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2007 Medical Innovation Summit

Panel: Innovation is lifeblood, not bane of healthcare in U.S.

By **HOLLAND JOHNSON**

Medical Device Daily Managing Editor

CLEVELAND — New healthcare technologies generally cost more than older, standard technologies. That's obvious, and also an all-too-available scapegoat for those citing increased healthcare costs.

Seeking to make the case for the absolute necessity of innovation in the healthcare field here at the fifth edition of the Innovation Summit of the **Cleveland Clinic** was the two-person panel composed of Bill Hawkins, newly appointed CEO of medical device powerhouse **Medtronic** (Minneapolis), and Steve Hemsley, CEO of healthcare insurance company **UnitedHealth Group** (Minneapolis).

Hawkins said that there are three primary things that must be understood about the role that medical technology plays in addressing healthcare cost issues.

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AdvaMed 2007: The MedTech Conference

'Scenario planning' critical in a world with some other ideas

By **MARK McCARTY**

Medical Device Daily Washington Editor

WASHINGTON — The **Advanced Medical Technology Association** (AdvaMed; Washington) held its first-ever med-tech conference here this week, running concurrently with a meeting of the Global Harmonization Task Force, thus giving the event an international punch.

Many of the sessions focused on the nuts and bolts of getting a medical device to market, as well as a look into how device makers will have to work to stay in business tomorrow.

A Monday session, titled "Future Scenarios for Medical Device Innovation," was an overview of how device firms can best anticipate changes to their markets, based on a business school study of the paradigm commonly employed in business forecasting.

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International report

Siemens forms HIT joint venture with Kameda Healthinformatics

A Medical Device Daily Staff Report

Siemens Medical Solutions (SMS; Malvern, Pennsylvania) and **Kameda Healthinformatics Institute** (Tokyo) reported the establishment of a joint venture company, **Siemens Kameda Healthcare IT Systems K.K.**

SMS will hold two-thirds ownership and Kameda the remainder.

SMS said the establishment of Siemens Kameda Healthcare IT Systems K.K. strengthens its position in the growing Japanese healthcare market by advancing the availability of information technology (IT) solutions and clinical systems in that country. According to YANO Research, Japan is currently the second largest market for healthcare information systems.

Janet Dillione, president, Health Services, the Healthcare IT Division of SMS, said: "By further strengthening our global presence in the healthcare IT sector, we are continuing to deliver as one of the world's largest suppliers to the

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Spectranetics launches PATENT trial for SFA instent restenosis

By **OMAR Ford**

A Medical Device Daily Staff Writer

In-stent restenosis is a major issue when it comes to percutaneous coronary intervention of coronary vessels, often requiring patients to undergo repeat procedures, or more invasive surgery. And this is an even more vexing problem when it comes to occluded vessels of the lower leg.

Med-tech companies have been struggling to find a solution for this area of the vasculature.

"You can try balloon angioplasty," Will McGuire, COO of **Spectranetics** (Colorado Springs, Colorado), told *Medical Device Daily*. "But data will tell you the success rate of this is fairly low."

Spectranetics is banking on a technique combining its Turbo elite laser catheters in combination with its recently FDA-cleared Turbo-Booster. The Turbo-Booster functions as a guiding catheter facilitating directed ablation of blockages in the main arteries at or above the knee.

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INSIDE:

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NxSTAGE MEDICAL COMPLETES BUY OF MEDISYSTEMS FOR \$78.7M3

 **AHC Media LLC**

*Court Report***LCA hit with class action charging false, misrepresented statements****A Medical Device Daily Staff Report**

The law firm of Schiffrin Barroway Topaz & Kessler reported that it has filed a class action lawsuit on behalf of all purchasers of securities of **LCA-Vision** (Cincinnati, Ohio).

LCA provides fixed-site laser vision correction services at its LasikPlus vision centers. The complaint charges that LCA and certain of its officers and directors failed to disclose and misrepresented various material adverse facts which were known to defendants or recklessly disregarded by them:

- that procedure volume at existing stores had significantly declined;
- that overall growth was solely coming from new store openings;
- that the company was operating under defective assumptions about its marketing budget and deferred revenue;
- that the company lacked adequate internal and financial controls;
- and that, as a result, the company's statements about its financial well-being and future prospects were lacking in a reasonable basis.

On July 31, the company "shocked investors when it reported abysmal second quarter 2007 financial and operational results, which included a decline in same-store procedure volume and a substantial rise in patient acquisition costs," according to the lawsuit charges.

Additionally, the company reported lowering operating income, net income, and earnings per share ("EPS") than in the comparable 2006 quarter. As a result, the company significantly lowered its EPS guidance from between \$2.05 to \$2.15 for full-year 2007 down to between \$1.90 to \$2.00 for full-year 2007.

On this news, the company's shares declined \$7.48 a

Today's MDD food for med-tech thought

... "forget about the past" and "start from the outside in,"

— Jim Austin, of Decision Strategies International, describing the first steps in planning a company's future business strategies, "Scenario planning' key in a world with some other ideas," pp. 1, 7, 9, 10.

share, or 17.4%, to close on July 31, 2007, at \$35.51 a share, on unusually heavy trading. The following day, the company's shares declined an additional \$2.11 a share, or almost 6 % to close on August 1, 2007, at \$33.40 a share, again on heavy trading. ■

Audio conference explores new FDA reauthorization powers

New FDA legislation just enacted by Congress reauthorizes and amends the Medical Device User Fee, the Prescription Drug User Fee, and also provides other wide-ranging changes in the FDA's powers and responsibilities.

These changes will be explored in a *Medical Device Daily* audio conference on Oct. 24, "FDA Reauthorization Legislation: Essential Changes You Must Know Now," from 1 p.m. to 2:30 p.m. The sessions will explore what companies and regulatory professionals must know to make sure they are in compliance with the new requirements.

Speakers Dan Kracov of Arnold & Porter, Kurt Karst of Hyman, Phelps & McNamara, and Wayne L. Pines of APCO Worldwide will guide listeners through the intricacies of the changes and highlight concerns for the med-tech and pharma industries.

The audio conference is just \$299 per listening site. It includes presentation handouts and a half-hour Q&A session with the speakers. A CD (MP3 format) of the conference is available. For more information or to register, call 800-688-2421 or 404-262-5474, and be sure to mention conference code T07480.

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ATLANTA NEWSROOM: Executive Editor: **Don Long**. Managing Editor: **Holland Johnson**. National Editor: **Jim Stommen**. Washington Editor: **Mark McCarty**. Staff Writers: **Omar Ford**, **Amanda Pedersen** and **Karen Young**. Production Editor: **Rob Kimball**.

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

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

INTERNET
www.medicaldevicedaily.com

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*Deals roundup***NxStage Medical completes buy of Medisystems for \$78.7 million****A Medical Device Daily Staff Report**

NxStage Medical (Lawrence, Massachusetts), maker of the NxStage System One portable kidney dialysis machine, said it has completed its acquisition of **Medisystems** (Seattle) for 6.5 million share of NxStage stock.

The deal to acquire Medisystems, a private developer of devices for use in dialysis and blood-related treatments, was first disclosed in June (*Medical Device Daily*, June 6, 2007). The company said at the time that the transaction was valued at \$78.7 million, based on a stock price of \$12.11.

"I believe that we now have the components in place to realize the significant opportunities that we see in each segment of the dialysis market – hospital, in-center and home-based therapies. Our acquisition of Medisystems establishes us as a vertically integrated manufacturer and distributor of innovative dialysis products, with greatly expanded scale and capabilities," said Jeffrey Burbank, president/CEO of NxStage. "I am more confident than ever in our ability to continue to lead and grow the home hemodialysis market, as we begin a new era for NxStage."

Medisystems makes disposables for in-center dialysis therapy. For the first six months of 2007, Medisystems recorded \$32 million in revenues, including \$3.7 million in sales to NxStage.

NxStage develops systems for the treatment of end-stage renal disease and acute kidney failure.

In other dealmaking news:

- **PerkinElmer** (Waltham, Massachusetts) said it plans to acquire **ViaCell** (Cambridge, Massachusetts), a biotech company specializing in the collection and preservation of umbilical cord blood stem cells.

PerkinElmer will begin a cash tender offer to buy all of the outstanding shares of ViaCell for \$7.25 a share, for an aggregate purchase price of about \$300 million, or \$260 million net of cash. The transaction is expected to close in 4Q07.

PerkinElmer provides products and services for the life and analytical sciences, optoelectronics and fluid sciences.

- **Teleflex** (Limerick, Pennsylvania) reported completing its \$2 billion acquisition of **Arrow International**, a provider of catheter-based access and therapeutic products for critical and cardiac care.

The deal was first disclosed in July (*MDD*, July 24, 2007).

Arrow shareholders will receive a cash payment of \$45.50 for each outstanding share of Arrow common stock.

- **Respironics** (Murrysville, Pennsylvania) said it has acquired 100% of the outstanding shares of **Apollo Light Systems** (Apollo Health; American Fork, Utah), a private manufacturer of light therapy systems for melatonin suppression and circadian rhythm sleep disorders.

The base cash purchase price is \$6.5 million, with pro-

visions for additional payments to be made based on Apollo's operating performance over the next year. Total potential earn out payments are less than the base purchase price, the company said. Apollo has annual revenues of about \$5 million.

Respironics said the acquisition would not have a material impact on revenues or earnings and the company will not be changing its financial outlook or guidance based on the deal.

Apollo's product line includes the briteLite Series Light Boxes, which use Britewave technology to create specific wavelengths that produce a circadian response while eliminating UV hazards, and the goLite series handheld light therapy devices, which feature Bluewave technology, a narrow range of blue light found in natural sunlight.

Respironics develops products and programs for the global sleep and respiratory markets.

- **Caxton-Iseman Capital** (New York), a private investment firm, reported that it has acquired **Conney Safety Products** (Madison, Wisconsin), a marketer of personal protective equipment, safety equipment, first aid supplies, and various other safety products, from **K+K America**, for about \$48 million.

GMAC Commercial Finance and BlackRock Kelso Capital provided financing for the transaction.

- **Nuance Communications** (Burlington, Massachusetts), a supplier of speech and imaging solutions, said it has acquired **Commisure** (New York), an imaging software company that provides speech-enabled radiology workflow optimization and data analysis solutions.

Financial details of the transaction were not disclosed.

The deal allows Nuance to broaden the capabilities of its Dictaphone solutions for the medical imaging industry, to extend the company's domain expertise in the radiology market and accelerate revenue growth through software as a service offering, the company said.

- **Iron Mountain** (Boston) said it has acquired **RMS Services — USA** (Southfield, Michigan), a \$27 million records management company and a provider of outsourced file room solutions for hospitals.

Terms of the deal were not disclosed.

Iron Mountain says it offers comprehensive records management and data protection solutions.

- **Air Methods** (Denver), an air medical transportation company, said it has acquired 100% of the outstanding common stock of **FSS Airholdings** (West Mifflin, Pennsylvania), parent company of **CJ Systems Aviation Group** (Pittsburgh) for \$25 million.

The deal was first disclosed in August (*MDD*, Aug. 3, 2007).

The company said the deal was primarily financed through a new five-year, \$50 million term loan and a new five-year, \$50 million line of credit with a commercial bank group. The existing Air Methods term loan and CJ indebtedness were paid off with the proceeds from these new lending facilities as well, Air Methods said. ■

*Agreements***Sanarus teams up with centers to offer its Visica 2 treatments****A Medical Device Daily Staff Report**

Sanarus Medical (Pleasanton, California) reported a partnership with breast care physicians from centers across the country, including breast care physicians from Connecticut to California, to increase the awareness and availability of a non-surgical treatment option for women with benign breast tumors, known as fibroadenomas.

Sanarus will host a gathering of these new centers prior to the **American College of Surgeons** (ACS; Chicago) annual meeting in New Orleans, Oct. 7-11. These centers will participate in regional and national efforts to increase patient and primary care physician awareness of the Visica 2 treatment as a minimally invasive, safe and effective treatment alternative to surgical excision. These centers will participate in a patient registry to document the clinical outcomes and patient satisfaction rates following Visica 2 treatment.

Additionally, the centers will seek to expand private health insurance coverage of this treatment option, making it more widely available to women across the country.

Sanarus said it plans to include as many as 20 centers in this program before the end of the year.

"I am very pleased to be a part of this important program that will offer more options to my patients. This technology makes cryoablation easier and faster than ever before and not only does that make sense for my practice, it makes the procedure very appealing to my patients," said Andrew Kenler, MD, a Connecticut surgeon practicing at one of the new Visica 2 Reference Centers.

The original Visica Treatment System received FDA clearance in 2002, with more than 1,500 fibroadenomas treated since then. The Visica 2 System has been available at "select sites" since April of 2007. The Visica 2 Treatment System uses liquid nitrogen as the freezing agent, avoiding the need for large, high pressure tanks of argon and helium used in the original Visica system.

The procedure can be completed in the physician's office, with most treatment times under 15 minutes. Early experience has shown excellent physician and patient satisfaction with the new Visica 2 Treatment System, Sanarus said.

Sanarus develops minimally invasive, office-based breast care management solutions from diagnosis/treatment to follow up.

In other agreements:

- **Dermacare Laser & Skin Care Clinics** (Scottsdale, Arizona), a laser skin-care franchisor, reported a partnership with the **University of Florida** (UF; Gainesville, Florida). The university's division of plastic and reconstructive surgery faculty members will use Dermacare's technology to train Dermacare physicians and other clinicians

in laser techniques at the **Dermacare of Gainesville** clinic and training center, one of three Dermacare training centers.

"This is an historic arrangement, the first of its kind between an aesthetic skin care clinic and a major university, and validation of our constant focus on safety and evidence-based practices," said Carl Mudd, Dermacare president/CEO.

UF will assign a physician specializing in plastic and reconstructive surgery as the training center's onsite medical director, who will: analyze critique and approve training protocols; design and implement quality-control procedures; consult on treatment plans; and supervise the clinic's medical and medical/administrative tasks.

Dermacare franchises are located in 12 states and will expand to Asia with a clinic opening in Singapore this month.

- **GeneGo** (St. Joseph, Michigan), a systems biology tools company reported that **Organon** (Roseland, New Jersey), the healthcare business unit of **Akzo Nobel** (Oss, the Netherlands), has extended its GeneGo software and database licenses. In addition to extending the MetaCore license, Organon has also added MetaLink so that it can upload its own interaction data and visualize it in the context of MetaCore's manually curated content.

GeneGo says it offers automated workflows now also available through its new product 1-2-3 workflow, a pay-as-you-go business model. GeneGo also covers human, mouse, rat, dog, worm, chicken, fly, chimpanzee and yeast.

"GeneGo has demonstrated the capability to develop a good pharma oriented bioinformatics tool in the past years," said Peter Groenen, project manager for pharmacogenetics at Organon. "We have now started to use their software for more advanced projects to support our translational medicine efforts." ■

BRIEFLY NOTED**NAS receives NASDAQ notice**

North American Scientific (Chatsworth, California) said that it received a notice from the NASDAQ stock market indicating that the company does not comply with the minimum \$10 million stockholders' equity requirement under Maintenance Standard 1 for continued listing on The NASDAQ global market set forth in Marketplace Rule 4450(a)(3). In addition, the company does not comply with the minimum \$50 million market value of listed securities under Maintenance Standard 2 for continued listing.

In accordance with NASDAQ requirements, the company will submit a plan that it believes will allow it to achieve and sustain compliance with all NASDAQ global market listing requirements, including the minimum stockholders' equity standard.

Contracts/Grants**Digital Angel teams with USDA for animal identification deal****A Medical Device Daily Staff Report**

Digital Angel, (ST. Paul, Minnesota), a developer of rapid and accurate identification, location tracking and condition monitoring, reported that it has received an order for 630,000 compliant radio frequency identification (RFID) ear tags valued at more than \$600,000 from the **United States Department of Agriculture (USDA)** for the National Animal Identification System (NAIS). The cattle ear tags will be used for USDA Animal and Plant Health Inspection Service (APHIS)/Veterinary Services State-Federal Cooperative Disease control and eradication efforts in targeted, increased-risk geographic locations.

Barry Edelstein, interim president/CEO of Digital Angel, said that the order "exemplifies our expertise in providing high-quality products at competitive prices. We were the first animal tag manufacturer to be designated as an Animal Identification (AIN) tag manufacturer by the USDA, which signifies that our tagging system is capable of identifying livestock with the unique, lifetime animal identification number that is being established as a national standard through the NAIS. We are proud that we continue to be a provider of choice for the USDA."

Since 1948 Digital Angel's livestock tags have been utilized by ranchers across the world to protect their property from theft or loss and, more recently, to control the spread of disease and improve herd management.

Following the December 2003 incident of Mad Cow Disease (Bovine Spongiform Encephalopathy) in the state of Washington, the USDA initiated the development of a national animal identification program for cattle, with a target completion date of 2008-09. The NAIS, a cooperative program between state and federal governments and the livestock industry to help trace, manage and eradicate animal diseases like Mad Cow Disease, Foot and Mouth Disease, Pseudo-Rabies Disease and Porcine Reproductive and Respiratory Syndrome in pigs, is being run by APHIS. APHIS launched the voluntary NAIS in 2004 with the premises registration system and is now continuing its advancement by implementing the animal identification component.

Under the NAIS, electronic ID (EID) devices must be approved by USDA. Digital Angel has approval on its EID and transponder devices for livestock. The company said it will be submitting its new sheep and goat EID device for approval shortly.

In other contract news: **Dialog Medical** (Cary, North Carolina), a provider of informed consent and patient education systems for hospitals and physician practices, reported a contract for its iMedConsent application with **Piedmont Hospital** (Atlanta).

iMedConsent includes procedure-specific consent forms for more than 2,100 medical and surgical procedures;

patient education documents for thousands of diagnoses and treatments; and an extensive anatomical image gallery that allows the physician to annotate images and simplify complex topics for the patient. In addition, the application automates the completion of patient documentation ranging from HIPAA disclosures to advance directives, including the digital capture of signatures, paperless storage of signed documents and electronic notation in the patient's medical record.

In grant news: The **University of Michigan Health System** (Ann Arbor) has received a \$22 million from A. Alfred Taubman to develop the **A. Alfred Taubman Medical Research Institute**.

Taubman's gift creates an endowment whose earnings will fund the institute, and the research of individual Taubman Scholars within the institute.

The first five Taubman Scholars have already been chosen from among the medical school's top scientists, selected for creativity and research. ■

BRIEFLY NOTED**CMS approves QMed's special needs plans**

QMed (Eatontown, New Jersey) said that the **Centers for Medicare and Medicaid Services** has approved its two Medicare special needs plans (SNPs) for New Jersey as well as three SNPs in South Dakota, which QMed operates in collaboration with DAKOTACARE. The approvals cover the company's SNPs for heart conditions and stroke, which have now been expanded to include beneficiaries with certain arrhythmias; its two SNPs for a new chronic disease; and the dual eligible SNP for South Dakota. These plans can be marketed in both states as of October 1st and enrollment begins Nov. 15 for coverage beginning Jan. 1, 2008.

There are nearly 27,000 Medicare beneficiaries for the new chronic SNP and about 20,000 beneficiaries with arrhythmias in the company's current New Jersey service area. Added to 68,000 beneficiaries currently eligible for its SNP for heart conditions and stroke, there will be 125,000 beneficiaries eligible for its two New Jersey 2008 offerings. In South Dakota, there are about 9,000 Medicare beneficiaries for the new chronic SNP and 6,000 who have some form of arrhythmias. Added to the 19,000 beneficiaries currently eligible, the total beneficiaries eligible for the two SNPs in the state will be 34,000.

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Innovation

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First he said, "there needs to be a clear understanding of how innovation takes place in the medical technology industry."

Secondly, he said that "any healthcare reform needs to foster and to reward innovation."

And finally, "we must evaluate medical devices over the course of the therapy, not just evaluate the up-front cost."

According to Hawkins, in the U.S alone, 83% of healthcare spending is associated with chronic diseases. And once people reach the age of 60 and beyond, as are the Baby Boomers, they are likely to have one or more chronic diseases.

And these aging Boomers will drive a "silver tsunami," a steady increase in both chronic disease and healthcare spending.

By the year 2014, he said, healthcare costs are projected to climb to more than \$20 trillion, or roughly 20% of the U.S. gross national product, compared to the current figure hovering around 15%.

Hawkins said that advances in medical technology will help to staunch some of the wasted monies currently being poured into medical services of questionable value. "As advances in medical technology occur, we are able to create solutions along the entire continuum of care, from diagnostics to cure."

As an example, Hawkins cited the implantable cardioverter defibrillator (ICD) — not surprisingly, a leading product for Medtronic — a device that, though still expensive, has dramatically declined in cost over the past decade.

Hawkins said that in 1990 ICD implantation took two to four hours to perform via major surgery, entailed an average 12-day hospital stay and cost about \$100,000. The device had a battery life of less than two years and an associated mortality rate of nearly 4%.

Today, he said, an ICD is one-sixth the size if the original device, takes about an hour to implant through a key-hole incision, with hospital stays about two days and with some procedures done on an outpatient basis. It has an associated mortality rate of less than 1%, with total cost of about \$35,000. The newest devices have a seven-year battery life and can be used to diagnose and monitor a patient's condition remotely.

"Now that's, I would contend, an example of medical innovation," he said.

To accomplish breakthroughs like [the ICD], our industry must invest heavily in R&D, driven by constant innovation and shortening product lifecycles."

Medical innovation, he added, is "chock full of possibilities," including drug/device combinations able to deliver cell therapy throughout the vascular system to local organ sites and the prospect of a closed-loop blood glucose monitoring systems that will mimic the insulin secretion of the human pancreas.

While there is a lot of promise, getting these products

to market, he said, is becoming an increasingly expensive proposition for companies even as large as his, Hawkins said.

"It is critical to note that device innovation is a dynamic, complex and often, incremental process, one that is taking longer and costing more."

He said that device innovation, unlike that in the pharma sector, is firmly rooted in day-to-day interchange between clinicians and device manufacturers. "Fostering and honoring this collaboration with clinicians is the key to maintaining our global leadership in R&D and in new product development.

He argued that med-tech innovation spurs economic growth by returning patients more quickly to their jobs, thus generating productivity and tax revenues.

He pointed to his company's recently FDA-approved Bryan artificial cervical disc as a key example of this.

"Patients receiving this therapy return to work as much as 26% sooner than those that are treated with the alternative therapy," fusion surgery

Hawkins said that U.S. healthcare should be structured to reward true innovation, taking into account that the value proposition for devices often plays out over years, not days or months. "Many often put too much emphasis on the up-front costs and don't account for the life-long benefits of the therapy," he said.

UnitedHealth Group's Hemsley, discussing his vision for an added-value marketplace, said that the sector "is a very long way from the efficiency or maturity of other segments of the U.S. economy, and so innovating to improve our country's performance in those dimensions benefits literally everyone."

UnitedHealth collects and analyzes healthcare information, he said, "to monitor and assess and help improve healthcare. We believe this integrated data is helping scientists, physicians and technologists design a better healthcare experience for consumers."

He said that UnitedHealth is a healthcare system serving some 70 million Americans and is connected contractually to about 85% of the "U.S. healthcare delivery assets," and believes it is pioneering the use of healthcare IT.

It provides bank-style cards to nearly 20 million of its members in an attempt to improve efficiencies on the "front end," of healthcare administration, he said. The cards contain a patient's medical information that can be used to automatically debit money from healthcare spending accounts and automate claim submissions for a large percentage of transactions providing patient eligibility information on the spot.

"We estimate that broad adoption of this innovation . . . would pull hundreds of millions of dollars out of the administration costs of healthcare and will result in more affordable premiums for consumers," Hemsley said.

On the back end of healthcare administration costs, he
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AdvaMed

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Panel moderator Jim Austin, director of life sciences at consulting firm **Decision Strategies International** (DSI; Conshohocken, Pennsylvania), used as his text a recent **Wharton School of Economics** (Philadelphia) study on how the U.S. device industry “might evolve in the next five to 10 years.” He said that Scenario Planning, the primary tool used in the study, will tell us where we might be “in 2012 or 2015” and “where we might work from the outside in,” rather imposing a business plan on a world that has other ideas.

A recent study from Charles Schwab, he said, reported that the share values of the top nine firms in the device industry have grown almost 67% over the past five years, while in that same period “the Dow increased 26% — and had you purchased stock in the top six pharmaceutical companies, you would have lost 6% of your money.”

Three-fourths of global medical device sales are for products made in the U.S., Austin said, and compound average growth rate for med-tech stocks was better than 7%.

But he suggested that this growth rate might be modified in the future as the result of concerns about questionable company payments to physicians and the rise in medical tourism, noting that “a knee replacement is about half the cost” in overseas hospitals compared to U.S. hospitals.

Why Scenario Planning?

Austin said that most conventional forecasting analysis focuses on what drives “asset value change” and that the drivers for asset value change can be put into three categories:

- 55% for factors that companies can have some control over;
- 10% industry conditions;
- and 35% consisting of external effects such as general economic conditions, the politics of the day and “random noise.”

Scenario Planning, he said, focuses on that 35% slice. It starts with forecasting what the outside influences will look like. Then, firms must ask “how our company is positioned to respond to those challenges,” rather than letting wild cards be dealt with as they arise.

As just one illustration, Austin said that in the early 1980s, **Halliburton** was the industry leader in oil drilling supplies and equipment, but that its forecasts “did not take into account major changes” in tax legislation that had a profound impact on the company’s bottom line.

To build a scenario plan, Austin said that Step One is to “forget about the past” and “start from the outside in,” to determine what external conditions will be like in one year and in five years. And in Step Two, the company should determine what will do well in that industry.

Terry Fadem, managing director for corporate alliances at the **University of Pennsylvania School of Medicine**

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Coleman: ‘health should not be turned over to government’

A luncheon speaker at the inaugural AdvaMed med-tech conference was Norm Coleman, Republican senator from Minnesota — home of several giants in the med-tech industry. And he expressed his suspicion of government intervention in healthcare by paraphrasing perhaps the most famous Minnesota governor (and, somewhat ironically, a Democrat), Hubert Humphrey: “Government can do something to you or for you — but it will do something.”

Coleman called this a major cause for concern because trade and reimbursement are both critical issues in the nation’s capital, which he called “a town of a thousand issues and few priorities.”

As to key current healthcare debates, he said: “As I look at this room today, I see the reason that health should not be turned over to the government,” and that nationalized healthcare would lead to more non-productive work for the private sector and more litigation for attorneys. “We cannot legislate or litigate our way into the future.”

And, “as Congress continues to debate issues such as SCHIP and FDA reform,” Coleman promised to do all he can to restrain Congress from needless intervention. Putting government in charge, he said, “is an easy solution to articulate” but healthcare decisions put “in the hands of bureaucrats” is not the solution to current healthcare dilemmas.

“We were headed for a trainwreck on SCHIP,” he acknowledged, predicting that the House would likely not override a veto.

He said of trade: “the new majority will probably not give us a whole lot and that should be an area of concern.”

About global competitiveness, he said that he hears complaints from Americans about low wages in Mexico, has heard the same complaint from Mexican businessmen about workers in China, and that Chinese businessmen grumble about workers in Viet Nam.

Coleman said that the low-wage race is obviously not something that the U.S. can win. So the economy must rely on innovation to maintain robustness and that the medical device industry is one of the keys to maintaining the innovation that will sustain U.S. economic growth.

“We pay one way or the other” for healthcare, he said, so universality of access is an imperative. Good healthcare needs “more technology, not less.”

Concerning upcoming spending bills, he was pessimistic about any immediate action. “I think we’ll be sipping eggnog before we get out” with a full series of spending bills.

— MARK McCARTY

Europe

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healthcare industry. We look forward to collaborating with Kameda to continue introducing the Japanese market to innovative technologies”

The new company will focus on enhancing Kameda Healthinformatics Institute’s clinical informatics system, KAI, which encompasses electronic medical record, computerized physician order entry and nursing documentation functionalities. The system is being used by nearly 30 hospitals in Japan to assist in managing the workflow of patient care delivery at their facilities.

Toshitada Kameda, chairman, Kameda Healthinformatics, said, “We have seen great success with KAI, and we are confident that Siemens’ expertise will help us to further develop this solution.”

Dillione was appointed chairperson of the j-v, and Kameda was appointed as vice-chairperson. Shinji Tanaka, currently president of Kameda Healthinformatics Institute, will serve as president of the j-v.

Kameda Healthinformatics is one of the group companies of **Kameda Medical Center** (KMC; Kamogawa City), a supplier of electronic medical record systems to Japan. The company also holds numbers of Japanese and foreign patents in the area of HIT, and has granted patent licenses to some major vendors in Japan.

3M completes buy of Abzil Industria

3M (St. Paul, Minnesota) reported completing its purchase of **Abzil Industria e Comercio** (Sao Paulo, Brazil), a manufacturer of orthodontic products. Terms of the transaction were not disclosed.

Abzil manufactures brackets, bands, tubes and wires used in orthodontic procedures, complementing 3M’s offerings through 3M Unitek, a provider of Clarity Ceramic Braces, APC Adhesive Pre-Coated Brackets, and most recently, SmartClip Self-Ligating Braces, and Clarity SL Ceramic Self-Ligating Braces.

Abzil Industria e Comercio, which says it is the second largest manufacturer of orthodontics products in Brazil, employs about 300.

Firstsource Solutions completes MedAssist buy

RoundTable Healthcare Partners (Lake Forest, Illinois) reported completing the sale of MedAssist Holding to an affiliate of **Firstsource Solutions** (Mumbai, India) for \$330 million in cash.

Firstsource is a provider of business process management services to financial and media services and healthcare.

MedAssist is a provider of outsourced revenue cycle management services to healthcare, including eligibility services, receivable management services, and collections services. RoundTable acquired a majority interest in MedAssist in May 2003.

Joseph Damico, a founding partner of RoundTable and

the chairman of of MedAssist said, “The MedAssist team, led by founder and CEO, Michael Shea, COO Tom Watters, and CFO Frank Stellato, has established MedAssist as a national industry leader in the healthcare revenue cycle management industry. They have grown the company’s revenue and profitability significantly, expanded the company’s geographic footprint and service offerings, and increased the company’s customer base. They will be an excellent strategic partner with Firstsource as they work together to serve their customers and pursue their growth initiatives.”

Shea said, “The entire MedAssist management team is excited to be part of a larger company with both global reach and resources and a commitment to help us grow our business.”

InterCure launches Australian distribution

InterCure (New York) reported that its RESPeRATE hypertension treatment device, designed to lower blood pressure, will launch into retail distribution in Australia through its local marketing and distribution partner, **High Tech Health** (HTH; Maroochydore, Australia).

RESPeRATE will be distributed through Australia’s three largest pharmacy wholesalers into leading pharmacy chains nationwide, including Chemmart, Terry White and Think Pharmacy.

High Tech Health will introduce RESPeRATE into 300 retail pharmacy locations in early Q4, with its merchandising specialists training pharmacy staff concerning the use and benefits of the device, InterCure said. They will establish merchandising programs at the store level and hold community patient education sessions on hypertension management and the use of RESPeRATE.

Erez Gavish, president/CEO of InterCure, said, “The vast majority of our prospective customers tell us that they would prefer to buy RESPeRATE at their local pharmacy. Our move into the Australian pharmacy channel will allow consumers to buy at their preferred retailer for health products, while building a strong retail presence for InterCure.”

It is estimated that about one in three Australians have high blood pressure, and according to the **National Heart Foundation of Australia** (Sydney), hypertension is the most frequently managed problem in general physician practices. ■

Innovation

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said that the company hopes to bring through enterprises like UnitedHealth’s financial services business, electronic payment clearance innovation into the medical administration.

“Traditional banks don’t have the capability to process transactions of this complexity, and they’re not hooked up to the medical community as we are. I believe this model is going to become pervasive throughout the healthcare services domain.” ■

Spectranetics

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The Turbo-Booster, combined with Turbo elite laser catheters, enables removal of large amounts of plaque material within the superficial femoral artery and popliteal arteries, Spectranetics says, and the company has just started a prospective registry of 100 patients, the PATENT trial, at up to 10 sites in Germany, with enrollment of the first patient.

The company submitted its 510(k) application to the FDA for its Turbo-Booster in May (*Medical Device Daily*, May 11, 2007). That came just two months after the company said it stopped its CELLO trial, with the FDA's approval, after completing about three quarters of enrollment. The trial was stopped, the company told *MDD* at the time, because its preliminary data was strong enough to meet the endpoints (*MDD*, March 16, 2007). It then received FDA clearance of the Turbo-Booster in July.

So why the additional trial?

The details are devilish, the company says.

"We don't have [FDA] clearance to treat in-stent restenosis using both of the technologies," McGuire said — meaning both the Turbo elite laser and the Turbo-Booster. "In Europe we have a pretty broad clearance. But the PATENT trial will allow us to collect clinical data in a controlled manner. We would like to get a similar indication in the states."

Data derived from the trial will be able to give the company more ammunition to win FDA approval.

The trial will assess patency with the use of duplex ultrasound at various intervals up to 12 months following the procedure. It will also follow patients for up to one year as a measure to see if there are any adverse affects.

PATENT is expected to be completed within 30 months, according to the company.

Spectranetics said that in the first procedure a patient with four local lesions was treated with the Turbo-Booster and Turbo elite 2.0 mm catheters in a 20 cm long SFA.

"The initial result from this Spectranetics device looks very promising, as the new features allow for ablation of more tissue in larger vessels," said Andrej Schmidt, MD, of the **University of Leipzig-Heart Center**.

"In-stent restenosis in a superficial femoral artery represents one of the most challenging procedures in our practice, he said. "The current standard of care, such as repeat balloon angioplasty, does not have good results as these lesions tend to reoccur. We are very excited with the start of this study in Germany, and we look forward to examining the mid- and long-term results of this new therapy."

If successful, the company could have the first procedure to deal with in-stent restenosis in this sector.

John Schulte, president/CEO of Spectranetics, in a company statement, said, "We believe that in-stent restenosis in the superficial femoral artery may represent 25% to 35% of all above-the-knee procedures." And he expressed hope

that the trial will help offer help where "there is currently not a good solution for this challenging lesion subset."

Spectranetics laser systems are used to ablate lesions into tiny particles that are absorbed into the bloodstream. The company's disposable catheters use high-energy "cool" ultraviolet light to vaporize arterial blockages in the legs and heart, as well as scar tissue encapsulating pacing and defibrillation leads.

The company reports that its CVX-300 excimer laser is the only system approved in the U.S., Europe, Japan and Canada, for use in multiple, minimally invasive cardiovascular procedures. ■

AdvaMed

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(Philadelphia), said that the drivers of medical device value include recent advances in technology, many of which are fueling "the huge drive to convergence" between drugs and devices.

For him, a key example is deep brain stimulation, of great interest because it offers the potential to treat some neurological conditions that pharmaceuticals have yet to tackle effectively.

On the subject of society's perception of industry ethics, Fadem said there is a deep concern about conflicts of interest, and so transparency will become more important in order to avoid public or congressional backlash.

As for getting paid for one's devices, Fadem said that "the real value driver there is reimbursement, not pricing." And despite all the hubbub about the cost of care in the U.S., "the real driver in the U.S. is demographics — we're going to be driven by the Baby Boomer demographic bulge."

With regard to overall healthcare costs and "outcomes-based care, he said, "You're beginning to see a change right now," given that emphasis by the **Centers for Medicare & Medicaid Services**. "Were going to be rewarded . . . or not" for providing therapies that give payers the long-term outcomes they are seeking.

Fadem said an area of particular uncertainty will be the future role of the consumer in device selection. "I don't know how much influence information technology will have [in shaping choices], but we're beginning to see that right now" as patients check in at the doctor's office with preconceived ideas about treatments. Consequently, he advised that device makers need to track information flow carefully.

Fadem emphasized the role of the primary care physician as "the one person in the entire system who receives no information" about the implanted device, calling this a "huge hole." He said that primary care physicians are purportedly responsible for coordination but are largely shut out of from device selection and information about that device. Free flow of information about device technology depends on universally adopted healthcare IT (HIT) stan-

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PRODUCT BRIEFS

- **Smith & Nephew Endoscopy** (S&N Endoscopy; Andover, Massachusetts) reported the launch of the Kinsa RC 5.5 suture anchor, designed to provide secure repair of shoulder injuries stemming from tears to the rotator cuff, the group of muscles and tendons that control shoulder motion. Surgeons can repair these injuries using arthroscopic, minimally-invasive techniques with specialized instruments and devices such as the KINSA RC Suture Anchor, which re-attaches the torn tissue to restore mobility. The product is the second in S&N Endoscopy's line of Kinsa suture anchors. The original Kinsa anchor, for treatment of shoulder instability, was released in 2006. Both Kinsa anchors encase a sliding, self-locking knot that permits the surgeon to secure the repair without tying knots on top of the tissue. Surgical knots in arthroscopic repairs can sometimes loosen or cause irritation of surrounding tissue. The Kinsa RC anchor instead delivers "low profile" repair, without knots or protrusions to interfere with the joint motion.

- **SonoSite** (Bothell, Washington) reported the introduction of the M-Turbo ultrasound system for use in the full range of clinical applications at the point of care. The M-Turbo system delivers an exponential increase in raw processing power for superior image clarity across all exam types, plus seamless connectiv-

ity for digital image export in a hand-carried product weighing less than 8 pounds. SonoSite plans to begin customer deliveries later this quarter. SonoSite's new M-Turbo system offers a 16-fold increase in processing power yet weighs slightly less than the MicroMaxx system.

- **TeleTracking's** (Pittsburgh) exclusive BedTracking mobile, the industry's only bed tracking tool for handhelds, will be displayed during the 2007 Annual ASHES Conference and Marketplace September 30-October 4, in St. Louis. BedTracking mobile transfers the gold standard performance of BedTracking to a PDA so environmental services supervisors can avert patient flow problems and speed bed turnover from anywhere in the hospital. The wireless version provides real-time bed status, including pending transfers and discharges. Users communicate directly with staff via 'taps' on the PDA screen. Other features include 'alerts' when bed cleaning requests are delayed, re-assigning tasks on the fly, and much more. It is one of several wireless patient flow solutions either in service or soon to be available as part of TeleTracking Technologies' expanding mobile strategy, which is based on the recognition that to avert patient flow problems, supervisors sometimes need to be on the move instead of at a desktop PC. TeleTracking Technologies makes automated solutions which relieve hospital overcrowding, provides software and process redesign services that make real-time patient flow management possible.

PEOPLE IN PLACES

- **BioInformatics** (Arlington, Virginia), a provider of market research and consulting services to the life sciences, reported three additions to its management team: Robin Rothrock, PhD, was promoted from director of market research to VP of client relations; John Lewis was named VP of marketing and business development, most recently serving as director of marketing at PRA International; and Jeff Gardner was named director of research and advisory services after most recently holding the position of senior VP at nxtMOVE.

- Ralph Makar has been named president/CEO of **Bioject Medical Technologies** (Portland, Oregon). Makar previously was VP and general manager of the therapeutics business unit at Berlex Labs. Bioject makes needle-free drug delivery systems.

- **DCL Medical Laboratories** (Indianapolis, Indiana) has named Michael Hanbury as CEO and board member. He succeeds Roger Wall who founded the company and is retiring after 37 years in laboratory medicine and 23 years at DCL. Hanbury has over 25 years of medical, professional and associated corporate management experience in clinical diagnostic and medical laboratory sectors. DCL provides laboratory services and consultative pathology solutions.

cal diagnostic and medical laboratory sectors. DCL provides laboratory services and consultative pathology solutions.

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dards, he said, and that the lack of information will suppress sales to doctors, patients and payers when a device exhibits problems. Also suffering will be device development.

"We don't know how to share data," Fadem said, adding that the various specialty physicians, business analysts and device makers "never attend the same meetings."

Asked how to put together a decent model of health-care information technology allowing investors to reap the financial benefits, Fadem told *Medical Device Daily*, "I think ultimately, it will require a government initiative" because Uncle Sam is the largest payer.

However, he said that "a public-private partnership" may be necessary in order to garner buy-in from industry as well as to pull in the techno-savvy that the private sector is more widely thought to possess, compared to government agencies. ■