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CMS proposes Medicare cuts for many outpatient services

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

Among a laundry list of proposed changes to policies and payment for hospital outpatient services unveiled on Tuesday, the Bush administration, via the **Centers for Medicare & Medicaid Services** (CMS; Baltimore), asked for a cut of 5.1% across the board in Medicare payments for services provided by doctors to elderly and disabled patients in the outpatient setting in 2007.

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It said the reduction is necessary because spending for these services has been increasing faster than expected and faster than the annual goals set by a statutory formula.

The increase will directly affects beneficiaries because their premiums are set each year to cover about 25% of projected spending under Part B of Medicare, which pays for

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P4P leadership summit

Pilot program shows well, but duration of effect not yet known

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

BOSTON − The plethora of pilot projects designed to evaluate pay-for-performance (P4P) initiatives was itself the subject of some discussion at the P4P leadership summit here this week, and at least one of these — the rather large effort by the **Centers for Medicare & Medicaid Services** (CMS; Baltimore) and **Premier** (Charlotte, North Carolina) − has yielded data suggesting that outcome-driven reimbursement may be more than just the *flavor du jour*.

Richard Norling, CEO of Premier, provided a breakdown on the first eight quarters of returns from the Medicare P4P pilot project, but also advising that the analysis covered only the first four quarters (the numbers from the second four quarters not yet fully analyzed).

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Report from Europe

Chasing next-generation stents, Axordia working with Lombard

By NUALA MORAN
***Medical Device Daily* Contributing Writer**
And *MDD* Staff Reports

Axordia (Sheffield, UK) reported plans for the clinical application of one of its proprietary stem cell lines in a next-generation stent that will prevent restenosis without the increased risk of late-stage thrombosis that can occur with existing drug-eluting stent (DES) devices.

The company will collaborate with **Lombard Medical Technologies** (Oxford, UK) in the development of the so called "regenerative" stent. The project will involve combining Axordia's stem cell-derived endovascular cells with Lombard's polymer coating, which can be programmed for the timed release of the active ingredient.

The current generation of DES devices is designed to restrict local vascular repair following angioplasty. That prevents restenosis, an inflammatory thickening of the artery. However, recent evidence suggests that there are

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Financings roundup

Xtent latest device firm in IPO waters; Medical CV pulls offer

A *Medical Device Daily* Staff Report

Xtent (Menlo Park, California) has broken a several weeks hiatus of initial public offering (IPO) filings in the device sector, reporting yesterday that it has filed a registration statement with the Securities and Exchange Commission for an IPO potentially raising up to $103.5 million. The numbers of shares to be offered and the price range have not yet been determined.

The company said it intends to use the net proceeds for clinical trials, R&D activities, building commercialization infrastructure, general corporate purposes and working capital.

It plans to list its stock on the Nasdaq Global Market under the symbol XTNT.

Xtent says it is addressing the fact that a single DES doesn't fit all anatomies or that there is frequent need for more than one stent and more than one procedure. It banners its system as offering a "customizable" approach to

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Washington roundup

FDA rolls out new task force focusing on nanotech issues

By DON LONG
***Medical Device Daily* Managing Editor**

In an initiative that some might place under the "about time" category, the FDA yesterday reported launch of a Nanotechnology Task Force, charged with determining regulatory approaches that encourage the development of FDA-regulated products that use nanotechnology materials.

In a statement, the agency said that the tasks force "will identify and recommend ways to address any knowledge or policy gaps that exist so as to better enable the agency to evaluate possible adverse health effects from FDA-regulated products that use nanotechnology materials." It said it will address these "product-specific . . . issues on an ongoing basis."

The statement provided no information concerning the membership of this group.

The task force will:

• Chair a public meeting on Oct. 10 to help FDA further its understanding of developments in nanotechnology materials, including issues pertaining to biological interactions that may lead to either beneficial or adverse health effects.

• Assess the current scientific knowledge concerning nanotechnology materials for carrying out FDA's mission.

• Evaluate the effectiveness of the agency's regulatory approaches to meet any challenge presented by the use of nanotechnology materials in FDA-regulated products.

• Explore opportunities to foster innovation using nanotechnology materials to develop drugs, biologics and devices, and to develop safe foods, feeds, and cosmetics.

• Strengthen FDA's relationships with other federal agencies, and international regulatory bodies, professionals and other stakeholders to gather information regarding nanotechnology materials.

• Consider vehicles for communicating to the public concerning issues in nanotechnology.

The Task Force is being asked to submit its initial findings and recommendations to Andrew von Eschenbach, MD, acting commissioner of the agency, within nine months after the Oct. 10 meeting.

"As this exciting new area of science develops, FDA must be positioned to address both health promotion and protection challenges that it may present," von Eschenbach, MD, said. "Through this task force, we are leveraging our expertise and resources to guide the science and technology in the development of nanotechnology-based applications."

PET identifies 'few puffs' addiction

The newest advanced imaging systems have been used to look at all sorts of mental processes, and so it is not particularly surprising that these systems are being used to consider the problems of addition.

The **National Institute on Drug Abuse** (NIDA) of the **NIH** (Bethesda) has just reported findings concerning the use of positron emission tomography, which it said demonstrated the addictive quality of nicotine.

It said the study showed that the nicotine received in just a few puffs of a cigarette appears to "exert a force powerful enough" to drive continued smoking – and thus the addiction.

The researchers found that the amount of nicotine contained in just one puff of a cigarette can occupy about 30% of the brain's most common type of nicotine receptors, while three puffs of a cigarette can occupy about 70% of these receptors.

"When nearly all of the receptors are occupied (as a result of smoking at least 2 and one-half cigarettes), the smoker becomes satiated, or satisfied, for a time. Soon, however, this level of satiation wears off, driving the smoker to continue smoking throughout the day to satisfy cigarette cravings," according to a NIDA statement.

Arthur Brody, MD, of the David Geffen School of

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Deals roundup

Edwards selling its perfusion products business to Nipro

A *Medical Device Daily* Staff Report

Edwards Lifesciences (Irvine, California) reported that it has agreed to sell its remaining perfusion products business to **Nipro Group** (Osaka, Japan), a global supplier and manufacturer of medical devices. Financial terms were not disclosed.

The transaction is expected to close in 4Q06, pending regulatory approvals, Edwards said.

Nipro Medical (Sao Paulo, Brazil), a Nipro Group subsidiary, will acquire the perfusion products business, also based in Sao Paulo. These products are sold in Latin America, Asia, Eastern Europe and parts of the Middle East and Africa.

About 140 Edwards employees who work in perfusion products are expected to transfer to Nipro.

"The sale of our remaining interests in perfusion products allows Edwards to focus on its core businesses and on commercializing new, advanced technologies for patients suffering from cardiovascular disease," said Michael Mussallem, company CEO and chairman.

Since 2000, Edwards has divested its perfusion products operations in the U.S., Japan and Western Europe.

The business being acquired by Nipro was estimated to contribute about $20 million in revenue and $2 million in earnings to Edwards in 2006. Impact of the transaction on 2006 earnings will not be material, the company said.

In other dealmaking activity:

• **Emdeon** (Elmwood Park, New Jersey) said it has entered into a definitive agreement to sell its Emdeon Practice Services (EPS) segment to **Sage Software** (Irvine, California), a subsidiary of UK-based **The Sage Group,** for $565 million in cash.

Deal closing is expected in September

The sale represents the conclusion of a part of the process that Emdeon disclosed on Feb. 16 to explore alternatives for its EPS and Emdeon Business Services (EBS) segments (*Medical Device Daily*, Feb. 17, 2006). Emdeon said it continues to explore alternatives for the EBS segment.

In connection with the transaction, EPS has entered into an agreement with EBS and amended agreements with **WebMD** (also Elmwood Park, New Jersey). EBS will continue as the exclusive provider of electronic healthcare transaction services and patient statement services for EPS through 2013. EPS also will continue its relationship with WebMD and will exclusively integrate WebMD's personal health record with its clinical products, including its electronic medical record.

Emdeon was represented by The Blackstone Group and Citigroup Corporate and Investment Banking in this transaction.

• **Encore Medical** (Austin, Texas) reported that the FTC has granted early termination of the antitrust waiting period for its acquisition by affiliates of **The Blackstone Group** and that two purported class action lawsuits have been filed against Encore and its directors.

In July Encore entered into the agreement to be acquired by affiliates of Blackstone in a going-private merger for about $870 million.

The shareholder complaints seek to enjoin the acquisition of Encore by Blackstone, alleging that Encore directors accepted an inadequate acquisition price.

The complaints allege that the company's directors will receive substantial benefits from the acquisition that supposedly will not be shared with other stockholders, and that the directors and Blackstone timed the deal so that the agreement would be reported before Encore released its 2Q06 results, which would have caused the stock price to rise.

The complaints further charge that the directors who approve the deal were not sufficiently independent and disinterested, and that they did not conduct an auction.

The complaints seek to block the acquisition and rescind any actions taken to consummate it, damages and the plaintiffs' costs and attorney fees. One of the suits also seeks an accounting of all "profits and any special benefits" obtained

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Advanced Warning launches software consulting business

A *Medical Device Daily* Staff Report

Advanced Warning Systems (AWS; Carlsbad, California), a provider of healthcare information technology solutions, reported the launch of its healthcare and life sciences consulting services in the area of software design and implementation.

AWS Consulting said it is focused on improving the delivery of information to the end user through application of principles in Human-Computer Interaction (HCI). Services include usability analyses, strategic planning, evaluations, training and custom software development. It says it can conduct usability analyses, measuring before, interim, and completed state user performance relating to time, money, and resources lost, wasted, or misused as a result of software inefficiencies.

"Most software is designed to be one size fits all, with little thought given to end user or environmental factors," said J.P. Pollak, vice president of product development. "By adhering to a user-centered design strategy with frequent user involvement and *in situ* usability testing, software is far more effective, completed sooner, requires fewer patches, and will be more widely adopted by users and customers."

The AWS Consulting says that its team consists of usability and software designers, specializing in information visualization and architecture for unconventional data problems.

Grants/contracts

Applied Bio in pathogen system R&D via $24.5 million from DoD

A *Medical Device Daily* Staff Report

Applied Biosystems (Foster City, California, a business of **Applera**, reported that the U.S. Department of Defense (DoD) has awarded it a $24.5 million contract to push the development of a prototype instrument system to improve the way infectious diseases are identified for epidemiological and biosecurity purposes.

The system will be designed to give reproducible results in less than one hour following sample processing via streamlined workflow and the ability to simultaneously analyze multiple pathogen targets in a single test.

Applied Bio said that last month it presented key components of the prototype to the U.S. Air Force, which will be responsible for validating the next-generation pathogen identification system.

By developing a system simplifying the processing and analysis of pathogen detection tests, Applied Bio said it expects to enable a new generation of decentralized molecular detection systems that can be deployed in diverse locations and operated by a broader range of public health and safety professionals. The new systems are also will have a modular design enabling rapid customization of new test panels to detect emerging pathogens.

It said early prototypes have demonstrated the ability to identify up to 10 pathogens simultaneously on a credit card-sized test array and are expected to provide more detailed information about the nature of each sample.

In other grant news:

• **GeneGo** (St. Joseph, Michigan), a provider of databases, software and services in systems biology, reported receiving a $750,000 Phase II SBIR grant from the DoD to develop a systems biology suite for functional analysis of proteomics data. In Phase II, GeneGo will adapt its data-mining platform, MetaCore for handling different types of proteomics data and implement new algorithms for reconstruction of protein-state specific biological networks and pathways.

GeneGo will work in collaboration with Professor Austin Yang's group from the **University of Southern California** (Los Angeles), **Rosetta Biosystems** (Seattle) and the **Michigan Proteome Consortium** (Ann Arbor).

GeneGo develops systems biology technologies, its first platform allowing an integration and analysis of different kinds of experimental data (mRNA expression, proteomics, metabolites, phenotypic data) and active chemistry (metabolites, drugs, other xenobiotics) within the framework of biological pathways and networks. The company's first product, MetaCore, assists in target selection and validation, identification of biomarkers for disease states and toxicology.

• **Affiliated Computer Services** (Dallas), a provider of business process outsourcing and information technology solutions, reported signing a two-year, $19.9 million contract with the South Carolina Department of Health and Human Services (SCDHHS; Columbia). The contract includes options for three, one-year extensions.

ACS will provide third-party liability (TPL) insurance verification, benefit recovery, and health insurance program administration services. ACS also will develop a new electronic imaging, workflow and data entry system. And it will provide consultative services to SCDHHS for identifying and verifying new payers and for cost avoidance and cost recovery processes.

ACS reports supporting more than 20 million program recipients and processes nearly 475 million Medicaid healthcare claims annually, representing more than $47 billion in provider payments. ■

Deals

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by Encore's directors and asserts a claim for damages.

The deal remains subject to satisfaction of other conditions, including approval of the transaction by Encore stockholders.

Encore is a diversified orthopedic device company.

• **NWH** (New York), the parent company of healthcare payer services organization **Electronic Network Systems** (Pueblo, Colorado), reported that the merger with **Ingenix** (Minneapolis), a health information company that is also a subsidiary of **UnitedHealth Group** (Minnetonka, Minnesota) was completed.

NWH is now a wholly owned subsidiary of Ingenix.

NWH and Ingenix entered into an agreement in May under which NWH stockholders receive $18.24 per share in cash (*Medical Device Daily*, May 30, 2006).

NWH, a holding company, owns and operates Electronic Network Systems, which offers e-commerce connectivity between healthcare providers.

• **Kindred Healthcare** (Louisville, Kentucky) said it has entered into agreements to acquire the real estate related to 11 nursing centers leased from H**ealth Care Property Investors** (HCP; Long Beach, California). The company also has entered into agreements for a sale and leaseback transaction with HCP with respect to three hospitals owned by the company.

In these transactions, Kindred will acquire the nursing centers that are currently leased from HCP in exchange for the hospitals. The company also will make a one-time payment of about $35 million to HCP, and it will amend its master lease with HCP to terminate the current annual rent of about $9.9 million on the nursing centers; add the hospitals to the master lease with an annual rent of about $6.3 million; and extend the initial expiration date of the master lease until Sept. 30, 2016.

Kindred said it intends to dispose of the nursing centers "as soon as practicable," thereby generating $55 million to $65 million in proceeds. ■

CMS

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doctors' services and other outpatient care.

Mark McClellan, MD, CMS administrator, said in a Tuesday conference call on the proposed changes that the premium would probably rise to $98.40 next year, up $9.90, or 11% over this year's premium. These figures do not include separate premiums paid by many beneficiaries for prescription drug coverage.

Budget estimates are based on the assumption that doctors' fees under Medicare will be cut in 2007 and later years, as required under the statutory formula. Congress often steps in to block or moderate such cuts, but it normally looks for some way to offset the cost of its action, often by trimming payments to other healthcare providers.

McClellan said it would cost the government roughly $13 billion over five years if it blocked the cut scheduled for 2007, without giving doctors any allowance for inflation.

"It's a lot of money, and that's why we think it's so important not just to put more money into a payment system that is clearly broken and clearly not sustainable but rather, to make some real progress now towards a more sustainable quality-focused payment system for physicians," McClellan said.

He noted that hospital outpatient payments have increased substantially over the past few years, and that between 2005 and 2006, hospital outpatient expenditures grew by nearly 12%.

"Our current projections are for growth of close to 10% between 2006 and 2007," he said, adding: "this is a real challenge for the program and a challenge for beneficiaries who pay more in copays and pay for 25% of these expenditures in their premiums."

"Our current system of paying for physician services is simply not sustainable, from the point of view of taxpayers or Medicare beneficiaries," McClellan said. He added that the alarming increases in hospital outpatient service payments "is clearly showing that our hospital outpatient perspective payment system is not doing the job when it comes to maintaining a sustainable rate of growth, and so we're going to be looking diligently and urgently at alternatives."

CMS also proposed the payment system for services provided in ambulatory surgical centers (ASCs) that, if adopted, would be implemented in 2008.

In what McClellan termed a "budget neutral" proposal for calendar year 2008, CMS would add 14 procedures to the list of surgeries for which Medicare would make a facility payment to ASC's.

ASC payment rates under the revised system for the expanded list of approved surgical procedures would range from $3.68 to $16,146.03, reflecting 221 groups of surgical procedures under the revised system. In contrast, the nine current payment rates are based on a 1986 survey of ASC costs that range from $333 to $1339.

"The goal is to help beneficiaries get the outpatient care they need in the most appropriate setting by addressing the payment differences that may inappropriately favor one outpatient setting over another and that consequently may lead to overall increases in Medicare costs," McClellan said. This will be achieved, he said, by aligning "the payments between the ASC system and the hospital outpatient system to encourage the most efficient and appropriate choices of outpatient care for beneficiaries."

As part of a final report to Congress on implementing a strategic plan for so-called specialty hospitals, the Bush administration said that it would require hospitals to provide the government with information on their "investment and compensation relationships with physicians." Hospitals that specialize in cardiac, orthopedic or surgical care will have to inform patients if any staff doctors have "an investment interest" in the hospital.

Hospitals look to doctors as a source of referrals. But Medicare officials said doctors could be violating federal law if they received financial returns out of proportion to their investments

Hospitals that do not comply with the new disclosure requirements will face civil fines of up to $10,000 a day.

In response to traditional full-service hospitals who have expressed concern that specialty hospitals can promote better coordination between the facility and the staff physicians because of the opportunity for physician ownership, CMS has proposed "leveling the playing field" by enabling hospitals to provide better financial support for high quality, low-cost care via gainsharing initiatives.

"We're going to implement demonstration programs to support hospital/physician collaboration, CMS will implement demonstration programs to support better hospital-physician collaboration" via gainsharing, MClellan said. "We're entering a new era in terms of disclosure and transparency and oversight of the specialty hospitals."

More than 42 million people are insured by Medicare. Officials estimate that the program will pay $61.5 billion to 875,000 doctors and other healthcare professionals next year.

Such spending has increased sharply in recent years, McClellan said, because of "increases in the number and complexity of services furnished to Medicare beneficiaries, including more frequent and intensive office visits, and rapid growth in the use of imaging techniques, laboratory services and physician-administered drugs." ■

P4P

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Despite this note of caution, however, Norling clearly was excited about the statistics and their positive implications.

He referred obliquely to the change in mindset needed to make P4P work by stating that "clinical quality and financial performance are inseparable." Efficiency without quality is "unthinkable," he said, and quality without efficiency "unsustainable."

As is widely known, the CMS/Premier project examined how P4P influences outcomes for five areas of hospital practice: hip and knee replacements; coronary bypass grafts; infarction; community-acquired pneumonia; and heart failure. Hospitals improved on all composite quality scores in each condition in each of the eight quarters, which Norling termed "dramatic and sustained improvement."

He said that this is the first "significant study showing the association between more reliable care and lower cost," with his presentation focusing on the pneumonia and bypass sections of the study, which drew from the records of roughly 75,000 patients.

Hospitals that scored in the top 25% quartile for adherence to the performance guidelines incurred an average expense of roughly $8,400 for each pneumonia patient. Hospitals in the second quartile ran up an average bill of more than $9,100 per patient, and those in the lower half spent on average almost $10,300 per pneumonia patient, a 22% bump from the hospitals at the top.

An even more dramatic difference cropped up in the analysis for bypass graft surgery. The top quartile in terms of adherence to best practices averaged just over $30,000 in expenses for each bypass operation compared to more than $41,500 for those operating in the lower half of the performance grid – a boost in cost of roughly 38%.

Extrapolation is a dangerous science, but Norling opted to make use of a projection all the same. The numbers indicated that improving care for bypass surgery alone across the U.S. could eliminate almost 3,500 "avoidable deaths" annually. And reduction of complications from both bypass surgery and pneumonia treatment could total 5,950. The reduced number of readmissions across the U.S. for both conditions would be more than 5,800.

The most eye-popping numbers from an economist's point of view, however, were those for patient hospital-days and raw cost.

According to Norling, improved care for bypass and pneumonia alone could cut the number of hospital days by about 470,000 a year, and bringing all care up to these standards produces more than $925 million in total annual savings.

Norling offered a cautionary note, however, pointing out that much of the physician and nurse cohort was made up of baby boomers and that the mindset needed to sustain these improvements must be transmitted across time and place.

"Knowledge transfer is institutionalized and continuous" in a system that sustains such improvements, he said.

Disease management companies might want to make note of these developments. If Norling's view proves out, "paying disease management companies to manage hospitals and doctors is an extra, unnecessary step."

Hunter Kome, Premier's vice president for communications and public relations, said that the study did not draw data on the financial condition of the participating hospitals, so there is no way at present to establish whether financial health affects a hospital's ability to put P4P measures in place.

However, he said that "what we're seeing is that costs go down as patients receive more of the recommended care." Premier is of the opinion that each of the participating hospitals operates on a not-for-profit basis.

Healthcare researchers have often cited geographic differences in care delivery, but that concern may be out the window by the end of the CMS/Premier study. Kome said that "We have not seen significant variation by region."

The study does not capture the amount of time physicians spend with their patients at hospitals, but Kome stated that none of the measures require more time from doctors. "Most of the measures tracked in this project can be implemented by hospital staff."

The implication is that nurses may end up with additional duties, at least as such programs start out. In this assumption, the lower rate of readmissions and complications might make up the loss of time on the back end, so to speak.

However, Kome stated that those services do not constitute an "extra" burden. Whether nurses in the real world would agree with him is unknown.

The casual observer might be inclined to ask whether the so-called Hawthorne effect might be responsible for the improvement in care – produced when an individual or group feels that it is receiving positive attention.

Kome admitted that "recognition for top performers" is part of the P4P pilot, but he said that a number of other factors are also at play. Among these are "incentive payments . . . the sense of competition inherent among participating hospitals and so on."

He added: "The issue is whether the factors at play in the project appear to be driving improved performance, and they do." ■

Europe

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higher rates of thrombosis, where a clot forms at the end of the stent. It is believed clot formation is linked to the delayed healing of the blood vessel.

Axordia said the endovascular cell line will promote healing at the site where the stent is implanted while at the same time reducing inflammation and creating a localized immune-privileged site to prevent the body from rejecting the stent.

Alistair Taylor, chairman of Lombard, said there is significant potential for a regenerative stent that will reduce restenosis without prompting late-stage thrombosis. "A system that engenders normal healing of the tissues may well reduce these late complications."

It would be the first clinical application of Axordia's stem cell technology. The company, which spun out of **Sheffield University**, has concentrated on developing cell lines for use in drug discovery and in refining and developing GMP-grade manufacturing processes for stem cells.

Paul Gerskowitch, CEO of Axordia, said the collaboration is evidence that the company is in a leading position in delivering safe clinical applications for stem cells. Another UK stem cell company, **NovaThera**, is taking a similar approach to commercializing clinical applications of stem cells, by working with manufacturers of artificial lung and heart machines.

Axordia and Lombard agreed to collaborate on the project over the next 2-1/2 years, but did not reveal the terms of the agreement. The current global market for DES devices is estimated at $6 billion.

UK fair-trade office eyes U.S. firms

The UK Office of Fair Trading (OFT) has received a complaint about three Minneapolis-area companies allegedly involved in price fixing, but hasn't started a formal investigation yet, a spokeswoman said on Sunday.

London's *Sunday Times* reported the OFT is looking into whether **Medtronic** (Minneapolis), **St. Jude Medical** (St. Paul, Minnesota) and **Boston Scientific**'s Guidant division (also St. Paul) allegedly colluded to boost the prices paid by the UK's **National Health Service** for pacemakers.

The UK Department of Health recently sought bids for pacemakers, and none of the three companies that control an estimated 90% of the U.S. market submitted "valid'" bids, according to the *Sunday Times*.

A Boston Scientific spokesman told the newspaper the company's actions were appropriate and in the best interests of doctors and patients. A Medtronic spokesman said the allegations "are wholly fabricated."

A spokeswoman for the Department of Health said Monday the agency has asked the Office of Fair trading to "consider issues relating to the operations of the market," but declined to comment further.

UK company acquired by Sigma-Aldrich

Sigma-Aldrich (St. Louis) reported that it has acquired **Pharmorphix** (Cambridge, UK), a company that offers solid-form research services to the global pharmaceutical and biotech markets.

It said the addition of Pharmorphix will broaden **SAFC Pharma**'s manufacturing services customer base and enhance its technology services offering for existing customers.

Terms of the purchase, which were not disclosed, were paid in cash.

All current employees, including the existing Pharmorphix management team, will remain with the company.

Pharmorphix operates in facilities in Cambridge Science Park near London. ■

Washington

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Medicine at **UCLA** (Los Angeles) and his team used PET to scan the brains of 11 smokers and assess nicotine distribution there. During the scanning sessions, the participants smoked one of five amounts — none, one puff, three puffs, one full cigarette, or until their craving was satisfied (2-1/2 to three cigarettes). Craving was measured with the "Urge to Smoke" scale, which assesses responses to 10 craving-related questions. The scientists also conducted MRI to help localize regions on the PET scans.

"This study illustrates the powerfully addictive impact of even small amounts of nicotine. Every time a smoker draws a puff from a cigarette, they inhale numerous toxic chemicals that promote the formation of lung cancer, and contribute in a significant way to death and disability worldwide," said NIDA Director Dr. Nora Volkow.

"We saw on our PET scans that the radiotracer 'disappeared' over time as the nicotine receptors became occupied by nicotine from cigarettes," said Brody.

The scientists found that the highest levels of nicotine binding occurred in the thalamus (a portion of the brain that acts as a conduit for all sensory information that reaches the brain's cerebral cortex, and which contains the highest concentration of these nicotine receptors), the brainstem (which controls various automatic functions, such as respiration, heart rate, and arousal), and the cerebellum (the portion of the brain responsible for the coordination of movement and balance).

Results of another recently published NIDA-supported study suggest that a portion of the cerebellum called the vermis may be a key factor in modulating the brain's dopamine and reward systems, and may be more involved in drug abuse and addiction than previously thought.

"Although craving was only reduced with near total occupancy of these receptors, there remains the question of whether other, less common types of nicotine receptors are equally important in tobacco dependence," said Brody. "This is an important area of focus for future research."

The study appears in the August 2006 issue of the *Archives of General Psychiatry.* ■

Financings

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stenting and the ability to place different stent lengths (as opposed to multiple stents) in one procedure or multiple stents with one device and without multiple procedures (*Medical Device Daily*, May 19, 2006).

Xtent licenses a bioabsorbable polymer from **Biosensors** International (Singapore) and its drug formulation from **Occam International** (Eindhoven, the Netherlands), a Biosensors subsidiary (*MDD,* May 27, 2004).

Earlier this year, the company said it had received funds in a Series D round but did not disclose the amount (*MDD*, May 12, 2006). And in early 2005, it brought in $25 million (*MDD* March 3, 2005)

For its IPO, Piper Jaffray & Co. will be acting as the book-running manager and Cowen and Company, Lazard Capital Markets and RBC Capital Markets are acting as co-managers.

Xtent is a portfolio company of The Foundry (Redwood City, California), a medical device incubator.

MedicalCV (Inver Grove Heights, Minnesota), a cardiovascular surgery company, has requested withdrawal of its registration statement, filed with the SEC on May 19, "due to continuing unsettled conditions in the equity markets," it said in a statement.

Marc Flores, president and CEO, said, "In the best interest of the company and its shareholders, we have decided to take the focus of the management team away from fundraising in a difficult market. We continue to focus on the introduction of the minimally invasive Atrilaze system for cardiac tissue ablation. We will carefully manage our resources which we believe will be sufficient to support our planned introduction to the market and physician training."

MedicalCV's Atrilaze ablation system utilizes laser energy in cardiac tissue ablation procedures in open-heart surgery.

The Atrilaze system is currently being used as a potential means to treat atrial fibrillation in concomitant open-heart surgical procedures.

In other financing activity:

• **Sonic Innovations** (Salt Lake City), a manufacturer of digital hearing aids, reported an agreement for the private placement of 3.2 million shares of common stock, to a group of new and existing institutional investors, to garner $12 million in proceeds.

The company said it will use the net proceeds from the placement to expand its global retail operations. It said it expects to close the transaction on or before Aug. 18.

Piper Jaffray & Co. acted as the sole placement agent.

• **Norwood Abbey** (Melbourne, Australia) reported that it has raised about A$4 million through the sale of 10.1 million shares in **Norwood Immunology**.

The company also said that it is "progressing further fundraising options" that will be reported upon completion.

• **Longport** (Glen Mills, Pennsylvania), a developer of high frequency, high-resolution ultrasound, reported receiving $1.5 million in new financing — about $400,000 in equity and a debt component of about $1.1 million.

It said the funds will be used to conclude clinical studies in the fields of pressure ulcer prevention and skin cancer assessment, and for working capital.

The company said the data from these studies will help validate the clinical and financial benefits of its technology.

The financing was provided by a long-term equity holder, the First Baptist Church of Southwest Broward, Florida.

• **Unilens Vision** (Largo, Florida) reported that TSX Venture Exchange has approved its normal course issuer bid so that the company may purchase for cancellation up to 224,190 of its common shares, representing 5% of its issued and outstanding common shares.

The bid will commence on Aug. 21, 2006, and end on Aug. 20, 2007. All shares purchased will be affected solely through the facilities of the TSX Venture Exchange. Unilens said it has not purchased any of its common shares over the last 12 months.

Unilens through its subsidiary **Unilens USA**, licenses and manufactures specialty contact lenses under the C-Vue, Unilens, Sof-Form, Aquaflex, SoftCon, Lombart and LifeStyle brands. ■

BRIEFLY NOTED

Clinical Data to discuss testing regulation

Clinical Data (Newton, Massachusetts) said it has received a letter from the FDA regarding the regulation of genetic testing.

The letter invited the company to meet with the FDA to discuss the nature and appropriate regulatory status of the company's tests and, if any regulatory requirements apply, the least burdensome ways that the company may fulfill them. Clinical Data said it would meet with the FDA "in the near future."

The company said it will be reviewing the regulatory status for all tests conducted on behalf of end-users including Familion, its CLIA-certified test for cardiac channelopathies that requires a prescription by healthcare providers.

Clinical Data notes that while it conducts DNA assays for one nutrigenomic test on behalf of a third party customer, the test is not marketed by the company and revenue from this test is not material to its business.

The company said it believes it is in compliance with all applicable state and federal regulations and will continue to work with the appropriate regulatory agencies to remain so.

PRODUCT BRIEFS

• **Focus Surgery** (FSI; Indianapolis), developer of the Sonablate 500, said the FDA has granted the device a provisional Investigational Device Exemption (IDE), which will allow the device to be used in a multi-center clinical study to collect safety and efficacy data for final FDA approval. The study will use High Intensity Focused Ultrasound (HIFU) for the treatment of low-risk, localized prostate cancer, enrolling an expected 466 patients at 24 institutions. Narendra Sanghvi, CEO and president of FSI, said, "In collaboration with USHIFU, we will be announcing details on the specific site locations in the next 90 to 120 days." HIFU is a targeted treatment that uses sound waves to rapidly heat and kill targeted tissue while sparing the surrounding tissue. The Sonablate HIFU procedure is performed on an outpatient basis and international studies suggest a substantial reduction in common side effects such as impotence and incontinence. The system already is approved in Canada, Europe and Asia.

• **Halozyme Therapeutics** (San Diego), which is developing and commercializing recombinant human enzymes, said it has initiated and dosed the first three patients in a clinical trial of Enhanze Technology, Halozyme's enzyme-based drug delivery platform based on recombinant human PH20 hyaluronidase, intended in this trial to enhance the absorption of a representative large-molecule protein therapeutic. This trial is designed to compare the pharmacokinetics, safety and tolerability of a large-molecule protein therapeutic agent subcutaneously injected both with and without rHuPH20. Halozyme's recombinant human enzymes may replace current animal slaughterhouse-derived extracts that carry potential risks of animal pathogen transmission and immunogenicity.

• **Longport** (Glen Mills, Pennsylvania), which is focused on high-frequency/high-resolution ultrasound imaging, reported the implementation of a pilot project at Wesley Health Care Center (Saratoga Springs, New York), a 356-bed long-term nursing care provider. The project is designed to explore the cost benefit of using the Episcan I-200 for pressure ulcer detection and prevention. Principal investigator Ronald Shannon, president of Global Health Economic Projects, will explore the use of the Episcan I-200 for improved clinical detection of pressure ulcer risk and the subsequent reduction of wound care costs. Shannon said, "The timing is right for a cost-effective, diagnostic tool that will give early insight into non-visible pressure ulcer injury so treatment and prevention can begin early."

• **PPD** (Wilmington, North Carolina) launched PPD GlobalView EventNet, a customizable global event management and adjudication system for expeditious review of safety and endpoint-driven data from large-scale clinical trials or registries. Built on PPD's electronic data capture (EDC) technology for conducting global registries and trials, the system provides access to safety events contained within clinical and/or safety databases. A secure Internet, network-based system GlobalView EventNet accelerates review of data, particularly when studies with multiple sources of information on individual patients require review by a board of independent physicians. Features of the technology include online tracking of safety events, status reporting for activities and e-mail alerts to prompt and encourage timely review. PPD is a global contract research organization providing discovery, development and post-approval services as well as compound partnering programs.

PEOPLE IN PLACES

• Donald Huffman has been appointed CFO of **Guava Technologies** (Hayward, California), a developer of clinical diagnostics. Huffman most recently was CFO and principal of Sanderling Ventures. Previously, he was CFO for Genteric. Guava is a provider of on-demand, single-cell analysis systems.

• **Quovadx** (Greenwood Village, Colorado), a software and services company, reported the resignation of Mark Rangell, executive vice president of marketing and corporate services to assume the position of CEO of a privately-held software start-up firm in the financial services sector. He will step down Sept. 1. Quovadx has three divisions: the Integration Solutions division (ISD), which offers software infrastructure to facilitate system interoperability; the CareScience, providing care management and analytical solutions; and the Rogue Wave Software division, providing software and services for enterprise-class application development.

• **Satellite Healthcare** (Mountain View, California), appointment of Sergio Fernandez to the position of senior vice president of business development for Satellite Healthcare (Mountain View, California) and a member of the company's executive team. He will coordinate business development efforts for Satellite's two dialysis provider subsidiaries: Satellite Dialysis and WellBound. Most recently, Fernandez was vice president of U.S. sales and a member of the senior management team of Baxter Healthcare's U.S. renal business.

• Louis Shapiro has been named president/CEO of the **Hospital for Special Surgery** (HSS; New York). Shapiro will leave his post as executive vice president and clinical enterprise chief operating officer of Geisinger Health System (Danville, Pennsylvania) this fall. Shapiro will replace John Reynolds, who announced last year that he would step down upon the completion of a search for his successor. HSS bills itself as a "world leader in orthopedics, rheumatology and rehabilitation."