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SEMDA 2013

Shuren says FDA addressing concerns with review process

By OMAR FORD
***Medical Device Daily* Staff Writer**

ATLANTA — For years medical device makers have fired off concerns and criticisms of the FDA's regulatory process – at times going so far as to call it unpredictable. Last week, during the Southeastern Medical Device Association's (SEMDA; Norcross, Georgia) annual conference held at the **Georgia Institute of Technology Global Learning Center** (Atlanta), med-tech firms got the chance to hear directly from the Center for Devices and Radiological Health's (CDRH) director – Jeffrey Shuren.

Shuren appeared via closed-circuit-television, citing that a challenging budget situation hindered him from being there in person. He told the audience that he would be following a similar format for all his talks in the country

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Forget optimism, worldwide pressures continue in 2013

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Last year at this time Richard Cohen, president of **The Walden Group** (Tarrytown, New York), had expected the healthcare market to start looking up in 2013 (*Medical Device Daily*, Feb. 22, 2012). That optimism was possibly too high, Cohen told *Medical Device Daily* last week after the firm released its annual Strategic Healthcare M&A report.

The industry continues to be impacted by "worldwide economic sluggishness" and the fact that healthcare reform is becoming a reality, Cohen says. Other factors at play include reimbursement challenges, accountable care, consolidation among hospitals and an increase in hospital-employed physicians.

"There are so many companies with technologies that have been approved but they are not getting high

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State of the Spine Industry

Evolution, fusion, and PODs head the list of concerns

By ROBERT KIMBALL
***Medical Device Daily* Staff Writer**

It is accepted practice that business and industry leaders benefit from periodic study of past and current market trends and situations, while also speculating on the future of the industry. Recently, analysts at **Wells Fargo Securities** (New York) did just that, and hosted a conference call on the state of the spine market. The featured speaker was John Peloza, MD, who is the founder and director of the **Center for Spine Care**, with three locations in Texas (Dallas, Frisco and Rockwall).

Peloza is an internationally recognized orthopedic surgeon specializing in spine care. He is a pioneer in minimal access technology and has performed more minimally

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Washington roundup

FDA releases draft guidance on recall versus enhancement

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

The meaning of the term "recall" has been a sore spot between FDA and device makers for more than a decade, and FDA reported in the Feb. 22 edition of the *Federal Register* that it has inked a draft guidance to distinguish between a recall of a faulty product and an enhancement to a product in distribution.

The *FR* announcement notes that device makers "may have trouble identifying whether a change to a device meets the definition of a recall" as well as "when FDA should be notified of a recall." FDA notes further, "continuous improvement activities, as part of an effective quality system, often have a favorable impact on medical device

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reimbursement, which is a motivator for getting anything out on the market," Cohen said.

According to the firm's report, the med-tech sector is undergoing "seismic changes and that companies adapting to the new environment will be in a better position to thrive, while those companies failing to change will be more likely to struggle. The firm also notes that since the great recession of 2008, sector organic revenue growth (effects of acquisitions and currency) and earnings growth declined significantly.

The better performers in the industry are those companies that have new standard-of-care technology that improves patient outcomes, enhances efficiencies for healthcare workers, and lowers overall costs. The report noted **Edwards Lifesciences** (Irvine, California) for its Sapien transcatheter aortic heart valve and **Intuitive Surgical** (Sunnyvale, California) for its DaVinci robotic surgical system as examples of companies that have performed well in the current environment.

"We are moving from a fee-for-service regime to a bundled payment regime," Cohen said when asked about some of the key takeaways of this year's M&A report. Healthcare providers are going to be more accountable for the quality of their care, patient outcomes and the cost of providing their care, he added.

This shift also is generating a lot of consolidation among hospitals and motivating a lot of physicians to join hospitals instead of running a private practice. Between 2000 and 2012, the number of specialty physicians employed by hospitals jumped from 5% to 25% and the number of employed primary care physicians doubled to about 40%, according to the report. The shift is driven in part by lower reimbursements for physicians and the pressure to invest in new technology such as electronic medical records. Meanwhile hospitals are driven to acquire private physician practices because of incentives to integrate services, reduce waste and improve care.

This makes for larger customers in the marketplace and such customers can only deal with a finite number of vendors, which in turn is going to continue adding pressure on smaller companies, he said. "You need feet on the street to better penetrate hospitals and call points in person," which is more difficult for a smaller company to do. Some such companies are already seeing the writing on the wall and selling out, he added.

Of course no discussion of the current healthcare environment would be complete without mentioning the higher and unclear regulatory burdens, which is another key point in The Walden Group's latest M&A report. According to the report, the number of days from submission to FDA 510(k) clearance increased every year from 2006 to 2010, rising 40% to 135 days over the five-year period.

The dreaded medical device tax and comparative effectiveness also play a role in the changing environment. "Comparative effectiveness . . . looks like it's a blueprint that is either going to be mandated or is going to be referenced in judging these more expensive advanced technologies versus less expensive alternatives that may be comparatively as effective," Cohen said.

On the flip side, technologies that work effectively and cost effectively will be rewarded, he said.

Med-tech companies will continue to review operations to gain efficiencies and leverage core operations with synergistic acquisitions. In some cases, the report notes, skillful diversifying acquisitions are being made. One noted example is **Agilent Technologies**' (Santa Clara, California) $2.2 billion acquisition of Danish cancer diagnostics firm **Dako** (*MDD*, June 22, 2012). Another, less recent but still significant, example is **C. R. Bard**'s (Murray Hill, New Jersey) acquisition of **Lutonix** (Minneapolis) for $225 million at closing with an additional $100 million upon PMA approval of Lutonix's drug-coated percutaneous transluminal angioplasty balloon (*MDD*, Dec. 21, 2011).

A key point the firm makes in the annual report is that as Western markets falter, medical device companies are looking to expand in China. Among the many examples, the report notes that **Stryker** (Kalamazoo, Michigan), **Johnson & Johnson** (New Brunswick, New Jersey), **Boston Scientific** (Natick, Massachusetts) and **Medtronic** (Minneapolis) have all invested in emerging markets such as China. ■

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People in the News

• **CombiMatrix** (Irvine, California) said Mark McDonough, currently the company's chief commercial officer, will become CEO following the retirement of CEO Judd Jessup, who has announced his retirement, effective March 15. McDonough came to CombiMatrix in 2012 with more than 15 years of experience in sales and business development with a specialty in diagnostics. CombiMatrix is a molecular diagnostics company.

• **Fibrocell Science** (Exton, Pennsylvania) said Christine St.Clare, a former KPMG partner, joined the company's board, serving as chair of the Audit Committee. St.Clare recently completed a 35-year career with KPMG where she served a four-year term on the firm's board and chaired the board's Audit and Finance Committee. Fibrocell Science is an autologous cellular therapeutic company focused on the development of innovative products for aesthetic, medical and scientific applications.