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FDA allows first mobile app to monitor and share glucose data

By Amanda Pedersen, Senior Staff Writer

Managing diabetes remotely just got easier. The FDA notified Dexcom (San Diego) late Friday that it would allow marketing of its Dexcom G4 Platinum continuous glucose monitoring (CGM) system with Share. The Dexcom Share receiver is designed to use a secure wireless connection via Bluetooth between a patient's receiver and an app on the patient's smartphone to transmit glucose information to apps on the mobile devices of up to five designated recipients, or "followers", without the need for a dedicated docking cradle. These followers can remotely monitor a patient's glucose information and receive alert notifications initially via their Apple iPhone or iPod touch and in the future on Android devices. The Share and Follower apps will be available

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Midwest sees steady funding flow, early stage investments elusive

By Omar Ford, Staff Writer

Midwest healthcare companies attracted \$1.8 billion in new investments across 243 companies in 2014 according to the BioEnterprise (Cleveland) Midwest Healthcare Growth Capital Report. The totals are the highest recorded in both dollars and number of companies funded since BioEnterprise began compiling the report in 2005, surpassing the banner 2007 by 46% and 2013 by 135%.

The Midwest Healthcare Capital Report includes medical device, biotechnology and software/service investments, specifically seed, venture, individual and group angel funding, private equity, growth equity, bridge funding, convertible debt, foundation funding with equity component, strategic and

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ASIA IN THE SPOTLIGHT

Asian demand to drive 'Internet of Things' toward medical devices

By Kristine Yang, Staff Writer

HONG KONG — Owing to strong economic growth, inadequate healthcare infrastructure, a large and aging population plus a swelling middle class, Asia's healthcare market is rightly seen as a source of significant growth potential for medical device manufacturers.

As a result, Asia is rapidly emerging as a destination for some of the most advanced healthcare technologies. The Internet of Things (IoT) is one of the more promising areas for such innovations in this part of the world.

"IoT is a phrase to describe the fact the Internet is used not

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INSIDE THE BELTWAY

DCRI's Robert Califf appointed as deputy commissioner of FDA

By Mark McCarty, Washington Editor

FDA reported Jan. 22 that it had appointed Robert Califf of Duke University (Durham, North Carolina) to the position of deputy commissioner for medical products and tobacco. The FDA statement indicates that Califf was the founder of the Duke Clinical Research Institute (DCRI; Durham, North Carolina) and that the former physician will "provide executive leadership" to the affected centers at the agency. The news suggests an interest in clinical trial science at the agency, given Califf's experience.

The FDA statement notes that Califf will "manage cross-cutting clinical, scientific and regulatory initiatives in several

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INSIDE

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IN \$43 BILLION COVIDIEN ACQUISITION
FDA CLEARS OLYMPUS' NBI FOR BETTER
VISUALIZATION OF BLADDER CANCER

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CARDIOLOGY EXTRA

Senior Staff Writer Amanda Pedersen
on one of med-tech's key sectors

[Read this week's Tuesday Special](#)

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FDA clears Olympus' NBI for better visualization of bladder cancer

By Amanda Pedersen, Senior Staff Writer

The FDA recently cleared Narrow Band Imaging (NBI) from **Olympus** (Center Valley, Pennsylvania), as enabling effective targeting of biopsies not seen under white light and improved visualization of tumor boundaries in non-muscle-invasive bladder cancer patients. Based on a weighted average, the aggregated FDA-reviewed studies show NBI has visualized NMIBC lesions in 17% additional patients when compared with white light; 24% additional tumors; and 28% additional carcinomas *in situ* (difficult-to-detect flat lesions).

Olympus said this provides new treatment opportunities for urologists both in-office and in the operating room. Additionally, it offers the potential for improved cost reduction and better patient outcomes resulting from earlier detection, the company noted.

NBI is a patented endoscopic light technology designed to enable effective targeting of biopsies not seen under white light without the use of dyes or drugs. NBI is not intended to replace histopathological sampling as a means of diagnosis, Olympus said. The technology is intended to enhance visibility of vascular structures on the mucosal surface. Unlike white light, which uses all colors in the spectrum, NBI uses only blue and green. Blue and green light are strongly absorbed by blood and appear darker than normal tissue. Blue light (415 nm) highlights the shallow capillaries and green light (540 nm) highlights deeper veins.

"We believe that NBI has the potential to revolutionize how bladder cancer is detected and treated, helping our customers meet the triple aim of healthcare reform by improving quality of care, decreasing costs and enhancing patient satisfaction," said Richard Reynolds, executive VP of sales, marketing and shared services in the Medical Systems Group at Olympus Corporation of the Americas.

In addition to urology, NBI has clinical applications throughout the anatomy including gastroenterology, pulmonary and rhinology (ENT). Olympus has received FDA-clearance for the screening and surveillance of Barrett's esophagus and is currently exploring other claims for NBI both in gynecology and general surgery.

Reynolds told *Medical Device Daily* that Olympus introduced NBI more than 10 years ago with varying degrees of success in the endoscopy community but this FDA clearance for the detection of bladder cancer is significant because it is based on several clinical studies the company has done over the past five to 7 years around the globe. Prior to that, NBI's potential visualization of bladder cancer symptoms had been acknowledged by the medical community, according to the company. More specifically, it is based on a 2013 meta-analysis that reviewed more than 30 disparate studies on the topic, which provided enough support to submit to the FDA, Olympus said.

"It is very apparent that by using NBI it provides clear detection of early stage lesions," Reynolds said.

From a product perspective, the technology is not something additional that existing customers would have to buy or invest in, he explained, because NBI is already built into Olympus' products. It's just a matter of switching it on if they already have an Olympus system, he said.

"The detection of occult lesions in patients with de novo and recurrent bladder cancer results in markedly improved outcomes," said Daniel Canter, vice chairman of the **Urologic Institute of Southeastern Pennsylvania** and the Department of Urology of the Einstein Healthcare Network and an associate professor at **The Fox Chase Cancer Center**. "An improved view into the underlying vascularity of the lining of the bladder means an improved ability to detect and treat not just the visible, obvious tumors but also the lesions that may have been missed with traditional white light cystoscopy only. This is something most urologists have known and would agree with, but it is now backed by the FDA, which should translate into improved patient care." //

PEOPLE IN PLACES

- Kevin Fitzpatrick has been named executive VP and chief innovation officer of the **American College of Cardiology** (Washington). The ACC says it is committed to fulfilling its mission to provide the best possible care to patients while supporting efforts to improve heart health around the world.

- **CentraState Medical Center** (Freehold, New Jersey) has named Michael Greller, president of advanced orthopedics and sports medicine institute in Freehold, has been elected assistant chief of the medical staff at CentraState. Dr. Greller has been a member of the staff at CentraState Medical Center since 2000, as chairman of credentials and vice chairman of the department of orthopedic surgery.

- **Cook Medical** (Bloomington, Indiana) said Cynthia Kretz, who has served as general counsel since 2008, has been promoted to VP, general counsel. Prior to joining Cook, Kretz served Wabash National from 1999-2007 where she formed the legal department and eventually served as VP, general counsel and secretary to the board of directors. Cook Medical has worked closely with physicians to develop technologies that eliminate the need for open surgery.

- **EyeCare Services Partners Holdings** (Baltimore) reported the addition of two new senior executives to the company's management team: David Thomas will become president and chief operating officer; and Christopher Fusco will become VP of business development. The company also said that Richard Edlow, who served as ESP's president, will be elevated to the role of executive chairman. Previously, Thomas was a managing partner and board director at Alva Labs. Fusco led business development for Dermatology Solutions Group. EyeCare Services Partners Holdings consolidates locally dominant, clinically differentiated eyecare services practices and affiliated surgical centers in selected geographies.