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Leadership Summit on Healthcare Quality & Pay-For-Performance

Cost-effective technology could reduce 50% health cost bloat

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

BOSTON – In an afternoon keynote on the second day of the Pay-For-Performance leadership summit, Arnold Milstein, MD, of **Mercer Human Resources Consulting** (New York), provided the payer perspective on P4P, bringing with him several years' experience as a member of the **Medicare Payment Advisory Committee** (MedPAC).

He said that the No. 1 problem with healthcare in the U.S. today is "rapidly spreading unaffordability," in large part driven by waste.

"There appears to be an opportunity" to save as much as 50% on the nation's healthcare tab "without reducing quality of care," Milstein said, basing his comments on a 2005 study by **Rand Corporation** (Santa Monica, Calif-ornia) that

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Tough legal issues hover over payment-for-quality terrain

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

BOSTON – Proponents of pay for performance (P4P) may feel they have already slogged up a steep road just to get a few pilot projects under way, but the coronation of the practice of tying compensation to healthcare quality is not yet a *fait accompli*.

While antitrust exemptions have been crafted to keep public and private payers in these programs out of the legal woodshed, new considerations are likely to make themselves heard, and the likelihood is that sooner or later judges and attorneys will enter the picture

That was the assumption surrounding the overview of the legal terrain surrounding P4P presented by Michael Costa, a senior associate at the law practice of **Greenberg**

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Report from Europe

Respironics, German firm in accord on CO_2 sensor tech

A *Medical Device Daily* Staff Report

Sartorius (Goettingen, Germany) and **Respironics** (Murrysville, Pennsylvania) have signed an agreement that provides for certain Respironics carbon dioxide sensor technology to be used with Sartorius's disposable bioreactors.

During the term of the agreement, and subject to certain terms and conditions, Sartorius will have the exclusive right to sell Respironics' Capnostat 5 mainstream carbon dioxide sensor and LoFlo Capnostat 5 sidestream carbon dioxide sensor with the German company's disposable bioreactor in the measurement of the amount of carbon dioxide being generated in the fermentation/bioreaction process in use of living cells in the manufacture of drugs.

Sartorius plans to integrate Respironics' sensor technology into its disposable bioreactors in an effort to become the first company worldwide to offer bioreactors enabling required off-gas analysis using disposable technologies dur-

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Deals roundup

Celsi International buys IVT for $30 million and earn-outs

A *Medical Device Daily* Staff Report

Celsis International (Chicago), a life science products and services company, reported that it has acquired **In Vitro Technologies** (IVT; Baltimore) for $30 million in cash and an earn-out consideration capped at $5 million.

Celsi said that the acquisition adds products and services to its portfolio for the *in vitro* ADME (absorption/distribution/metabolism/excretion) toxicology market.

IVT supplies products and services to improve the drug discovery and development process with a portfolio that includes proprietary ADME-Tox products such as fresh and cyropreserved cells and enzymes.

An estimated 50% of drug candidates fail in clinical trials due to unanticipated pharmacokinetic and toxicology issues, Celsis said in a statement, and the integration of IVT into Celsis "creates the selection of candidates for the clinical trial stage."

Jay LeCoque, CEO of Celsis, said the acquisition creates "clear cross-selling opportunities which we expect to

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INSIDE:

THOMSON

Orqis adds $10M debt funding; Dilon wraps up $7.25M offering

A *Medical Device Daily* Staff Report

Orqis Medical (Lake Forest, California), a clinical-stage company developing devices for the treatment of congestive heart failure (CHF), yesterday reported a $10 million venture debt commitment from Lighthouse Capital Partners (Menlo Park, California/Cambridge, Massachusetts).

Orqis said the new capital would enable it to accelerate the development of its Exeleras System, an implantable device for patients with mid- to late-stage CHF. The system incorporates a pump, about the size of an implantable cardioverter defibrillator, placed in a minimally invasive manner.

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It said it plans its first human implant with the Exeleras in the next 12 months. Ken Charhut, president/CEO of Orqis, said, "We now have the ability to fast-track the Exeleras program to address the enormous unmet needs of CHF patients."

"Orqis Medical has emerged as a leader in the development of novel devices to treat congestive heart failure," said Cristy Barnes of Lighthouse. "Exeleras now positions the company with a chronic therapy complementing [its] Cancion acute device, resulting in one of the most exciting opportunities in the cardiovascular area."

Orqis's percutaneous Cancion System, for the treatment of acutely decompensated patients with chronic heart failure, is CE-marked and currently under an investigational device exemption investigation in the U.S. in the MOMENTUM pivotal trial.

Lighthouse invests capital in the form of secured loans to early- and expansion-stage technology and life science companies that have received equity financing from top-tier venture capital firms.

Dilon Technologies (Newport News, Virginia), a manufacturer of high-resolution molecular imaging systems said it completed an equity offering of $7.25 million placed by Taglich Brothers (New York), an investment banker focused on microcap companies.

Dilon is developing a product dubbed Breast-Specific Gamma Imaging (BSGI), an imaging technique enabled by Dilon's camera technology and an imaging component for breast cancer detection that it says is not found in other types of breast imaging. With the system, a patient receives a small dose of a radiopharmaceutical tracing agent absorbed by the cells of the body. And because cancer cells have a higher rate of metabolic activity, they absorb up to nine times more of the agent to reveal focal points, or "hot spots" indicating cancer.

Michael Taglich, president of Taglich Brothers, said, "Based on the spectacular clinical results that the Dilon 6800 Gamma Camera has shown in detecting breast cancer, we are convinced that it should be regarded as an integral part of the standard of care for breast cancer detection and preoperative planning."

"The capital infusion provides funding for the advancement of our national sales operations and international business ventures," said Lon Slane, president of Dilon.

Dilon says that other possible applications of the compact system include treatment of the parathyroid and pediatrics, and other body parts "small enough to fit within the 6 inch by 8 inch field of view."

In other financing activity, **Uroplasty** (Minnetonka, Minnesota) reported the closing of a $2.1 million financing, principally with institutional investors. Uroplasty issued about 1.4 million shares of common stock at $1.50 a share, and five-year warrants exercisable at $2.50 a share to purchase 695,000 additional shares.

The company said the funding would support expansion of U.S. sales and marketing and for working capital and general corporate needs.

Uroplasty, with subsidiaries in the Netherlands and the UK, manufactures products used to treat voiding dysfunctions, including urinary and fecal incontinence, overactive bladder and vesicoureteral reflux.

Its Urgent PC neuromodulation system is a minimally

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ATLANTA NEWSROOM: Executive Editor: **Jim Stommen**. Managing Editor: **Don Long**. Associate Managing Editor: **Holland Johnson**. Staff Writer: **Karen Young**. Washington Editor: **Mark McCarty**.

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

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

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

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Financings roundup

OrthoClear adds $10M in 'D'; MedaSorb gets $5.25 million

A *Medical Device Daily* Staff Report

3i Venture Capital (Menlo Park, California) reported leading a $10 million series D investment in **OrthoClear Holdings** (Boston).

Orthoclear said the financing would be used to fund capital expenditures, and support sales and marketing and upcoming expansion into Europe and the Far East.

Founded in early 2005, OrthoClear has developed a system of tooth aligners that it describes as "invisible and customizable." It also has developed web-based software, OrthoView, so that orthodontists can track the progress of treatments.

Since product launch in May 2005, OrthoClear says it has captured more than 20% of the North American clear removable aligner market.

Allan Ferguson, senior partner with 3i, said, "OrthoClear [provides] the most sophisticated and clinically effective solution at a compelling price."

Paul Badawi, director with 3i and board member of OrthoClear, said, "OrthoClear has been very open with us regarding its outstanding litigation with **Align Technology** [Santa Clara, California], and after careful consideration the issue has not affected our willingness to invest." With the investment, Badawi will be joining OrthoClear's board of directors.

Cowen and Co. advised OrthoClear on the financing.

3i manages more than 200 investments across Europe, the U.S., Asia and Israel in excess of $1 billion, its investments falling into four sectors: healthcare, telecommunications, software and electronics/semiconductors.

MedaSorb Technologies (Monmouth Junction, New Jersey), a company developing products for removing toxic compounds from the blood, said that its stock began trading yesterday under the symbol OTC BB: MSBT.

MedaSorb completed a reverse merger transaction on June 30 and immediately closed a $5.25 million private placement of its Series A 10% cumulative convertible preferred stock and warrants to purchase common stock.

Al Kraus, president/CEO of MedaSorb, said, "We believe that our medical devices, which use absorption technology, unlike current technologies, could be a dramatic improvement in the care of sepsis and dialysis patients."

MedaSorb's initial products, CytoSorb and BetaSorb, are hemoperfusion devices incorporating adsorbent polymer technology. It says its products have a variety of other applications.

In other financing activity:

• **Uroplasty** (Minnetonka, Minnesota) reported the closing of a $2.1 million financing, principally with institutional investors. Uroplasty issued about 1.4 million shares of common stock at $1.50 a share, and five-year warrants exercisable at $2.50 a share to purchase 695,000 additional shares.

The company said the funding would support expansion of U.S. sales and marketing and for working capital and general corporate needs.

Uroplasty, with subsidiaries in the Netherlands and the UK, manufactures products used to treat voiding dysfunctions, including urinary and fecal incontinence, overactive bladder and vesicoureteral reflux.

Its Urgent PC Neuromodulation System is a minimally invasive nerve stimulation device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. The Urgent PC system is sold in the U.S., Canada and countries recognizing the CE mark. Outside the U.S., Urgent PC also is indicated for treating fecal incontinence.

The I-STOP Mid-Urethral Sling is a biocompatible, tension-free sling used to treat female stress urinary incontinence.

Macroplastique Implants, Uroplasty's soft-tissue bulking agent, is used to treat both female and male urinary incontinence and to treat vesicoureteral reflux in children.

• **United Surgical Partners International** (USPI; Dallas) and its subsidiary, **United Surgical Partners Holdings** (Holdings), reported that the consideration to be paid in Holdings' previously announced tender offer and consent solicitation for its outstanding 10% senior subordinated notes, due 2011.

Holdings had received, as of 5 p.m. EST on Monday, tenders and consents from holders of $149.9 million principal amount of the notes, representing about 99.3% of the outstanding notes, in connection with the offer.

USPI also reported entering into a new $200 million term credit facility.

Total cost of the offer is expected to be about $163 million. The balance of the proceeds from the new credit facility will be used to repay existing debt under USPI's revolving credit facility.

Bear, Stearns & Co. is dealer-manager for the tender offer and solicitation agent for the consent solicitation. ■

Financings

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invasive nerve stimulation device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. The Urgent PC system is sold in the U.S., Canada and countries recognizing the CE mark. Outside the U.S., Urgent PC also is indicated for treating fecal incontinence.

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Court report

Delcath files vs. ex-staffer in its dispute with Laddcapp

A *Medical Device Daily* Staff Report

Delcath Systems (Stamford, Connecticut) reported filing a complaint in Connecitcut Superior Court in Stamford against former employee Jonathan Foltz, alleging that Foltz misappropriated certain Delcath trade secrets and other proprietary information and has shared this information with various Laddcapp investment vehicles.

Laddcapp is currently attempting to place its nominees on the board of Delcath and Delcath has filed suit vs. Laddcap Value partners and related parties, claiming that Laddcap has made various proxy misstatements concerning its nominees (*Medical Device Daily*, Aug. 8, 2006).

Delcath alleges that Foltz, former director of operations of Delcath, violated various trade secrets laws and breached various duties that he owed to Delcath.

Delcath said that in accordance with a recent order by a Connecticut Superior Court judge, Foltz was ordered not to disseminate any of Delcath's confidential information to others, including to the Laddcap entities or employees. Foltz further was ordered not to destroy or remove any Delcath materials or property.

The company said that on Monday a court-appointed custodian, a forensic computer expert and a Connecticut marshal went to Foltz's home to take temporary control of all of his computers and similar electronic devices and to make copies of certain materials.

It said Foltz must appear before the court on Aug. 21 to demonstrate why the current prohibitions on his conduct should not be extended.

Delcath is a developer of isolated perfusion technology for organ or region-specific delivery of therapeutic agents.

In other legalities, the Federal Trade Commission said that **Walsh Optical** (Hoboken, New Jersey) and its owner, Kevin Walsh, have settled charges of violating federal law by failing to verify consumers' prescriptions as required.

They will pay $40,000 in civil penalties and are prohibited from further violations. In addition to the $40,000 penalty, the settlement contains provisions that allow the FTC to monitor compliance.

The defendants run three web sites that sell contact lenses, and the FTC charges that the defendants often sold contact lenses without obtaining a prescription or verifying the prescription with the prescriber.

The commission said this is first enforcement under the Fairness to Contact Lens Consumers Act of 2003 and the Contact Lens Rule, issued in 2004, requiring that prescribers provide consumers with a copy of their prescription after they are fitted for lenses and that sellers either obtain a copy of the prescription or directly verify it with the prescriber before selling contact lenses.

The FTC said these laws are designed to allow consumers to obtain their prescriptions and comparison shop for lenses, and also protecting ocular health by prohibiting the sale of contact lenses without a valid prescription. ■

Grants/contracts

InterSystems in DoD contract valued at up to $63 million

A *Medical Device Daily* Staff Report

InterSystems (Cambridge, Massachusetts) said it has been selected to provide its CACHE post-relational database software for the U.S. Department of Defense (DoD) Health Affairs and Composite HealthCare System. The contract, with an initial value of about $14.7 million, includes option periods which, if exercised, will bring the cumulative value to an estimated $63 million, InterSystems said.

"We are very pleased that this contract award will put InterSystems database software at the core of healthcare delivery at 70 hospitals and more than 400 clinics serving over 8 million people," said Paul Grabscheid, InterSystems vice president of strategic planning.

The CACHE post-relational database and Ensemble rapid integration software are designed to enable developers in every industry sector to create, deploy and integrate high-performance applications. InterSystems has offices in 20 countries and provides support to customers in 88 countries.

In other grants/contracts news:

• **Criticare Systems** (Milwaukee) reported that it has received an order to replace all vital signs monitors in more than 50 domestic plasma collection centers. This is a multi-year agreement with the initial order exceeding $1 million.

The company said it is targeting complete shipments against this requirement by the end of the current fiscal quarter.

In other news, the company reported its preliminary, unaudited fiscal 2006 net sales. Criticare achieved net sales of $31,350,000 in fiscal 2006 compared to $26,780,000 in fiscal 2005, an increase of $4,570,000 or 17%.

Criticare manufactures patient monitoring systems and noninvasive sensors for hospital and alternate healthcare environments worldwide.

• **Saint Clare's Hospital** (Weston, Wisconsin) reported that it plans to enhance patient safety by installing **Medhost**'s (Addison, Texas) full-suite Emergency Department Information System (EDIS). Saint Clare's chose Medhost to automate its Emergency Department (ED) with its full-suite of software solutions, which feature next-generation processes that increase patient safety, reduce individual wait times, and streamline financial processes by improving charge capture.

Medhost also will provide Saint Clare's with ongoing consulting, integrated customer support and valuable on-

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Agreements roundup

Advocos promotes EndoTool in MD Scientific accord

A *Medical Device Daily* Staff Report

Advocos (Kennesaw, Georgia), a contract sales organization that provides sales and marketing services to the pharmaceutical, biotech and medical device industries, reported that it has entered into a multi-year agreement with **MD Scientific** (Charlotte, North Carolina) to promote that company's EndoTool glucose management system to hospitals. EndoTool received FDA clearance in June (*Medical Device Daily*, June 22, 2006).

Advocos will provide multiple sales teams to be launched in August and October, with the potential to expand the sales teams over time.

Robert Godfrey, president of Advocos, said, "Our experience within the hospital sector provides Advocos with the background to quickly launch and impact this market. We are excited about the opportunity to work with MD Scientific in an effort to increase awareness while also expanding the use of EndoTool within hospitals throughout the U.S."

Shade Mecum, CEO of MD Scientific said, "As our reach expands nationally, we continue to build out the team that can help ensure the impact of EndoTool and safe glucose control in critical care settings."

SurgiCount Medical, a wholly owned subsidiary of **Patient Safety Technologies** (both Los Angeles), said it has entered into a three-year agreement to provide its Safety-Sponge system for the prevention of retained sponges after surgery to the entire network of **Integris Health System** (Oklahoma City, Oklahoma), Oklahoma's largest not-for-profit healthcare organization. This new contract will take the Safety-Sponge system from two hospitals currently to the entire network which includes 11 hospitals. Financial terms were not disclosed.

SurgiCount says the Safety-Sponge is the only computer-assisted system FDA-cleared for counting sponges. The system is a program of thermally affixed, data matrix-tagged surgical sponges, line-of-sight scanning technology and documentation offering a solution to gossypiboma, sponges accidentally left inside a human body after surgery.

Based on estimates by Patient Safety Technologies management, gossypiboma occurs in an estimated 3,000 to 5,000 surgical procedures each year in the U.S., and liability settlements and other costs related to retained sponges amount to $500 million to $750 million annually.

Integris owns or leases hospitals, primary care clinics, mental health facilities, rehabilitation centers, fitness centers, hospice services, home health agencies and independent living centers throughout Oklahoma.

SurgiCount's Safety-Sponge system works much like a grocery store check-out system. Every surgical sponge and towel is pre-labeled by the manufacturer with an individual and unique bar coded label, and a scanning counter is used to read and record the labels.

No change is required in a hospital's established counting procedures; sponges are counted and recorded by the system at the beginning of the procedure and again as they are removed from the patient. ■

Grants

Continued from Page 4

site training.

Saint Clare's hospital nurses and physicians will be able to utilize a touch screen interface and Medhost's Administrative ToolKit, which allows facilities to customize clinical content to fit their particular needs. The company's solutions provide hospitals with methods designed to improve patient tracking, nurse charting, physician documentation and order entry. ■

BRIEFLY NOTED

CryoCor 'cures' Nasdaq non-compliance

CryoCor (San Diego), which is focused on the treatment of cardiac arrhythmias, reported the receipt of a letter from Nasdaq regarding a brief period of non-compliance with Nasdaq's requirement that all members of a newly public company's audit committee be considered independent under applicable Nasdaq and SEC rules within one year of the company's initial listing date on the Nasdaq Global Market.

Dr. Arda Minocherhomjee, who may not be considered independent for audit committee purposes under applicable SEC rules, remained on CryoCor's audit committee for the five-day period from July 14, the one-year anniversary of CryoCor's initial listing date, to July 18.

This non-compliance was cured on July 19 when Mark Hattendorf, CPA, who is considered independent for purposes of applicable Nasdaq and SEC rules, joined CryoCor's board of directors, including its audit committee, replacing Minocherhomjee as a member of the audit committee.

Minocherhomjee remains on the company's board of directors.

Nasdaq indicated in its letter that, upon disclosure via press release of receipt of the letter and filing of a related 8-K with the SEC, the matter would be closed.

CryoCor reported it does not expect any financial penalties or further questions or issues associated with this matter.

CryoCor's primary product, the CryoCor cardiac cryoablation system, is designed to treat cardiac arrhythmias through the use of cryoenergy, or extreme cold, to destroy targeted cardiac tissue.

Summit

Continued from Page 1

detailed a variety of metrics of healthcare in the U.S.

Another metric is the well-known numbers of America's uninsured.

"Most of us in this room are in the lucky half" of Americans who can afford fairly comprehensive healthcare coverage, he said. Those who cannot afford any coverage at all are in no enviable state, but that the "middle quintile of income" is feeling the greatest pressure for finding affordable care.

The MedPAC commissioner referenced a **Dartmouth College** (Hanover, New Hampshire) study indicating a "gap" in spending between the lowest-spending regions and all other regions in the U.S. He characterized the difference in spending for these equal outcomes on the order of 30%.

Furthermore, he posited little difference in healthcare quality between the "lowest-spending providers and all other providers within the lowest-spending regions," to which he chalked up a cost differential of 15%, and a gap between the lowest-unit cost care delivery methods and all other methods, crunching out to a difference of 20% to 30%.

He called this lack of difference "quality-neutral."

"The problem is not lack of conscientiousness" in caring for patients, Milstein said, but rather "a medical miracle-powered shark" that devours resources disproportionately to the benefits delivered. Not only are these medical miracles more expensive, they often are more time-consuming to administer.

Thus, he showed numbers indicating that inflation of healthcare expenditures outstripped real GDP growth by 4% in 2003 and will likely outstrip GDP growth by 3% in 2006, the bulk attributable to the latest medical thing.

To stem the tide, society must "rapidly adopt" today's most cost-effective delivery methods and "perpetually gain efficiency to out-swim the medical miracle shark," he said. This would have to be accompanied by a transition from "making quality fairly reliable" to "making quality highly reliable."

"Your only chance of changing healthcare is to employ a few simple rules," he argued, in the process eschewing lots of arcane regulations and standards.

The first of these simpler approaches, he said, is transparency. "In the absence of that, nothing else will happen," Milstein said.

Much of the transparency he advocated relates to cost, noting that the difference in cost between U.S. and overseas providers has fueled the surge in medical tourism that has surfaced over the last few months (*Medical Device Daily*, June 28, 2006).

To reinforce this point, Milstein noted a study published in *Health Affairs* in July 2005 showing that 35% of Wisconsin hospitals that made public the results of a review of their obstetrics services improved those services, whereas less than 5% of this group experienced a decline in obstetric services quality.

Of those hospitals whose reports were held in confidence, more than 20% showed significant improvement while nearly 15% showed some decline.

The second simple rule would be to design health plans that are sensitive to performance and to provider payments.

The third principle would be "faster discovery and uptake of care delivery innovations," all of which would hopefully be followed by "large annual gains in affordability and quality."

He quoted Robert Pearl, MD, the CEO of **Kaiser Permanente Medical Group** (Oakland, California), as saying that "medicine . . . is a century behind in applying technology effectively." Assuming this is the case, adoption of technology will aid society's efforts to make healthcare more affordable.

And he offered the view that U.S. physicians will be leaders in this effort. "American doctors take pride in their work and once they're aware" of deficiencies, they will take action, assuming decent options are available. Public disclosure can add octane to that effect, he said.

But as with much of Milstein's commentary, this silver lining surrounded a large cloud. He noted the many impediments to adopting a more-effective, less-wasteful approach to healthcare.

He said that one is bilateral complacency, a mindset in which practitioners agree that there is waste, but that the individual who is asked about systemic waste will insist that the problem lies elsewhere. Likewise, patients do not see their use of medical resources as wasteful, but that the problem results from the unnecessary activities of others.

For the physician he noted a moral hazard – that if he or she does not experience waste there is no motivation to avoid it. This then supports the need for more transparency; the appropriate use of standards of care and concomittant disclosure of actual practices would make waste more apparent.

Milstein said that the biggest single impediment to the adoption of P4P is none of these. It is the providers who lose out on performance-based pay. These providers might then create distractions and leverage their resources to derail P4P. He urged attendees not to let such a scenario rule the day.

"It's up to us to build a system that will capture that 2.5% savings" and keep healthcare affordable long into the future, Milstein said. ■

P4P

Continued from Page 1

Traurig (Boston) on the last day of the P4P leadership summit here.

While billing P4P as "really the wave of the future," Costa outlined a number of legal issues that have cropped up and will continue to do so as these arrangements play out.

Costa reminded the audience that however exculpatory an incentive payment might seem, P4P involves price fixing, even when incentive payments are weighted for variables that might seem to skew payment.

And then there's human nature. "Any time you get a group of people together and talk about prices, that raises antitrust issues," he said.

Among the considerations that authors of P4P programs will have to remain mindful of are whether the payment structure is voluntary or mandatory and how much anti-competitive pressure such a payment system might produce in the healthcare market.

He said that programs able to pass legal muster should specify the desired cost-saving actions and disallow "cherry-picking." Hidden incentives also are a perennial concern hovering over these issues.

On the other hand, Costa said that tiered compensation systems by payers do not present a legal problem "if they're [paid at] fair-market value" and do not involve referrals or payments tied to referrals.

And providing patients with incentives to seek services from upper-tier practices and facilities does not violate a law because there is no action on the part of the provider, he said.

However legally tidy P4P might seem to its enthusiasts, Costa said that trade associations have sued governments over issues that were similar to P4P in terms of government's interaction with the normal function of the market.

"It's still early in the process, but we will see litigation on the posting of performance and quality data," which could be pursued via laws covering defamation and slander, Costa said. Such actions could be undertaken by individual entities, but class action is not ruled out in this scenario.

Finances also may play a role in stimulating legal resistance to P4P, according to Costa. A day earlier at the P4P conference, Arnold Milstein, MD, a consultant who is a member of the **Medicare Payment Advisory Committee,** alluded to potential legal problems with providers who can't conform to the appropriate P4P requirements and so will turn to legal recourse to eliminate or reduce some of the incentives (see accompanying story).

The first challenge to P4P, he said, may come "on an administrative basis," essentially by questioning whether Congress is legitimately empowered to craft laws that enable P4P in the first place. Further action may be predicated on whether such arrangements constitute "an undue burden on business" via burdensome reporting to government entities or other payers on practices, outcomes or finances. (Here, reference Sarbane-Oxley requirements.)

States also may enter the legal fray should they find federally-mandated P4P nettlesome. Legal action is not available to states over programs run or financed wholly by Washington, Costa said, but they can do battle with the federal government over programs involving dual financial responsibility.

"They are already doing that in dealing with Medicare Part D," Costa observed in reference to the federal attempt to force states to cover drug costs for beneficiaries who are enrolled in both Medicare and Medicaid.

The Department of Justice and Federal Trade Commission share jurisdiction over much of the medical marketplace, and the two conducted a review of a number of healthcare law issues in 2003. This effort was detailed in a 2004 report that gives some insight as to what these two agencies see as potential problems.

The cover sheet from that report notes that where P4P is concerned, "arrangements among a group of physicians may constitute a form of financial risk-sharing" that would by permissible. However, an approach such as this has to pass a test or two before it can be assured of clear sailing.

The document suggests that "clinical integration" is indemnifying and can be satisfied "by considering a number of questions, such as the goals of the joint venture, the likelihood those goals will be met, and the nexus between joint contracting and the attainment of those goals."

The report says little about what specific states of affairs either or both would pursue.

In one of the few passages specifically addressing P4P, the report says that: "In determining whether a physician network joint venture is sufficiently financially integrated to avoid per se condemnation, the agencies will consider the extent to which a particular P4P arrangement constitutes the sharing of substantial financial risk among a group of physicians, and the relationship between the physicians' pricing agreement and the P4P program." ■

2nd FDA compliance/regulatory symposium

The second annual FDA Regulatory and Compliance Symposium, a leading event for the medical device and drug industries, will be held Aug. 22-25 on the campus of **Harvard University** (Cambridge, Massachusetts).

The symposium is intended to supply solutions to the challenges of eliminating or reducing risks throughout the product life cycle.

Speakers include top FDA and Centers for Medicare & Medicaid Services executives and nearly 50 other experts from business and academia discussing regulatory and compliance topics in five separate tracks. In addition, there will be a pre-conference workshop and networking sessions.

For more information about registration, go to www.fdasymposium.com or phone 800-684-4549 Monday-Friday, 9 a.m.-5 p.m. PST.

Celsi

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deliver material growth in the coming years. Celsis is well positioned to continue its track record of strong growth both organically and by acquisition."

Celsis provides products and services to the pharma, biopharma, and personal care and beverage industries through three businesses; rapid detection systems, analytical services and *in vitro* technologies. The company is listed on the London Stock Exchange.

In other dealmaking activity, **Bioheart** (Sunrise, Florida) said it has acquired an option to the worldwide exclusive rights to adiopose-derived therapeutic cell technology from **Tissue Genesis** (Honolulu, Hawaii), being developed to treat heart attacks and congestive heart failure.

The agreement provides for up-front payments – the amount not disclosed – and milestone payments to Tissue Genesis. Upon successful completion of animal studies and approval of an investigational new drug application, Bioheart said it expects to launch human clinical trials in the U.S. and Europe.

The company plans to administer the adipose-derived cells into patients via a combination of coronary infusion and direct intramyocardial injection with its MyoCath needle-injection catheter.

Bioheart says that adipose-derived cells are an abundant tissue source rich in microvascular, myogenic and angiogenic cells and easily removed from patients and that Tissue Genesis' TGI1200 cell isolation system will rapidly process adipose tissue to isolate and produce large quantities of regenerative cells for treating patients suffering a heart attack.

Bioheart will have the exclusive right to negotiate a worldwide exclusive license to all of Tissue Genesis' patents and technology for use in the heart attack and heart failure markets.

"The Tissue Genesis cell isolation system will allow us to broaden our portfolio of product candidates and hopefully give cardiologists a way to prevent some of the damage caused by heart attacks," said Howard Leonhardt, CEO and chairman of Bioheart. "It has always been a goal of our company to develop an acute treatment for heart attack patients in addition to our proposed MyoCell therapy for chronic heart failure.

"We intend to demonstrate the benefits of a two-part, percutaneous treatment plan: first, a quick bolus of isolated non-cultured cells shortly after the heart attack, and then a full dose of the cultured MyoCell myogenic cells about 14 to 18 days later to attempt to recover the remaining scar tissue."

Bioheart is focused on developing cell-based therapies for the treatment of cardiovascular diseases, including myocardial infarction and CHF.

It is currently enrolling patients in its European Phase II/III clinical trial named SEISMIC to test its lead product candidates, MyoCell and MyoCath. The MyoCell implantation therapy is designed to regenerate areas of damaged myocardial tissue. MyoCath is a percutaneous needle-injection catheter engineered to deliver cell therapy or other compounds to myocardial tissue.

Tissue Genesis says that its cell isolation technology supports a family of platform systems enabling autologous, point-of-care, adipose-derived therapeutic cell isolation in under two hours. ■

BRIEFLY NOTED

$12 million a device marketing 'average'

The average marketing investment for a new medical device is $12 million, according to a new report from research firm **Cutting Edge Information** (CEI; Research Triangle Park, North Carolina).

However, CEI researchers warn not to get too excited about that figure. It is skewed by two far-flung investments – $75 million and $41 million. Removing those two data points brings the average down to $1.8 million, the report says.

"Medical Device Product Management: Benchmarking Development, Marketing and Promotion," shows that companies consider a device's commercial potential when determining marketing investment levels. An adequate marketing investment prepares new medical devices for commercial success, but disparities among technologies, companies and markets drive differences in marketing budgets.

Devices also need adequate staffing. Throughout device approval, manufacturing and the first year on the market, average staff headcount is 22.5 full-time equivalents (FTEs). That figure includes staff from several other functions such as R&D, commercialization, manufacturing, legal, executive and accounting. The function with the most staffing support is manufacturing.

"Given the short shelf life of most medical devices, product launch is a critical period," says Research Team Leader Eric Bolesh. "It is critical for companies to have a solid marketing strategy in place, as well as enough staffing to execute the strategy and maximize product potential in a limited timeframe."

The report provides benchmarks for development, marketing and post-market issues such as sales force management and technical support.

Europe

Continued from Page 1

ing the fermentation/bioreaction process. This is a critical parameter for cell culturing in the fermenter or bioreactor to obtain active medical ingredients, Sartorius said.

Together with measurements of the substances added to the cell lines and of the parameters in the bioreactor, such as temperature or pH, off-gas analysis delivers information on cell activity and process stability of fermentation. Until now, this analysis had been carried out with equipment that had to be sterilized after every sampling procedure and that entailed a capital outlay of up to $25,000.

Respironics, which Sartorius cited as the industry leader in carbon dioxide sensor technology, has historically offered the Capnostat 5 mainstream and LoFlo Capnostat 5 sidestream sensor and carbon dioxide monitoring technology for use during and recovery, in the intensive care unit, in emergency medicine/transport and for respiratory care.

The mainstream and sidestream devices can be integrated with virtually any patient monitoring system, Respironics said, and provides advanced measurement of end-tidal carbon dioxide and respiration rate.

The U.S. firm said it looks forward to expanding markets for its sensor technology, including the biopharmaceutical market through its collaboration with Sartorius.

Sartorius and Respironics said the agreement shows how an already established technology in medical applications can be transferred to other market segments.

French firm launches rejuvenation technique

Medicamat (Malakoff, France), a manufacturer of medical and surgical devices, has just launched Aquarejuvenation, its new technique for face and neck rejuvenation.

Non-invasive and painless, the hydrodynamics-based therapy involves a three-step process — biopeeling, penetration of high-pressure water microjets and application of specific cosmetics. It is applied by beauticians, cosmetic medicine specialists, dermatologists and plastic surgeons.

The process, which has been patented, involves three stages. It starts with stratum corneum biopeeling, achieved by projecting a powder made of powdered fruit pits, which regenerates the live cells of the epidermis and facilitates micro-jet penetration.

Next is the penetration of high-pressure water microjets. Pressure ranges from 220 psi to 290 psi, depending on the facial area being treated. The microjets include active cosmetic substances — vitamin C, minerals and plant extracts – that are natural anti-aging agents. The water and activeagents s penetrate through to the papillary dermis.

The last step is the application of specific Medicaderm cosmetics, including a concentrated anti-aging serum (Medica Rejuv) and a protective and dermis-healing cream (Medica Derm).

This line is completed by an anti-UV cream for pigmented spots (Medica Sun), a bleaching serum (Medica White) and an anti-seborrhoea serum for acne-prone and oily skins. All of these products are hypoallergenic and free of perfume, coloring or paraben- and phenoxyethanol-type preservatives.

Depending on the type, age, and condition of the skin and desired outcome, an initial treatment of three to five sessions, 10 to 15 days apart, is recommended, followed by one to three sessions of maintenance therapy which is generally sufficient for achieving the desired results. These include revived radiance, well-hydrated skin with an even complexion, reduction of fine lines and wrinkles, fading of pigmented spots, attenuation of acne scars, considerable improvement of skin firmness and elasticity on the face and neck, and a redefined facial contour.

Medicamat has signed agreements with various distributors throughout North America.

Proof-of-concept results good for VR040

Vectura Group (Chippenham, UK) reported the successful outcome of a Phase II "proof of concept" clinical study for its VR040 product for the treatment of induced "off" periods in patients with Parkinson's disease (PD).

The company said the study demonstrated that VR040 was safe, well tolerated and successfully recovered patients from an induced "off" episode with a rapid onset of action, which also was durable. VR040 is Vectura's proprietary formulation of apomorphine, delivered by oral inhalation to the lungs using the company's Aspirair dry powder inhaler.

As Parkinson's disease progresses, therapeutic control diminishes and patients experience motor complications ("off" episodes) which become more frequent and severe, and are disabling and often of sudden onset. VR040 aims to provide rapid, non-invasive relief from such symptoms.

The randomized, ascending-dose study was designed to assess the safety and tolerability profile of VR040. The study evaluated six fine particle doses and placebo in 24 PD patients who experience "off" episodes. Recovery from "off" status was determined by patient self-assessment of disease state, with the time to onset of effect and duration of effect recorded.

Safety was determined via vital signs, lung function, volunteered adverse events and electrocardiograph measurements, with blood samples collected for measurement of plasma apomorphine concentration and subsequent PK analysis.

No serious or severe adverse events were reported at any dose and no patients withdrew from the study. The profile of adverse events for all treatments, including placebo, was similar, with no reports of hypotension or syncope.

Apomorphine-induced conversion from an "off" state was observed in 10 out of 18 PD patients. The median onset of therapeutic effect in responders was 10 minutes after inhalation of apomorphine, the effect lasting for up to 60 minutes, with a median duration of 25 minutes.

Dr. Chris Blackwell, chief executive of Vectura, said the study demonstrated that VR040 "can provide rapid relief from 'off' episodes . . . within minutes of inhalation." He said future clinical development will focus on determining optimal dosage. ■

PRODUCT BRIEFS

• **Calypso Medical Technologies** (Seattle) said the FDA has granted 510(k) clearance for the Calypso 4D Localization System, which uses electromagnetic technology in conjunction with implanted Beacon transponders in the prostate. The product platform is designed to provide objective, accurate and continuous tumor location information during external beam radiation therapy without adding ionizing radiation. The Calypso System offers what the company said is the only available means to continuously and objectively monitor prostate organ motion during radiation therapy of prostate cancer patients. Calypso said continuous knowledge of the tumor location is expected to provide greater confidence to clinicians and patients that the radiation beam is always on target. The system was evaluated in clinical studies in patients undergoing prostate radiation treatment between 2003 and 2006 at a number of U.S. cancer centers. Results from the company's recently completed clinical study will be presented at the American Society for Therapeutic Radiology and Oncology in November.

• **FlowCardia** (Sunnyvale, California), a company focused on coronary and peripheral catheter-based systems for chronic total occlusion (CTO) recanalization, said it has completed enrollment in the FlowCardia's Approach to Chronic Total Occlusion Recanalization (FACTOR) pivotal study. The 19-hospital, 125-patient study was designed to assess the safety and efficacy of the company's Crosser catheter in chronically occluded coronary arteries. Wick Goodspeed, president and CEO, said, "We hope to file a request for Crosser 510(k) clearance in September [and] anticipate clearance from FDA before the end of this year." FlowCardia also said that it received approval from the FDA to start the pivotal phase of the Peripheral Approach To Recanalization In Occluded Totals (PATRIOT) study after completion of the feasibility phase in June. The 10-hospital, 85-patient U.S. pivotal study is designed to determine the safety and efficacy of the Crosser catheter in totally occluded peripheral arteries. The Crosser System is a monorail catheter delivered over standard guide wires to the site of a CTO. It uses high-frequency, mechanical vibration and is designed to facilitate crossing of CTOs, allowing for subsequent debulking, balloon angioplasty and stent placement.

• **Smith & Nephew**'s Endoscopy division (Andover, Massachusetts) has launched its Dyonics Arthropak Customized Procedure Kits, which contain medical devices used in the most common arthroscopic procedures. The kits are designed to increase operational efficiencies and lower overall costs by helping to reduce the amount of time facility staff spend ordering and pulling supplies, such as cannulae, sterile tubing and arthroscopic resection blades for each procedure. Instead, the surgery center staff simply designates which supplies and devices the kits should contain. "There are devices we use in almost every procedure," said Dr. Joseph Abate of Fletcher Allen Health Care (Burlington, Vermont). "With the Dyonics Arthropak kit, you open the box and get everything the surgeon will want to use. For the facility, Arthropak kits offer increased efficiency and reduced costs." Each kit has its own SKU product identifier so when the time comes to replenish supplies, the purchasing staff can simply order a new kit instead of individual devices.

• **Zimmer Dental** (Carlsbad, California), a provider of dental rehabilitation products and a subsidiary of **Zimmer Holdings** (Warsaw, Indiana), reported the availability of the new Zimmer Surgical Motor System for surgical specialists who perform implantology and maxillofacial surgeries. The Zimmer Surgical Motor System offers programs with 20:1 and 1:1 reduction ratio to facilitate implant placement and also wisdom teeth and bone shaping/grafting procedures. The system includes a motor, console, one-piece disposable irrigation tubing and foot pedal. It offers a motor speed range of 300 rpm to 40,000 rpm and is compatible with a variety of handpieces.

PEOPLE IN PLACES

• Michael Adams has been named president/CEO of **CardioTech** (Wilmington, Massachusetts), replacing Dr. Michael Szycher. Adams has been serving as vice president of regulatory affairs and business development and will continue to serve in those capacities. CardioTech's board of directors also appointed William O'Neill as its new chairman. O'Neill has served on the company's board of directors since 2004. CardioTech manufactures products for the treatment of cardiovascular, orthopedic, oncology and other diseases. Its flagship product is CardioPass, a synthetic coronary artery bypass graft.

• Helen Barold, a cardiac electrophysiologist, has been named chief medical officer for **CryoCor** (San Diego) and will lead CryoCor's efforts to obtain regulatory approval for its Cardiac Cryoablation System for the treatment of atrial fibrillation and atrial flutter. Previously, Barold was a medical officer for the FDA, in the Office of Device Evaluation of the Center for Devices and Radiological Health, and is currently in the practice of cardiology and cardiac electrophysiology at the National Naval Medical Center (Bethesda, Maryland). CryoCor manufactures a disposable catheter system based on its proprietary cryoablation technology for the minimally invasive treatment of cardiac arrhythmias.

• Kelly McCrann has been appointed senior vice president for **DaVita** (El Segundo, California). McCrann most recently was president/CEO of PacifiCare Dental and Vision. DaVita provides services at kidney dialysis centers and home peritoneal dialysis programs in 41 states and the District of Columbia, serving some 98,000 patients.