INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Doctors, Hospitals Received $6.5B From Device and Drug Companies

Boston Scientific paid a combined $44.7 million last year to doctors and teaching hospitals, with money going toward meals, consulting fees and grants. In the more than 106,000 transactions, the device giant spent about $26.3 million in general payments and the rest for research.

Overall, device and drug manufacturers spent nearly $6.5 billion on research activities, gifts, speaking fees, meals or travel for physicians and academic medical centers in 2014, according to the Centers for Medicare & Medicaid Services' Open Payments database.

The website allows interested parties to review and download statistics on the 11.4 million transactions connected to more than 600,000 physicians and 1,100 teaching hospitals that transpired last year. The financial reporting is required under the Physician Payments Sunshine Act provision of the Affordable Care Act.

According to the database, St. Jude Medical spent $46.3 million in total general payments and $7.3 million in total research payments in more than 97,000 transactions.

(See **Database***, Page 2)*

FDA Device Regulations: Too Harsh or Just Right?

Are U.S. medical device regulations too tough? The answer, according to Matthew Grennan and Robert Town, professors of healthcare management at the University of Pennsylvania's Wharton School, may surprise those critics who view the FDA as hampering innovation.

"We weren't sure what we would find," the two tell *IDDM* of the results of a paper, *Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices*, that examines this question.

Using data from the Millennium Research Group, they focused on the coronary stent market in the U.S. and EU, given the wealth of data and the constant stream of innovative products manufacturers develop.

(See **FDA v. EU***, Page 4)*

Database, *from Page 1*

Meanwhile, Zimmer Holding, now part of Biomet, reported $50.8 million in general payments and almost $3 million in research payments in more than 40,000 transactions. Smith & Nephew reported $41.8 million in general payments and $2.5 million in research payments in more than 69,000 transactions.

It's not always easy to determine how much money a company has given, however. A search for Medtronic yields six company results.

CMS says it plans to upgrade the database at least annually to include updates to data disputes and corrections made since the initial publication. An update to the 2014 data will be published in early 2016. — Elizabeth Hollis

Vote on 21st Century Cures Could Come This Week

The full House of Representatives could vote on the 21st Century Cures Act as early as Thursday after the House Rules Committee meets to consider possible amendments to the bill.

As written, the massive overhaul bill H.R. 6 would allow a single central review board to monitor multiple trial sites, thereby reducing the complexity of U.S. clinical trials of medical devices. Currently, these studies must be cleared by a local IRB at each research site.

In addition, the bill would permit FDA-accredited third parties to conduct inspections when a devicemaker submits minor device design changes, such as those made under a 30-day or special PMA supplement.

The audit provision hews closely to the ongoing Accredited Persons Inspection Program, which was first authorized as part of device user fee legislation in 2002. Success in a third-party audit replaces a regular FDA inspection (*IDDM*, May 15).

The House Energy & Commerce Committee voted unanimously to send the bill to the full House in May. No similar legislation exists in the Senate, but House members hope to have the bill on the president's desk by the end of the year.

Read H.R. 6 here: www.fdanews.com/7-15-HR6.pdf. — Elizabeth Hollis

MHRA Presents Business Plan As Part of Five-Year Strategy

Ensuring efficient implementation of EU device regulations is a key activity the UK's Medicines and Healthcare products Regulatory Agency has tasked for itself over the next year, according to a new business plan.

The plan is part of a five-year strategy to promote effective regulation for devices and drugs and further develop the National Institute for Biological Standards and Control and the Clinical Practice Research Datalink.

Specific device-related goals in the 2015-16 plan include collaborating with international agencies, such as the International Medical Device Regulators Forum, to harmonize global regulatory standards. Part of this goal is clarifying the European position on implementing elements of IMDRF's medical device single audit program by the end of the third quarter. Implementing the MDSAP program in the EU has proven challenging because every participant must have confidentiality agreements with every other player. Agreements for each of the 28 nations would need to be negotiated individually.

The plan is part of thee MHRA's plan to revise its medical device funding model. According to the business plan, funding for device regulation is half the level it was in 2003 in real terms. That comes even as adverse event reporting has increased more than 50 percent since 2009. Over the next year, the plan calls for about U.S. $14.3 million in funding and investment in efficiencies from the Department of Health.

To read the full report, visit www.fdanews.com/07-06-15-mhrabusinessplan.pdf.
– Elizabeth Hollis

FDA Aims to Clarify Surgical Gown Classification

The FDA is reminding manufacturers of surgical gowns that they need to submit a 510(k) application to commercially distribute their products.

The reminder comes in the form of draft guidance, issued June 30, explaining the premarket regulatory requirements and performance testing needed to support liquid barrier claims for gowns used in healthcare settings.

According to the agency, inconsistent terminology in the field has led to confusion over what constitutes a surgical gown, a Class II device subject to premarket notification. Other gowns used in nonsurgical situations in healthcare, such as isolation gowns, are exempt from this regulatory requirement.

The guidance highlights an American National Standards Institute and Association for the Advancement of Medical Instrumentation standard related to protective barriers, which describes four levels of barrier performance — Level 1 being the lowest level of protection and Level 4 the highest. As FDA spokeswoman Deborah Kotz tells *IDDM*, the definitions of the gowns detailed in the standard were not harmonized with those in a 2000 final rule from the FDA on surgical apparel.

The new draft guidance differentiates between Class I and II gowns, saying the former must be labeled as a gown other than a surgical gown and, if it has statements related to barrier protection, they are for minimal- or low-barrier protection. Class II surgical gowns must be labeled as such, have statements related to moderate- or high-level barrier protection and/or have statements that they are intended for use during surgical procedures.

Manufacturers that don't have an existing clearance must submit an application to the FDA within 60 days of the final guidance's publication. The agency has 75 days from publication to accept the application for review and gowns must have clearance within six months of publication.

Kotz says between 275 and 300 manufacturers are involved in gown production, packaging and distribution in the U.S. The FDA has no immediate plans to address other forms of personal protective equipment, she tells *IDDM*.

Comments on the draft are due Aug. 31. Read it at www.fdanews.com/07-06-15-surgicalgowns.pdf. — Elizabeth Hollis

Draft Guidance Puts Spotlight On Safety in MRI Environment

To reduce possible burn injuries, the FDA is recommending that manufacturers of magnetic resonance-conditional devices assess radiofrequency-induced heating in MR environments.

The assessments would be used to support MR-conditional labeling claims, the agency says in draft guidance released June 29.

The guidance addresses multiconfiguration passive medical devices that can conduct electricity and lead to patient injuries during MRI scans. Many commonly used device types fall into this category, including stents, orthopedic devices, external fracture fixation devices and head fixation frames.

Due to the many possible configurations and combinations for a passive device, it's nearly impossible to compare RF-induced heating between the various sizes and dimensions.

To reduce the number of possible device configurations or combinations "to a manageable number" and assess RF-induced heating risks, the agency recommends the following steps:

- Define and describe the proposed scan conditions, e.g., magnetic field strength, scan area;
- Use animal data, published literature or scientific rationale to establish heating acceptance criterion;
- Define and describe all possible device configurations and combinations in which a device is intended to be used in clinical practice;

(See **RF Heating**, *Page 4)*

RF Heating, *from Page 3*

- Use a scientific rational or scientific method to create potential worst-case device configurations and combinations for heating assessments;
- Assess the RF-induced heating for each device configuration/combination and within each MR environment for which the device is intended;
- Provide an estimate of the accuracy of the results; and
- Estimate the expected worst-case *in vivo* heating to demonstrate the safety of the device in the MR environment, particularly if observed *in vitro* heating exceeds the specified heating acceptance criterion.

The "assessment paradigm" outlined in the guidance would be used in conjunction with the information provided in FDA's current guidance on *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*, the FDA says.

Interested parties may comment on the draft guidance through Aug. 28. Read it at www.fdanews.com/06-29-15-RF-heating.pdf.
— Elizabeth Hollis

FDA v. EU, *from Page 1*

Grennan and Town acknowledge that the FDA requires more information from manufacturers than its EU counterparts before it will allow a device to go to market. While that may delay access to innovative devices and impose higher entry costs, the data obtained in clinical studies to demonstrate safety and effectiveness can help FDA reviewers weed out underwhelming performers.

Because the EU only requires companies to demonstrate safety, many companies choose to offer their products in those markets, the two say.

From 2004 to 2013, an average 49 percent of stents used in the EU were unavailable in the U.S., according to their research. There were also more stent manufacturers offering their products in EU markets. However, despite the greater choice, "products in the EU experience less usage overall and higher volatility in usage patterns when first introduced," according to the report.

One problem is that EU consumers have less access to data about devices than those in the U.S. On average, U.S. clinical trials enrolled more than 1,200 patients and lasted three years. In the EU, trials enrolled a third of the patients and were 66 percent shorter. While it could be argued that EU patients have faster access to advanced technologies, they also face a greater risk, given that products are introduced earlier in their lifecycle and with less data backing them, the researchers say.

"For the set of devices on which we have data, we estimate that the U.S. is close to the optimal policy, but the EU is too lax," the report says.

Would this conclusion hold true for all device types? "It all depends on the tradeoff between access and risk for the device," Grennan and Town explain. "For a different device with the same level of risk, but a bigger technological benefit relative to the status quo, our model would suggest less premarket testing. On the other hand, if the benefit were similar with more uncertainty, our model would suggest more testing."

The authors see several avenues for additional research as a result of their conclusions. "One puzzle from the EU-U.S. differences in stents is why products in the EU don't undergo more voluntary testing, when the consumer benefits from greater certainty seem to be so high. It seems like there is a gap in the value of testing between the private benefit to manufacturers and the public benefit to consumers, and we are actively working on trying to understand what is behind that gap."

Read the report here www.fdanews.com/07-06-15-grennantown.pdf. — Elizabeth Hollis

FDA to Exempt Dozens of Devices From Premarket Requirements

The FDA is exempting 120 device types from premarket notification requirements after determining they pose little risk to users.

In final guidance issued July 1, the agency says it doesn't intend to enforce compliance with 510(k) requirements for these devices, which fall into the Class I, Class II or unclassified categories, and won't require devicemakers to submit 510(k)s for these devices.

Among the devices are certain oscillometers, teething rings and medical support stockings. The decision comes as part of the agency's commitment under the reauthorization process for the Medical Device User Fee Amendments.

Based on a comment on the August 2014 draft guidance, the FDA added product code OYS, patient bed with canopy or restraints, to the exemption list. As it finalized the guidance, the agency identified an additional 15 device types for the list.

The FDA also determined that two device types in the draft guidance — certain thermometers and cranioplasty plates — should still be subject to 510(k)s.

On thermometers, the agency notes that the devices treat a range of conditions, including screening for potential pandemic contagious diseases.

Cranioplasty plates warranted stricter controls because they are permanent implants and may be constructed of polymeric materials, which could be resorbable, the FDA says.

Because some manufacturers of these two device types may not have submitted a 510(k) as a result of the draft guidance, the agency's Center for Devices and Radiological Health will give them 90 days following the publication of the *Federal Register* notice to submit an application.

The guidance is available here: www.fdanews.com/07-01-15exemptdevices.pdf.
— Elizabeth Hollis

Former Executive Facing Time For Shipping Adulterated Device

A federal judge in New Jersey has sentenced Charlie Chi, the former CEO of device startup OtisMed, to two years in prison for intentionally distributing a medical device whose marketing application had been rejected by the U.S. FDA.

Chi, 46, pleaded guilty to three counts of distributing an adulterated device in violation of the FD&C Act. In addition to the jail time, U.S. District Judge Claire Cecchi slapped Chi with a $75,000 fine and a year of supervised release. He had faced up to a year in jail and a fine of up to $100,000 for each count.

"With everything else people have to deal with when they are facing surgery, they shouldn't have to worry whether their doctor is using equipment that has been approved for use," U.S. Attorney for the District of New Jersey Paul Fishman said.

The government's case, *United States of America vs. Charlie Chi*, revolved around the distribution of the OtisKnee, a cutting guide for use in total knee replacements. Despite lacking FDA approval to market the device, the company sold about 18,000 units between May 2006 and September 2009, resulting in revenue of about $27.1 million.

According to the government, the company had falsely informed physicians and purchasers that the device was exempt from premarket requirements.

OtisMed finally sought clearance in October 2008, and the FDA denied the company's marketing submission in 2009, determining the company had failed to demonstrate its product was as safe and effective as other products already on the market.

In the wake of the FDA's decision, legal and regulatory counsel advised the company to stop

(See **Chi**, *Page 6)*

Saudi Health Officials Introduce New Barcode Requirements

Medical device manufacturers looking to sell items for home use in Saudi Arabia now will need to include barcodes on the product packaging.

For devices with a unique device identifier-compliant barcode, manufacturers should enter the static device identifier information only, according to a new FAQ document released by the Saudi Food & Drug Authority. If the device lacks a UDI-compliant code, the applicant should use the International Article Number barcode, if available. If neither of those is used, the applicant may use any other type of barcode.

Manufacturers of software-only devices, as well as products that either have a small container or are packaged in a material that does not lend itself to barcoding, may provide a justification for an exemption to the SFDA.

The requirements, which are already in effect, apply, at a minimum, to the unit of sale packaging.

Companies whose applications are under review should take steps to ensure their products are properly coded. If their first SFDA after-payment review took place June 7, 2015, or later, they must submit the barcode information through the device application.

Firms whose first review took place prior to that date may submit the information in the application, or through a new barcode module after their product is approved.

The SFDA intends to provide a barcode verification system through smartphone applications.

"By scanning a device barcode, information about the device as well as the manufacturer and authorized representative will display to the public to make sure that this device has been authorized by SFDA," says Azzam Alothman, quality and risk director for the authority's medical device sector. The tool will provide fast, easy access to that information, Alothman adds.

Alothman tells *IDDM* that companies making any type of medical device may submit barcode information, even for products not intended for home use.

The regulator intends to extend its track and trace requirements to other device categories, and this marks the beginning of the initial enforcement stage.

The FAQ document can be read at www.fdanews.com/07-06-15-saudibarcode.pdf.
— Elizabeth Hollis

Chi, *from Page 5*

shipping the product — a stance the board of directors unanimously endorsed. Chi feared the reputation of his young company would take a hit.

Further, Stryker had offered as much as $100 million to buy the company on the condition the FDA cleared OtisKnee prior to the acquisition's close. Hiding news of the FDA's rejection from Stryker, he decided to ship 218 guides.

Chi then asked an employee to take steps to hide shipments, including using Chi's personal Federal Express account and a temporary employee to handwrite airbills. As he left, he intimated to the employee that "this conversation did not happen," according to court documents filed in the U.S. District Court for the District of New Jersey. He later informed the employee the shipment would occur the following day.

The adulterated devices were sent to surgeons across the U.S., including six in New Jersey. The employees who shipped the items didn't use the surreptitious methods Chi had suggested.

Last December, Stryker and OtisMed agreed to pay more than $80 million to resolve criminal and civil liability related to the distribution of OtisKnee. Stryker also agreed to establish a compliance program to ensure all marketed products have the necessary approvals (*IDDM*, Dec. 15, 2014). — Elizabeth Hollis

AG Industries Warned on MDRs, GMPs After Nebulizer Shocks Child

The FDA has warned AG Industries on medical device reporting failures related to a complaint of a mini-nebulizer shocking a child and other good manufacturing practice violations.

The St. Louis manufacturer of respiratory replacement supplies failed to complete a Medical Device Report review and file an MDR on the complaint, according to the June 12 warning letter.

AG's standard operating procedure requires it to evaluate complaints for reportability, but instead of an MDR review, the firm passed the complaint information on to the supplier and then failed to follow up, the letter says.

The company also failed to validate certain equipment and its process for adding reground plastic scrap material to fresh resin when making plastic components. And AG lacked any specification for the rework of scrap plastic for use in device manufacturing, the letter notes.

The equipment validation issues related to a complaint about defective filters returned in July 2014, which prompted AG to modify and validate a welder. The validation used a certain sampling size, but there was no documented justification for reducing the sample size from the company's SOP sampling plan, the letter says. Eleven samples failed the flange thickness measurement test, but AG changed the specification and tolerances of the part to match the measurement test results.

Another sampling issue related to a checklist in AG's device history record. The checklist called for an acceptable quality limit sampling approach, with a certain AQL level for assembled devices. However, AG had no documented justification for a reduced AQL level and no documentation that it was even performing sampling according to the reduced AQL sampling, the letter states.

AG also lacked documentation to show that nonconforming materials are reviewed and dispositioned. The company's SOP says that nonconformances should be documented in a nonconformance report and identified with a "REJECT" tag, but, in practice, AG either reworks plastic product or throws out paper product without any investigation, the letter says.

Meanwhile, the devicemaker lacked procedures to ensure routine calibration, inspection and maintenance of equipment. AG has injection molding machines in its facility, but maintenance logs for three of them don't include any calibration activities or inspections since the installation date.

CAPA Observations

The FDA also dinged AG's handling of corrective and preventive actions. For example, a CAPA issued in December 2010 to address a Form 483 observation from the previous month was still open as of March 2015.

Another complaint, from April 2014, involved the mini-nebulizer that had shocked a child. As of March 2015, AG had not adequately completed steps of its customer complaint form for receipt of return product, complaint investigation and determination of corrective actions required.

In another case, the company initiated a CAPA and determined the root cause was an inadequate weld, but the investigation didn't identify which lot numbers were included in the returned products and didn't eliminate the possibility of failures found during quality investigation reports on finished goods before the complaint, the warning letter says.

Of 119 customer complaints received since Jan. 1, 2013, about 15 were still open during the inspection. The warning letter followed a March 26 to April 13 inspection by the FDA's Kansas City district office.

AG Industries did not respond to a request for comment by press time. Read the letter at www.fdanews.com/06-23-15-AG.pdf. — April Hollis

BRIEFS

Malfunctions Prompt Maquet Recall

Maquet Critical Care AB has recalled its FLOW-I Anesthesia system following 10 reports of a patient cassette locking device not working properly. The company initiated the Class I recall April 2 for 1,641 units. If the locking device on the system fails to function properly, it can release the patient cassette from the mount, allowing anesthesia gas to leak. No injuries or deaths have been reported. The system may be used on patients ranging from neonatal to adult.

Medtronic Recalls Tracheostomy Tubes

Medtronic is recalling certain lots of its Covidien Shiley neonatal and pediatric tracheostomy tubes manufactured after Nov. 29, 2012, because they were formed with a wider angle bend than standard models. The Irish devicemaker began alerting customers May 8 after receiving reports of 12 serious patient injuries, including discomfort when using the device and breathing difficulties that affected oxygen levels immediately upon tube placement. The company advises replacing the tubes with products manufactured before Nov. 29, 2012.

Amaze Trial Secures FDA Approval

The U.S. FDA has signed off on SentreHeart's Amaze clinical trial evaluating the Lariat suture delivery device for closure of the left atrial appendage, as an adjunct to ablation in patients with persistent or longstanding persistent atrial fibrillation. The goal is to demonstrate that use of the device with with pulmonary vein isolation ablation reduces recurrent atrial fibrillation at a higher rate than PVI ablation alone, the Redwood City, Calif., devicemaker says. The Lariat device has both FDA 510(k) clearance and CE Mark certification for other indications.

Sleep Apnea Device Gains 510(k) Clearance

The FDA has cleared SomnoMed's oral SomnoDent device for mild to moderate obstructive sleep apnea, the Australian devicemaker says. The product provides continuous open airway therapy by positioning the jaw slightly forward. A micro-recording feature developed by Braebon that allows medical professionals to track patient compliance is included in the device.

Optetrak Logic Prosthesis Wins FDA Nod

Exactech's Optetrak Logic constrained condylar prosthesis for revision knee arthroplasties has snagged FDA 510(k) marketing clearance, the Gainesville, Fla., devicemaker says. The prosthesis is indicated for patients undergoing total knee replacement surgery caused by osteoarthritis, osteonecrosis, rheumatoid arthritis and post-traumatic degenerative problems.

Integra to Buy TEI Biosciences

Integra LifeSciences has entered into an agreement to acquire TEI Biosciences and TEI Medical in for $312 million. The TEI buyout expands Integra's portfolio of reconstructive surgery and regenerative wound care products, and gives the Plainsboro, N.J., devicemaker access to TEI's flagship PriMatrix dermal repair scaffold. The deal is expected to close in the third quarter of this year. Waltham, Mass.-based TEI generated revenues of about $63.5 million in 2014.

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Managing Device Purchasing Controls

The FDA is placing an ever-keener eye on device manufacturers' purchasing controls, especially supplier qualification processes and vendor-related record keeping.

If you're concerned – and you should be – rush to order a brand-new management report from FDAnews, **Managing Device Purchasing Controls**, that will make a significant difference to you and your company.

This report is written especially to help devicemakers like you avoid problems by outlining 5 simple steps tied closely to the precise regulatory language governing purchasing controls:

- Step 1: Evaluate Your Suppliers
- Step 2: Determine the Necessary Level of Control over Suppliers
- Step 3: Establish and Maintain Record-Keeping Procedures
- Step 4: Establish and Maintain Purchasing Data for All Suppliers
- Step 5: Establish and Follow Acceptance Criteria and Activities

Commit to following the 5 steps and you'll quickly go from noncompliance to establishing and implementing a robust purchasing controls program that will meet – and may even surpass – the FDA's Quality System Regulation (QSR) requirements.

Included in the report are tried-and-tested tips such as:

- Best practices for establishing acceptance criteria to demonstrate sustained suitability of a supplier. (Merely conducting audits isn't enough.)
- The 5 items that each approved vendor's file MUST contain.
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Medical Device Recall or Product Enhancement? *Understanding the FDA's Part 806 Guidance*

Based on the FDA's most recent recall guidance, devicemakers now have to wonder if their product enhancements are an acceptable product enhancement, a recall, a product enhancement that's now considered a recall, or neither a product enhancement nor a recall.

The determination whether an enhancement reduces a risk to health is not always easy. So what about any enhancements you are currently making — or considering? Are you sure they are not recalls? And if so, do you know what you need to do?

This timely management report from FDAnews will:

- Examine the inherent contradictions between the draft guidance and existing statutory and regulatory statements.
- Make recommendations on developing a plan of action for reporting recalls and enhancements.
- List key factors to consider when developing a plan and options related to making product changes.
- Explain other product actions and how they might be affected by the draft guidance.
- Describe the history of medical device recall and enhancement reporting and the traditional procedures of device manufacturers to comply with existing regulations.
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