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IN THIS ISSUE

Congress Passes 21st Century Cures Act

After more than a year of work, the Senate yesterday gave final congressional approval to the 21st Century Cures Act in a 94-to-5 vote.

The bill now goes to President Barack Obama, who said he plans to sign it into law as soon as it reaches his desk. The House passed the bill last week, 392-to-26.

The legislation establishes a program to speed up development of devices featuring "breakthrough" technologies that are designed to diagnose or treat serious conditions and have no approved or cleared alternatives. The program builds on the FDA's Expedited Access Pathway, chiefly by permitting access to 510(k) devices (*IDDM*, Dec. 2).

(See **Cures**, *Page 6)*

Califf and 14 FDA Officials Look to Temper Expectations for Real-World Evidence

Fifteen FDA officials, including Commissioner Robert Califf, called for broader uses of research methodologies, such as intervention and randomization, in real-world settings outside the typical venues of clinical trials.

But they cautioned against expectations for "quick wins" in saving time and money in development, and asked for appropriate expectations of what the data can illustrate.

In an opinion piece in the New England Journal of Medicine, they said that in order to gain confidence in the use of real-world studies, their distinguishing characteristic must be defined as the context in which the evidence is gathered, such as under clinical care or in home or community settings. The distinction should not be based on interventions or randomizations of participants, because those methods are entirely compatible in the real-world setting, they said.

Limitations in source data could lead to flawed conclusions, they wrote. However, the authors were optimistic that the data can add

(See **Evidence**, *Page 2)*

Written MDR Procedure Lands Miramar Labs a Form 483

Miramar Labs' Inc. received a Form 483 after an inspection revealed defects in its medical device reporting (MDR) procedures and other issues.

When Miramar's Santa Clara, Calif., facility was inspected from July 25 to Aug. 1, investigators discovered that the company's written MDR procedure did not include a way to ensure timely and effective identification, communication, and evaluation of events that might have required reporting.

In particular, the MDR procedure did not have instructions to file MDRs for overseas incidents reported to foreign authorities for devices also marketed in the US. For example, the company filed a report in Belgium related to a patient complaint about its sweat-reduction microwave treatment miraDry, but did not file an MDR for this incident in the US where the product is also sold.

Investigators also said that Miramar failed to document all corrective and preventive actions according to its written procedures.

The full letter can be read here: www.fdanews.com/12-05-16-miramarlabsinc483.pdf.

Evidence, *from Page 1*

important perspectives to medical device assessments, generate hypotheses for prospective trials, help generalize findings from controlled trials, and measure quality in health care delivery.

Prospective registries or single-group trials with external controls have been accepted for regulatory purposes in evaluating medical devices, but because refinements are made over the course of a product's life cycle, substantial knowledge is available tracking treatment effects and confounding factors.

The authors said they plan to hold public workshops and meetings on real-world evidence, and ultimately publish draft guidances. Indeed, such steps will soon be required of the agency, following the enactment of the 21st Century Cures Act passed by Congress.

The FDA and others are also currently working to develop a system that would combine real-world data with patient registries to monitor safety and effectiveness, they wrote, and the agency plans to develop policy for both drugs and devices under the proposed reauthorization of PDUFA VI next year, as well as in the fourth iteration of the Medical Device User Fee Amendments. — Conor Hale

Final Order Puts Computerized Cognitive Aids in Class II

On the heels of approving two devices that help evaluate brain function after an injury or suspected concussion, the FDA has placed all similar devices into Class II and listed required steps to limit misevaluations.

In August, the FDA granted approval to Impact Applications' Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) device and ImPACT Pediatric. These were the first devices the FDA indicated for cognitive testing after a brain injury (*IDDM*, Aug. 25).

An FDA final order terms all devices similar to ImPACT and ImPACT Pediatric "computerized cognitive assessment aids for concussion" and requires special controls to mitigate risks of false positives. These controls include clinical performance testing; software verification, validation, and hazard analysis; and specific labeling.

The labeling must include a summary of any clinical testing conducted to show that the device works properly; warnings that the device should only be used by trained health care professionals, does not identify the presence or absence of a concussion or make other clinical diagnoses, and is not a stand-alone diagnostic; and any instructions technicians must convey to patients.

After the final order's Dec. 6 effective date, any firm submitting a premarket notification for a computerized cognitive assessment aid for concussion has to comply with these special controls.

Read the final order here: www.fdanews.com/12-05-16-concussiondevice.pdf. — Jeff Kinney

Aesculap Gets Form 483 For Untimely Reports

Aesculap Inc. was cited in a Form 483 for neglecting to file timely medical device reportable (MDR) events and establish timely corrective and preventive actions in response to complaints.

A September inspection of Aesculap's Hazelwood, Mont., facility discovered that the surgical instrument manufacturer had not filed about 25 medical device reportable events within 30 days of learning that one of its devices may have caused or contributed to a death or serious injury. Sixteen of the 25 late reports resulted from not entering complaints into the firm's complaint handling system in a timely manner.

The inspector also found that Aesculap failed to establish a timely corrective and preventive action report after learning of a significant quality system deviation. The firm became aware in October 2015 that 16 complaints were not entered into its complaint handling system and thus were not given MDR determinations. However, no corrective action was established until June 30, 2016.

The full letter can be read here: www.fdanews.com/12-06-16-Aesculap483.pdf.

Higher Heart Failure Rates Found In MoM Implant Recipients

A recent Australian study suggests a higher incidence of first hospitalization due to heart failure among a group of male patients with ASR XL metal-on-metal (MoM) hip implants when compared to a similar group who received metal-on-polyethylene (MoP) implants.

However, the authors said more work is needed to establish whether having an ASR XL implant actually causes a higher incidence of heart failure.

According to Australia's TGA, mounting evidence suggests that because the two moving parts of a MoM hip implant wear against each other, they can release trace amounts of cobalt and chromium, especially during the first 18 months after the operation.

The study authors found no evidence of a higher rate of heart failure in either female patients with ASR XL implants or in patients of either gender who had another type of MoM implant, compared with patients who received MoP implants.

The TGA said the study has several limitations, including that there were only 121 ASR XL recipients in the cohort and that the participants' median age was relatively high compared to Australia's general population. As a result, the implications of the study for following up with patients who have an ASR XL implant are uncertain, and TGA is facilitating another study using a much larger group of patients.

Read the entire study here: www.tandfonline.com/doi/full/10.1080/17453674.2016.1246276.
— Jeff Kinney

Lack of Corrective Action Procedures Earn Hansen Ophthalmic Form 483

Hansen Ophthalmic Development Lab, Inc., received a Form 483 for not establishing procedures for corrective and preventive action, and for not maintaining a complete device history record.

Inspectors visited Hansen's Coralville, Iowa, facility in October and found that the company had failed to establish and implement procedures to document corrective actions from identified quality system deviations and other sources.

The inspectors also found that a Class II medical device's history record was incomplete. Specifically, Hansen failed to establish, implement, and document procedures describing the assembly and testing of the device's electrodes. The device history record also lacked documentation related to dimensional or functional testing.

Read the entire letter here: www.fdanews.com/12-05-16-hansenopthalmicdevelopmentlabinc483.pdf.

TGA Halts Study on St. Jude Medical Nanostim Leadless Pacemaker

Australia's TGA has issued a warning and halted a clinical study of St. Jude Medical's Nanostim leadless cardiac pacemakers due to battery malfunctions.

The pacemakers were implanted in 22 Australian patients as part of the Nanostim Leadless II IDE/CAP clinical study, which has been halted. The company reported that 0.5 percent of the implanted Nanostim leadless cardiac pacemakers have experienced battery malfunction.

The study was being conducted at 56 centers in the U.S., Canada and Australia. To date, 1,423 devices have been implanted worldwide, according to St. Jude Medical.

There have been seven reports of patients participating in the study who experienced loss of telemetry and pacing. Each of those cases occurred more than two years after implantation. No injuries were reported. Symptomatic bradycardia was identified in one patient, St. Jude Medical said.

The other six patients were asymptomatic, and the device malfunctions were discovered during routine scheduled follow-up visits. The company said that no injuries were reported.

According to an analysis of the first 300 patients in the study, serious adverse events were observed in 6.7 percent of patients in the primary analysis cohort at six months post implantation. Those events included device dislodgement, cardiac perforation and pacing-threshold elevation. An FDA advisory committee said that those results provided reasonable safety assurance.

Leadless cardiac pacemakers, like standard pacemakers, deliver electrical impulses to treat slow heart rate. Unlike a standard pacemaker, a leadless cardiac pacemaker is implanted into the patient's heart via a catheter into the right ventricle and does not require a pacing lead, connector, or pulse generator pocket.

Read the TGA safety notice here: www.fdanews.com/12-02-16-StJudeAustralia.pdf. — Tamra Sami

FDA Will Not Enforce Certain Requirements for Hearing Aid Sales

The FDA will not enforce existing medical evaluation or recordkeeping requirements for the sale of air-conduction hearing aids to people 18 and older, in an effort to improve accessibility of the devices.

Under guidance that is effective immediately, the FDA will not enforce regulations requiring all prospective hearing aid users to be evaluated by a licensed physician no more than six months before receiving the device. It also will not enforce regulations requiring dispensers to retain copies of medical evaluations.

The FDA said that according to recent reports, the medical evaluation requirement provides little patient benefit and can present an unnecessary barrier to access.

The guidance applies to Class I air-conduction and Class II wireless air conduction hearing aids. It does not apply to Class II bone-conduction hearing aids.

The agency will continue to enforce an existing regulation requiring dispensers to give prospective users, prior to the sale, an instructional brochure containing specific labeling that applies to all hearing aid devices. The brochure must include:

- General instructions for use, maintenance, and service;
- A statement that hearing aids will not restore normal hearing;
- A warning advising dispensers to promptly refer any prospective user to a licensed physician if the dispenser detects certain listed medical conditions that may indicate a medically treatable cause of hearing loss;
- A notice stressing the importance of a medical evaluation; and
- Technical data useful in selecting, fitting, and checking the performance of a hearing aid.

Read the guidance here: www.fdanews.com/12-07-16-hearingaids.pdf. — Jeff Kinney

UK Issues Safety Notices for Milling Handpiece, Anesthesia Devices

The UK's Medicines and Healthcare products Regulatory Agency released urgent field safety notices for a range of medical devices, including Zimmer Biomet's patello-femoral joint milling handpiece, Avance and Amingo anaesthetic machines and monitors, and Fujifilm's flexible duodenoscope.

Zimmer Biomet issued an urgent field safety recall for all distributed Gender Solutions PFJ Milling Handpieces, following complaints of inoperability. The complaints were related to a lack of preventative maintenance.

The affected units were distributed between September 2007 and August 2016.

The company said an inoperable handpieces may result in surgical delay and or increased risk of infection. There are no specific patient monitoring instructions related to this field action, and company representative can check the functionality of specific handpieces. Malfunctioning handpieces should be returned to Zimmer Biomet.

Read the Zimmer Biomet notice here: www.fdanews.com/12-08-16-Zimmer.pdf.

Avance and Amingo Safety Issues

Datex-Ohmeda issued an urgent field safety notice that certain Avance CS2, Avance, and Amingo anesthesia devices can show a system malfunction if the lower storage drawer containing the optional large tray insert accessory is closed with too much force.

The notice says that if the devices show a system malfunction, they will:

- Automatically activate alternate oxygen flow within a few seconds;
- Provide high priority audible and visible alarms;
- Provide on-display instructions to set the oxygen flow and manually ventilate the patient; or
- Continue to deliver anesthetic agent at the existing vaporizer setting.

The company said an unresolved system malfunction could result in loss of patient ventilation and hypoxia. However, there have been no injuries reported as a result of this issue.

All Avance CS2, Avance, and Amingo anesthesia devices with the optional large tray insert accessory installed are susceptible to the problem. Datex-Ohmeda said the devices may continue to be used after the large tray insert is removed, and it provided instructions for doing so.

The company asked clinical users receiving the notice to destroy all large tray inserts in their possession.

The large tray insert can also be used with the Aespire family of devices, but they are not susceptible to this issue. The small tray insert does not pose a problem.

Read the Datex-Ohmeda notice here: www.fdanews.com/12-08-16-DatexOhmeda.pdf.

Fujifilm Duodenoscope Operations Manuals

Fujifilm issued an urgent field safety corrective action noting that revised operations manuals have been issued for its ED-530XT and ED-530XT8 Duodenoscope.

The revised manuals reflect newly validated manual cleaning and high-level disinfection procedures in light of reports of multi-drug resistant bacteria on endoscopes used for endoscopic retrograde cholangiopancreatogram procedures. The company has been working with the FDA to validate the new reprocessing procedures.

The revisions modify the cleaning and disinfection processes and require the use of a new disposable distal end cleaning brush for cleaning the duodenoscope's distal tip, forceps elevator, and elevator recess, in addition to the use of the existing Fujifilm valve cylinder cleaning brush.

Fujifilm is providing all users of the devices with revised operations manuals and samples of new disposable distal end cleaning brush.

Read the Fujifilm notice here: www.fdanews.com/12-08-16-Fujifilm.pdf.

TGA Issues Alerts for MoM Implants, Knee Replacement Inlays

Australia's TGA has issued hazard alerts for Microport Orthopedics metal-on-metal (MoM) hip implant components and Mathys Orthopaedics balanSys unicompartmental convex polyethylene inlays.

Patients with Microport Orthopedics MoM hip implants, most of them outside of Australia, are suffering possible tissue reactions to metal debris and need an increasing number of revisions. Affected implant components include the onserve resurfacing cup, dynasty metal liner, rim lock metal liner, and lineage metal liner.

There have been few users in Australia and the rate of revision there has been low, in part because these components have not been used in the country since 2013 and have been cancelled from the Australian Register of Therapeutic Goods.

The TGA also said that Mathys Orthopaedics is recalling some of its balanSys unicompartmental convex polyethylene inlays, which are used in knee replacement procedures, due to a higher-than-expected breakage rate.

There have been seven reports worldwide of these inlays breaking after about five years.

New Zealand Expands Reimbursement For Range of Medical Devices

New Zealand's single payer of drugs and devices will offer reimbursement for 11 new categories of medical devices.

The Pharmaceutical Management Agency (PHARMAC) makes reimbursement decisions for District Health Boards (DHBs) for public hospitals. It is slowly taking over more product categories from services provider healthAlliance, which is owned by four DHBs.

PHARMAC will now cover the following medical device categories: Anesthetic consumables, IV equipment and consumables, needles and syringes, negative pressure wound therapy, respiratory equipment and consumables, endomechanical and electrosurgical medical devices; interventional technologies, enteral feeding devices, ostomy and continence devices, and renal dialysis and urology devices.

The agency will seek proposals for national agreements to supply these categories in the first half of 2017. It recently expanded its role to include medical devices and previously offered reimbursement for six categories of hospital devices.

In comments on the expanded categories, industry stakeholders voiced concern about the transition to PHARMAC from healthAlliance. Industry was particularly concerned about potential delays to existing healthAlliance processes that could impact DHBs.

In response, PHARMAC said it would continue to work with DHBs, healthAlliance, and New Zealand Health Partnerships to coordinate the transition.

Cures, *from Page 1*

In addition, the bill identifies five categories of medical software that will not be regulated as a medical device, requires FDA reviewers to consider the least burdensome means necessary for demonstrating safety and effectiveness, and requires the FDA to recognize national or international standards for medical device review.

The House passed its first version in July 2015, followed by a Senate package of 19 separate bills that were never acted on.

While parts of the measure include funding, most of the FDA's activities included in the measure would have to be funded by a separate appropriations bill.

The House is currently considering a temporary measure to fund the FDA and other government agencies through April 28. That continuing resolution contains the first round of appropriations for the 21st Century Cures Act, with the FDA receiving an additional $20 million for the 2017 fiscal year.

BRIEFS

Malaysia's MDA Releases Device, Drug Classification Criteria

New guidelines from Malaysia's Medical Device Authority (MDA) identify four criteria for determining whether a health product qualifies as a medical device or a drug.

The four criteria are:

- The primary intended purpose of the product;
- The primary way the product achieves its desired purpose or effect – medical devices function by physical means, and drugs function based on pharmacological, immunological, or metabolic action;
- The active ingredient, indication, and pharmaceutical dosage form, which are the main criteria for classifying drugs; and
- Classification of the product or a similar product in the US, EU, Canada, Australia, and Japan.

Device and drug manufacturers also may ask the MDA for classification determinations using designated procedures.

Ireland Creates Innovation Office To Provide Regulatory Advice

Ireland's Health Products Regulatory Agency is creating a new Innovation Office to help support development of novel products, including medical devices and technologies.

The agency stressed the importance of understanding regulatory issues early in the development process to "support a timely trajectory from product concept to market access."

The regulator will offer a dedicated confidential online query service to be managed by a team of regulatory experts, and the office will respond to queries within 20 working days. The regulator said it would not publish the questions it receives or the responses given to maintain confidentiality.

For more information, visit: https://www.hpra.ie/innovation-office.

Applications Solicited For Single Audit Program

Additional candidate auditing organizations are invited to apply for participation in the Medical Device Single Audit Program (MDSAP) in 2017.

Starting January 1, 2017, the program will be open for applications from new candidate auditing organizations. In addition, a small number of successful applications from candidates already operating under a third-party medical device regulatory scheme will be assessed further in 2017.

The procedure for submitting an application can be found at: www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377581.htm.

Medtronic Wins CE Mark Expansion for Endurant II/IIs

The European Union expanded Medtronic's CE Mark for Endurant II/IIs stent graft for treating abdominal aortic aneurysms.

The update includes an implantation method called ChEVAR, which utilizes an expandable balloon to increase the artery area.

This expanded indication also allows the device to be used in aneurysm patients with short aortic neck length as small as 2mm, down from 10mm previously.

Abiomed Receives Expanded FDA Approval for Heart Pump

The FDA approved Abiomed's Impella 2.5 heart pump use in high-risk percutaneous coronary interventions.

The pump stabilizes the heart by reliving the load on the left ventricle.

The device was previously approved for treatment of ongoing cardiogenic shock immediately following heart attack or open heart surgery as a result of isolated left ventricular failure that is not responding to conventional treatment.

(See **Briefs**, *Page 8)*

Talk to Me Tech Gets Form 483 For Procedural Violations

Talk to Me Technologies landed a Form 483 for not establishing corrective and preventive action procedures or performing quality audits.

According to an inspection conducted at the company's Cedar Falls, Iowa, facility in October, it failed to establish procedures to describe methods for documenting corrective actions to quality system deviations.

The firm also failed establish an internal quality auditing procedure and conduct internal audits of its facility quality system.

Read the Form 483 here: www.fdanews.com/12-05-16-talktometechnologies483.pdf.

Briefs, *from Page 7*

J&J Ordered to Cough Up $1B Over Verdict on Metal Hip Implants

J&J is charged to pay $1 billion to plaintiffs who claimed injury from the company's metal-on-metal hip implants.

Six cases were selected out of 8,000 lawsuits filed against J&J device manufacturer, DePuy Orthopaedics, who reported injuries such as tissue death and bone erosion that plaintiffs blamed on poor device design.

While the company refutes wrongdoing, it stopped selling the implants in August 2013, following an FDA announcement saying it would step up its review process for new versions of the product. J&J will appeal the verdict.

Kyocera Medical Gets FDA Clearance for Initia Hip System

Japan-based Kyocera Medical Corporation has gained FDA marketing clearance for its Initia total hip system.

The Initia system includes zirconia-coated alumina ceramic femoral heads.

It is also available with cobalt chrome femoral heads, giving surgeons the option of ceramic or metal heads. The Initia system includes 16 tapered-wedge stem sizes.

EU Device Trade Groups Merge Into One Unit

The European Diagnostic Manufacturers Association and the European Medical Device Manufacturers Association have formally consolidated into a single body called MedTech Europe.

At the helm, Serge Bernasconi and the association retains the ability to help in-vitro diagnostics and medical devices manufacturers of all sizes operating in Europe with their respective concerns.

Voluntis Scores FDA Clearance And CE Mark for Insulia

Voluntis has received FDA marketing clearance and the CE Mark for Insulia.

The application software gives patients insulin dose recommendations and coaching messages in response to blood glucose values and other diabetes-related data.

A clinician programs the range in which patients need to be. The dose adjustment calculations are synced into the application and are accessible to the patient via a web portal or by smartphones and tablets.

Insulia will be available in the first half of 2017.

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Winning Device EU Marketing Approval: *Seven Steps to Writing Clinical Evaluation Reports*

If you want to market your device in Europe, you need to provide clinical evidence that the product is safe and effective. But if your development phase didn't include clinical trials, how can you make that argument?

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GCP Questions, FDA Answers

What subject information are you allowed to collect under HIPAAA? Which members of the study's staff are allowed to dispense the investigational product to subjects? What do you do if your principal investigator resigns? What constitutes a "certified copy" of an electronic record?

The FDA's Office of Good Clinical Practices (OGCP) fields questions like these from clinical research professionals just like you every day.

FDAnews' staff has culled through hundreds of questions submitted to OGCP and curated more than 175 of the most relevant responses for you — segmented by category — saving you the time and frustration of sifting through the questions and responses.

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