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IN THIS ISSUE

FDA Panel Addresses Challenges Of Maintaining Heater-Cooler Devices

FDA is recommending that device manufacturers redesign heater-cooler devices used in surgeries because cleaning maintenance challenges have been linked to infections and patient deaths.

In the interim, FDA's Circulatory System Devices Panel recommends healthcare facilities clean heater-cooler devices more frequently and thoroughly. The panel concluded that more research needs to be done before it could recommend best practice guidelines to eliminate transmission of infections via the devices.

Heater-coolers can spread nontuberculous mycobacteria (NTM) when bacteria growing within the water tanks aerosolize into the environment. For example, FDA warned healthcare providers recently that Sorin's Stocker 3T heater-coolers could be contaminated with *M. chimaera* if purchased before 2014 (*IDDM*, May 6).

All commercially available heater-cooler units carry similar risks, the FDA said, and tracking and estimating the rate of infection

(See **FDA Panel***, Page 2)*

Q2 MDUFA Report: PMA Approvals Down Slightly

The rate of premarket approvals is down slightly in 2016, according to the FDA's quarterly report tracking Medical Device User Fee Act performance.

So far this year, 86 percent of premarket approval applications (PMAs) have been approved, compared with a high of 95 percent in 2015. PMAs were approved at a rate of 85 percent and 86 percent in 2013 and 2014, respectively.

The number of substantive interactions for PMA originals and panel track supplements appears to be down compared with last year. The agency conducted 16 substantive interactions in the first two quarters of this year, compared with 68 for all of fiscal 2015.

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FDA Panel, *from Page 1*

is difficult because patients can become symptomatic years after the initial procedure.

Daniel Diekama, director of the University of Iowa's Division of Infectious Diseases, presented a retrospective analysis after an outbreak at the university showed the number of infected patients tripled compared to what was initially reported.

Nagging Safety Questions

The FDA panel concluded that the benefits of open chest cardiac surgery with cardiopulmonary bypass outweigh the risks. However, until more clinical data is provided, the panel provided specific recommendations on:

- Clinician awareness of NTM infections associated with heater-cooler devices;
- Latency of symptoms;
- Unknown data on prevalence of the issue and additional investigations;
- Insufficient resources in the workforce across facilities;
- Lack of standardization of device design and cleaning guidelines to minimalize biofilm formation, disinfectant strategies and water quality;
- Current water quality standards on mitigating NTM proliferation and adhering to instructions for use;
- Case definitions and patient and provider notifications; and
- Present and future device considerations for reducing risk of NTM infections.

When asked what water standard should be used for heterotrophic plate count, the panel was split between 100 cfu/ml and 500 cfu/ml, but it agreed that facilities should change water daily and document disinfection processes. The panel did not reach a consensus about whether older machines can meet and maintain water quality standards.

The FDA felt it did not have enough clinically based evidence to change manufacturer

(See **FDA Panel**, *Page 8)*

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Patient and Device Counts Reported in MDRs by Manufacturer and Brand Name

Manufacturer and Brand Name	Total Number of MDRs	Infected Patients[1]		Patient Deaths[2]		Contaminated Devices[3]	
		US	OUS	US	OUS	US	OUS
LivaNova/Sorin Stockert 3T	160	40+	21+	7+	5	33+	111+
Maquet HCU20, HCU30 & HCU40	9	0	0	0	0	0	9
Cincinnati Sub-Zero 333W and Hemotherm	3	1	0	0	0	6	0
Terumo HX2	8	4	0	2	0	0	0
Total	180	45+	21+	9+	5	39+	120+

Note that MDRs may include information on more than one patient and/or device.
[1]Patient infection identifies the total number of patients reported in the MDRs as having an infection.
[2]Patient death identifies the number of patient deaths reported in the MDRs from the number of infected patients.
[3]Device contamination identifies the total number of devices as reported as being contaminated with or without known patient infection.

Study Cites Flaws in Approvals Of High-Risk OB-GYN Devices

A number of high-risk women's health devices gained FDA approval based on inadequate data, according to a new study from Northwestern Medicine.

The researchers call on regulators and physician organizations to create and support more rigorous approval standards and stricter postapproval tracking requirements for these devices. Physicians should also be more proactive about postmarketing monitoring and adverse event reporting, they said.

The study, published in *Obstetrics and Gynecology*, looked at 18 high-risk devices and found:

- Four were approved despite failing to show efficacy in clinical trials;
- Six were not required to undergo postmarket studies;
- Three were taken off the market after approval; and
- Of those three, two were not reviewed by the FDA's Obstetrics and Gynecology Advisory Committee. The other was reviewed by the committee but not recommended for approval.

Most of the devices were approved between 2000 and 2015 for endometrial ablation, contraception and fetal monitoring. The study highlighted Bayer's Essure device, which was approved in 2002 with short-term evidence and not enough postmarket follow-up, the authors say. The device is now being evaluated in light of numerous adverse event reports (*IDDM*, March 7).

Implications of the Study

Senior author Steve Xu questioned the logic of holding high-risk medical devices to a lower standard of evidence than drugs. "There are no explicit requirements about conducting randomized-controlled trials or post-market surveillance for medical devices. Requirements are decided on a case-by-case basis," he noted.

The researchers also raised concerns that the House-passed 21st Century Cures Act would weaken medical device regulation, broadening the definition of "valid scientific evidence" that can prove medical benefit. "Our concern is that this would lead to more devices getting approved with even less clinical evidence that they are both safe and effective," said author Jessica Walter. The bill is now pending in the Senate.

Walter and Xu are calling on clinicians to improve their understanding of FDA regulation and become more proactive about collecting and reporting data on device complications and adverse events. "Given that post-marketing surveillance is often passive voluntary reporting, physicians need to be more than mere end-users," said Xu.

The study also points out that almost all the obstetrics and gynecology devices approved via the PMA pathway had subsequent supplements. "A high number of supplements increases the risk of device creep where small incremental changes become additive and substantial over time," it says. "Thus, the number of supplement applications is another important consideration of postmarketing regulation."

In addition to higher-quality studies and greater emphasis on supplement applications, the study recommends more input from expert advisory committees and increased use of device-specific registries.
— Joya Patel

ANVISA Medical Device Importation Process Moves to All Electronic

Brazil's ANVISA has switched over to a wholly electronic submission system for importation of devices.

Effective May 31, all applications will need to be submitted thru ViCOMEX, a streamlined platform that provides step-by-step guidance.

Foreign manufacturers and importers must first register the licensed importer on Brazil's Siscomex, foreign trade portal. The new directive RDC 76/2016, can be found here (in Portuguese): www.fdanews.com/06-08-16-ANIVSADirective.pdf.
— Joya Patel

Zimmer Biomet in Hot Water With FDA Warning Letter

FDA handed Zimmer Biomet Holdings a warning letter dated May 27, citing GMP non-conformities at the company's facility in Montreal, Canada.

The firm received a Form 483 in January for similar deficiencies, the company stated in a June 6 SEC filing.

The Canadian facility is the principal location for Zimmer's wholly owned subsidiary ORTHOsoft.

The warning letter does not restrict production or shipment of the company's products from the Montreal facility or require the withdrawal of any product from the marketplace nor does it restrict the company from seeking 510(k) clearance of products. It does, however, deny approval of premarket approval applications for Class III devices until the violations have been corrected.

Since the inspection, Zimmer provided responses to the FDA outlining its corrective actions. The company said it can't estimate how long the resolution process would take.

Last week, Australia's Therapeutic Goods Administration cautioned healthcare providers that Zimmer's Trabecular metal knee implant may contain non-sterile implant components that could result in post-operative infection (*IDDM*, June 3).

In separate news, Zimmer Biomet announced on June 7 that it would acquire fellow medical device maker LDR Holding for $1.07 billion.

LDR, based in Troyes, France, and Austin, Texas, specializes in implantable spine devices and surgical technologies. Mobi-C CDR is the company's first and only FDA-approved device to treat both one and two level adjacent damaged cervical discs.

Earlier this year, Zimmer Biomet completed its acquisition of Arizona-based Cayenne Medical, a developer of soft tissue repair and reconstruction for the knee, shoulder and extremities (*IDDM*, May 18).

Read the 8-K here: www.fdanews.com/06-08-16-ZimmerBiomet8-K.pdf. — Joya Patel

FDA Outlines How Devicemakers Should Share Data with Patients

FDA is outlining how manufacturers should share patient-specific information derived from medical devices used to treat or diagnose patients.

Even though the FD&C Act does not require sharing data with patients, manufacturers may share patient-specific information at the patient's request, without obtaining prior additional premarket review, according to draft guidance released June 9.

Patients can contact their healthcare provider to obtain the information from a medical device, or they may also contact the manufacturer directly to request access to their patient-specific information.

The guidance defines patient-specific information as information unique to an individual patient or unique to that patient's treatment or diagnosis that may be recorded, stored, processed, retrieved or derived from a medical device. This information may include recorded patient data, device usage and output statistics, healthcare provider input, alarms and records of device malfunctions.

In addition, categories for patient-specific information include data that a healthcare provider inputs to record status and treatment for a patient and data stored by the device to record usage, alarms or outputs.

Information Must Be Interpretable

FDA recommends that manufacturers disseminate content that is understandable and useful to the patient and to avoid information that could be misinterpreted.

Depending on the type and scope of information being shared, the manufacturer may choose to provide supplementary instructions, materials or references to aid patient understanding," states the FDA. If this supplemental material meets the definition of labeling, it would be subject to relevant regulation.

Read the draft guidance here: www.fdanews.com/06-10-16-MedicalHER.pdf. — Joya Patel

Telemedicine Systems Maker Warned On Investigations, Complaint Handling

General Devices, a maker of mobile telemedicine systems, has been warned for not finding the root causes of problems or documenting complaint evaluations.

During a 2015 inspection of the Ridgefield, N.J., company, the FDA found an unsigned standard operating procedure on its corrective and preventive actions policy. The SOP did not require root cause investigations for:

- "Known issues previously reviewed under CAPA";
- Failed "purchased industry standard off shelf components";
- "Normal wear and tear or age-related" nonconforming products; and
- Nonconforming products caused by ''user abuse or damage."

The CAPA policy also did not require the company to analyze various quality data to find the causes of nonconforming products or recurring problems, according to the June 1 letter posted to the FDA's website June 7.

A review of service records from March 4, 2013, to June 2, 2015, showed that certain Carepoint EMS Workstation monitors were sent to suppliers to be exchanged following malfunctions, but the company didn't conduct a CAPA investigation to find the root cause of the malfunctions, the letter says.

The FDA also cited the company for its medical device reporting SOP, which did not require an internal system to identify and evaluate events for medical device reportability.

Another unsigned SOP — this time on the change notification system — did not require the company to verify or validate design changes before implementation. These changes included new versions and upgrades of software.

General Devices did not respond to a request for comment by press time. The warning letter is available at www.fdanews.com/06-07-16-General Devices.pdf. — April Hollis

MDUFA, *from Page 1*

The report notes the average number of days to substantive interactions has dropped since last year — from 92 in 2015 to 90 so far this year. This is in line with the agency's goals under MDUFA III, to reduce both the time and cost for market approval of a device. In fiscal 2013, the average number of days was 110.

The report did not have figures for 2016 on the average number of FDA days to make a MDUFA III decision. However, this has dropped from a high of 359 in fiscal 2013 to 206 in fiscal 2015 for PMA original and panel track supplements with panel review. During that same period, the number of days for applications without panel reviews went from 225 to 183.

The average number of industry days to a MDUFA III decision, with panel review, increased from 108 to 119 days for PMAs. For applications without panel review, the number dropped from 167 to 59 days.

For 510(k) submissions, 83 percent were found to be substantially equivalent so far in 2016. This is a slight drop from 85 percent for 2015 but an increase over 2013's rate of 79 percent.

MDUFA III decisions have taken the agency an average of 55 days in fiscal 2016, so far, compared with 72 days in fiscal 2015. The average number of industry days during the same period went from 50 to 11.

The number of substantive interactions also declined, from 3,441 in fiscal 2015 to 1,061 in FY 2016, so far.

The report did not include data, metrics, or goals on clinical laboratory improvement amendments or de novo requests, as those will be included in the FDA's annual report. Also included in the annual report will be more information on the agency's 510(k) metrics and goals.

The document is part of the FDA's 2012 commitment under MDUFA III to release quarterly and annual reports on the program's implementation. Following a third-party review of the agency's performance in 2013, it identified several measures to bolster efficiency, the first stage of which should largely be implemented.

These measures include: mandatory, full staff training for three key IT systems that support MDUFA reviews; identifying better metrics and methods to assess review process training satisfaction; and a multi-pronged approach to five quality component areas that can help standardize process lifecycle management activities and improve review consistency.

The last component incorporates corrective and preventive action and continuous process improvement, resource management, document management and system evaluation.

As of March 31, the FDA had collected $110. 5 million in medical device user fees — 80 percent of an authorized $137. 6 million.

Read the report here: www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM504583.pdf. — Jason Scott

India Greenlights First Medical Device Park

India has approved funding for the country's first medical device park. It will have specialized laboratories, warehousing, testing centers and up to 150 independent manufacturing units.

The effort is part of the 'Make in India' effort to reduce India's dependence on imported medical devices (*IDDM*, Nov. 13, 2015). The new medical device park is expected to be completed in about five years.

Currently, India imports more than 80 percent of its high-end medical devices and at least 60 percent of other devices, as local companies cannot afford to invest in manufacturing facilities. — Joya Patel

FDA Investigates Burn Risk Of Zecuity Migraine Patch

The FDA is investigating the risk of serious burns and potential permanent scarring with the use of Teva's iontophoretic transdermal patch Zecuity to treat acute migraine headaches.

Since September 2015, numerous patients have reported burns or scars on the skin where the patch was worn, according to the agency.

The patch delivers a dose of sumatriptan using iontophoresis — a drug delivery method using a low electrical current with a single-use battery-powered patch wrapped around the upper arm or thigh.

In two long-term, open-label studies in which patients were allowed to treat multiple migraine attacks for up to one year, 15 percent withdrew from the study because of an adverse event.

The most common adverse events were application-site pain, contact dermatitis, paresthesia and discomfort.

Clinicians are advised to consider a different formulation of sumatriptan or to switch patients to an alternative migraine medicine.

The FDA is investigating adverse events to determine whether future regulatory action is needed.

Read the FDA's safety communication here: www.fdanews.com/06-08-16-ZecuitySafetyCommunication.pdf. — Joya Patel

B. Braun Sues Becton, Dickinson for Patent Infringements

B. Braun Medical and Affiliates have filed a lawsuit against Becton, Dickinson and Company and Becton Dickinson Infusion Therapy Systems for infringing 10 U.S. patents relating to IV catheter safety mechanisms.

B. Braun alleges that Becton Dickinson infringed its patents by manufacturing and distributing the BD Insyte, Autoguard BC IV Catheter and BD Nexiva Closed IV Catheter System. The company is seeking an injunction and damages from BD.

The lawsuit, filed on June 6 in the United States District Court for the District of Delaware, follows patent litigation victories in Germany, Austria and the European Patent Office involving a European manufacturing counterpart to three of the U.S. patents in the current suit.

B. Braun has additional lawsuits involving foreign counterparts of the patents in question pending in Belgium, Australia and the Netherlands. — Joya Patel

Inner Mongolia Seeks To Create Independent FDA

Inner Mongolia has created a framework to establish an independent FDA in an effort to monitor the safety and efficacy of products sold within the territory.

The notice proposes establishing a regulatory team proportionate to Inner Mongolia made up of qualified inspectors and grass-roots team building.

Read the proposal here: www.fdanews.com/05-26-16-MongoliaDocument.pdf.

FDA Update on EAP Program: 29 Decisions in First Year

A year into FDA's Expedited Access Pathway program, the agency has made 29 decisions on requests — accepting 17 and denying 12 — with review decisions usually made in 30 days.

Requests have included heart, brain and kidney devices from both startups and major corporations.

Launched by the FDA in April 2015, the program facilitates access to breakthrough medical device technologies for life-threatening conditions (*IDDM*, April 10). The FDA works with device sponsors throughout the process, beginning with development.

"Companies who benefit most from this program are those that have a preliminary proof of principle for how their device works, but haven't undertaken formal studies to support future submissions to FDA," the agency says.

"For these companies, discussing their Data Development Plan with the FDA and agreeing on a roadmap to their marketing application and beyond is an important part of a successful review."

For devicemakers interested in the EAP program, the FDA recommends being prepared with a thorough Data Development Plan for future submissions.

The Data Development Plan should include three sections:

- An explanation and justification for the proposed balance of premarket and postmarket data collection, if a premarket-postmarket data shift is proposed and applicable;
- A description and summary of the data collection plan, including study synopses and study design; and
- A timeline for the development and marketing of the device, as well as for the postmarket data collection.

Meanwhile, lawmakers are also working to improve access to breakthrough technologies. The Senate HELP Committee advanced a bill in March to expand the expedited review of breakthrough medical devices by including all classes of devices, rather than only Class III.

Reduced Compliance Timeframes

The bill would also reduce compliance time frames and allow shorter and smaller clinical trials (IDDM, March 28).

In April, Senators introduced the Ensuring Patient Access to Critical Breakthrough Products Act to expedite CMS decisionmaking for innovative medical technologies for Medicare recipients with life-threatening illnesses.

Read the FDA's update on the EAP here: www.fdanews.com/06-02-16-EAPUpdateFDABlog.pdf. The Ensuring Patient Access to Critical Break through Products Act can be found here: www.fdanews.com/06-02-16-HR5009.pdf. — Joya Patel

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FDA Panel, *from Page 2*

recommendations, and panelists were hesitant to override validated manufacturer recommendations.

Once biofilm has taken up residence in a device, it is impossible to eradicate through routine cleaning and disinfection alone, the panel said, noting that clinicians need to diligently follow manufacturer's instructions for use.

Future HCD devices should be designed so that the water pathways, tubing and interior of tanks can easily and routinely be inspected.

In the meantime, facilities should routinely clean and disinfect devices to slow the production of biofilm, yet panelists said this may not be enough to truly sterilize a heater-cooler device. A "deep cleaning" service performed by the manufacturer may be necessary to bring quality back to acceptable levels, the panelists said.

FDA will review additional data on the benefits and risks associated with the use of HCDs during cardiothoracic surgery and generate evidence-based recommendations on how to mitigate infections. — Joya Patel

Esco Medical's Embryo Incubator Approved

In-vitro fertilization company Esco Medical has secured FDA 510(k) approval for its embryo incubator.

The newly cleared Miri TL is a multi-room incubator with a built-in microscope and camera designed to continuously capture images of development until the embryo is ready to transfer.

Traditional assessment is limited to static observations at pre-defined time intervals, which requires the embryo to be taken out from the incubator. The Miri TL can incubate up to 84 embryos at the same time without disturbance.

FDA Approves First Insomnia Treatment Device

FDA granted approval to Cerêve's sleep system, a prescription device that reduces latency to Stage 1 and Stage 2 sleep for the treatment of insomnia.

The Cerêve System is a software-controlled bedside device that cools and pumps fluid to a forehead pad that is worn through the night, in order to reduce activity in the frontal cortex.

The system is the first of its kind to replace the most common medical treatment, sleeping pills, many of which have known safety risks. Nearly 9 million adults have taken prescription sleeping pills in the last 30 days, according to Eric Nofzinger, a board-certified sleep physician and the company's founder.

The Pennsylvania-based company developed its device based on imaging studies that showed increased brain function during sleep in patients with insomnia.

The FDA evaluated the company's application under a *de novo* classification for novel, low-risk devices based on three independent clinical studies conducted with 230 patients over 3,800 research nights.

The Sleep System is slated to launch during the second half of 2017. — Joya Patel

Foundation Medicine, AZ Partner To Develop Assay for Lynparza

Foundation Medicine and AstraZeneca have partnered to develop a diagnostic assay for Lynparza designed to identify patients most likely to benefit from the treatment.

A poly ADP-ribose polymerase inhibitor, AZ's Lynparza works by exploiting tumor DNA repair pathway deficiencies to preferentially kill cancer cells.

Under the agreement, Foundation Medicine will develop the assay that will aim to detect multiple classes of genomic alterations across a range of genes involved in homologous recombination repair. Financial terms of the deal were not disclosed.

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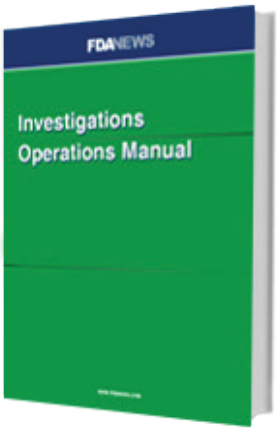

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