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High costs and potential 'yucks' are barriers to nanotechnology

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

WASHINGTON — The first day of this week's two-day conference on nanotechnology hosted by the **National Academy of Sciences** (Washington) included discussions of technological advances as well as the public perceptions faced by those who would do business in nanotechnology.

While the range of topics was wide, the regulatory aspects that will confront nanotechnology received little attention, despite the FDA conference on just such concerns this past October (*Medical Device Daily*, October 12, 2006) and the agency's recent guidance on *in vitro* diagnostic multivariate assays (*Medical Device Daily*, Feb. 12, 2007).

Jeffrey Schloss, PhD, program director for technology development coordination at the **National Human Genome Research Institute** (NHGRI), gave an overview

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AACE meeting

New diabetes report highlights huge clinical, financial impacts

By KAREN YOUNG
***Medical Device Daily* Staff Reporter**

Media reports have alerted many Americans to the crisis of obesity in America, particularly in children, with the frequent resulting health complications, such as Type 2 diabetes.

Now, a new report, titled "State of Diabetes Complications in America," paints a broad picture of the financial toll, as well as the clinical impact, of Type 2 diabetes, the more severe form of the disease.

Results from the report were released at the **American Association of Clinical Endocrinologists**' (AACE; Jacksonville, Florida) 16th Annual Meeting and Clinical Congress ongoing in Seattle.

The report looks at the prevalence and cost of the complications of Type 2 diabetes, made worse by the co-

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World Healthcare Congress

Despite gains, home care has formidable barriers in Europe

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

BARCELONA, Spain — At the World Healthcare Congress Europe, held here at the end of March, the chief executive for the UK's **National Health Service** (NHS) neatly described a significant problem that he shares with colleagues from the 26 other member states of the European Union. And he then presented a solution.

"On any day, one-fourth of hospital beds are filled with patients with more than one chronic condition, and most could be better served in their community," said David Nicholson, who went on to show how England's Connecting for Health program is an IT-centered strategy that enables delivery of healthcare services for the chronically ill at the community level.

Jennifer Dixon, director of health policy at the **King's Fund**, set off a buzz among the 500 conference participants with her presentation of an interactive tool used by

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Financings roundup

Epocal, AST close on 'C' rounds of $31M and $28M, respectively

A *Medical Device Daily* Staff Report

Epocal (Ottawa), a private developer of point-of-care blood diagnostic products, reported the closing of a $31 million Series C equity financing.

The Series C round was led by Highland Capital Management (Dallas) and also included participation from founding investor, Genesys Capital Partners.

The company said that proceeds of the financing will be used to commercialize Epoc, the company's FDA 510 (k) approved blood diagnostic platform, as well as develop its immunoassay technology.

The company says that its Epoc system, an "enterprise" point-of-care blood analysis platform, combines smart-card-like diagnostic cards containing biosensors and fluidics-on-flex circuits with bedside card readers. The readers communicate wirelessly to a mobile handheld computer or PDA for immediate bedside results and to a portal on a hospital network for centralized data management.

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Deals roundup

Ventas sweetens offer for Sunrise by $1.50 a share to C$2.28 billion

A *Medical Device Daily* Staff Report

Ventas (Louisville) and **Sunrise Senior Living Real Estate Investment Trust** (Toronto) have agreed to amend the purchase agreement they entered into on Jan. 14 to reflect an increase in the amount paid to unitholders of Sunrise from C$15 per unit to C$16.50 per unit. The total value of the transaction including debt is C$2.28 billion (about $1.97 billion), an increase over the $1.8 billion that Ventas originally offered

The sweetened offer would appear to put to rest Ventas' threatened legal action against Sunrise in regards to a standstill agreement that company had with a rival bidder, **Health Care Property Investors** (HCP; Long Beach, California).

After a formal bidding process in which Ventas emerged victorious, HCP made a late proposal to buy Sunrise in a transaction that valued each Sunrise unit at C$18 ($15.45). It said its offer represented a 20% premium over the C$15-per-unit price on offer in Sunrise's proposed sale to Ventas.

At the conclusion of Sunrise's bidding, Ventas said that HCP withdrew and declined to submit a final proposal "apparently because it was unable to reach the necessary agreements with the various parties. "

As a part of the amended terms, if the purchase agreement is terminated for any reason other than a breach by Ventas, Sunrise has agreed to reimburse Ventas for up to C$10 million in expenses. The agreement also contemplates that, conditioned on the closing of the transaction, Ventas and Sunrise will settle the outstanding litigation that Ventas has filed against Sunrise.

In connection with the amendment to the agreement, the Sunrise special meeting of unitholders to consider the proposed transaction has been scheduled for April 19.

Michael Warren, chairman of Sunrise REIT and the special committee of the Sunrise REIT board of trustees formed to consider the transaction, said: "With Ventas' 10% purchase price increase, the final price represents a premium of approximately 57% over the volume weighted average trading price of the REIT's units on the Toronto Stock Exchange for the 20-day period immediately preceding the announcement of the original transaction in January.

Debra Cafaro, president/CEO and chairman of Ventas, said that while her company continues to be excited about the Sunrise portfolio and development pipeline, "it is important to underscore, however, that C$16.50 is Ventas' 'best and final' price; if we do not complete this transaction at this price, we will focus our attention on the other attractive acquisition opportunities in our pipeline."

Ventas is a healthcare real estate investment trust. Its portfolio of properties in 43 states includes independent and assisted living facilities, skilled nursing facilities, hospitals and medical office buildings.

Sunrise was formed to indirectly acquire, own and invest in income-producing senior living communities in major metropolitan markets and their surrounding suburban areas in Canada and the U.S.

In other dealmaking news:

· **Refac Optical Group** (Fort Lee, New Jersey) reported that its board approved the delisting of its common stock from the American Stock Exchange in connection with the merger of the company with ROG Acquisition, with Refac becoming a private company.

The delisting will become effective 10 days after the filing. However, the company could withdraw the form before the delisting becomes effective.

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

"There's a very strong mistrust of U.S. technology," in other countries, largely invisible to those in the U.S.

*— Vikki Colvin, PhD, professor of chemistry and chemical engineering at **Rice University**, in discussing nanotechnology and potential pitfalls for its adoption. "High costs and potential 'yucks' are barriers to nanotechnology," p. 1, 5.*

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

SENIOR VICE PRESIDENT
Donald R. Johnston,
(404) 262-5439

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MDD science scan

Study confirms meningitis risk linkage with cochlear implants

A *Medical Device Daily* Staff Report

Confirming again what physicians have frequently speculated, a new study published in the April edition of *Otolaryngology-Head and Neck Surgery* says that the presence of cochlear implants increases the risk of bacterial infections that can cause meningitis. The report says that the finding increases the need to educate the public on the need for meningitis vaccinations in potential cochlear implant recipients.

The study involved making cochleostomy incisions — that is, opening of the inner ear spaces of the cochlea, the most important moment in the procedure — in the ears of 54 healthy rats, implanting cochlear devices in 36 of them, and then monitoring them for the presence of meningitis. A third of the rats with cochlear implants were stricken with meningitis.

The report reconfirms early reports by the FDA, in 2002, and in an article in the *New England Journal of Medicine* in 2003, that children are at risk for meningitis when implanted with certain cochlear implants and not vaccinated against bacterial meningitis, researchers said (*Medical Device Daily*, Aug. 1, 2003).

And researchers at the **National Center on Birth Defects and Developmental Disabilities** of the **National Institutes of Health** found that children with cochlear implants with "positioner" attachments were at significantly higher risk of developing the disease.

The new study indicates that cochlear implantation lowers the threshold needed for pneumococcal bacterial infection, the bacterium that causes meningitis. The authors stress, however, that they still believe that the benefits of cochlear implants far exceed the risk of meningitis, which can be managed by education and vaccination efforts.

Worldwide, 90 of the 60,000 people receiving cochlear implants have been stricken with meningitis, drawing concern within the international medical community.

Otolaryngology Head and Neck Surgery is the journal of the **American Academy of Otolaryngology-Head and Neck Surgery** (Alexandria, Virginia), which represents more than 12,000 physicians and allied health professionals who specialize in the diagnosis and treatment of disorders of the ears, nose, throat, and related structures of the head and neck.

Stem cells successful in diabetes treatment

As the U.S. Senate debates new ways to support stem cell research, a Brazilian study indicates that stem cell transplants in patients with Type 1 diabetes may boost the ability of the pancreas to produce insulin again. Some patients that have received the treatment have gone 20 months without needing insulin. The study is published in the current issue of the *Journal of the American Medical Association (JAMA)*.

Since 1996, other autoimmune diseases have been treated successfully by suppressing the immune system and then transplanting blood stem cells to kick-start fresh cell production of damaged tissue. This transplant of blood stem cells is called autologous nonmyeloablative hematopoietic stem cell transplantation or AHST. Also, previous trials have shown that newly diagnosed Type 1 diabetes responds to moderate suppression of the immune system and can stop further loss of the cells that produce insulin, as well as reduce the need for external insulin.

The new study is said to be the first to combine both the immunosuppression and the stem cell transplant in newly diagnosed Type 1 diabetes patients. Julio Voltarelli and colleagues from the **Regional Blood Center** (Hemocentro), **University of Sao Paulo** (Sao Paulo, Brazil), enrolled 15 recently diagnosed Type 1 diabetes patients, ages 14 to 31, all dependent on supplemental insulin.

After receiving drugs to stimulate stem cell production, the patients had some bone marrow removed to harvest a supply of blood stem cells. Then their immune systems were suppressed with drugs, and they also took antibiotics and stayed in isolation to protect them from infection. After two weeks their extracted and conditioned stem cells were infused into their bloodstream via the jugular vein.

The treatment took place between November 2003 and July 2006 with further observation until February 2007 at the Bone Marrow Transplantation Unit of the **School of Medicine** (Ribeirão Preto, Brazil).

As the treatment took effect, the patients gradually, at different rates, reduced their need for external insulin; 14 of the 15 patients were insulin-independent over the seven to 36-month follow-up period. The average insulin free-period was nearly 19 months. One patient was insulin-free at 35 months, another four for 21 months, seven for 6 months and two with late response were insulin-free for 1 and 5 months, respectively. The treatment failed in the first patient, probably because his beta cell count was too low when they started the treatment. The remaining patients were more carefully selected after this.

In an accompanying editorial, Jay Skyler, director of the Diabetes Research Institute at the **University of Miami** (Miami), said the results should be assessed cautiously. He noted in recently diagnosed Type 1 patients a "honeymoon" period where for some reason they experience a rise in their own bodily insulin production. And he noted that the study used no control group that would have compared for the effects of a honeymoon period.

Also, he said it was not clear if the insulin level went up because the stem cells generated extra beta cells, or because the immune system stopped attacking the beta cells and the 20 or so percent that were still left in the patients was enough to keep insulin production at the right level, or a mixture of the two. ■

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Patent watch

Cyberkinetics issued patent for treatment of spinal cord injury

A *Medical Device Daily* Staff Report

Cyberkinetics Neurotechnology Systems (Foxborough, Massachusetts), a neurotechnology company developing neurostimulation and neural sensing products designed to restore function, said that it has been issued U.S. Patent No. 7,199,110, titled "Method of Treatment for Spinal Cord Injury," by the U.S. Patent and Trademark Office.

The patent relates to the company's Andara Oscillating Field Stimulator (OFS) Therapy neural stimulation technology platform.

Timothy Surgenor, president/CEO of Cyberkinetics, said, "In February 2007, Cyberkinetics filed a Humanitarian Device Exemption to market the Andara OFS System to treat people with spinal cord injuries within 18 days following their injuries [*Medical Device Daily*, Feb. 23, 2007]. This new patent covers the use of Cyberkinetics' Andara OFS System in combination with a growth factor, which may ultimately enable us to treat people with spinal cord and other nervous system injuries suffered months or years earlier."

The company reports that its intellectual property portfolio now includes five patents issued and more than 50 pending, covering systems, methods, devices and compounds for nerve repair, as well as neural interface technologies for diagnostic, therapeutic and functional restoration products. ■

Agreements roundup

Given Imaging, Fujinon in R&D, marketing, distribution pact

A *Medical Device Daily* Staff Report

Given Imaging (Yoqneam, Israel), a leader in capsule endoscopy, and **Fujinon** (Saitama City, Japan), a developer of optical technologies and endoscopic equipment, reported signing an agreement to collaborate in R&D, component sourcing, marketing and product distribution worldwide, except in Japan. The companies will collaborate to develop future products for the gastrointestinal endoscopy and diagnostic field.

The agreement grants Fujinon nonexclusive rights to distribute Given's equipment and small bowel products, including its RAPID workstation and data recorders, PillCam SB, and Agile Patency capsules in certain countries worldwide, determined by the companies "on a case-by-case basis," they said.

Homi Shamir, president/CEO of Given, said, "Together with Fujinon, we will work to develop the next generation of less-invasive gastrointestinal products, leveraging on the combined resources and technologies of both companies to provide more effective treatment options for patients with gastrointestinal disorders."

Takeshi Higuchi, representative director and president of Fujinon, said, "Being able to offer Given's capsule endoscopy products alongside our own product portfolio gives our customers a powerful set of diagnostic and therapeutic tools and solidifies our position as the leading provider of GI Imaging solutions."

Given's technology platform is the PillCam Platform, featuring the PillCam video capsule.

Fujinon says it has "continually developed" as an optical equipment manufacturer of Fujifilm Group.

In other agreements:

• **Caprius** (Hackensack, New Jersey) said its subsidiary, **M.C.M. Environmental Technologies** (also Hackensack), has entered into a five-year nonexclusive distribution agreement with **McKesson Medical-Surgical** (Richmond, Virginia), a business unit of **McKesson** (San Francisco) and a provider of healthcare products and services to surgical centers, granting McKesson distribution rights to market MCM's SteriMed systems for on-site medical waste processing to ambulatory surgical centers (ASCs) in the U.S.

MCM says that its SteriMed systems process all regulated medical waste generated by surgical centers, including red bag waste, suction canisters and intact sharps containers. These units shred the waste and mix it with a proprietary disinfectant, rendering it "unrecognizable and disinfected," and dispose of it as regular waste.

MCM says its patented technology offers an alternative to hauling and incinerating medical waste.

• **Phase Forward** (Waltham, Massachusetts), a provider of data management solutions for clinical trials and drug safety, reported that **Quintiles Transnational** (Research Triangle Park, North Carolina), a global leader in pharmaceutical services, has signed a multi-year license agreement to extend its use of Phase Forward's InForm electronic data capture solution for clinical trials.

Phase Forward's InForm solution has been used in nearly 90% of all Quintiles EDC trials to date, and will continue to be a technology on which Quintiles provides services to its customers.

The two companies' relationship dates to 1999, when Quintiles initially selected the InForm software to enhance the speed and quality of the clinical trial research process.

• **Premier Purchasing Partners** (Charlotte, North Carolina), a group purchasing organization, reported that new agreements for neurological equipment and related products have been awarded to **Bio-logic Systems** (Mundelein, Illinois); **Cadwell Laboratories** (Kennewick, Washington); **Nihon Kohden America** (Foothill Ranch, California); and **Viasys NeuroCare** (Madison, Wisconsin).

The 36-month agreements are effective May 1 and offer discounted pricing for electroencephalograph (EEG), electromyograph (EMG) and evoked potential (EP) diagnostic and monitoring systems for acute-care and continuum-of-care members of the Premier alliance. ■

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Nanotechnology

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of recent efforts in gene sequencing and the nanotechnologies that have aided that effort.

NHGRI, a division of the **National Institutes of Health**, has mapped the genome, but "clearly, we don't know nearly everything we need to know" about using genomic information, he said.

Schloss said that one of the ways NHGRI has attempted to economize on this expensive investment has been to sequence the genomes of other life forms because "by looking across evolution, we get a lot of information about the human genome." He also cited the continued high cost of mapping genes.

"The cost of sequencing had come down quite a lot . . . but it has still has taken us 10 years to get two orders of magnitude reduction in cost," he said, adding that in the early years of the effort the mapping equipment consisted of "lots of big machines handling lots of sequences," so that sequencing labs looked "like a factory."

In 2005, NHGRI reported that it will focus on getting the cost of mapping a mammalian genome down to $100,000, with a longer-term aim of reducing this cost to $1,000.

The development of appropriate nanotechnologies is "an important goal" in getting to that cost, Schloss said.

He said that Richard Mathies, a professor of chemistry at the **University of California at Berkeley** in 1994**,** led a team that built a high-speed microfabricated capillary array electrophoresis instrument that drove down sequencing times, doing the job in "in a much smaller volume [of space] in a much faster time." That innovation employed chemically etched glass and photolithography to electrically excite and steer DNA into separate channels, or capillaries, for further analysis. Though at the time, the technique was quite advanced, it required three months for mapping a genome with the use of a single machine.

In the mid-1990s, **454 Life Sciences** (Brandford, Connecticut) developed a system that capturee and cloned genomic fragments for analysis with "a relatively simple machine, a detector and a camera," Schloss said, employing a reaction known as pyrosequencing, which types genetic material by picking up the release of pyrophosphate and allowing a lab to read 800 bases of DNA at a time vs. the 200 for then-existing technology.

454's equipment was desktop sized, much smaller than the factory-sized equipment that was current. (Last month, 454's parent company, **Curagen** (New Haven, Connecticut) agreed to sell 454 to **Roche** (Basel, Switzerland) for about $150 million) (*Medical Device Daily*, March 30).

"The next step is sequencing by synthesis," or SBS, Schloss said, and "to do this on an array" that will process hundreds of thousands of molecules at a time instead of dozens or hundreds.

Solexa (Hayward, California), recently bought out by former rival **Illumina** (San Diego), has made a clonal single-molecule arrays that uses SBS, and generating up to "a billion bases of usable data per run," which the firm's site says is 100 times the speed of conventional methods.

Other companies cited by Schloss in this particular race include **Pacific Biosciences** (Menlo Park, California), working on a method to visualize enzyme activity on DNA in real time; and **Visigen Biotechnologies**, working on massively parallel arrays that, according to the company's web site, use "DNA polymerases and nucleoside triphosphates to function as direct molecular sensors of DNA base identity." The site states that its arrays "will allow us to achieve a sequencing rate of 1Mb/sec/machine."

Vikki Colvin, PhD, professor of chemistry and chemical engineering at **Rice University** (Houston), discussed nanotechnology sustainability, pointing out that it doesn't take much for a novel approach to medicine, food or anything else to go "from wow to yuck — it can happen." She said this could just as easily happen in nanotechnology.

One of her cases in point was dichloro-diphenyl-trichloroethane (DDT), used to tamp down mosquito populations to reduce the incidence of malaria, "but we don't use that chemical because of the environmental consequences," despite uneven evidence of its harm to humans.

Colvin warned the backers of nanotechnology that "you often cannot anticipate the consequences" of a new technology, but failure to look into the possibility can "basically shut down the technology completely."

Colvin reminded the audience that the "yuck factor" for nanotechnology includes the novel "Prey," by Michael Crichton, a 2002 entry on the *New York Times* list of best-sellers. "Prey" tells the story of an experiment that results in the inadvertent release of a cloud of nanoparticles functioning as intelligent micro-robots with a predatory bent.

However, "another type of yuck factor are the controls" with which technology is applied, and in foreign nations, these often violate the local sense of social justice., Colvin said. "There's a very strong mistrust of U.S. technology," largely invisible to those living in the U.S., Colvin remarked.

Dealing with misperceptions of a new technology is "a challenge, a risk communication challenge," Colvin said.

She said that many in industry are inclined to think that the bad news is the only news that gets into print, but he pointed to studies of media coverage showing that "80% of the stories are positive."

However, one-sided representations of new technologies can "create polarization between groups where none existed," she commented, adding that "its not surprising that we see these simplistic" treatments of profoundly complicated subjects.

For the public, "the jury is still out," she said

And she emphasized that to avoid the potholes that have claimed other promising technologies, attention to communication is vital.

"Risk communication, finding ways to convey information to the public and policymakers, is critical" to the continued viability. ■

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Diabetes

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presence of other diseases among about 58% of those with Type 2 diabetes, the combination creating a massive financial drain on U.S. health spending.

In 2006, the nation spent an estimated $22.9 billion on direct medical costs related to diabetes complications, according to the report, which estimates costs as adjusted for inflation to reflect 2006 costs.

The report says that the estimated annual healthcare costs for a person with Type 2 diabetes and its complications are about three times higher than that of the average American without diagnosed diabetes.

Such complications — heart disease, stroke, eye damage, chronic kidney disease and foot problems, frequently leading to amputations — costs a person with Type 2 diabetes almost $10,000 each year. And people with diabetes complications pay nearly $1,600 out of their own pockets for costs not reimbursed by insurance, such as co-payments and deductibles.

That amount is significant, considering that according to the National Health Interview Survey, an estimated 40% of adults with diabetes reported an annual family income of less than $35,000 in 2005, indicating the significant financial consequences for some families.

The report was developed as a follow-up to a 2005 AACE study showing that two out of three Americans with Type 2 diabetes had elevated blood sugar levels, which can lead to diabetes complications.

And the report shows that an estimated 33.3% with the disease has one other serious health problem; about 10% with the disease have two other serious health problems; 6.7% with the disease has three other serious health problems; 7.6% has four or more other serious health problems — adding these, leading to the total of two out of three with co-presence of other disease.

"The report makes it clear that we have a major national issue when it comes to diabetes management, and that urgent action is needed," said Daniel Einhorn, MD, secretary of the AACE board.

The report synthesizes data from two large national studies examining the issue of diabetes-related complications in the U.S. Data on the prevalence of diabetes-related complications were derived from the National Health and Nutrition Examination Survey and combined with economic data from the Medical Expenditure Panel Survey.

The report estimates that in people with diabetes, there are specific health problems that are more prevalent than in people with normal blood sugar levels:

• Congestive heart failure occurs in 7.9% of people with diagnosed diabetes vs. 1.1% of those without.

• Heart attack occurs in 9.8% of people with diabetes vs. 1.8% without diabetes.

• Coronary heart disease occurs in 9.1% of people with diabetes vs. 2.1% of those without.

• Stroke occurs in 6.6% of people with diabetes vs. 1.8% of those without.

In terms of microvascular complications, which relate to small blood vessels, the prevalence is as follows:

• Chronic kidney disease occurs in 27.8% of people with diabetes vs. 6.1% of those without.

• Foot problems such as foot/toe amputation, foot lesions and numbness in the feet occur in 22.8% of people with diabetes vs. 10% of those without.

While type 2 diabetes is closely tied to the development of these complications, it is possible that some people may have developed these health problems independent of their diabetes, due to family history or other underlying medical conditions.

"Beyond the impact on quality-of-life, health complications from Type 2 diabetes also contribute to substantial national and individual healthcare costs," said Willard Manning, PhD, professor in the **Harris School of Public Policy Studies** at the **University of Chicago**. "My hope is that the report will call attention to the issue of diabetes-related complications and bring about change in the way we manage Type 2 diabetes to help reduce both the physical and financial burdens."

Regarding annual healthcare costs for people with Type 2 diabetes, heart attack is the most costly complication, at $14,150 per person, followed by chronic kidney disease ($9,002); congestive heart failure ($7,932); stroke ($7,806); coronary heart disease ($6,062); foot problems ($4,687); and eye damage ($1,785).*

"As great as these financial burdens are, this is a conservative estimate, as it only includes direct medical costs," said Manning. "Costs attributed to lost employment or productivity, premature death and disability have not been included, and if we factor in those costs, the overall burden would be far greater."

The report was presented by AACE in partnership with the members of a diabetes complications consortium: the **Amputee Coalition of America** (Knoxville, Tennessee); **Mended Hearts** (Dallas), a support group; the **National Federation of the Blind** (Baltimore); and the **National Kidney Foundation** (New York); and supported by pharma giant **GlaxoSmithKline** (London). ■

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World Health

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NHS primary care trusts to target in real-time patients requiring an intervention for chronic disease prevention.

And the creation of a 100-bed virtual ward for chronic disease management at the UK's Croyden Primary Care Trust was promoted by **Capgemini** (Paris) as a model for community-based treatment. Patients are identified using the Combined Predictive Model from the King's Fund and assigned to a virtual ward team that meets daily.

Patients are cared for in their own homes. Specialists, including pharmacists, social workers and physiotherapists, are called upon to respond to what are often multiple-morbidity conditions.

The enthusiasm for the pioneering British model, though, gave way at the conference as delegates returned to the sobering workshops on topics such as healthcare financing, data security, patient safety concerns and the fragmented state of IT systems that impede, rather than encourage, such programs, which while aligned with their ambitions, are for the moment far beyond their grasp.

As in the U.S., almost 80% of European healthcare spending is consumed by care for patients with one or more of the "dirty five" chronic conditions: congestive heart disease, congestive heart failure, diabetes, asthma and chronic obstructive pulmonary disease.

Several European pilot programs have reported benefits identical with the American experience, most critically savings of 30% to 40% when care is moved to a home setting or a community clinic.

Where the NHS program builds upon capabilities emerging with the IT "spine" developed by Connecting for Health and sophisticated online tools, other countries have taken a lower-tech approach to chronic disease management.

Rather than reinventing the wheel, the Netherlands created the Maastricht Chronic Care Model "by nicely paralleling the **Kaiser Permanente** (Oakland, California) model," according to Cor Spreeuwenberg, dean of health sciences at the **University of Maastricht** in the Netherlands.

"All aspects are integrated," he said. "Outreach from hospital to community, active planning and management, promotion of self-responsibility and self-care, shared care between professionals and with patients and their families."

Spreeuwenberg added: "We've seen improved clinical outcomes overall, brought down overall costs, and have more satisfied patients."

The results are mainly attributable to nurses, he said. "The nurses are much better suited to dealing with high-risk patients than the GPs." But, he added, "We need more powerful systems for self-management."

Dr. Orlaith O'Reilly, director of public health for the Republic of Ireland's **Health Service Executive** (HSE), described results from a seven-month pilot conducted in the southeastern region that concluded in December.

Described as a "highly scalable system linking expert systems with remote monitoring," the Irish program, more simply put, connected nurses with patients over the telephone.

To reach her goal of a "third-generation disease management" model based on the possibilities of the 21st century, rather than being linked to the episodic acute-care model of the last century, will require "convincing decision makers of the need to change," O'Reilly said.

A survey of the European clinicians and public health administrators at the conference in Barcelona revealed unanimous support for empowering patients and supporting self-care with 100% of participants ranking such a strategic shift as important or very important.

"The many European e-health programs now under way are going to put an infrastructure in place to monitor effectiveness and patient use of medical systems," said Gunther Illert, head of the Central European Life Sciences group for Capgemini. "This is necessarily going to lead us to patient-focused care."

He added: "The focus on the patient is helping people awaken to the insight that we need to change," but more

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Costs, reimbursement, legal barriers block home care

BARCELONA — The obstacles to home care using sophisticated medical devices include the costs of such equipment, realigning reimbursement models and contending with legal barriers.

Petra Wilson, a former deputy director of the **European Health Management Association** who worked with the European Commission to draw up country-by-country, e-health action plans, said at-home monitoring of chronic disease, and more widely the shift toward a personal responsibility for health poses a "fundamental conundrum" for Europe.

"Healthcare is a service for Europeans and the fear of an erosion of these rights is one of the factors that led to the Dutch and French veto of the EU constitution in referendums last year," she said.

Another issue is whether the European medical community is legally able to accept medical devices for personal care, said Wilson, a lawyer by training who directs the Public Sector Healthcare unit in the UK for **Cisco Systems** (San Jose, California).

"There are considerable legal barriers across Europe, liability issues and data protection regulations," she said, "which all means European doctors may not, or can not, accept data from personal health devices."

"The more and more these devices are being asked to work together," said Wilson, "the more and more healthcare providers will find themselves acting upon information coming from these devices."

But the EU and businesses "only have soft tools for affecting things," she said, "so the changes may come very slowly."

— *John Brosky, Contributing Writer*

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Epocal

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The platform delivers lab quality results to the bedside at a significantly lower manufacturing cost of conventional point-of-care testing solutions, the company said. The product development pipeline includes cards for a variety of test applications including immunoassay biomarker tests, general chemistries, hematology and hemostasis.

Aquilo Partners, a life science investment bank, was placement agent for the transaction.

Applied Spine Technologies (AST; New Haven, Connecticut) reported closing a $28 million Series C round of financing led by Investor Growth Capital. MB Venture Partners also participated in the round.

The company said a portion of the proceeds will finance a U.S. investigational device exemption clinical trial, a pivotal study now under way, comparing posterior dynamic stabilization using AST's Stabilimax NZ dynamic spine stabilization system to patients receiving traditional fusion stabilization to treat degenerative lumbar spinal stenosis.

Stabilimax NZ is designed to support an injured or degenerated spine and to be substantially less-invasive for patients currently limited to fusion and already implanted in several patients at medical institutions across the country.

"Back pain patients remain one of the most underserved clinical populations today. Many years of research have led to the development of Stabilimax NZ," said Thomas Wood, president/CEO of AST. "This device is designed to be a dramatic advance in back and leg pain treatment by stabilizing the spine without eliminating motion. This therapy has the potential to be far less invasive than fusion, and the technique can be easily adopted by most spine surgeons. Equally important, Stabilimax NZ may delay or prevent progression of degenerative spine disease, while leaving the door open to future treatments, such as fusion, should they be necessary."

Stephen Campe, managing director of Investor Growth Capital, has joined AST's board in connection with the financing.

In other financing news:

• **Tutogen Medical** (Alachua, Florida) said it has entered agreements with institutional investors for the placement of about 1.6 million shares of its common stock, at $7.38 a share.

Net proceeds to Tutogen from the sale of the shares will be about $11.5 million and will be used for working capital and general corporate purposes, Tutogen said.

The company said it expects to close the transaction on or prior to April 30.

Institutional investors participating in the placement included HealthCor Management, acting on behalf of funds managed by HealthCor, Visium Asset Management, and Deerfield Capital Management.

Tutogen manufactures biological implants made from human and animal tissue, using its Tutoplast Process of tissue preservation and viral inactivation to manufacture bioimplants for spinal/trauma, urology, dental, ophthalmology, and general surgery procedures.

• **Andover Medical** (North Andover, Massachusetts), a provider of orthopedic, podiatric and urological durable medical equipment (DME) and incontinence treatment solutions, said it has closed a $5.6 million private financing.

Proceeds from the offering totaled $5,612,492. Participating investors purchased in the aggregate 112 units of the company's securities, representing principal amount of 6% Series A convertible preferred stock at $50,000 per unit.

Each unit consists of: $50,000 face value of 50 shares of preferred stock, convertible at 35 cents a share into 142,850 shares of common stock; class A warrants exercisable for five years at 35 cents a share to purchase 142,850 shares of common stock; and class B warrants exercisable for five years at 35 cents a share to purchase 142,850 shares.

"I believe Andover Medical is now adequately capitalized to pursue our near term business objectives," said Edwin Reilly, CEO of Andover. "These proceeds will be used — in part — to acquire and integrate new companies into a nationwide subsidiary network, which will assist practitioners in providing quality care and services to their patients." ■

World Health

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infrastructure is required to provide accurate information and incentives for the regulators and providers to take things further.

"Where is the burning platform that will push us there?" he asked, adding: "It is not a natural market."

Another survey at the conference showed that more than half of participants believe the biggest barrier to implementing a scalable disease management program in their country is, flatly, payment or financing.

Another one-fourth said healthcare professionals are the problem, though the survey did not explore if this was due to resistance to change, or a shortage of professionals.

"The evidence abounds and demonstrations are clear," for home care of chronic diseases, according to Gérard Comyn, head of information and communications technology for health for the **European Commission**. "We expect a lot from IT for home care, with mobile health systems, wearable health monitors and ambient intelligence for the home setting."

Moving forward, he said, the obstacles to plugged-in home care using these sophisticated medical devices are less technological and more a demonstrable value-added business case realigning reimbursement models to reflect the shift in care from medical centers, and contending with legal barriers, especially where the care is to be offered by the national system.

In many cases, he said, "we simply cannot do what is blocked by a legal framework." ■

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BRIEFLY NOTED

CryoCor 10-K has 'going concern' statement

CryoCor (San Diego), which is focused on the treatment of cardiac arrhythmias, reported that its annual report on Form 10-K included an audit opinion with a "going concern" qualification. A going-concern qualification is a statement from the company's independent registered public accounting firm expressing substantial doubt, based upon current financial resources, whether the company can continue to meet obligations over the next year.

In its annual report, CryoCor indicated that it had sufficient working capital to fund its operations until December 2007 and to pay off its existing debt, and that additional capital would be needed to fund operations into 2008. CryoCor is a medical device company and has filed an application for pre-market approval, or PMA, for the treatment of atrial flutter with the FDA. CryoCor has previously announced that it expects to receive a decision from the FDA on this PMA by August 2007. Additionally, CryoCor said it expects to complete the enrollment in its pivotal trial for the treatment of atrial fibrillation in the second quarter of 2007.

UPMC to move into U.S. Steel Tower

UPMC (Pittsburgh) said that it has signed an agreement that will make U.S. Steel Tower its new corporate headquarters. The new site in downtown Pittsburgh will consolidate UPMC's corporate, administrative and integrated business functions in one location.

UPMC anticipates approximately 2,250 employees will move into the building in phases over the next four years. Relocated departments will include the executive staff, finance and treasury, corporate communications, legal, planning and marketing, human resources, payroll and benefits, and information technology services.

UPMC is the largest integrated health care enterprise in Pennsylvania and one of the leading nonprofit medical centers in the country.

Quality concerns addressed by HemoSense

HemoSense (San Jose, California) received acknowledgement from the FDA that it has satisfactorily addressed the concerns about its quality management system detailed in a warning letter from the FDA in November 2006. The Company also announced it has successfully completed its first ISO 13485:2003 inspection audit. ISO 13485:2003 is the internationally recognized standard for medical device development and manufacturing, which the company first achieved in 2006.

"Our commitment to maintaining world-class design, manufacturing and quality management systems to provide superior products to our customers is illustrated by these recent developments," said Jim Merselis, president/CEO. HemoSense is a point-of-care diagnostic healthcare company that makes handheld blood coagulation systems for monitoring patients taking warfarin.

NASDAQ news . . .

Thoratec files 10-K late, subject to delisting

Thoratec (Pleasanton, California), which focuses on products to treat cardiovascular disease, reported completing review of its historic equity-based compensation practices and filed its annual report for the fiscal year ended Dec. 30, 2006.

On March 1, the company reported that it had filed with the Securities and Exchange Commission for a 15-day extension to file its 2006 Form 10-K because it was in the process of completing a review of its equity-based compensation practices, including a review of the underlying documentation and procedures, and related accounting, for such practices.

The company said review is now complete. Although the company identified certain grant documentation and accounting errors, which resulted in additional non-cash equity-based compensation charges of about $100,000 associated with its historic stock option grants for the fiscal years 2001 through 2005, the company concluded that these accounting errors are immaterial to its financial statements in each of the periods to which such charges would have related.

As the company did not file the 2006 Form 10-K within the 15-day extension period under SEC rules, it anticipated and received on March 19 a NASDAQ Staff Determination Letter indicating that the company had failed to comply with the filing requirement for continued listing set forth in NASDAQ Marketplace Rules, and that its securities are subject to delisting from the NASDAQ Global Select Market. However, since that time the company has submitted its filing and said it expects NASDAQ to withdraw the Staff Determination Letter and cease delisting proceedings.

Deals

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Refac bills itself as a leader in the retail optical industry and the sixth largest retail optical chain in the U.S. It operates 517 retail locations in 47 states and Canada.

· **InfoLogix** (Hatboro, Pennsylvania), a provider of mobile intelligence technology solutions, said it acquired a cutting edge patent portfolio surrounding RFID technology that manages medication management and delivery.

The company said the acquisition strengthens its ability to extend the function of its Mobile Care Stations with automated medication tracking, in addition to complementing the capabilities of InfoLogix's RFID-based software systems, HealthTrax and BedCentral ED, which help manage workflow and locate clinicians, patients and assets in hospitals.

The purchased patent portfolio consists of five U.S. patents and 10 pending patent applications, and allows coverage to be extended to applications in more than 30 countries including China and Japan, as well as countries in Europe and North America. ■

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PRODUCT BRIEFS

• **DePuy Mitek** (Raynham, Massachusetts) reported the launch of the Versalok next generation rotator cuff anchor. Versalok was developed to provide greater versatility in rotator cuff repair. It allows surgeons the ability to address various tear pathologies with one implant and a variety of suture passing configurations including single row, dual row and suture spanning. The anchor expands by 29% from 4.9mm to 6.3mm post-deployment to provide solid fixation under the cortical bone. The anchor is designed to firmly lock the suture in place completely between the sections of the implant and not the bone. This prevents suture unloading and suture creep to provide strength and durability of the repair. DePuy Mitek, a Johnson & Johnson company, makes surgical sports medicine devices.

• **HepaLife Technologies** (Boston) reported that its 'PICM-19' cells, under development for use in artificial liver support and *in vitro* toxicology testing, have outperformed the world's most widely used human liver cell line in important tests of liver-specific metabolic functions. The production of urea is a highly-important function in the removal of toxic ammonia from the bloodstream, a capacity demonstrated by HepaLife's PICM-19 liver cells. According to results from HepaLife's most recent lab tests, its PICM-19 cells synthesized 100% of the ammonia present, nearly four times more than HepG2-C3A, the world's most widely-used human liver cell line today. Results from the same tests also demonstrated that PICM-19 cells are able to express high levels of cytochrome P-450 enzymes, a key liver-related function in the detoxification of drugs and xenobiotics. In contrast, HepG2-C3A showed very low, or no detectable P450 activity at all. HepaLife Technologies is a biotechnology company focused on the identification and development of cell-based technologies and products.

• **Imaging Diagnostic Systems** (Fort Lauderdale, Florida) reported the publication of a significant medical study, "Role of CTLM in Early Detection of Vascular Breast Lesions." The study highlights the importance of imaging the presence and extent of angiogenesis in breasts as a means to improve breast cancer detection and management methods. Angiogenesis is the formation of new blood vessels. In the breast, such new vessels are associated with cancer growth. Imaging Diagnostic Systems, a laser optical breast imaging company, is seeking FDA premarket approval for the CTLM system to be used as an adjunct to mammography.

• **MicroVention** (Aliso Viejo, California) said that that the 500th and final patient has been enrolled in the independent, physician-designed and -managed, international trial of its HydroCoil embolization system for treating cerebral aneurysms. The trial, titled HydroCoil endovascular aneurysm occlusion and packing study (HELPS), compares the results derived from the HydroCoil system to results from approved bare platinum coils, currently considered the mainstay of endovascular aneurysm therapy. MicroVention makes minimally invasive treatments for cerebral and peripheral vascular diseases.

• **Toshiba America Medical Systems** (Tustin, California) has developed three imaging techniques for its MR product line, including the Vantage systems, that allow for contrast free imaging during MRA procedures. Contrast-free imaging is particularly important because gadolinium, the common contrast agent used for MRI and MRA exams, recently has been directly linked to nephrogenic systemic fibrosis also known as nephrogenic fibrosing dermopathy, a sometimes fatal disease that occurs in patients with renal insufficiency. Specifically, Toshiba's equipment utilizes three proprietary contrast-free imaging techniques that can successfully perform MRA, fresh blood imaging, contrast-free improved angiography and Time-SLIP. Toshiba America Medical Systems makes diagnostic imaging systems, and coordinates clinical diagnostic imaging research for all modalities in the U.S.

PEOPLE IN PLACES

• Karen Sarid has been named chief financial and operations manager of **Galil Medical** (Yokneam, Israel). She will also be the company's general manager. Sarid previously was general manager at Orex Computed Radiography. Galil makes cryotherapy systems to treat cancer and non-cancerous tumors.

• Thomas Venable was appointed executive VP of sales and marketing of **InnoCentive** (Andover, Massachusetts). Venable comes to InnoCentive from Digital River. InnoCentive describes itself as providing "on-demand innovation."

• Peter Bye has been named a managing director and senior equity research analyst covering medical devices and diagnostics companies for **Jefferies & Company** (New York), the principal operating subsidiary of Jefferies Group. Previously, Bye had a similar role at Citigroup/Smith Barney. Jefferies provides capital markets and financial advisory services, institutional brokerage, securities research and asset management.

• Bernard Haffey has been named president/CEO of **NDO Surgical** (Mansfield, Massachusetts), and he also will serve on the company's board. Haffey was formerly executive VP and chief commercial officer at IntraLase. NDO develops endoscopic technologies for gastrointestinal diseases.

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