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House Member Raises Questions Over Risks of Power Morcellators

The drama surrounding power morcellators continues to heat up, with a federal lawmaker raising questions over whether Johnson & Johnson and Brigham & Women's Hospital failed to notify the FDA of risks posed by the devices, used to treat uterine fibroids.

Rep. Tim Murphy (R-Pa.), chairman of the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee, addressed the issue during a Nov. 17 hearing, maintaining J&J "was apparently aware of the dangers of this device as early as 2006, based upon a report from Dr. Robert Lamparter, a pathologist from central Pennsylvania, who cited about one out of 300 samples of morcellated tissue from his hospital had evidence of a hidden cancer."

Murphy made his comments in a hearing on the regulation of diagnostic tests and laboratory operations, during which Jeffrey

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Malaysia Issues New Rules on Incident Reporting, Device Labeling, GDP, Conformity Assessment

With an eye toward ensuring patient safety, Malaysia's Medical Device Authority has provided its thinking on how companies should report incidents involving medical devices.

The regulator earlier this month unveiled the first edition of its draft guidance on mandatory problem reporting that encourages devicemakers to consult the user or healthcare professional involved in an adverse device event, if possible.

"All establishments [that] place medical devices in the market should be vigilant for any changes in trends or frequency of occurrences of incidents with regards to medical devices they deal in," according to the document.

The draft guidance explains the responsibilities of devicemakers or their authorized representatives if a reportable incident occurs, including informing the MDA, investigating the incident and taking corrective actions and, in the case of user error, reviewing labeling for any potential inadequacies.

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Morcellator, *from Page 1*

Shuren, head of the FDA's device center, testified. When Murphy asked whether the hospital had reported these findings to the FDA, Shuren replied that he wasn't aware of what actions the healthcare facility took.

Power morcellators have received a lot of scrutiny over the past couple of years, particularly related to the cancer link.

Earlier this year, the Federal Bureau of Investigations launched an investigation after cardiac surgeon Hooman Noorchashm, of Philadelphia, reported that his wife's cancer spread throughout her body following a morcellation procedure at Brigham & Women's Hospital in 2013 (*IDDM*, May 29).

Morcellators, which have been on the market for more than 20 years, are used to shred tumors.

The FDA issued a safety alert for the devices in April 2014, and in November of that year warned against their use in most women undergoing myomectomy or hysterectomy for treatment of fibroids.

Also, Brigham & Women's Hospital was aware of the dangers in 2012, Murphy pointed out. A patient named Erica Kaitz was seriously injured in 2012 by the device and then died in 2013, Murphy said.

Shuren said hospitals and manufacturers are required to report certain events to the FDA, adding, "What I can tell you is that we have been looking into those concerns that have been raised."

The FDA's safety alert said morcellator blades could spread unsuspected cancers in as many as one in 350 cases.

However, Murphy pointed out the FDA has admitted that the one out of 350 risk does not address other types of malignancies, which would add to that risk.

Also, the FDA identified studies showing that morcellated patients had worse outcomes than those who had not undergone morcellation, added Murphy.

Shuren responded, "In terms of tests we looked at, we think where we have constrained it right now for use is where the benefits outweigh the risks. But we are continuing to look at new data as it arises and if so, we will act accordingly."

Earlier this year, a bipartisan group of lawmakers called on the Government Accountability Office to investigate the FDA over morcellators, saying the agency, industry and many gynecologists had pointed to the risk of a hidden cancer as being only 1-in-10,000 (*IDDM*, Aug. 14).

The GAO has accepted the request, and the work is set to get under way in January or February, agency spokesman Chuck Young tells *IDDM*.

Brigham & Women's Hospital declined to comment. J&J did not respond to a request for comment by press time. — Jonathon Shacat

Cyberdyne Gets MHLW's Thumbs Up For Robotic Therapeutic Device

Calling it a first for Japan, Cyberdyne has revealed that the country's Ministry of Health, Labour and Welfare has approved the HAL for medical use, a robotic therapeutic device to improve patients' walking function.

Intended to help patients with slowly progressing neuromuscular diseases — such as spinal muscular atrophy and amyotrophic lateral sclerosis — HAL had received designation as a medical device for orphan diseases.

As a result, the Tsukuba, Japan-based company received regulatory signoff within eight months of the March 25 application submission date.

Discussions on the treatment's coverage under public medical insurance are under way, according to the company. — Elizabeth Hollis

FDA Takes Companies to Task For Selling Unapproved DTC Tests

Shrugging off complaints that it is hindering innovation, the FDA is looking into whether five companies are selling unapproved diagnostic tests.

In separate letters sent to Kalios Genetics, Harmonyx, DNA-Cardiocheck, DNA4Life and Interleukin Genetics, the agency expresses concern that these companies are using a direct-to-consumer marketing model for their laboratory developed tests, as they appear to meet the criteria of medical devices. None of the tests have been cleared by the FDA.

The letters were sent regarding the following tests:

- The Kailos Test for analyzing multiple genes for indications of disease risk as well as the response to over 50 types of medicine;
- Harmonyx tests for antiplatelets, statins, ADHD and pain;
- DNA-Cardiocheck to test for DNA genetic markers linked to thrombophia, deep-vein thrombosis, cardiovascular disease and stroke;
- DNA4Life's Pharmacogenetic Report for predicting how patients will respond to more than 120 of the most prescribed medications; and
- Interleukin's PerioPredict Genetic Test, Osteoarthritis Genetic Test and Weight Management Genetic Test.

Harmonyx and Kailos say they are in compliance with regulations and they will work with the agency to address its concerns. The other companies could not be reached for comment by press time.

The letters come as the FDA mulls over how it will regulate LDTs. Earlier this month, Jeffrey Shuren, head of the FDA's Center for Devices and Radiological Health, told a congressional panel that final guidance is expected next year on how the agency will enforce the regulation of LDTs (*IDDM*, Nov. 23).

A draft version of that guidance has been met with stiff resistance from some stakeholders that see the FDA's proposal as regulatory overreach (*IDDM*, Jan. 23).

"Some of the criticism has been that we are trying to stymie innovation or slow people down, but really we are not. We need to make sure these tests are safe and effective, and do exactly what they say they are going to do," CDRH spokesman Eric Pahon tells *IDDM*.

Read the letters to Interleukin, DNA-Cardiocheck, Harmonyx, Kalios and DNA4Life here, respectively: www.fdanews.com/11-15-DTC-Letter1.pdf, www.fdanews.com/11-15-DTC-Letter2.pdf, www.fdanews.com/11-15-DTC-Letter3.pdf, www.fdanews.com/11-15-DTC-Letter4.pdf and www.fdanews.com/11-15-DTC-Letter5.pdf. — Jonathon Shacat

Ireland's MDA Identifies Key Priorities for Next Government

The Irish Medical Devices Association has laid out an ambitious set of priorities it hopes to see acted on by the next government to maintain the country's competitiveness in the medtech sector.

In a report — Priorities for the Next Government: Innovating for Ireland's Future Health and Care, Driving Economic Growth in the Medical Technology Sector — IMDA points out that Ireland is home to 18 of 25 of the world's top medtech companies. With the evolving healthcare models worldwide, the medtech sector is poised to provide innovative solutions to enhance patient outcomes, the group asserts.

To that end, the group identifies six priority areas that it wants to see addressed:

- Adopting the newest information systems, innovations and the best business models;
- Incentivizing clinical industry engagement to support commercialization of innovations;
- Changing the procurement process to promote long-term results to help reduce healthcare costs;

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Ireland, *from Page 3*

- Reforming the capital gains tax and share option schemes to encourage new medtech startups;
- Ensuring that higher education institutions prepare students with the skills to gain jobs and promote entrepreneurship; and
- Making sure that the Knowledge Development Box— akin to the UK's patent box — supports the generation of intellectual property.

The report discusses each priority area, providing recommendations on how each could be addressed. For example, in addition to reforming the capital gains tax, the group suggests creating an equivalent to the UK's Seed Enterprise Investment Scheme, which aims to remove barriers to trade for small startups.

IMDA Director Sinead Keogh said in a prepared statement that attracting clinical research to Ireland should be "underpinned by state of the art infrastructure to support work with cutting edge technologies like robotics, surgery simulation, cell manufacturing and 3D printing."

To read the report, visit www.fdanews.com/11-30-15-ireland.pdf. — Michael Cipriano

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Malaysia, *from Page 1*

Manufacturers or authorized representatives must report incidents within 48 hours if they represent a serious threat to public health, within 10 days if they have led to death or serious injury and within 30 days if a recurrence may lead to death or serious injury.

Reporting is not required in certain circumstances, such as if the deficiency is found by the user prior to use, if the device's service life or shelf life has been exceeded, or if side effects are based on expected and foreseeable outcomes.

The draft guidance was released along with three other documents, covering device labeling requirements, good distribution practices and conformity assessment procedures.

The MDA's first edition draft guidance on labeling spells out requirements for the format, content, language and location of device labels.

Labels should be attached to the device — when practical — or on the packaging itself. The label should contain details, such as the product's name, model, lot or serial number, manufacturing date, expiration date, instructions and the manufacturer's contact information.

Home-use devices must contain both Bahasa Malaysia and English, while English should be used on other types of devices. Other languages may be used as necessary.

The MDA also released its first edition of draft guidance on conformity assessment procedure for devices that have been approved by recognized foreign regulatory authorities or notified bodies. It explains the requirements to perform a verification process and how the MDA approves conformity assessment certificates.

The MDA also issued a first revision of good distribution practices. The document, which is largely unchanged from the July 2013 version, contains a new list of device categories under the scope of certification in Annex 1.

Read the draft guidance on conformity assessment procedure here: www.fdanews.com/11-15-Malaysia1.pdf. The draft guidance on mandatory problem reporting is here: www.fdanews.com/11-15-Malaysia2.pdf. The draft guidance on device labeling requirements is here: www.fdanews.com/11-15-Malaysia3.pdf. The revision on good distribution practice is here: www.fdanews.com/11-15-Malaysia4.pdf. — Jonathon Shacat

House Members Push for Device Tax Repeal in Larger Legislative Package

A bipartisan group of 44 freshmen members of Congress is urging House Speaker Paul Ryan (R-Wisc.) to include medical device tax repeal provisions in a larger legislative package by the end of the calendar year.

In a Nov. 19 letter, the group, led by Rep. Elise Stefanik (R-N.Y.), says the 2.3 percent excise tax requires devicemakers to pay an estimated average of $194 million per month in tax payments. That means the industry is subject to one of the highest corporate tax rates in the world.

"In a competitive global economy, this tax threatens an innovative industry that directly employs 400,000 Americans, generates approximately $25 billion in payroll, and invests nearly $10 billion in research and development annually," the letter says.

The Medical Imaging & Technology Alliance has commended the group of Congress members for writing the letter.

AdvaMed says it looks forward to working with Congress to address the device tax this year.

The letter follows a June 18 House vote of 280 to 140 to repeal the device excise tax under H.R. 160, known as the Protect Medical Innovation Act of 2015 (*IDDM*, June 19).

Two bills introduced in the Senate — the Medical Device Access and Innovation Protection Act (S. 149) and A Bill to Repeal the Medical Device Excise Tax, and for Other Purposes (S. 844) — have failed to get out of the Finance Committee, despite bipartisan support.

Read the letter here: www.fdanews.com/11-15-TaxRepeal-Letter.pdf. — Jonathon Shacat

Cellulite Reduction Claims Help Earn Warning Letter for A-1 Engineering

Failing to evaluate potential suppliers and making claims that its therapeutic massagers can help reduce cellulite and wrinkles have helped earn A-1 Engineering an FDA warning letter.

The Nov. 19 warning letter follows a March 2 to 18 inspection of the company's Rancho Cucamonga, Calif., facility, during which FDA officials determined the company had failed to maintain device master records and history records.

In addition, it had not maintained schedules for adjustment and cleaning of equipment or established quality system procedures.

The company — which makes the Neurotris SX-Series Machines and Neurotris PICO Toner therapeutic massagers — also is dinged for not evaluating and keeping documentation on component and parts suppliers.

In addition, the company did not maintain complaint files or schedules for the adjustment, cleaning and other maintenance of equipment.

Further, while the company told the inspector that its devices are exempt from premarket notification, the agency has reached a different conclusion.

The letter points out that the therapeutic massagers generally are intended to relieve minor muscle aches and pains, but the company is marketing them for uses such as wrinkle reduction, face lifting, neck tightening, cellulite reduction and muscle toning.

"To date, we have not received a response from you concerning our investigator's observations," the letter states, adding that A-1 should cease activities that have resulted in the device being misbranded.

A-1 Engineering did not respond to a request for comment by press time.

Read the warning letter here: www.fdanews.com/11-15-A1WarningLetter.pdf. — Jonathon Shacat

Durable Medical Equipment Company Owner Sentenced for Medicare Fraud

A Texas man who owned two Houston-area durable medical equipment companies must serve five years and three months in prison and pay $1.96 million in restitution for his role in a scheme to defraud Medicare, the U.S. Department of Justice announced.

Huey Williams Jr., 46, of Katy, Texas, who operated Hermann Medical Supplies and Hermann Medical Supplies II from December 2006 through July 2010, was sentenced Nov. 20 by Judge Melinda Harmon of the U.S. District Court for the Southern District of Texas.

In March, Williams was convicted of one count of healthcare fraud during a jury trial, after evidence showed he oversaw a scheme to defraud Medicare by submitting $3.4 million in false and fraudulent DME claims, according to the Justice Department.

Medicare paid Hermann Medical $1.96 million on the claims.

Specifically, Williams caused Hermann Medical to bill Medicare for components of an "arthritis kit," which included expensive, rigid braces and orthotics with adjustable joints that required fitting and adjustment.

In reality, he provided beneficiaries with inexpensive, flimsy neoprene braces and equipment — to the extent he provided any equipment at all.

News of sentencing comes shortly after the conviction of Valery Bogomolny, owner of Royal Medical Supply.

Bogomolny was convicted Nov. 6 of healthcare fraud in U.S. District Court for the Central District of California after receiving $2.7 million related to false claims for power wheelchairs, back braces and knee braces (*IDDM*, Nov. 13).

He is scheduled for sentencing on Feb. 29, 2016, before Judge James Otero.
— Jonathon Shacat

FDA Issues Proposed Rule on Classifying Bacillus IVD Test Kits

The FDA is re-proposing classifying in vitro diagnostic devices for Bacillus species detection into Class 2 with special controls, a move the agency says would help assure the safety and effectiveness of the devices.

The agency originally proposed to classify these devices into Class 2 in May 2011, but withdrew the draft guidance this May — along with other guidances it had not been finalized — as part of a transparency initiative.

The FDA also has released final orders classifying ultraviolet radiation chamber disinfection devices and reclassifying electrical salivary stimulator systems.

UV radiation chamber disinfection devices are now in Class 2 with special controls. The salivary stimulator system, a postamendments Class 3 device, is now reclassified into Class 2 with special controls.

In addition, the FDA issued a final order exempting electric positioning chairs, Class 2 devices, from premarket notification requirements. To be 510(k)-exempt, the devices must meet certain conditions, such as testing that shows the safety controls are adequate to prevent user falls if the devices fail, the ability to withstand the rated user weight load, and the longevity of the devices to withstand external forces.

The Federal Register notice on the proposed rule on Bacillus species is here: http://www.fdanews.com/11-15-FDA-Rule.pdf. The notices on the final orders on classifying UV radiation chamber disinfection devices and on reclassifying electrical salivary stimulator systems are here, respectively: http://www.fdanews.com/11-15-FDA-Order1.pdf and http://www.fdanews.com/11-15-FDA-Order2.pdf. The notice on the final order on electric positioning chairs is here: http://www.fdanews.com/11-15-FDA-Order3.pdf. — Jonathon Shacat

FDA Working 'Expeditiously' On Review of Bayer's Essure

In the wake of more than 5,000 adverse events reports, including four deaths, the FDA says it plans to communicate next steps it plans to take on Bayer's Essure contraceptive implant by the end of next February.

The controversial implant has received a lot of negative publicity, with women saying they had experienced numerous adverse events after implantation with Essure, such as bleeding, autoimmune diseases, painful sexual intercourse, unplanned pregnancies, weight gain, tooth and hair loss and excruciating pelvic and abdominal pain.

The FDA has taken notice. "This is a high priority issue for the agency, and we are working expeditiously to conduct an evidence-based review of the available information and identify appropriate next steps," the FDA says on a notice posted to its website.

During a September meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, several women testified about pain and other adverse events they had experienced (*IDDM*, Sept. 25). The panel recommended that a patient registry be created to document these events.

The agency says it is reviewing information from the panel meeting, an associated public docket, as well as medical literature and adverse event reports published or received since the panel meeting.

Several members of Congress have called on the FDA to remove Essure from the market. A bill that would move that effort forward — H.R. 3920, The E-Free Act — was introduced by Rep. Michael Fitzpatrick (R-Pa.) earlier this month (*IDDM*, Nov. 13). Reps. Marsha Blackburn (R-Tenn.), Christopher Smith (R-N.J.) and nonvoting member Gregorio Sablan (I-N. Mariana Islands) are cosponsoring the effort. The bill has been referred to the House Energy and Commerce Committee. — Elizabeth Hollis

BRIEFS

Medtronic Acquires Aircraft for $110M

Irish devicemaker Medtronic has acquired Aircraft Medical, a developer of video laryngoscopes used by anesthesiologists to intubate patients, through an all-cash transaction valued at $110 million. Medtronic says the deal will expand its portfolio of solutions for dealing with difficult airways and addresses respiratory compromise. Aircraft's devices enable clinicians to quickly insert the breathing tube into the trachea, allowing them to see the vocal cords. Medtronic will report revenue from Aircraft's product line as part of its Patient Monitoring & Recovery division within its Minimally Invasive Therapies Group.

SurModics Acquires Creagh for $32M

Eden Prairie, Minn.-based SurModics has acquired percutaneous transluminal angioplasty balloon catheters manufacturer Creagh Medical for about $32 million. SurModics says it made the purchase to help transform its device business from being a provider of coating technologies to offering whole-product solutions to the global interventional vascular market. Many of Creagh's products have been cleared for commercial sale in Europe, the U.S and Japan.

St. Jude's Spinal System Approved

The FDA has granted approval to St. Jude Medical's Proclaim Elite spinal cord stimulation system for people suffering from chronic pain. The system enhances patient convenience, as it does not need to be regularly recharged, the St. Paul, Minn.-based devicemaker says. It also contains a platform that enables patients to access future upgrades, such as new stimulation waveforms. The approval also includes conditional magnetic resonance labeling for the system, allowing patients to undergo head and extremity MRI scans. It further covers St. Jude's new clinician programmer, which allows for the use of an Apple iPad mini mobile digital device to program spinal cord stimulation therapy.

Biosense Webster Buys Coherex Medical

Johnson & Johnson unit Biosense Webster has acquired Coherex Medical for an undisclosed sum. Coherex manufactures the minimally invasive WaveCrest device, designed to block the most common source of blood clots and prevent strokes in at-risk patients with atrial fibrillation. The device — which has received the CE mark — closes off the left atrial appendage to prevent the release of clots into the bloodstream.

FDA Clears Visunex's Imaging System

Fremont, Calif.-based Visunex Medical Systems has won FDA clearance for its PanoCam LT wide-field imaging system for newborn infants. A wireless imaging system, PanoCam LT is designed to detect external, anterior and posterior segment vision disorders that may result in negative long-term effects on the vision. Vision disorders may affect between 10 and 20 percent of newborns worldwide, according to the company. Visunex adds that early detection of retinal hemorrhages and other disorders can lead to prompt intervention and potentially prevent vision loss.

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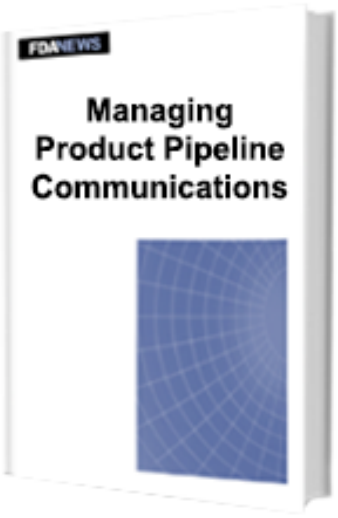

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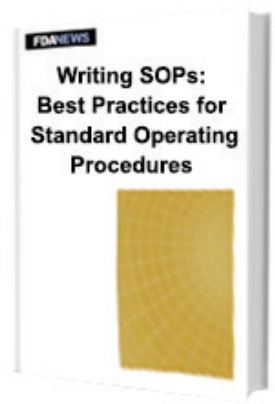

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