

# MEDICAL DEVICE DAILY™

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PAGE 1 OF 11

## Boston Sci's Tobin to retire, Zimmer's Elliott is named CEO

By OMAR FORD

*Medical Device Daily Staff Writer*

For a decade Jim Tobin has been at the helm of **Boston Scientific** (Natick, Massachusetts). Throughout his tenure, he's faced unique situations and challenges, such as the med-tech industry's meteoric rise following the bursting of the dot.com bubble, and Boston Sci's highly controversial commitment of \$27 billion to buy **Guidant** (Indianapolis).

Tobin, who is just two months shy from his 65th birthday, said on Thursday that he was retiring from the company and that the board of directors has appointed Ray Elliott, former CEO of orthopedics powerhouse **Zimmer Holdings** (Warsaw, Indiana), to take the posts of CEO/president of the interventional technologies company, effective July 13.

"From my point of view I have been here now for 10 years and that's enough," Tobin said during a teleconference. *See Boston Sci, Page 6*

*Report from Europe*

## ConforMIS receives CE mark for iDuo bicompartamental knee

A *Medical Device Daily Staff Report*

**ConforMIS** (Burlington, Massachusetts), which develops and commercializes personalized, minimally invasive medical devices for the treatment of osteoarthritis, reported receipt of CE-mark certification for its iDuo bicompartamental knee resurfacing implant and companion jig instrumentation.

The CE-mark approval means ConforMIS can begin sales of these products throughout the European Union.

The company said the iDuo is the first and only patient-specific, bicompartamental resurfacing implant on the market. It is designed for patients whose arthritic damage is limited to either the medial or lateral compartment of the knee, in addition to the patellofemoral compartment.

Each iDuo is custom-designed and manufactured from an individual patient's CT scan using ConforMIS' iFit technology, allowing for an entirely personalized fit.

The iDuo resurfaces only the affected areas, preserving. *See Europe, Page 8*

*EAES 2009*

## Endoscopic surgery's safety record alarms Dutch ministry

By JOHN BROSKY

*Medical Device Daily European Editor*

PRAGUE, Czech Republic – "We have had heavy weather in the Netherlands from the Dutch Health Care Inspectorate," said endoscopic surgeon Ivo Broeders, MD, PhD, of the department of surgery at **University Medical Center Utrecht**.

Charged with updating colleagues at the annual congress of the **European Association of Endoscopic Surgery** (EAES), held here last week, on concerns over the safety of endoscopic surgery raised by the Dutch Health Ministry, Broeders said, "This report is about our business at this very moment, not off in the future with new procedures like in the NOTES discussions."

Noting what it called a higher incidence of serious adverse surgery events and deaths among young adults. *See EAES, Page 7*

*CT scans of special concern . . .*

## 'Smart card' proposed to track increasing radiation dosages

By DON LONG

*Medical Device Daily National Editor*

"Managing in the presence of data is far better and easier than managing in its absence."

That was the keynote, and very basic, statement summarizing the point of a recent meeting in Vienna, Austria, of the **International Atomic Energy Agency** (IAEA; Vienna).

But for patients, that basic tenant is overlooked – or. *See Radiation, Page 9*

### A little something Extra

You asked for it . . . you got it. Tacked onto the end of your regular issue today are two pages of *MDD's Cardio Extra*, which we have tagged "Additional Developments in One of Med-Tech's Key Sectors." This is now a regular weekly feature of the publication as part of increasing *MDD's* value to you.

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INGENESIS WINS A U.S. ARMY DENTAL CONTRACT WORTH \$110M .....3

**AHC Media LLC**

*Financings roundup***Medidata tests IPO waters with \$75.9 million offering**By **HOLLAND JOHNSON****Medical Device Daily Managing Editor**

**Medidata Solutions** (New York), a global provider of hosted clinical development solutions, became one of the first companies involved the med-tech sector to test the IPO waters in a long time when it reported the pricing of its initial public offering of 6.3 million shares of common stock at \$14 per share for estimated net proceeds of about \$75.9 million, after deducting underwriting discounts and commissions and estimated offering expenses.

In addition, selling stockholders have granted the underwriters a 30-day option to purchase up to 945,000 shares of common stock at the initial public offering price to cover any over-allotments.

Medidata's common stock began trading on the Nasdaq Global Market today, under the ticker symbol MDSO.

The company said in its SEC filing that it expects to use the net proceeds for general corporate purposes, including working capital, capital expenditures and potential acquisitions. It said it may also repay all or a portion of its \$14.6 million senior secured credit facility, plus accrued interest and any fees relating to our prepayment, in the event that it is unable to restructure the credit facility or obtain alternative debt financing on more favorable terms.

The company's customers include pharmaceutical, biotechnology and medical device companies, academic institutions, contract research organizations (CROs), and other organizations engaged in clinical trials to bring med-

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

*"I believe and have always believed that 10 years is sort of a natural limit as to how long a CEO can expect to be effective and I've reached that."*

– Jim Tobin, announcing plans to retire as president/CEO, "Boston Sci's Tobin to retire, Zimmer's Elliott is named CEO," pp. 1, 6, 10.

ical products to market and explore new indications for existing medical products.

The company's principal offering, Medidata Rave, is a platform that integrates electronic data capture (EDC) with a clinical data management system in a single solution that replaces traditional paper-based methods of capturing and managing clinical data.

Medidata, which began providing EDC services in 2001 said in its SEC filing that it has had operating losses in each year from 1999 through 2008, and its cumulative operating loss since 1999 totaled about \$86.3 million as of Dec. 31, 2008. The company also reported that it has identified a number of material weaknesses in its internal controls over financial reporting.

While the company said it has initiated a remediation plan to address these issues, it has only limited operating experience with the remedial measures that have been implemented to date due to these problems, the company said it has had to restate its consolidated financial statements for the years ended Dec. 31, 2005, 2006, 2007 and 2008.

Citigroup Global Markets and Credit Suisse Securities were joint bookrunning managers for the offering. Jefferies & Co. and Needham & Co. were co-managers.

In other financings news, **Medical International Technology** (MIT; Denver) reported that it has received a

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Agreements/contracts**InGenesis wins a U.S. Army dental contract worth \$110M****A Medical Device Daily Staff Report**

**InGenesis Medical Staffing** (San Antonio) said the U.S. Army has awarded the CONUS Dental-South East Region contract to one of its **InGenesis Aora** (IA) joint ventures. The single-vendor, five-year contract – valued at about \$110 million – would place an estimated 270 dentists and other dental ancillary providers at 10 Army facilities in five states.

Specifically, IA healthcare employees will work at U.S. Army Dental Treatment Facilities operating in Georgia (Fort Stewart, Fort Benning, Hunter Army Airfield, Fort McPhearson, Fort Gordon); Alabama (Fort Rucker, Redstone); Mississippi (Camp Shelby); Kentucky (Fort Campbell); and South Carolina (Fort Jackson).

The U.S. Army Medical Command Center for Health Care Contracting notified the company on June 22 that it had won the award, which goes into effect Oct. 1.

“InGenesis looks forward to providing first-class dental health care to Army servicemen and women as well as their families,” said Veronica Edwards, president/CEO of InGenesis. “It’s important for our troops to have access to all kinds of expert dental services to keep them in optimal health and maintain the overall ‘readiness’ of America’s military.”

Edwards said she expects the majority of employees now holding these dental positions will re-apply for their jobs and transition from the existing vendor(s) to IA. If additional personnel are needed, IA will find them via its extensive candidate databases and other targeted, nationwide recruiting efforts, the company said.

The CONUS contract was awarded just two weeks after InGenesis reported another IA joint venture had won 12 Army contracts (part of a \$1.2 billion multiple-vendor award) placing physicians, nurses and ancillary healthcare providers in military facilities nationwide. Earlier this year IA landed two other substantial contracts: a \$97.5 million single award staffing dental assistants at Navy facilities on the West Coast; and a contract worth nearly \$186 million placing healthcare professionals at Navy facilities on the East Coast.

IA is comprised of InGenesis Medical Staffing and **The Arora Group** (Gaithersburg, Maryland), a national medical staffing firm.

In other agreements/contracts news:

- **Flamel Technologies** (Lyon, France) said it has entered into two new feasibility agreements to apply its Medusa platform with two additional companies. One program is designed to deliver a controlled release of a marketed hormone; the other is a Medusa formulation of a therapeutic peptide. The company said it is currently working on 19 feasibility programs with 15 partner companies.

Flamel Technologies is a biopharmaceutical company

**Clarification**

A story in Thursday’s issue of *MDD* about a study on opportunities in the peripheral vascular disease market issued by Scientia Advisors did not mean to imply that the study was a direct outgrowth of a project being done for one of the firm’s clients. The company said the study grew out of its own interest in potential opportunities for companies in the PVD space.

principally engaged in the development of two polymer-based delivery technologies for medical applications. Micropump is a controlled release and taste-masking technology for the oral administration of small molecule drugs. Flamel’s Medusa technology is designed to deliver controlled-release formulations of therapeutic proteins, peptides, and other molecules.

- **CareMedic Systems** (St. Petersburg, Florida) and **Healthland** (Glenwood, Minnesota) reported an expanded partnership to provide additional value to the healthcare industry. Under the new agreement, Healthland will recommend CareMedic’s Audit Management solution to its client base. Currently, Healthland offers CareMedic’s direct-access Medicare solution and its claims and compliance management applications.

CareMedic, a provider of end-to-end revenue cycle solutions, developed Audit Management in response to the Centers for Medicare and Medicaid Services (CMS) rollout of the Recovery Audit Contractor (RAC) program. Under the RAC program, independent contractors perform both automated and complex audits of historical paid Medicare claims to identify overpayments, which are then “taken back” by CMS. Audit Management not only assists in tracking record requests, deadlines and appeals, but identifies potential risk and includes RAC-specific edits to prevent future problems, the company said.

Healthland specializes in solutions designed to enable small community hospitals to deliver the best in healthcare by helping to create one patient chart across the community, be it a hospital, clinic, home healthcare or long term care facility. According to the company, the outcome of its integrated applications is increased operational efficiencies, improved departmental and organizational communication, and reduced cost, due to more effectively managing patient records and optimizing reimbursement while ensuring regulatory compliance. ■

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*Washington roundup***Bill reauthorizing two grant programs advances in Senate**By **DONNA YOUNG****Medical Device Daily Washington Writer**

Legislation introduced earlier this month by Sens. Mary Landrieu (D-Louisiana) and Olympia Snowe (R-Maine) to reauthorize the Small Business Innovation Research and the Small Business Technology Transfer programs was quickly passed last week by the Senate Committee on Small Business and Entrepreneurship.

Those programs fund more than \$2 billion annually in early-stage R&D projects at small technology companies, including life sciences companies. If not reauthorized, the SBIR program will sunset July 31, while the STTR program is set to end Sept. 30.

If enacted, the SBIR/STTR Reauthorization Act of 2009, S. 1233, would permit small companies that receive the majority of their financing from venture capital to be considered eligible to compete for SBIR grants, overturning eligibility requirements added in 2003 that disqualified firms with venture-capital investments greater than 50%.

Since that 2003 reinterpretation, the applicant pool at the National Institutes of Health has been shrinking, said Jim Greenwood, CEO of the **Biotechnology Industry Organization**.

"For six years, more than half of all small, private U.S. biotech companies have not been allowed to compete for SBIR grants due to a bureaucratic ruling," Greenwood said, adding that under the new Senate bill, more biotech start-ups will be allowed to compete for the funds.

Reauthorizing the SBIR and STTR programs, Snowe said, would "unleash the groundbreaking innovation potential of our nation's small businesses," noting that the grants are needed now more than ever, given the economic climate.

"By assisting thousands of pioneering small businesses with the development and promotion of scientific breakthroughs, the SBIR and STTR programs keep America ahead of the curve," Snowe said.

The SBIR program was established by Congress in 1982 and the STTR program in 1992 to provide competitive grants to small businesses in the U.S. to encourage exploration of new technologies.

Federal agencies with an annual external R&D budget of more than \$100 million must allocate 2.5% of their extramural R&D dollars to the SBIR program. Agencies with an annual external R&D budget of more than \$1 billion must allocate an additional 0.3% to the STTR program.

The last comprehensive reauthorization of the SBIR program occurred in 2000. That program, which was

reauthorized for eight years, received two temporary extensions, first to March 20 and the most recent to July 31. The STTR was last reauthorized in 2001, also for eight years.

If enacted, the bill would reauthorize the programs for 14 years and would adjust the amount of SBIR and STTR awards to reflect inflation costs.

Similar bills were introduced in the 110th Congress, but stalled. ■

**PEOPLE IN PLACES**

- Paul McCormick was named executive chairman of **Cardiogenesis** (Irvine, California). McCormick was named chairman of the board in 2007. He is the former CEO of Endologix. Cardiogenesis specializes in therapies for the treatment of chronic cardiac ischemia.

- Mike Wiltermood was named president/CEO of **Enloe Medical Center** (Chico, California), effective July 1. Wiltermood has served as interim CEO since March. Enloe Medical Center is a 391-bed, non-profit hospital.

- **Luminex** (Austin, Texas) reported three executive appointments, all effective July 1. Michael Pintek has been named senior VP, operations. Pintek joins Luminex from Roche, where he most recently was VP/GM, blood screening. Jeremy Bridge-Cook, PhD, has been named senior VP, assay group. Bridge-Cook has previously served as VP of Luminex Molecular Diagnostics. Nancy Kronic, PhD, has been named VP, Luminex Molecular Diagnostics. Kronic has previously served as associate VP, clinical and regulatory affairs, with Luminex Molecular Diagnostics. Luminex makes biological testing technologies with applications throughout the diagnostic and life sciences industries.

- Joseph Whitters was elected to the board of **MyoScience** (Redwood City, California). Whitters is formerly chairman of the board of Mentor. MyoScience is a development-stage company focused on developing a non-toxic treatment for dynamic facial wrinkles.

- Jason Hein has been promoted to senior VP, sales, marketing and product development for both the Vascular Intervention and Lead Management businesses of **Spec-tranetics** (Colorado Springs, Colorado). Hein has been with Spectranetics since July 2006.

- **Staar Surgical** (Monrovia, California) reported the appointment of Richard Meier, the former president/COO of Advanced Medical Optics, to the company's board of directors. Staar Surgical makes minimally invasive ophthalmic products.

### *New ventures*

## Taris focuses on drug-delivery tech for bladder diseases

### **A Medical Device Daily Staff Report**

**Taris Biomedical** (Lexington, Massachusetts), a specialty pharmaceutical company specializing in the field of drug-device convergence for targeted therapies, launched this week and reported it has secured \$15 million in Series A financing.

Venture capital firms Flagship Ventures, Flybridge Capital Partners and Polaris Venture Partners co-led the investment in TARIS, which was founded by scientists from the **Massachusetts Institute of Technology** (MIT; Cambridge) – Michael Cima, PhD, and Robert Langer, PhD — along with Christine Bunt, chief operating officer and former executive with **CombinatoRx**, **Merck & Co** and **Hoffmann La-Roche**.

According to the company, the core platform technology, which was developed by MIT, enables local sustained delivery of drugs directly to the target tissue through drug-device convergence. Taris is focusing its development efforts in disease areas with high unmet need in which current therapies or systemic treatments have failed.

Bladder diseases, which are difficult to treat with systemic therapies, affect 50 million people in the U.S. alone. These diseases include interstitial cystitis (IC)/painful bladder syndrome (PBS), bladder cancer, overactive bladder, urinary tract infections and chronic pelvic pain syndrome.

Taris has developed a lidocaine-releasing intravesical system (LiRIS) that supplies a sustained release of lidocaine directly into the bladder. Lidocaine has been shown in scientific literature and clinical practice, to decrease symptoms associated with bladder diseases, such as bladder pain and urgency when instilled directly into the bladder, the company said.

IC/PBS, a bladder disease associated with significant pain and disability, as well as urinary urgency and/or frequency, will be the initial therapeutic area of focus for Taris. People with severe cases of IC/PBS may urinate 25 to 60 times a day, including frequent nighttime urination, also called nocturia, the company noted.

Taris said IC/PBS can “dramatically impact” quality of life, including loss of work and reduced sexual intimacy. IC/PBS is associated with suicidal rates five-to-seven times the national average. New therapeutic options for IC/PBS are desperately needed, the company said. More than 4 million people in the U.S. alone suffer from IC/PBS, for which only two medications are approved, both associated with “significant” efficacy limitations, according to Taris.

“Current approaches to the treatment of bladder diseases such as IC/PBS are often ineffective, painful and cumbersome to the patient. This is an important unmet medical need for Taris to address,” Cima said.

“With deep domain expertise in therapeutics and drug-

delivery, we are pleased to have the support of Flagship, Flybridge and Polaris as investors in the company,” Bunt said. “The proceeds from this financing will support the ongoing development of our first product into marketable applications for bladder diseases. We are preparing to initiate clinical development with the LiRIS system this fall with the goal of entering Phase II clinical studies in 2010.”

Taris also reported an expansion of its current board of directors by welcoming Dennis Ausiello, the Jackson Professor of Clinical Medicine at **Harvard Medical School** and chief of medicine at **Massachusetts General Hospital** (both Boston) and Ernest Mario, PhD, CEO/chairman of **Capnia** (Palo Alto, California).

In conjunction with the funding, Ed Kania, managing partner and chairman of Flagship, Michael Greeley, general partner at Flybridge, and Kevin Bitterman, principal at Polaris have joined the Taris board of directors along with Cima, Langer, and Bunt. ■

### *Deals roundup*

## Cephalon scraps all licensing agreements with Acusphere

### **A Medical Device Daily Staff Report**

**Acusphere** (Tewksbury, Massachusetts) reported a \$1 million payment by **Cephalon** (Frazer, Pennsylvania), the cancellation of Cephalon’s \$15 million senior secured convertible note and the amendment of its March and November 2008 license agreements with Cephalon for the oncology applications of Acusphere’s Hydrophobic Drug Delivery System (HDDS) technology and AI-525, an intravenous formulation of celecoxib.

Under the amended terms of the license agreements, Cephalon is no longer obligated to make a \$15 million milestone payment or any royalty payments upon approval of AI-525 and Cephalon will assume primary responsibility for patent prosecution of licensed technology.

As a result of this transaction, Cephalon’s pledge and security agreement, and registration rights agreement have also been terminated and Cephalon no longer has a security interest in any of Acusphere’s assets.

Also as a result of this transaction, Cephalon no longer has any rights related to equity ownership in Acusphere nor any product rights to Imagify (perflubutane polymer microspheres) for injectable suspension, Acusphere’s lead product candidate.

Acusphere now has global rights to Imagify, a perfusion stress echo imaging agent for detecting coronary artery disease, the leading cause of death in the U.S. Imagify is being developed to offer a low cost, radiation free alternative to the 7 million nuclear stress imaging procedures performed each year in the U.S.

The company is seeking a partner for the continued development of Imagify. Previously, the company reported

*See Deals, Page 10*

## Boston Sci

*Continued from Page 1*

ence to investors and media. "I believe and have always believed that 10 years is sort of a natural limit as to how long a CEO can expect to be effective and I've reached that. Beyond that personally, it's the right thing to do too."

Questions regarding the quick transition, which is poised to happen in about three weeks, prompted speculation on Tobin's health, which he denied was an issue.

"This has actually been in process since last November," Tobin said of his retirement. "I asked that there be as short a period between the announcement and when the transition occurred to minimize the period of time when it would seem as if I was a lame duck in the position. So three weeks is about right, from my point of view."

He added, "This place is like a video game you know, there's something happening practically everyday, the shorter period of time there is someone running it in a lame duck status, the better off everybody's going to be. So that's what it is. There are no health problems or that sort of thing."

Tobin gave Elliott a stamp of approval and added that he was leaving the company in more-than-capable hands.

Elliott, 59, has more than 35 years of experience leading healthcare and consumer products companies. He led Zimmer for 10 years, joining the company as president and later adding the titles of chairman and CEO.

Prior to joining Zimmer, he served as president/CEO of **Cyber International** (Medway, Massachusetts), a medical rehabilitation and cardiovascular products company.

Elliott began his career in the healthcare industry with **American Hospital Supply**, now **Baxter International** (Deerfield, Illinois), where he served for 15 years in sales, marketing, operations, business development and general management positions, leading to his appointment as president of all the Far East divisions, based in Tokyo.

He also has served on a number of boards, including the **Advanced Medical Technology Association** (AdvaMed; Washington), where he was chair of its orthopedics sector. He was a member of the Boston Scientific board of directors from 2007 until earlier this year. In addition to serving as president/CEO of Boston Sci, he will rejoin the board.

"Included in that is his International experience, which for Boston Scientific is crucial because we're more or less 40% non U.S. and that number is only going to increase as the years go by," Tobin said. "On top of that, [Elliott] has extensive knowledge in the cardiovascular industry which at this point is where at least 80% of our sales are concentrating. So 25 years with two of the world's leading healthcare companies, international experience, broad experience in leadership roles. That adds up to the right guy from my point of view."

One of Elliott's first priorities will be to help the company tackle the warning letter it received from the FDA back in 2006, which prevents Boston Sci from winning



### BOSTON SCIENTIFIC LEADERSHIP CHANGE

New CEO Ray Elliott



Retiring CEO Jim Tobin

approvals of new products (*Medical Device Daily*, Jan. 30, 2006). The company received the letter one day after it emerged victorious in its bid to snag Guidant, beating out industry colossus **Johnson & Johnson** (New Brunswick, New Jersey).

The FDA cited Boston Sci's management for not properly tracking complaints over certain products, including its wildly popular Taxus stent, as well as Vaxcel catheters, Leveen needle electrodes and the Enteryx device used in surgery to treat acid reflux.

"We must complete the work and satisfy ourselves without a doubt that we are ready to take on and maintain the final actions required to lift the corporate warning letter," Elliott said. "It goes without saying that these actions need to meet the FDA's view of the goal, but in any event that's one problem that needs to go away and stay away."

Elliott added that there were other conditions that Boston Scientific would face and that would create challenges for the company in the future.

"The financial crisis has had some limited impact on us — cash is more scarce and we do have some obligations coming due but not until 2010 and 2011," he said. "As we continue to integrate prior acquisitions, including Guidant, it's tough to take on more complexity and more debt. Our current stock is certainly underappreciated, depressed and less valuable as currency to attract new businesses."

But the hope remains in the company's strong product portfolio and news such as this week's release of initial results from the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) (*MDD*, June 24, 2009) helps, promising to give a boost to the ICD market, where Boston Scientific has a strong stake.

Elliott said that the company needed to look to developing its other businesses beyond drug-eluting stents and the cardiac-rhythm management market.

"The first order of business for me each day at 7 a.m. is to review sales from around the world and begin the process of asking why or why not," he said.

Elliott comes to the company at a time when its stock

*See Boston Sci, Page 10*

## EAES

*Continued from Page 1*

who underwent endoscopic surgery, compared to traditional open surgery, the ministry launched an investigation of the risks presented by minimally invasive surgery (MIS) procedures.

The study covered surgeon competency as well as the quality of equipment and training programs at the eight leading surgical centers in the Netherlands.

The ministry was alarmed by general conditions, such as what it called a "variable and inadequate" training of surgeons in laparoscopic techniques, as well as highly variable reporting of results for surgeries that makes comparisons impossible across institutions.

The ministry's inspection also revealed specific concerns, such as an average of 36% of light cables in endoscopes not functioning properly and that almost a fourth of the devices had leaks in the outer linings.

The ministry report concluded that endoscopy "is a promising technique but the safety is not guaranteed."

"This is a very tough conclusion," said Broeders.

"In sports you may be called promising for a year or two, but we have been practicing endoscopy for 20 years and have demonstrated the effectiveness, yet the ministry is singling out endoscopy as being new and particularly unsafe," he told colleagues.

Heads began shaking in the audience as he listed the conditions the Dutch Health Ministry imposed on endoscopic surgeons and that the ministry says it will inspect for conformance this year.

The ministry has called for the implementation of uniform, national, pan-disciplinary training requirements for all basic laparoscopic techniques and the implementation of national guidelines for the inspection, maintenance and replacement of laparoscopic instruments and related equipment.

"Is this bad?" asked Broeders, who then shocked the audience by saying, "They have also called for video capture to be used as key tool for periodic control of surgeons."

The ministry's view, he said, is that periodic checks of pilots is mandatory, so why not surgeons?

To date, said Broeders, the Dutch societies of endoscopic surgeons "have done nothing in response to these conditions."

While hospitals are taking the ministry's report "very seriously," he said, the professional societies resent the singling out of endoscopy arguing the requirements for consistent training guidelines and equipment checks should be applied to all other areas of surgery as well.

"And what we do not have, and what we will oppose, is any program for periodic checking of surgeons and obligatory capture on video," Broeder said to approving nods from the audience.

"There is a lot of opposition among surgeons," he

added. "We feel there is a lot of anger and even aggression against endoscopic surgeons."

Broeders said, "These are seen as harsh measures based on Oxford level 5 evidence."

The Dutch surgeons concede the ministry's points about the inconsistencies in recordingkeeping, but cite this failing as the strength of their argument that there is no evidence to warrant such sweeping measures.

One surgeon in the audience said he would risk playing the devil's advocate, noting that the Dutch Ministry "correctly identified three key issues, despite the challenge to their evidence. We all know that accreditation is dismal," he said.

"The archiving of information we have available on our screens, while we say it is difficult, we all know it is not," he added.

"And finally, our failure to create a competency-based curriculum is exactly right," he said. "They hit the nail on the head in all three areas, and while we don't like the message, we know it is true."

As for periodic checks of surgeon competency, "we need to admit that 70% of surgery depends upon what we see on the screen and how we then manipulate the instrument, yet 10% of surgeons simply do not have, or have lost, the physical and mental capacity to coordinate these movements," he said. ■

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### Court report

## Courts issue final okay of Candela's settlement of suits

### **A Medical Device Daily Staff Report**

**Candela** (Wayland, Massachusetts) reported that the U.S. District Court for the District of Massachusetts granted final approval of the settlement of the previously-disclosed consolidated shareholder class action lawsuit brought against the company and certain of its current and former officers and directors.

In addition, the Superior Court for Middlesex County, Massachusetts, granted final approval of the settlement of the previously-disclosed derivative lawsuit brought against certain of Candela's current and former officers and directors, the company said.

Based on the final approval by both courts and consistent with the terms of the respective settlement agreements, all claims against Candela and its current and former officers and directors have been dismissed with prejudice and without any admission of liability or wrongdoing, the company said.

Candela makes clinical solutions designed to enable physicians, surgeons, and personal care practitioners to treat selected cosmetic and medical conditions using lasers, aesthetic laser systems, and other advanced technologies. ■

## Europe

*Continued from Page 1*

ing more bone than is true in traditional knee replacement surgery. The iDuo also preserves the anterior and posterior cruciate ligaments, which helps to maintain natural knee kinematics.

"The extent of tissue and bone conservation with the iDuo helps patients retain their future surgical options," ConforMIS said in a statement.

"We are pleased to be the first and only company to bring the clinical advantages of our personalized bicompartamental solution to the European market," said Chairman/CEO Philipp Lang, MD. "Together with our already approved iUni unicompartmental knee resurfacing system, surgeons now have the ability to treat their patients with resurfacing solutions that are far more bone conserving and minimally invasive than a traditional total knee replacement."

The iDuo surgical procedure features patient-specific instrumentation called iJigs that are designed from the same imaging data as the implant. The iJig cutting and placement guides eliminate manual sizing during surgery and provide tactile guidance to precisely place the implant, "significantly reducing the number of bone cuts required for the surgery, simplifying the steps, and increasing the reproducibility of surgical results," the company said.

The first iDuo surgery in Europe was performed by Joachim Grifka, MD, and Franz Xaver Köck, MD, at the department of orthopedics at **University Hospital Regensburg** (Bad Abbach, Germany) on June 18.

"We are very pleased that, thanks to the iDuo, we are now able to offer our patients an alternative to a total knee replacement," said Grifka, chair of the department of orthopedic medicine at the **University of Regensburg**.

Köck added, "Due to the fact that the iDuo requires only the damaged parts of the cartilage to be removed, the healthy cartilage and bone tissue can be saved. Only a very small bone resection is required to perform the surgery."

### First implant of Sorin's new ICD

**Sorin Group** (Milan, Italy), a developer of devices for the treatment of cardiovascular diseases, reported the commercial market release and first implant of its new-generation Paradym DR 8550 dual-chamber implantable cardioverter-defibrillator (ICD).

Paradym DR is the second product of a new platform with what Sorin terms "cutting-edge electrical performance," combining high-energy shocks, with an expected 9.5 years longevity in a 32.8 cc device.

Paradym can charge up to 42 Joules, and delivers the highest energy shocks on the market whenever needed to treat a life-threatening arrhythmia, according to the company.

Sorin said Paradym DR features its Parad+ detection algorithm, "providing accurate therapy based on superior specificity in discriminating supraventricular tachyarrhythmias [SVT]."

The company noted that ventricular arrhythmias often occur as regular ventricular tachycardia (VT). "In most cases, these VTs can be terminated by painless anti-tachy pacing (ATP), and a painful and stressful shock can be avoided."

It said Paradym DR is designed to detect and treat the VTs with ATP over a range of heart rates from 100 min up to 255 min.

Peter-Paul Delnoy, MD, of the **Isala Clinics** (Zwolle, the Netherlands), who implanted the first Paradym DR in a 60-year-old man, said, "Providing therapy options to my patients is of great importance. With Paradym, its four tachycardia detection zones and associated therapies, I can provide a customized treatment to each patient. I also especially value the superior SVT discrimination of Parad+, which gives me the capability to treat slow ventricular tachycardias."

Paradym DR also includes the SafeR function, which allows spontaneous atrio-ventricular conduction, while managing all three types of heart block (first, second and third degree). "In this way right ventricular pacing, which has been shown to increase the risk of congestive heart failure and atrial fibrillation, can be reduced to 0.1%," Sorin said.

### Somanetics extends distribution pact

**Somanetics** (Troy, Michigan) reported signing a three-year extension of its exclusive foreign distribution agreement with **Covidien plc**.

Covidien will continue to distribute Somanetics' Invos Cerebral/Somatic Oximeter in Europe, the Middle East and Africa. Invos measures changes in the blood oxygen levels of patients undergoing surgery and in critical care.

The extension will take effect Feb. 16, 2010, when the current agreement expires. ■

## Financings

*Continued from Page 2*

\$500,000 private placement from its Chinese partners and a new order of 200 units.

The private investment was done based on two issuances; the first for a total of \$250,000 at \$0.10 and the second \$250,000 at \$0.14. This investment and the new order show the beginning of a strong commitment and a step toward a successful long-term relationship between MIT and its Chinese partners, MIT said.

**Jiangsu Hualan MIT Medical Technology** (MIT China) is actively promoting and selling MIT's Agro-Jet needle-free jet injector for animal application, and Med-Jet for human application, and is in the process of obtaining certification for the production and sales of both models. ■

## Radiation

*Continued from Page 1*

perhaps more accurately, entirely ignored – in radiation technology, according to that organization. And that absence is correctable, with the development of new information technology in healthcare.

The IAEA is proposing the use of a “Smart Card,” or equivalent electronic collection system, as part of, or supplement to, an electronic medical record (EMR) that will document the amount of radiation an individual receives over his or her lifetime.

The need for this type of documentation is critical, those at the IAEA say, given the increasing use of ionizing radiation, especially computed tomography (CT), and the highly negative downstream results of frequent, accumulated dosages: ionizing-produced cancers.

Addressing this trend, one likely to grow even more rapidly, the IAEA held a meeting in late April to propose the Smart Card method for documenting the accumulation of radiation dosage over an individual’s lifetime; this, the organization said at the time, will be followed a report on the proposal in September and a follow-up meeting in January with a range of representatives from the “e-health” community and the various associations involved in the delivery of radiological procedures.

The need to track the accumulated doses of radiation a person is receiving is backed by authoritative concerns about the overall increase in radiological procedures worldwide.

IAEA cites the most recent estimates from the UN Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) that the estimated collective dose to the world’s populations from medical diagnostic and dental X-ray examinations is 4 million man Sv a year (man Sv [Sievert] being a unit defining a dose to a population in biological terms). This is the result of an estimated 4 billion diagnostic X-ray exams — overall an increase of more than 17% over the last 10 years in the collective global dose being delivered.

Drilling down into these basic statistics are two factors of special concern: the greater increase of dosages in the developed countries where X-ray machines are more prevalent and their use driven by robust reimbursement; and “defensive” medicine (this latter attracting increasing attention in the U.S.), thus adding to the total doses provided by new scanning procedures and, especially, via CT.

“During the last 100 years, improvements in technology have resulted in dose reductions for radiographic examinations by a factor more than 10-fold,” the IAEA says, in a review of the April meeting. But this same reduction is not the case for CT, it says: “Since its introduction in 1972, CT technology has improved substantially, making it possible to obtain better quality CT examinations. However, patterns of use have been con-

## Summit to address imaging overuse and ‘root causes’

**A Medical Device Daily Staff Report**

A meeting to address the issue of the overutilization of medical imaging will be held Aug. 6-7 in Washington, hosted by the **American Board of Radiology Foundation** (ABRF; Tucson, Arizona) in collaboration with **American Board of Radiology** (also Tucson) and the **National Institute of Biomedical Imaging and Bioengineering** of the National Institutes of Health. Participation is by invitation only.

The sponsoring organizations say it is believed that almost one-third of imaging procedures are considered inappropriate and that nearly half, when evaluated retrospectively, are considered non-contributory to improved patient diagnosis and treatment.

Overutilization of imaging has been identified as contributing to excessive medical costs, especially in the pay-for-service U.S. healthcare. But overutilization of these procedures also means “enhanced risks to patients and burden of non-essential information that must be managed,” according to ABRF.

The organization describes this meeting as a summit “to examine the root causes” of the overutilization of medical imaging.

tinuously changing, with increased utilization, and the percentage contribution of medical radiation dose from CT has continued to increase.”

To produce its 3-D views, the average radiation dose of a CT scan is equal to about 500 chest X-rays, according to IAEA, and the precision of CT images is a factor encouraging increasing CT use. But the organization cites a November 2007 report in the *New England Journal of Medicine*, estimating that up to 50% of all scans done today are not justified medically.

An alternative terminology for the Smart Card is “Smart Access,” IEAE says, because its intent is to provide consistency and greater unification of care for the patient “without affecting the diagnostic or clinical purpose.”

It says that confidentiality issues are being handled by e-health groups and that the Smart Card project “simply aims to add radiation exposure information of the patient in e-health systems being developed by many countries” – a statement rather problematical for the U.S., given its reluctant adoption of e-health systems and especially EMRs.

The organization is exploring several options for the system:

- A Smart Card containing a patient’s information to which radiation dose data can be added, with or without images.
- A Smart Card used only as a “digital signature” used for

*See Radiation, Page 11*

## Deals

*Continued from Page 5*

that it received in February a complete response from the FDA to its New Drug Application for Imagify. FDA's response stated that additional clinical work demonstrating Imagify's performance relative to non-contrast ultrasound would be required before approval for marketing in the U.S.

The amount of time and funding required to complete the additional clinical work will depend on the design of the clinical program, which will be developed collaboratively with the potential partner and FDA. The cardiovascular and renal drugs advisory committee of the FDA rendered a lopsided vote of 16-1 against approvability for Imagify this past December (*Medical Device Daily*, Dec. 12, 2008)

After the \$1 million payment from Cephalon, Accusphere said it has about \$2.8 million in unaudited cash which it expects will fund operations to 4Q09 based on the current operating plan.

In other dealmaking news, **Varian Medical Systems** (Palo Alto, California) reported that it has acquired the assets of **IKOEmed** and **IKOEtch** (both Houston), privately-owned suppliers of software used in the planning of radiotherapy and radiosurgery treatments.

The acquisition enables Varian to offer hospitals and clinics an additional software tool to automate and accelerate the most time-consuming portion of the treatment planning process, the company said.

Varian is paying about \$2.2 million plus an additional amount based on achievement of specified milestones to acquire the IKOE assets.

The software is designed to achieve greater than 50% reduction in the contouring portion of the radiotherapy treatment planning process, which typically takes anywhere from 30 minutes to 4 hours. It automates the contouring process by matching patient images with pre-contoured images from an expert database created by renowned radiation oncologists. This eliminates the need for clinicians to manually outline between 10 and 20 organs in each of anywhere from 100 to 200 images of a patient's disease site.

"This is another important step in our ongoing initiative to make cancer treatments better, faster, easier, and more cost-effective," said Tim Guertin, president/CEO of Varian. "This new tool should save a lot of time in planning for complex cases, particularly in cancers of the head and neck and lymph systems."

The IKOE software, which has FDA 510(k) clearance, complements Varian's existing segmentation tools currently used to automate planning for prostate, breast, and lung treatments, the company said.

Varian will sell the software initially in the U.S. as a standalone product that will work with most radiotherapy treatment planning software products in the industry. The company plans to integrate it with its Eclipse treatment

planning software for radiotherapy, radiosurgery, and brachytherapy.

Four IKOE employees and consultants are being offered jobs with Varian to support the product at Varian facilities in the U.S. ■

## Boston Sci

*Continued from Page 6*

price is about 56% lower than it was a decade ago. At one point stock for the company traded more than \$60-per-share. Those shares have dipped as low as \$5.41, but were around the \$10 mark yesterday.

Tobin will serve as a senior advisor the company and to Elliott until Nov. 30. The outgoing CEO will receive his current base salary of \$994,000 and will be eligible for a bonus of up to 120% of his base pay. ■

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## PRODUCT BRIEFS

• **Covidien** (North Haven, Connecticut) has released clinical data from a multi-center, prospective, randomized study on the company's DST Series EEA stapler and OrVil device. The study was designed to measure the impact of the circular staple height (3.5 mm vs. 4.8 mm) on clinical outcomes, including the incidence of GI hemorrhage, stomal stenosis and wound infection. The findings showed that the DST Series EEA stapler and OrVil device with a staple height of 3.5 mm reduces the rate of stomal stenosis by more than 75%, while trending toward a decrease in staple-line bleeding. The DST Series EEA stapler features DST Series stapling technology for the circular placement of double-staggered rows of titanium staples and a transoral configuration for LGB called OrVil.

• **Home Diagnostics** (Fort Lauderdale, Florida) reported the launch of TRUEmanager diabetes management software. The software allows patients to download blood glucose testing results from their meter directly onto a home computer. The system compiles patient demographics into seven reports that show patterns and trends in glucose results.

• **Medtronic** (Minneapolis) reported two clinical trials related to medical device interventions for stroke. First enrollments in the CRYSTAL AF trial have taken place. The trial will use the Reveal XT Insertable Cardiac Monitor (ICM) to assess the incidence of atrial fibrillation (AF) in patients with cryptogenic stroke (stroke of an undetermined cause) or transient ischemic attack (TIA) in order to aid physicians in determining the optimal course of treatment for these patients. A second trial, called SISTERS, is being initiated to compare the effectiveness of Intrathecal Baclofen (ITB) Therapy to best medical therapy in managing generalized, severe, post-stroke spasticity (tightening of the muscles). This clinical trial is designed to add to the body of clinical evidence for ITB Therapy.

• **Quick-Med Technologies** (Gainesville, Florida) said that Derma Sciences has begun selling and shipping Bioguard barrier dressings to customers. Bioguard uses Quick-Med's non-leaching Nimbus technology. Nimbus represents a next generation in advanced wound care and establishes precedent for a multitude of products with this combination of safe and effective properties. Nimbus is a platform technology that uses a large polyquatary biocide which is irreversibly bonded to any of several materials such as cotton, rayon and polyurethane for use in wound care products. Nimbus, unlike other antimicrobial agents that require release into the wound, does not interfere with wound healing and is not susceptible to originating bacterial resistance.

## Abiomed in 1st artificial heart implant outside of a trial

### A Medical Device Daily Staff Report

**Abiomed** (Danvers, Massachusetts) said that surgeons implanted its AbioCor artificial heart in a patient for the first time outside of a clinical trial.

Mark Anderson, MD, of the Robert Wood Johnson University Hospital in New Jersey, implanted the self-contained device in a 76-year-old man with congestive, end-stage heart failure. The AbioCor Total Replacement Heart is mostly made of titanium and plastic, and is designed to be fully implantable.

The hospital said the device has an internal motor that simulates a heartbeat, along with a rechargeable battery. Older artificial hearts have external power devices that patients must keep with them at all times.

This is the first AbioCor implant since the completion of clinical trials and Humanitarian Device Exemption approval from FDA in 2006 (*Medical Device Daily*, Sept. 7, 2006).

"The AbioCor is designed to give end-stage heart failure patients another treatment option to extend their quality of life when they are ineligible for all other medical therapies," said Michael Minogue, chairman/president/CEO of Abiomed.

## Radiation

*Continued from Page 9*

accessing data online, the website serving as a "virtual" card.

• Radiation dose data placed on some other e-health record in a manner that tracks individual patient exposures over time, interoperability providing access from anywhere.

• For those countries without e-health records, something like "a radiation passport, somewhat like vaccination card."

IAEA defines one of its main responsibilities as establishing standards for radiation safety and providing for application of these standards. In 2001 it established a radiation protection program and launched an international action plan that involves a number of international organizations and professional societies in the field of radiology, medical physics, nuclear medicine, radiographers, radiation protection and radiation oncology.

It says the approach is not regulatory but rather is geared to promotion through training, provision of guidance, projects in Member States that assess radiation dose to patients and attempt dose reduction without compromising image quality.

It says that a "visible example" of its efforts is its web site on radiation protection of the patient – <http://rpop.iaea.org> – that site receiving a half-million hits per month. ■

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# MDD'S CARDIO EXTRA

ADDITIONAL DEVELOPMENTS IN ONE OF MED-TECH'S KEY SECTORS

FRIDAY, JUNE 26, 2009

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*Keeping you up to date on recent headlines in cardiovascular healthcare:*

## **Report: Stem cell treatment of end-stage disease successful . . .**

Researchers have reported successful use of an adult stem cell therapy from **Regenocyte Therapeutic** (Bonita Springs, Florida) to treat a patient with idiopathic dilated cardiomyopathy and ejection fraction (EF) of 18%. At three months the patient's EF improved to 40% and at six months 51%. Regenocyte said it has treated several similar patients and they are demonstrating similar improvements. Athina Kyritsis, MD, chair of Regenocyte's scientific advisory board, said, "We have had consistent success in generating viable heart tissue and growing new vessels, treating diseases like cardiomyopathy and peripheral vascular disease. . . . [W]e have only begun to discover what adult stem cells can accomplish in altering the course of diseases until now thought to be untreatable." The Alliance for the Advancement of Adult Stem Cell Therapy and Research

## **Europace pushes use of remote monitoring . . .**

Only about 1% of patients in Europe with implantable cardiac devices are being monitored with remote devices despite wide availability of remote monitoring in many European countries. "Even in countries that have introduced remote monitoring, there are widespread disparities between centers," said Professor Angelo Auricchio, a spokesman for the **European Society of Cardiology** (ESC; Sophia Antipolis, France). Implants in Europe are estimated increasing 5%-10% per year, and Auricchio said that once a device has been implanted, it needs effective follow-up for greatest efficiency. "[M]ore than 2 million follow-up encounters with device patients are now needed in Europe each year, which is pushing the healthcare system to the breaking point," Auricchio said, and that there should be an increase in the number of devices interrogated remotely. The report was made at Europace 2009 in Madrid.

## **Endurance athlete arrhythmias a problem for sports cardiologists . . .**

Competitive sports and endurance training will increase the risk of cardiac arrhythmias and sudden death for athletes in middle age or with pre-existing cardiac diseases. Luis Mont, MD, of the **Hospital Clínic de Barcelona** (Barcelona, Spain) said, in a presentation at Europace 2009, that AF is more frequent in middle-aged individuals who formerly took part in competitive sports and continue to be active, or simply in those involved in regular endurance training without having actually participated in competitive sports. He added that the cost-effectiveness of routine pre-participation screening in a broad population of athletes and endurance sports participants has not yet been clarified. "Given . . . that an increasing number of individuals engage in regular endurance sports," said Mont, "it is certainly of great interest to define which recommendations for sport should be implemented in an individual patient, and how best to manage arrhythmias in participants."

## **'Harmless' EKG irregularity linked to arrhythmia . . .**

First-degree atrioventricular (AV) block, a PR interval longer than 200 milliseconds, is associated with a greater risk of atrial fibrillation (AF), pacemaker implantation, and all-cause mortality, according to Thomas Wang, MD, of the **Massachusetts General Hospital** (Boston) and colleagues. Previous studies, mostly conducted in young healthy men in the military, suggested that a finding of first-degree AV block on an electrocardiogram does not have serious consequences. The researchers turned to 7,575 participants (mean age 47) in the Framingham Heart Study who underwent routine EKG. In follow-up of four decades 481 participants developed AF, 124 received a pacemaker, and 1,739 died. Each 20-millisecond increase in PR interval was associated with an increased risk of each of the three outcomes: AF, pacemaker implant, and all-cause death. The study appears in *JAMA*. (<http://jama.ama-assn.org/cgi/content/short/301/24/2571>)

**Higher mortality for heart failure patients with cognitive impairment . . .**

A team of French and Italian researchers has analyzed data from three studies of 896 patients suffering from cardiac insufficiency, half of them cognitively impaired. They found heart failure associated with a high mortality rate, even among patients not cognitively impaired: 17.9 % (at 6 months), 25.6 % (at 12 months) and 68.2 % (at 60 months). The mortality rate was even higher in heart failure patients with cognitive impairment, with rates of 35.6 %, 40 % and 96.3 %. Clotilde Balucani, MD, from Perugia, Italy, said this data are "too scarce to identify whether this is just the result of an increased morbidity in patients with cognitive impairment or if there is a direct causal relationship due to under-treatment or poor compliance" and that more research is needed. Researchers presented the findings at the current meeting of the **European Neurological Society** (ENS; Basel, Switzerland). (ENS abstract O119: Balucani et al, "Does cognitive impairment influence outcome in congestive heart failure? A systematic review")

**Overweight a health concern, BMI only part of story . . .**

Overweight is a health concern, and Body Mass Index (BMI) is part of a larger picture, according to a new advisory from the **American Heart Association** (Dallas). Cora Lewis, MD, professor of medicine and public health at the **University of Alabama at Birmingham**, said, "This larger picture includes important relationships between BMI and other health outcomes, such as cardiovascular disease and its risk factors. Arguably, the most important relationship among the cardiovascular disease risk factors is diabetes, which is significantly more common in overweight than in normal-weight people." Lewis and colleagues conclude: Being overweight increases the risk of cardiovascular disease, Type 2 diabetes and other health conditions but more research is needed on the links between overweight and health and this should go beyond looking only at BMI and risk of death. "Meanwhile, we cannot afford to wait for this research to begin addressing the problem of overweight in our patients and in our society." The advisory is published June 8, online, by *Circulation* (DOI: 10.1161/CIRCULATIONAHA.109.192574).

**Weekly stroke clinics can't meet minimum standards . . .**

According to an audit published by the **Royal College of Physicians** (London), outpatient clinics in District General Hospitals operating on a weekly basis are not able to reach minimum standards for treating patients who have suffered a stroke. The study, published in *Clinical Medicine* journal, assessed the timeliness with which an urgent access neurovascular clinic was able to evaluate possible stroke victims between 2000 and 2006. Data showed that the clinic was not able to reach the UK National Clinical Guideline for Stroke's recommendation that patients who may have suffered a minor stroke or transient ischemic attack receive urgent evaluation within one week. Researchers at Stoke Mandeville Hospital surveyed GPs and found that high-risk patients were seen sooner than those who had been categorized as low or intermediate risk. But, in 2006, the average wait for high risk patients was still 17 days. The report appears in the June edition of *Clinical Medicine*. Royal College of Physicians.

**Inflammation markers linked to more fatal than non-fatal events in elderly . . .**

The presence of inflammatory markers in the blood can identify that an elderly individual is at higher risk for fatal rather than a non-fatal heart attack or stroke, according to a new study. Naveed Sattar of the **University of Glasgow** (Glasgow, Scotland) and colleagues used data from the Prospective Study of Pravastatin in the Elderly at Risk (PROSPER) trial, of participants ages between 70 and 82 who had or were at risk of cardiovascular disease. They examined if three inflammatory markers-interleukin-6 (IL-6), C-reactive protein (CRP) and fibrinogen-were each more strongly associated with fatal cardiovascular events than with non-fatal cardiovascular events over three years. The researchers found that in this group of elderly patients increased levels of all three inflammatory markers, and in particular IL-6, were more strongly associated with a fatal heart attack or stroke than with a non-fatal heart attack or stroke. The findings appear this week in the open access journal *PLoS Medicine*.

[www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed1000099](http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed1000099).

— **Compiled by Don Long, MDD National Editor**

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