally, in an interview with *USA Today*, Fred McCoy, president of Guidant's cardiac rhythm unit, promised that the company would make more information available to physicians implanting the devices.

In the company statement, McCoy said that Guidant's "return to the CRT defibrillator market is exceptionally important for patients with heart disease. It is the result of sound engineering, unwavering dedication to highest product quality and FDA's timely response to validated technical information and analysis."

The FDA approval follows the company's report last week that it had won CE-mark approval to re-launch Contak Renewal 4 cardiac resynchronization therapy defibrillators for use outside the U.S. (*Medical Device Daily*, July 26, 2005). The combination of these regulatory approvals clears the way for Guidant, it said, "to once again fully participate in the fastest growth area within cardiac rhythm management – cardiac resynchronization therapy defibrillators."

Guidant voluntarily removed these devices from implant and distribution on June 24 (*MDD*, June 27, 2005), after identifying problems with a magnetic switch component in the devices. Three recalls by the company were subsequently given Class I status by the FDA (*MDD*, July 6, 2005).

Guidant said that it has received no additional reports related to failure of the component following the initial

reports of failures.

The company said that it identified – and the FDA approved – a new component that resolves these concerns, after further testing and evaluation of the Contak Renewal 3 and 4 cardiac resynchronization therapy defibrillators.

Guidant previously provided physicians with a programming recommendation for Contak Renewal 3 and 4 cardiac resynchronization therapy defibrillators already in service. In addition, Guidant has received approval for U.S. distribution of new software designed to help physicians better manage existing Renewal 3 patients. The new software will be available outside the U.S. later this year, it said.

A cardiac resynchronization therapy defibrillator delivers small electrical impulses to both ventricles that may improve the heart's pumping ability. The device also monitors the heart for potentially fatal heart rhythms that can cause sudden cardiac death and, if such a rhythm is detected, delivers a lifesaving shock to restore normal heart rhythm. ■

Plastic surgery panel to meet Aug. 25-26

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee will meet Aug. 25-26, 8 a.m.-6 p.m., at the Hilton Washington DC North/Gaithersburg, in Gaithersburg, Maryland.

The committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health (CDRH) outlining its responsibility for the review of postmarket study design. The committee will discuss and make recommendations on the classification of five pre-amendments medical devices: bone wax, medical maggots, medicinal leeches, tissue expander, and wound dressing with a drug.

A pre-amendments device is one that was in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments.

Interested persons may present data, information, or views on issues pending before the committee. Contact David Krause of the CDRH at (301)-594-3090, ext. 141. ■

MEDICAL DEVICE DAILY™ (ISSN# 1541-0617) is published every business day by Thomson BioWorld®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. BBI® and MEDICAL DEVICE DAILY™ are trademarks of Thomson BioWorld®, a Thomson Healthcare Company. Copyright © 2005 Thomson BioWorld®. All Rights Reserved. No part of this publication may be reproduced without the written consent of Thomson BioWorld®. (GST Registration Number R128870672)

ATLANTA NEWSROOM: Executive Editor: **Jim Stommen**. Managing Editor: **Don Long**. Associate Managing Editor: **Holland Johnson**. Staff Writer: **Karen Young**. Washington Editor: **Chris Delporte**. Production Editor: **Kim Urquhart**.

BUSINESS OFFICE: Vice President/Group Publisher: **Donald R. Johnston**. Marketing Manager: **Chris Walker**. Account Representative: **Steve Roberts**.

REPRINTS: For photocopy rights or reprints, please call **Stephen Vance** at (404) 262-5511 or e-mail him at stephen.vance@thomson.com.

SUBSCRIBER INFORMATION
Please call (800) 688-2421 to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call (404) 262-5476. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

EDITORIAL
Don Long, (404) 262-5539
Fax: (404) 814-0759

VP/GROUP PUBLISHER
Donald R. Johnston, (404) 262-5439

INTERNET
www.medicaldevicedaily.com

THOMSON
™

Financings roundup

Vascular in \$50M shelf filing; GE, UVA in development pact

A Medical Device Daily Staff Report

Vascular Solutions (Minneapolis) reported filing a universal shelf registration statement with the Securities and Exchange Commission, covering up to \$50 million of undesignated securities.

Vascular Solutions said it has no immediate plans to commence an offering or to offer any securities under the registration statement.

"We are filing the universal shelf registration to prepare Vascular Solutions for possible long-term opportunities," said Howard Root, CEO of Vascular Solutions. "This filing does not indicate any change in our projection that our current working capital is more than adequate to meet all of our foreseeable capital requirements."

Vascular Solutions develops technologies for the interventional radiology and interventional cardiology fields.

GE Healthcare (Waukesha, Wisconsin), a unit of **General Electric** (Fairfield, Connecticut), reported signing a multi-year agreement with the **University of Virginia Health System** (UVA; Charlottesville) to develop new, minimally invasive surgery techniques. Terms were not disclosed.

Using GE Healthcare's surgical navigation tools, the InstaTrak 3500 Plus and OEC 9800 Plus, doctors at UVA will research less invasive methods of therapeutic and surgical intervention for the brain and spine.

"This research agreement is the beginning of an important relationship between the **University of Virginia** and GE Healthcare. The results of this study will enhance surgical technologies and deliver new, less invasive technologies that will improve physician efficiency and patient care," said Joe Hogan, president and CEO of GE Healthcare.

GE Healthcare and the University of Virginia plan to expand the research partnership ultimately to new non-invasive techniques like image-guided focused ultrasound techniques.

"This continued research agreement will allow us to improve interoperative visualization, or our ability to see tumors in the brain and spine more precisely," said Neal Kassell, professor and co-chair of neurosurgery at UVA. "As surgery becomes less invasive, surgeons have less visual contact with a patient's anatomy. Ultimately, our partnership with GE will enable us to utilize imaging technology, to better visualize the area where we are operating."

Designed to support minimally invasive procedures, the InstaTrak 3500 Plus provides surgeons with three-dimensional visualization of a patient's anatomy, along with the ability to track the position of instrumentation during surgery. GE Healthcare's OEC 9800 Plus, a digital mobile imaging system with a fully motorized C-arm, allows surgeons flexibility for exceptional visual detail and navigation in spinal surgery.

In other financing news:

- Pinnacle Asset Management (Bloomington, Indiana) reported that it has made what it called "significant" investments in three young Indiana-based companies within the medical device industry: **Renascence Medical** (Bloomington), **Symbios Medical** (Indianapolis), and **Morris Innovative Research** (MIR; Bloomington). Robert McCormack, president and chief operating officer of Pinnacle, reported the investments but did not disclose the specific amounts.

Renascence Medical was formed two years ago to develop medical products for the pre-hospital market. Over the past year, it has have been developing a gravity-driven intravenous (IV) device that allows the healthcare worker to choose between two different drop sizes (10 & 60 drps/ml) at any time during I.V. therapy.

Symbios was created to develop and sell disposable pain management systems that deliver analgesic pain medication to post-surgical sites.

MIR's focus has been the development of an arterial closure device for patients who undergo procedures that treat coronary or vascular disease. This closure device integrates a bio-tissue with an introducer sheath, one of the standard tools used in catheter labs.

Pinnacle Asset Management was founded in 1989 to optimize the growth and management of Pinnacle's expanding portfolio of operating businesses. It has since invested in companies across a variety of industries, including medical device manufacturing, hospitality services and information technology. ■

Align in manufacturing consolidation

Align Technology (Santa Clara, California), developer of Invisalign, a method of straightening teeth without wires and brackets, said it will consolidate some of its manufacturing process in Juarez, Mexico, as part of efforts to improve efficiency and reduce operating costs.

Beginning now and concluding in late IQ06, Align said it would execute a phased relocation of stereolithography (SLA) mold fabrication operations from Santa Clara to an existing facility managed by **TECMA Group** (El Paso, Texas) in Juarez, eliminating 21 positions at the Santa Clara facility in the transition.

The company said the move is in line with its long-term plan to consolidate and automate SLA and aligner fabrication; it will result in a two-day cycle time reduction and lowered operating costs. The company said it expects annualized savings of about \$1.3 million beginning in mid-2006.

Since 2003, Align has outsourced portions of its manufacturing processes to TECMA, which operates FDA- and ISO-certified facilities in Mexico.

Align will expense about \$800,000 in retention and severance, equipment move and other start-up costs as incurred through IQ06. It also will purchase \$2.6 million in capital equipment to facilitate the phased relocation. ■

*Court report***HealthSouth to pay \$7 million of \$25 million to settle lawsuit****A Medical Device Daily Staff Report**

Following the not guilty verdicts delivered for its founder and former CEO Richard Scrushy, aftershocks keep coming for rehabilitation chain **HealthSouth** (Birmingham, Alabama).

In filings with the Securities and Exchange Commission last week, the corporation reported that it has agreed to a \$25 million settlement in the class action lawsuit against it. The suit relates to losses in the company's employee retirement fund.

HealthSouth will pay \$7 million of the settlement, with insurance carriers paying the remainder.

The settlement is part of the continued fallout from the multi-year \$2.7 billion inflation of the company's financials and, when uncovered, the resultant quickly declining value of its stock.

A judge must approve the proposed agreement.

The settlement does not affect claims against former HealthSouth finance chiefs Aaron Beam, Mike Martin or Bill Owens, who all pleaded guilty in the overstatement fraud.

The suit also continues against fired Scrushy.

In other legalities:

- **Transonic Systems** (Ithaca, New York) reported that the U.S. Court of Appeals for the Federal Circuit has issued a ruling in its favor in its dispute with **Non-Invasive Medical Technologies** (d.b.a. **HemaMetrics**; Kaysville, Utah), concerning Transonic's U.S. Patent No. 5,685,989. HemaMetrics is the maker of the Crit-Line monitor that Transonic claims infringes its '989 patent.

Transonic said it prevailed "on all counts."

Ruling that the District Court of Utah had erred on three fronts, the appeals court reversed the lower court's non-infringement ruling. The U.S. District Court of Utah had determined that the Crit-Line Delta-H and Go/No-Go methods did not infringe Transonic's patent for measurement of access flow during dialysis.

Transonic said that the blood line reversal method of measuring access blood flow – the subject of the '989 patent – was invented by Dr. Nikolai Krivitski, its senior scientist, and co-worker Dr. David MacGibbon.

Cornelis Drost, president of Transonic, said that Krivitski's invention "is widely recognized as a pioneering contribution to hemodialysis patient care that prevents much patient harm and suffering." The new ruling "confirms that our patent on his inventions has a similar broad and ground-breaking scope."

He said that Transonic is pursuing its patent protection in "a parallel case against **Fresenius USA** and **Fresenius Medical Care Holdings**. We will now push for a rapid jury trial to bring this patent dispute and its financial impact on our company to a successful conclusion."

The Court of Appeals ruling confirms that a jury could find that HemaMetrics' Delta H and Go/No-Go methods for determining shunt flow during dialysis infringe claims of the Transonic patent and remands the case back to the lower court for further proceedings.

Transonic was represented by Knobbe, Martens, Olsen and Bear in the appeal.

Transonic says that its inventions led to breakthrough improvement in the management of stenotic disease in the hemodialysis access shunt: periodic surveillance of shunt blood flow with interventions to restore flow when indicated by a critical reduction in flow. Under the shunt flow screening program, standard surgery is averted and replaced by a minimally invasive procedure to restore flow. ■

ADA develops new association to address obesity in America**A Medical Device Daily Staff Report**

The **American Diabetes Association** (ADA; Alexandria, Virginia) reported the creation of "Shaping America's Health: Association for Weight Management and Obesity Prevention," with a mission to prevent excess weight and obesity and facilitate a better scientific understanding of weight management. The new organization will issue new clinical guidelines and address public health challenges through evidence-based initiatives, the ADA said.

Michael Jensen, MD, president of the new organization and professor of medicine at **Mayo Medical School** (Rochester, Minnesota), said that "Shaping America's Health" will provide "leadership and authoritative information to help families and communities make improved nutrition and greater physical activity a priority, especially for children."

The new organization will begin addressing the challenges of obesity through its first initiative, called Shaping America's Youth (SAY). SAY was initially launched in November 2003 as a public-private partnership, with the support of founding corporate supporters **Campbell Soup Company** (Camden, New Jersey) **McNeil Nutritionals**, a **Johnson & Johnson** company (New Brunswick, New Jersey) and **Nike** (Beaverton, Oregon).

The SAY initiative was conceived in 2003 in cooperation with the **Office of the Surgeon General, U.S. Department of Health and Human Services**; the **American Academy of Pediatrics** (Elk Grove Village, Illinois); **Academic Network** (Portland, Oregon); the Nutrition Department of the University of California at Davis; and the ADA.

FedEx (Memphis, Tennessee) and **Cadbury Schweppes** (London) are SAY's newest corporate supporters.

"Our nation's weight gain is resulting in long-term health consequences, especially for our youngest citizens,"

See Obesity, Page 9

Deals roundup

Qiagen buy of LCI, SuNyx adds assets for sample preparation

A Medical Device Daily Staff Report

Qiagen (Venlo, The Netherlands) reported that it has agreed to acquire key assets of **LumiCyte** (LCI: Fremont, California) and also assets related to the bioanalytical business of **SuNyx** (Cologne, Germany).

LCI recently initiated marketing of the first products based on its proprietary STS- (Surface Tension Segmented) Biochip sample preparation solution for MALDI (Matrix-Assisted Laser Desorption/ Ionization)-Mass Spectrometry (MS).

SuNyx has developed and is now marketing its MPep and MProtChip platforms for sample preparation of peptide and protein samples for analysis on Liquid Chromatography (LC)-MALDI (Matrix-Assisted Laser Desorption/Ionization) MS. These products allow examining of sample preparation via nanotechnology-based surface structures.

Qiagen will pay about \$3 million cash for the LumiCyte assets and additional considerations of about \$4 million and \$5 million after 18 and 30 months, subject to reaching certain financial targets. Still another milestone of \$4 million could be paid after 60 months.

Qiagen said it expects the LCI buy to add about \$2 million in sales and have a slightly dilutive impact of about \$500,000 on its net 2006 income and be accretive thereafter.

The purchase of SuNyx's bioanalytical business expands on a previous licensing arrangement. Qiagen will pay about \$800,000 in cash and potentially another \$800,000 in milestones. Qiagen said the purchase will add about \$1 million in net sales and will have a slightly dilutive impact of about \$500,000 on 2006 net income and be accretive thereafter.

LCI has created a product portfolio which combines the separation and concentration of proteins and peptides from complex mixtures. Its approach includes using a combination of surface chemistry with nanotechnology on a single mass spectrometry sample chip so that large samples dry down through various affinity surfaces to a non-binding, molecularly flat analysis zone, resulting in an up to 1,000-fold increased sensitivity and reproducibility in MS applications.

The SuNyx platform technology enables researchers to reduce the number of pre-analytical steps and increase sensitivity by measuring each LC-fraction on a ready-made chip with pre-deposited matrix spots on ultraphobic surfaces. This enables the analysis of proteomes and, in particular, low abundant proteins.

The combination of the acquisition of key assets of LCI, plus the acquisition of the bioanalytical business of SuNyx, "creates a complete, proprietary and technology-leading portfolio for Qiagen in the rapidly growing market segment of sample preparation of proteins and peptides for analysis using MALDI Mass Spectrometry," the company said.

Qiagen has developed a portfolio of more than 320 consumable products for nucleic acid and protein separa-

tion, purification and handling, nucleic acid amplification, as well as automated instrumentation, synthetic nucleic acid products and related services.

In other dealmaking activity:

- **Innocoll** (Ashburn, Virginia) reported signing an agreement with **Essex Chemie** (Lucerne, Switzerland), an affiliate of **Schering-Plough** (Kenilworth, New Jersey), to obtain marketing rights to Gentamicin Surgical Implant. Financial terms were not disclosed.

Gentamicin Surgical Implant is a biodegradable leave-behind implant impregnated with the broad spectrum aminoglycoside antibiotic, gentamicin, indicated as an adjunct to the treatment and prevention of post-surgical acquired infection in hard and soft tissues. It can be formulated for implantable or topical application as a lyophilized sponge or as a cast film.

The product was developed using Innocoll's collagen-based technology, CollaRx. Approved in 45 countries under different trade names, it is indicated for the treatment and prevention of post-operative acquired infection.

Innocoll said it will initiate its own marketing of the product in its approved territories and seek entry into other new markets, including the U.S. It also will develop new indications for the product, including a topical application for the treatment of leg ulcers.

"This acquisition represents a key step in our transformation to a fully integrated specialty pharmaceutical company," said Dr. Michael Myers, president and CEO of Innocoll.

- Hospital products manufacturer **Hospira** (Lake Forest, Illinois) reported completing its purchase of **Physiometrix** (North Billerica, Massachusetts), a developer of non-invasive medical devices, for about \$23 million in cash, plus repayment of about \$1 million in bank debt. The acquisition was first unveiled in June (*Medical Device Daily*, June 2, 2005).

The Physiometrix portfolio includes the PSA 4000, a real-time EEG, or brain-state monitor, that aids in evaluating the effects of anesthetic agents; and the SEDLine monitor (previously known as the PSA 5000), a next-generation platform with improved ergonomic design and enhanced user-interface. Launch of the SEDLine device is targeted for this year.

John Arnott, senior vice president, Global Commercial Operations, Hospira, said, "With the increasing importance of sedation monitoring in the hospital, Physiometrix's products will continue to be key during surgical and diagnostic procedures. We are also excited about the longer-term development potential for the technology platform."

- **Cardiac Science** (Irvine, California), a manufacturer of public-access automated external defibrillators, reported that the Securities and Exchange Commission has declared effective its statement related to its proposed merger with **Quinton Cardiology Systems** (Bothell, Washington) (*MDD*, March 4, 2005). The action allows stockholders of the companies to vote on the proposed merger at their respective special meetings.

CSQ Holding Company is a newly formed corporation established to facilitate the merger. ■

Viking

Continued from Page 1

and neurological surgery.

When we use the term 3-D, we're not talking about digital 3-D where we're modeling or creating 3-D images," Thomas Marsh, president and CEO of Viking, told *Medical Device Daily*. "What we're talking about is natural stereoscopic vision, the same thing you use every day in real life. And if anyone needs depth perception, it's the surgeon, especially one that's working on me."

The company established the **Vision Systems Group** (Westborough, Massachusetts) with the acquisition of the visualization business of **Vista Medical Technologies'** (Carlsbad, California) in 2004 (*Medical Device Daily*, April 23, 2004). The group's key products are the EndoSite 3Di Digital Vision System and the 2Di endoscopic vision platform.

The technology behind the EndoSite, like many others in the medical field, according to Marsh, evolved from government-funded initiatives, in this case, the military. And the head-mounted display (HMD), an integral part of the Endosite was originally developed for use by fighter pilots.

"This technology essentially took its current general form in the mid-90's," said Marsh. However, he noted that when it was first developed it did not do very well. The technology was ahead of its time and MIS surgical strategies were still evolving.

In the late 1990's, however, a surgeon named Alan Wittgrove, MD, director of the **Wittgrove Bariatric Center** (San Diego) and one of the preeminent bariatric surgeons in the country, began developing a laparoscopic approach for the gastric bypass procedure. He hooked up with Vista to further develop the technology for MIS, thereby spurring its adaptation and adoption.

Viking's solutions are assisting surgeons today in a variety of MIS procedures, including bariatric, pediatric, cardiac and neurological surgery.

Aside from developing the 3-D technology in-house, the Vision Systems Group is also the strategic visualization OEM partner for several procedure-specific medical device manufacturers.

According to Marsh, Viking has evolved into a \$6.5 million to \$7 million dollar-a-year company, about 50% of that being OEM business, specifically high-end medical camera sales to such prominent companies as **Aesculap** (Tuttlingen, Germany), **Medtronic** (Minneapolis) and **Boston Scientific** (Natick, Massachusetts).

The OEM business, Marsh stressed, involves only the 2-D cameras.

"We're really keeping that the differentiating [3-D] core technology of ours separate," he said, adding: "that business we're building out as a direct sales-branded Viking company around stereo 3-D vision head-mounted displays in the OR with Informatix."

Informatix is a critical component of the EndoSite system, providing the surgeon using the company's 3-D technology platform with additional information to enhance a procedure.

Informatix capabilities enable critical clinical images to be viewed in the HMD and the stereo camera, which incorporates three-chip technology for image clarity and two separate video channels to reproduce the eye's stereoscopic vision.

The Informatix technology also incorporates a voice-activation that enables viewing of secondary video and existing diagnostic reference images without leaving the patient. That thus eliminates the need for surgeons to divide their attention between a monitor and the surgical field as is typically the case with traditional 2-D cameras.

The system also displays existing clinical images from pre-surgical planning files or real-time secondary video in a picture-in-picture format, all from a voice-activated surgeon request.

A procedure can also be recorded in real-time, which could protect a surgeon – or have the opposite effect – in these highly litigious times.

And this recording option can be manipulated into a Powerpoint format, a particular boon for academic institutions and doctors who do podium presentations.

Another benefit of the company's system is the HMD's hands-free ergonomic design, enabling even greater focus on the surgical field and the reduction of fatigue associated with attempting to view a standard monitor.

Aside from the bariatrics market, Viking is focusing its 3-D efforts on laparoscopic MIS neurology and OB/GYN procedures.

The benefits of 3-D are evident in simple procedures, but they are particularly important if something should go wrong in a complex procedure, Marsh noted.

He cited the example of one patient who had already had three or four prior surgeries, making it difficult to complete an MIS procedure because of scarring and other issues. "The default response to that in most cases is that you have to open the patient up, you can't finish minimally invasively. I've been told by surgeons that in these cases, they can get through the [MIS] procedure with the 3-D technology because they can see what they're doing."

And he noted that it is much easier to train surgeons via 3-D than with traditional 2-D since the surgeon can focus more on doing the procedure itself, reducing the complexities of the minimally invasive approach.

In the macro sense, Marsh said that robotics companies like **Intuitive Surgical** (Sunnyvale, California) essentially do the same thing as the EndoSite, since they also incorporate 3-D stereo vision capabilities. However, he noted that Viking isn't in competition with these firms.

"We're not in the robotics business, but we do have a

See Viking, Page 7

AACC

Continued from Page 1

patient is treated with optimal concentration [and] doses" of drugs.

The "new" definition of therapeutic drug management is the "measurement [and] detection of drugs, physiological responses and genetic factors in order to deliver optimal patient care."

"So, really, we're talking about individual drug management," she told the audience at the Rosen Centre Hotel.

Drug management can be done via blood/serum, cerebrospinal fluid, urine and saliva samples, among others, to determine drug response or toxicity.

Langman said "traditional" drug concentration monitoring should be done "when there's serious toxicity" combined with a "poorly defined or difficult-to-detect clinical endpoint, or when there is a steep dose-response curve for which a small increase in dose "can result in a marked increased in desired or undesired response."

It should also be done when it involves drugs with a narrow therapeutic range, or to assess medication compliance.

With drug analysis, there can be "marked inter-individual pharmacokinetic variability," including differences in absorption, distribution, metabolism and excretion. It also is possible to have disease-based variation, resulting in gastro-intestinal, hepatic, cardiovascular or renal differences, such as when "elimination is altered," she said.

There are various ways, to "look at drug monitoring," including liquid chromatography mass spectrometry (MS) – which she said can "achieve high levels of specificity"; ion trap MS; and matrix-assisted desorption ionization – time-of-flight MS (MALDI-TOF), which she called much more expensive than other options.

As for the pharmacodynamics of drug monitoring, Langman said the "dosage adjustments or treatment can be made based on the physiological or biochemical response of the drug's target."

The techniques for pharmacodynamics include 2-D gel electrophoresis and protein microarrays. Electrophoresis is used to study proteins, a point when you have to "start talking about dollars and cents" and the impact of cost on the bottom line of the lab.

LC-MS/MS/, MALDI-TOF and proteomic assays Langman termed "high-cost systems."

In drug monitoring, labs are focusing more on pharmacogenetics. "[This] usually refers to genetic mutations vs. pharmacogenomics," which means how genetics works together, Langman told her audience.

There "has been a lot of literature coming out of basic research that indicates differential metabolism, differential response, efficacy or toxicity which has a genetic basis," she said. For example, "If you new a patient couldn't handle certain metabolites, you would give them a lower dose or a different drug."

Using genetic analysis could potentially avoid adverse reactions, optimize dose before the initial administration of a drug or enable a more effective drug selection by eliminating drugs that may be toxic or ineffective.

Many labs also have incorporated DNA testing into their offerings, she said, to detect, as just one example, inherited diseases.

And Langman discussed the fact that the FDA is beginning programs to encourage drug companies and diagnostics companies to develop "companion diagnostics" – tests in tandem to assess an individual's response to that particular drug.

The FDA is doing this in two ways, she said. First, the agency is offering federal matching funds to joint ventures between pharmaceutical and diagnostic companies, as well as extending "the exclusivity incentives of the Orphan Drug Act to certain drugs linked with companion diagnostics or pharmacogenomic assays."

But there are barriers to the development of companion diagnostics, or what is called "theranostics." For example, she noted the a lack of capital to maintain "innovative diagnostic development." Additionally, she said that drug companies may be reluctant to forfeit some of their potential income in the event a test could prove that certain people would either not benefit or would be adversely affected by taking a particular drug.

Langman also discussed another factor that she said will affect the immunoassays that the diagnostic industry – and she said she was "using this word globally" – will develop, and that is testing for regulated drugs.

She noted that "all sorts of safety [sensitive] industries" were looking at new ways to test for drugs of abuse, including alcohol. Many industries, such as the chemical, transportation and nuclear industries, already have such programs in place.

Of the 320,000 tests performed in 2004 at the Mayo Clinic Drug Lab, only 18,000 samples were for drugs of abuse, she said.

"We're a small drop in the bucket," she said, compared to others. ■

Viking

Continued from Page 6

3-D vision system that is as good as anything that's in the Intuitive da Vinci program."

He said that many surgeons have come to the company wanting a 3-D system they can use for all their laparoscopic procedures, not just those that can be currently performed on the da Vinci.

"Our strategy is really complementary to what da Vinci is doing," he said.

And the EndoSite also has a pricing advantage over the da Vinci, ranging from a base price of \$110,000 up to about \$160,000, he noted, or about "ten times less" than its competitor. ■

Europe

Continued from Page 1

"Our people and our facilities are well-prepared to deliver Endeavor to physicians and patients with no delays," he said.

Dr. Jean Fajadet, MD, **Clinique Pasteur Unite de Cardiologie Interventionnelle** (Toulouse, France), a co-principal investigator of the ENDEAVOR II pivotal trial, said, "The results from the ENDEAVOR trials to date have been both comprehensive and positive. I have had experience with each of the drug-coated stents on the market, and I believe that physicians in the European Union and elsewhere around the world will find that Endeavor represents an excellent course of treatment for their patients."

Medtronic reported strong clinical results in the ENDEAVOR II clinical trial, including a 47% reduction in Target Vessel Failure (TVF), the study's primary endpoint, between the Endeavor arm and the control group. It also demonstrated a 62% reduction in Target Lesion Revascularization (TLR). Safety data from the ENDEAVOR II study indicated a 50% reduction in the major adverse cardiac event (MACE) rate, compared to a conventional bare-metal stent, and just a 0.5% rate of stent thrombosis at 30 days – with no late thrombosis beyond 30 days and no late stent malapposition.

"The overall clinical results of the Endeavor stent are impressive, and I think Endeavor will be a valuable addition to the drug-eluting stent marketplace," said William Wijns, MD, co-director of the **Cardiovascular Center, OLV Ziekenhuis** (Aalst, Belgium), and a co-principal investigator of the ENDEAVOR II trial.

"Endeavor has proven to be highly deliverable and is effective in reducing clinical restenosis. It also offers an excellent safety profile, which is important to both physicians and patients."

Medtronic said it will report results of the ENDEAVOR III trial at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in October, and a fourth trial, ENDEAVOR IV, also is underway. The four trials will provide data on more than 2,000 Endeavor patients and will complete the information needed for submission to the FDA.

The Endeavor Drug Eluting Coronary Stent System combines the Driver bare-metal stent with a Sirolimus-analogue drug, known as ABT-578, and a biocompatible polymer, called PC Technology, to treat coronary artery disease. ABT-578 is a patented compound licensed to Medtronic by **Abbott Laboratories** (Abbott Park, Illinois) and designed to inhibit the cellular process leading to restenosis.

Medtronic also licenses Abbott's phosphorylcholine polymer coating technology (PC Technology), licensed under patents owned by **Biocompatibles** (Oxford, UK). PC Technology is designed to serve as the delivery matrix which controls the release, of ABT-578 directly into the arterial wall.

Abingworth fund has \$53M first closing

The UK venture capital firm **Abingworth Management** reported the first closing at \$53 million of a new fund

dedicated to investments in public companies.

"We are looking at this as an extension of our VC activities. A lot of small cap stocks have the look and feel of a private company – whether they've got a quote or not can be fairly arbitrary," Joe Anderson, manager of the BioEquities Fund, told *Medical Device Daily's* sister publication, *BioWorld International*.

The fund will invest in stocks that have the potential to deliver returns in the two- to four-year time-frame, of which Anderson estimates there are 500 to 600 spread across the U.S and Europe. He argued that while the quoted development-stage companies have high growth potential, because of market volatility, sparse coverage by analysts and pressure on institutional investors to get short-term results, they often are undervalued.

"The market is inefficient in regard to these companies, because it is chasing short-term performance. We have an opportunity because we can take a long-term view and stay with a company until it fulfills its investment potential," Anderson said. Abingworth will sell when a company reaches an endpoint – such as getting approval for a drug or doing a commercial deal – that is reflected in the share price.

"It is a good time to get involved. Basically the market has been trading sideways for the past five years – though, of course, no one can predict when you will get any upward movement."

Anderson said Abingworth does not intend to use the holdings to seek seats on company boards, or to force merger-and-acquisition activity.

The fund has made its first investments, but Anderson said Abingworth does not intend to disclose which companies it has interests in.

A second offering of shares is planned for later this year, though there is no decision yet on how much Abingworth will seek. The BioEquities fund is Abingworth's seventh life sciences fund and the first to be devoted solely to investments in public companies.

Terumo completes European clinical trial

Terumo Heart (Ann Arbor, Michigan) reported that the 20th patient was successfully implanted with its DuraHeart left ventricular assist system on July 19 at the **University of Vienna General Hospital** (Vienna, Austria), completing the European clinical trial of the device.

The company said the clinical trial has been very successful in demonstrating the safety and performance of the DuraHeart in the treatment of end-stage left ventricular failure. To date, five patients have been supported for more than six months, two patients more than one year, and one patient more than 16 months.

The company said it plans to receive the CE mark for the system in early 2006.

The DuraHeart is a third-generation circulatory support device intended for providing long-term cardiac support for patients who are at risk of death due to end-stage left ventricular failure. The product is not currently available in the U.S. ■

Washington

Continued from Page 1

Committee for Quality Health Care.

"A national health information network is crucial to achieving a U.S. healthcare system that provides safe, effective, affordable, and accessible healthcare to all Americans," said Karen Davis, president of Commonwealth. "This cost estimate is an important step towards realizing the goal of a truly high performance health system."

Findings from a Commonwealth Fund survey of physicians and their use of IT, published in "Medscape General Medicine" in December, revealed that start-up costs was the primary hurdle for physician adoption of IT, named a "major barrier" by 56%, and lack of uniform standards was second, with 44% of physicians saying it was a major barrier.

The survey of 1,837 physicians found that practice size plays a role, with physicians in solo and smaller practices more likely to cite barriers to IT adoption. Just 13% of physicians in solo practice said they use electronic medical records, compared with 57% of physicians in practices of 50 or more physicians.

Medical error system passed in Congress

A national system for reporting medical errors moved swiftly through both houses of Congress and President George Bush signed it into law on Friday.

The Patient Safety and Quality Improvement Act is intended to facilitate the reduction of medical errors and improve patient safety through a national database of health and disease information.

Healthcare officials would voluntarily report medical errors to patient safety organizations, which would use a network of computer databases to analyze the information and make recommendations on ways to improve healthcare.

The information would be treated as privileged and confidential.

Similar legislation passed last year, but the session ended before a final agreement could be reached. This time, the House and Senate bills were identical, so the bill only needed the president's signature before becoming law.

The House approved the bill last Wednesday on a vote of 428-3. The Senate approved the measure the previous week.

Increased reporting of errors would make it easier to identify harmful trends and find solutions, according to healthcare officials. Some feel that the current environment punishes openness because reporting could lead to the loss of credentials or a lawsuit.

The Congressional Budget Office estimates that the operation of the data collection system will cost about \$58 million over the next five years.

House passes medical liability bill

The House of Representatives on Thursday passed medical malpractice legislation that would limit awards in lawsuits for pain and suffering to \$250,000. The bill would

not limit economic damages for lost wages or medical expenses.

Called "Help Efficient, Accessible, Low-Cost, Timely Healthcare" or "HEALTH Act," the bill was approved 230 to 194. It now moves to the Senate for approval.

The House has approved malpractice reform legislation before, only to see efforts stall in the Senate.

Proponents of the legislation say rapidly increasing insurance premiums are forcing doctors, especially in high-risk specialties such as obstetrics and neurosurgery to stop practicing medicine.

Critics, mostly Democrats, say the \$250,000 awards cap is arbitrary and that the limits don't always work. Many states already have award caps in place.

Democrats also predicted that the bill will help make the insurance business more profitable but won't necessarily bring doctors any economic relief and may well harm patients.

The bill also would also limit lawyers' fees on a sliding scale, based on the size of the award. It would impose a three-year statute of limitations in most cases and would also have a higher threshold for awarding punitive damages.

President George Bush praised the House for its latest stab at malpractice reform, and said the nation's liability system is "badly broken," with frivolous lawsuits driving up costs and threatening access to care.

"The medical liability crisis is driving up healthcare costs through higher insurance premiums, higher medical bills, and the practice of defensive medicine," Bush said. "This crisis also is imposing substantial costs on the federal government and all taxpayers who bear the cost of Medicare and Medicaid."

He called upon the Senate to pass liability reform legislation when it returns from the August recess.

"The liability system diverts billions of dollars from patient care to legal expenses and drives healthcare professionals from their practices," Stephen Ubl, president of the **Advanced Medical Technology Association** (Washington), said in a statement. "We believe that our healthcare system needs to focus its spending on the delivery of healthcare, not legal costs and defensive medicine." ■

Obesity

Continued from Page 4

said U.S. Surgeon General Richard Carmona, MD. "We must continue collaborations across all sectors of American life to increase health literacy about the importance of daily physical activity and healthy eating."

In the coming months, the association's SAY initiative plans to hold four large regional town hall meetings that will engage a cross-section of more than 1,000 concerned citizens in each city. The first events are currently scheduled to be held in Memphis in September and in Dallas in October. ■

PRODUCT BRIEFS

- **Endologix** (Irvine, California) said it received FDA approval to enroll patients in its clinical trial using its Powerlink System to treat abdominal aortic aneurysm (AAA) in patients with large diameter aortic necks. If approved for marketing in the U.S., the Powerlink System would be the only endoluminal stent graft (ELG) for use in AAA patients with aneurysm neck diameters up to 32 mm. The FDA has allowed the company to include a large diameter Powerlink ELG in the ongoing suprarenal arm of its clinical study. This should accelerate enrollment and permit physicians to treat patients that cannot be treated with an FDA approved ELG, Endologix said. In addition, the company received approval to initiate a seven-center, 60-patient protocol using a large-diameter infrarenal cuff with its approved Powerlink bifurcated device. These two studies will permit Endologix to study alternative implant strategies to treat this subset of patients. The company said it expects to begin enrollment in both studies in the current quarter.

- **General Data** (Cincinnati), a provider of specialized labeling and identification products and solutions, introduced the Personal ID AC patient identification wristband, which combines the features, durability and print resolution of General Data's original Personal ID wristband with a new adjustable adhesive closure for patients of all sizes. The Personal ID line of patient identification wristbands are designed to help hospitals enhance their patient identification efforts using a combination of bar code technology and patient photos on a durable, easy-to-print wristband.

- **Regent Medical** (Norcross, Georgia), a medical glove company, introduced the latex powder-free Biogel

Eclipse, the first surgical glove made from highly-refined deproteinised natural rubber latex. Deproteinised natural rubber latex is the finished product of a patented process that reduces extractable latex proteins in the raw material by 90%. Biogel Eclipse provides a new level of fit, feel and comfort in natural rubber latex. The tensile strength and elongation standards for non-latex gloves are lower than those for natural rubber latex, based on American Society for Testing and Materials 3577-01a. The company said the new glove category represents a cost-effective safety option for facilities wanting to reduce exposure of health-care workers and patients to antigenic proteins found in standard latex surgical gloves without having to incur the cost of non-latex gloves for those not sensitized to latex proteins.

- **RITA Medical Systems** (Fremont, California) reported the introduction of the Vortex EZ and Vortex EZ MAX infusion ports designed for maximum patient comfort and clinical ease-of-use. The new plastic ports are part of the Vortex EZ Port Infusion System – the only port system in the industry to use a rounded chamber design and off-set stem clinically proven to promote more efficient infusion and aspiration flow dynamics – which has been approved by the FDA for use on any patient requiring repeated access of the vascular system or other selected body sites. The Vortex EZ and Vortex EZ MAX are MRI compatible with a “suture anywhere” silicone construction base designed to make implantation easier, and incorporate a low profile shape designed to improve patient comfort. The Vortex EZ and Vortex EZ MAX products have convenient depth markings on the entire catheter length to promote more accurate catheter placement. The EZ MAX port uses the FluoroMax high-radiopacity catheter and tip for better imaging during port placement. Both products are available with complete placement kits and safety infusion sets.

PEOPLE IN PLACES

- **Osteotech** (Eatontown, New Jersey) has named Mark Burroughs, Osteotech's vice president, finance, and treasurer, to succeed Michael Jeffries as executive vice president, CFO and secretary. Jeffries last week announced his retirement, effective Dec. 31, 2005. Jeffries served at Osteotech for 16 years. Osteotech is a provider of human bone and bone connective tissue for transplantation and developer biomaterial and implant products for musculoskeletal surgery.

- Thomas Dugan has been named senior vice president, marketing, and Robert Massa vice president, corporate accounts, at **SonoSite** (Bothell, Washington). From 2002 to 2004, Dugan was president of InterVascular, a subsidiary of Datascope, and was a corporate officer of Datascope. Massa most recently was national sales manager,

enterprise and strategic accounts, for the ultrasound division of GE Healthcare. SonoSite specializes in developing hand-carried ultrasound systems.

- James Smith has been named vice president and chief operating officer of **Suros Surgical Systems** (Indianapolis). Smith most recently was executive director of marketing and strategic planning for MacAllister Machinery and before that vice president at Hill-Rom. Suros is a developer of vacuum-assisted breast biopsy, recently receiving approval for its ATEC Breast Biopsy and Excision System in Canada.

- Joseph Cooper has been named to the new position of senior manager, radiology CT, for **Toshiba America Medical Systems** (TAMS; Tustin, California). Cooper previously was with Siemens Medical Solutions USA, his positions including CT-PET/CT product sales executive and senior CT applications specialist. TAMS markets and services diagnostic imaging systems, coordinates clinical diagnostic imaging research for all modalities in the U.S.