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India to Get First Device Park; AIMED Partners With Academia

With an eye toward reducing India's dependence on imported medical devices, the country's Association of Medical Device Industry is touting separate initiatives intended to boost Prime Minister Narendra Modi's 'Make in India' program.

Specifically, Shri Chandrababu Naidu, the chief minister of Andhra Pradesh, met with representatives of the association to discuss how to bolster the industry in India. As a result of the discussions, Naidu has decided to invest in a 200-acre medical device park — the first of its kind in that country.

The park will have a common manufacturing facility center to act as a hub for the small- and medium-sized enterprises sector, says Rajiv Nath, forum coordinator of AIMED.

(See **India***, Page 2)*

HPRA: More Than 900 Defibrillators May Fail to Work in Emergency

Ireland's Health Products Regulatory Authority is urging organizations — including schools, shopping centers and restaurants — to ensure their automated external defibrillators have undergone safety and maintenance updates after determining that more than 900 may not work as intended.

Specifically, roughly 940 AEDs in Ireland made by three manufacturers have not had an important corrective action completed. "We know that the manufacturers concerned have attempted to contact the owners directly with some also using national advertising to highlight the importance of carrying out the required upgrade or battery check," says Anne Tobin, HPRA's medical devices vigilance manager, in a prepared statement.

The models are: Physio Control's Lifepak CR Plus and Lifepak 1000, Zoll's AED Plus, and HeartSine's Samaritan PAD, 300, 300P and Samaritan 500P.

(See **Defibrillators***, Page 6)*

India, *from Page 1*

Efforts will focus on creating an ecosystem for high-end medical device manufacturing and import substitution with an eye for the export market, says Jitendar Sharma, head of the health technology division of the National Health Systems Resource Centre at the Ministry of Health & Family Welfare.

Nath says Naidu also promised to address industry's concerns at the state and national level to make India a manufacturing hub for medical devices and follow in the footsteps of the pharmaceutical sector. Currently, India imports roughly 70 percent of its medical devices. The "Make in India" program is aiming to boost domestic manufacturing in a number of sectors, including medical devices.

Academia Collaboration

In addition, AIMED has announced the UdaiMed forum in collaboration with the Sree Chitra Tirunal Institute of Medical Sciences and Technology.

According to the association, the initiative is needed because R&D institutions and engineering colleges do product development in isolation and industry has little or no idea of work being done. Often the research has no relevance for industry, says Nath.

Provided that the goals and objectives of the joint initiative are fulfilled, it is sure to be a shot in the arm for the Indian medical devices industry's pursuit of innovation and growth as a global R&D hub, says Vijay Venkatraman, managing director and CEO at consulting firm Oviya MedSafe.

"Bridging the disciplines of medicine, engineering, information technology and biotechnology is a very significant step in this direction, and UdaiMed could be one of the best engines to make that happen," Venkatraman tells *IDDM*. — Jonathon Shacat

Publication of ISO 13485 Expected Next Spring

A new version of ISO 13485 is expected to be published next spring, following revisions that have been under way since 2011.

ISO 13485 outlines a comprehensive quality management system for the design and manufacture of medical devices.

Some of the key changes to the new ISO 13485 include:

- Harmonization of regulatory requirements;
- Inclusion of risk management throughout the QMS;
- Additional clarity regarding validation, verification and design activities;
- Strengthening of supplier control processes;
- Increased focus on feedback mechanisms; and
- Software for QMS, manufacturing and devices.

The current revision of 13485 represents a significant update to the overall quality management process, bringing it in line with current industry practices, says Wil Vargas, director of standards at the Association for the Advancement of Medical Instrumentation.

"Another big impact is the inclusion of risk management throughout the QMS and not to treat it as a completely separate process. This inclusive systems approach will certainly make a positive impact to the overall medical device life cycle," he tells *IDDM*.

ISO 13485 does not align with ISO 9001:2015, but manufacturers will have a three-year transition period to reconcile the differences, says Vargas.

The ISO Technical Committee will discuss developing an understanding of the gaps that exist to the regulatory requirements, and where there are requirements in ISO 9001:2015 that are over and above the regulatory requirements, he says. — Jonathon Shacat

Endoscopes Top List of Tech Hazards in ECRI Institute Report

Flexible endoscopes have topped ECRI Institute's 2016 list of the top 10 health technology hazards, following a series of fatal infections associated with duodendoscopes that were inadequately reprocessed.

The list highlights concerns that the instrument's complex design and long, narrow channels can contribute to inadequate disinfection and sterilization. If biologic debris and other foreign material are left behind on the instruments as a result of improper cleaning, then disinfection and sterilization may not be effective, ECRI says.

To that end, facilities need to emphasize to their reprocessing staff that inattention to the cleaning steps can lead to deadly infections, ECRI adds.

The ascent of endoscopes to the top of the list caps a year of regulatory actions on the instruments. For example, in March, the FDA issued final guidance strengthening controls on reprocessing in response to the outbreak of antibiotic-resistant bacteria linked to duodenoscopes (*IDDM*, March 13). Last month, the FDA's Center for Devices and Radiological Health named proper reprocessing of reusable medical devices as one of its top challenges it hopes to tackle as part of its regulatory science priorities for fiscal year 2016 (*IDDM*, Oct. 23).

Endoscopes pushed the list's perennial number 1 hazard, safety risks from clinical alarms, to the number 2 spot.

The remaining hazards are as follows:

- Failure to monitor postoperative patients for opioid-induced respiratory depression;
- Inadequate surveillance of patients monitored in a telemetry setting;
- Insufficient training of clinicians on operating room technologies;
- Errors resulting from health information technology configurations and facility workflow not supporting each other;
- Unsafe injection practices exposing patients to infectious agents;
- Gamma camera mechanical failures leading to serious injury or death;
- Failure to appropriately operate intensive care ventilators, resulting in lung injury; and
- Misuse of USB ports leading to medical device malfunction. — Jonathon Shacat

Medical Supply Company Owner Convicted in Medicare Fraud Case

A federal jury has convicted the owner of a Los Angeles-area medical supply company for his role in a $4 million Medicare fraud scheme in which he submitted claims for durable medical equipment that either was not medically necessary or was never provided to beneficiaries.

Valery Bogomolny, 43, owner and president of Royal Medical Supply, was convicted Nov. 6 of six counts of healthcare fraud.

The U.S. Department of Justice says Bogomolny received $2.7 million related to false claims for power wheelchairs, back braces and knee braces through his scheme, which lasted between January 2006 and October 2009.

Bogomolny created false documentation to support his billing claims, including reports of home assessments that never occurred. Also, he personally delivered power wheelchairs to beneficiaries who were able to walk without assistance and signed documents falsely stating he had delivered equipment, the DOJ says.

The six counts are representative of the underlying scheme, but the court will consider the entire $2.7 million fraud amount at sentencing, says DOJ spokesman Peter Carr.

Bogomolny is scheduled for sentencing on Feb. 29, 2016, before Judge James Otero of the U.S. District Court for the Central District of California. Each count of healthcare fraud carries a maximum penalty of 10 years in prison.
— Jonathon Shacat

China's FDA Issues Order on Quality Supervision, Other Notices

Hospitals and other healthcare institutions must follow certain administrative measures for quality supervision on the use of medical devices, under a new regulation issued by China's FDA that focuses on procurement, maintenance, supervision and documentation.

The regulation, which takes effect Feb. 1, 2016, includes reminders to follow the rules, such as procurement needs to go through proper channels and only use CFDA-approved devices, says Helen Chen, head of L.E.K. Consulting's China life sciences practice.

"There are explicit statements that the Western audience would consider standard, such as the expectation that equipment should be properly maintained. That the CFDA would actually need to outline these steps explicitly is a sign that they recognize the variability within the Chinese hospital system, and that they want to get to a reasonably uniform standard around medical technologies management," she tells *IDDM*.

Chinese health regulators also are encouraging hospitals to leverage information technology for document retention tracking, ranging from five years after the service of an instrument to indefinite maintenance of the initial intake inspection records for implants, says Chen. Building hospital information technology infrastructure is one of the initiatives introduced as part of the 12th Five-Year Plan in 2011.

The CFDA makes it clear that it is serious about the violations, setting fines of up to $3,150.

In addition, the regulator issued a notice on interprovincial corporate registration, giving examples of what happens when companies are setting up, transferring or shutting down operations between two provinces. The information is geared towards domestic devicemakers, Chen tells *IDDM*.

The CFDA also issued a notice on implementing registration management practices for devices and in vitro diagnostic reagents. The document, released in response to questions about standards that took effect Oct. 1, 2014, clarifies topics such as biological testing, says Jack Wong, director of regulatory affairs for Asia Pacific in TerumoBCT's Singapore branch.

The agency also posted a document interpreting the medical device regulation to address confusion expressed by applicants regarding the registration process, such as which kind of changes are necessary to apply for modified registration and what are the requirements for notarization, Wong tells *IDDM*.

Read the administrative measures on quality management here: www.fdanews.com/11-15-CFDA-18.pdf. The notice on inter-provincial corporate registration is here: www.fdanews.com/11-15-CFDA-203.pdf. The interpretation of registration regulations is here: www.fdanews.com/11-15-CFDA.pdf. The notice on implementing registration management practices is here: www.fdanews.com/11-15-CFDA-247.pdf.
— Jonathon Shacat

GAO: Few FDA-Ordered Postmarket, Postapproval Studies Are Completed

A lawmaker is taking the FDA to task after a Government Accountability Office report determined that more than 70 percent of postapproval studies ordered by the agency since January 2007 are ongoing.

The report, requested by Rep. Rosa DeLauro (D-Conn.), examines the types of devices for which the FDA had ordered postapproval or postmarket surveillance studies, as well as their status — completed or ongoing. For ongoing studies, the GAO also examined whether adequate progress had been made or if the studies were delayed or inactive.

Putting Patients First

According to DeLauro, the GAO findings point out that medical devices are being put on the market without adequate evidence of their safety and effectiveness.

"People are not guinea pigs, and we should not be rushing devices to market," she says in a prepared statement. "I will continue to monitor this situation closely to determine whether Congress should be taking action."

According to the report, only 20 percent of postapproval studies ordered (62 of 313) had been completed, while another 8 percent were inactive. However, of the ongoing studies, 81 percent were progressing adequately, while the other 19 percent were delayed, as of February.

Although the report found that 88 percent of postmarket surveillance studies ordered were inactive (344 of 392), the GAO determined that 31 percent had been consolidated into another study. Another 31 percent had been terminated either because the manufacturer changed the indication or had demonstrated the objective of the study using publically available data. The remaining inactive studies didn't fit in either category for a number of reasons, including the device is no longer on the market.

Most of the postapproval studies focused on cardiovascular devices, such as stents and heart valves. Researchers and others have raised questions about FDA's oversight of the studies, including whether the agency ensures that they are completed, the GAO says.

Read the report here: www.fdanews.com/11-15-GAO-Report.pdf. — Jonathon Shacat

Sientra Sees Shake Up As CEO, Chair Step Down

Weeks after it put a temporary hold on all U.S. sales of devices made by a Brazilian contract manufacturer, Santa Barbara, Calif.-based Sientra has announced that founder and CEO Hani Zeini is stepping down.

Zeini will be replaced by board member Jeffrey Nugent, former head of Biolase. Zeini will continue to serve on the company's board and in a consulting capacity.

Zeini isn't the only Sientra executive making a change. Nicholas Simon is stepping down from his role as chairman, but will remain on the company's board. Meanwhile, the company says Joel Smith is resigning as general counsel, chief compliance officer and corporate secretary, effective immediately.

The company is scheduled to provide its third quarter results today.

Margaret Kaczor and Scott Schaper of William Blair say the announcement comes "somewhat of a surprise," adding that they view the underlying assets of Sientra as "valuable."

Brazilian Problems

In late September, the UK's Medicines and Healthcare products Regulatory Agency, along with other European health regulators, suspended CE certification for all products made by Brazilian contract manufacturer Silimed after particle contamination was discovered during a facility

(See **Sientra**, *Page 6)*

FCC Proposes Amending Rules For Hearing Aid Compatibility

A Federal Communications Commission proposal to amend hearing aid compatibility rules is coming under fire from one commissioner, who is concerned that some of the ideas expressed in the plan would allow for "inappropriate" FCC intervention in the standards development process.

Commissioner Michael O'Rielly voiced his concerns related to an FCC proposal intended to amend hearing aid compatibility rules. Its goal is to ensure that Americans with hearing loss are able to access wireless and wireline communications services through a wide array of phones.

To achieve this, the FCC would incorporate into its rules a revised industry standard developed by the Telecommunications Industry Association to help people with hearing loss select wireline phones with sufficient volume control. It also proposes to adopt a volume control rule and standard for wireless handsets, and to require manufacturers to use the 2011 American National Standards Institute wireless HAC standard for certifying future handsets.

O'Rielly says he mostly supports seeking comment on potential changes in volume control standards and other hearing aid compatibility rules. However, he raised concerns over seeking comment on how to implement the Twenty-First Century Communications and Video Accessibility Act.

O'Rielly disagrees with how the commission may interpret Congress's directive that the technical standard must be developed in consultation with standard-setting bodies.

"So, let me get this straight, staff will be able to designate an unlimited number of entities to sway the decisions of a so-called independent standards setting body and then have the right to codify the standard that they influenced. That could not possibly be the Commission's, or Congress's, intent and places the Commission's objective to be technologically neutral at great risk," he says.

Comments are due by Dec. 29. Read the notice of proposed rulemaking here: www.fdanews.com/11-15-FCC-NPRM.pdf. — Jonathon Shacat

Defibrillators, *from Page 1*

The HPRA advises owners of these AEDs to respond to requests from the manufacturer or supplier of their device. The owners also should ensure manufacturers have their correct contact details to keep them informed of necessary safety upgrades.

In addition, the HPRA warns that weather temperatures will affect a defibrillator's performance, and all AED devices should be stored correctly and regularly checked during over the winter.

AEDs recently have been a source of safety concerns. Between January 2005 and September of last year, the FDA received 72,000 adverse event reports involving the devices. During the same period, manufacturers staged 111 recalls involving more than 2 million AEDs, many of which were due to design and manufacturing issues.

In January of this year, the FDA issued a final order to require the filing of premarket approval applications for AEDs. (*IDDM*, Jan. 30).
— Jonathon Shacat

Sientra, *from Page 5*

inspection (*IDDM*, Sept. 25). Sientra, which uses Silimed, subsequently put a hold on sales of products manufactured by the Brazilian company.

The plot thickened last month, after a fire broke out at a Silimed facility that manufactures Sientra's breast implants. During a call, Zeini said the circumstances surrounding the Oct. 22 fire "remain under review," and Brazilian authorities are investigating. At the time of the call, the extent of the damage was unknown.

Silimed had informed Sientra that another smaller building could be modified to manufacture the implants. Doing so would require the reconfiguration of certain areas in the facility, as well as certification and approval by appropriate regulatory authorities.

Zeini added that Sientra would examine all of its options, including alternative manufacturing arrangements. — Elizabeth Hollis

Industry, FDA Move Forward On MDUFA IV Priorities

With negotiations on the fourth installment of the Medical Device User Fee Amendments moving ahead, medical device companies appear to be pleased with how the process is progressing, at least according to one industry insider.

"Industry, from what I understand, is happy with the way it is going," says Matthew Weinberg, CEO of The Weinberg Group in Washington, D.C. His comments come ahead of a Nov. 18 meeting, during which FDA officials and industry stakeholders will continue discussions to move the process forward.

The process kicked off at a July meeting at the agency's White Oak campus in Silver Spring, Md., during which officials heard feedback from industry about what worked well during MDUFA III, as well as what could be improved (*IDDM*, July 17). Subsequent meetings examined the agency's guidance process and capabilities and limitations of the device center's information technology systems.

At an Oct. 26 meeting, stakeholders and FDA officials nominated priorities for MDUFA IV, including: Incorporating patient perspectives in FDA reviews; using data from device and patient registries more efficiently for pre- and postmarket purposes; and coordinating FDA's work in areas such as combination products and companion diagnostics to ensure adequate user fee funding.

Stakeholders are trying to make sure the rules are logical, Weinberg says. If they are going to continue to pay for user fees, they want to make sure they are getting what the FDA promises, he adds. "The real question is, will the agency work in timely manner and allow for appropriate throughput of products as MDUFA promises," Weinberg tells *IDDM*.

The Oct. 26 meeting minutes on MDUFA IV negotiations are here: www.fdanews.com/11-15-MDUFA-Meeting.pdf. — Jonathon Shacat

House Bill Seeks to Withdraw Bayer's Essure From the Market

Efforts to remove Bayer's implantable contraceptive Essure from the market continue to mount, with the introduction of a House bill that would require the FDA to withdraw premarket approval of the device.

H.R. 3920, The E-Free Act, was introduced by Michael Fitzpatrick (R-Pa.) on Nov. 4 and is co-sponsored by Reps. Marsha Blackburn (R-Tenn.), Christopher Smith (R-N.J.) and non-voting member Gregorio Sablan (I-N. Mariana Islands). The bill was referred to the House Energy and Commerce Committee that same day.

The move has been met with applause from stakeholders. For example, Diana Zuckerman, president of the National Center for Health Research, says the introduction of H.R. 3920 shows that some members of Congress wondering why the FDA has lowered its scientific standards, and are pushing the agency to do a better job of protecting patients.

"Our research shows that Essure is much more dangerous than was shown in the data provided to the FDA — data that are still on the FDA website," Zuckerman tells *IDDM*. That information, she adds, misleads patients, many of whom have been harmed by the implant.

The FDA never should have approved Essure based on a study with no comparison group of women using a different type of long-term or permanent contraception, says Zuckerman. Further, the company's studies of Essure were conducted in a way that covered up terrible complications reported by patients.

The bill's introduction comes less than a month after Rep. Rosa DeLauro (D-Conn.) sent a letter to Acting FDA Commissioner Stephen Ostroff asking the agency to remove the device from the market (*IDDM*, Oct. 16).

Bayer, which acquired Essure when it bought Conceptus in 2013, has acknowledged that there are risks associated with the device, but insisted the implant has helped many women.

Bayer did not respond to a request for comment on H.R. 3920 by press time. Read the bill here: www.fdanews.com/11-15-HR3920.pdf. — Jonathon Shacat

BRIEFS

Medtronic Launches VenaSeal Closure System

Medical device giant Medtronic has launched its VenaSeal closure system in the U.S. The minimally invasive VenaSeal procedure uses a medical adhesive to close superficial veins of the lower extremities in patients with symptomatic venous reflux. It is the first and only nontumescent, nonthermal, nonsclerosant procedure approved to treat symptomatic venous reflux in the U.S., the Irish devicemaker says. The system is available in the U.S., New Zealand, Chile, South Africa, Australia, Canada, Europe, United Arab Emirates and Hong Kong.

Boston Scientific Purchases Radiology Portfolio

Boston Scientific has reached an agreement to acquire the interventional radiology portfolio of CeloNova Biosciences. Under the transaction — which consists of an upfront payment of $70 million with the potential for additional milestone payments — Boston Scientific will acquire microspheres designed to be loaded with chemotherapy drugs for delivery to cancerous tumors and spherical embolic products for the treatment of uterine fibroids and other conditions. The transaction is expected to close by the end of 2015.

FDA Grants Indication Clearance to Si-Bone's

San Jose, Calif.-based Si-Bone has received FDA clearance to include in the iFuse implant system's indication statement that the device improved pain, patient function and quality of life at 12 months post-implantation. This addition was based on a series of prospective and retrospective clinical studies, according to the company. The iFuse system is a minimally invasive surgical device indicated for sacroiliac fusion for certain disorders of the sacroiliac joint.

Biological Dynamics Secures Financing

Molecular diagnostics company Biological Dynamics has completed a round of $26.8 million Series C financing to advance regulatory clearance for its lead oncology diagnostic program, the TR(ACE) assay, and for general working capital purposes. The financing was led by a large institutional investor associated with a major university. Existing investors Heritage Group, Alexandria Venture and Irwin Jacobs also participated in the round. The San Diego, Calif.-based diagnostics company has incorporated alternating current electrokinetics technology in the field of molecular diagnostics. For example, its lab-on-chip platform isolates nanoparticles from high conductance physiological solutions such as whole blood, plasma and serum directly without the need for dilution. The TR(ACE) assay uses the platform to assist clinicians in evaluating whether a patient undergoing cancer therapy is responding.

Roche Launches Ventana HE 600 System

Roche has unveiled its Ventana HE 600 system, a hematoxylin and eosin tissue staining system intended to enhance patient and technician safety. The system brings improved consistency and quality in tissue staining by delivering fresh reagents on each individual slide without relying on user-supplied alcohol and deionized water, according to the company. The system is now available worldwide, excluding Latin America. It will be available in that region in early 2016.

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Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editor: Jonathon Shacat
(703) 538-7663
jshacat@fdanews.com

Ad Sales: Jim Desborough
(703) 538-7647
jdesborough@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
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Reporters: Kellen Owings, Michael Cipriano, Victoria Pelham, Cameron Ayers
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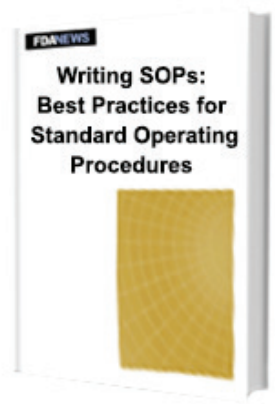

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