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IN THIS ISSUE



## 21st Century Cures Act Flies Through House

Organizations representing device manufacturers are heralding the passage of the 21st Century Cures Act, which advanced through the U.S. House of Representatives in a 344-77 vote.

Stephen J. Ubl, president and CEO of industry trade group AdvaMed, says the bill incorporates provisions that will enhance innovation. "This includes key improvements to FDA's premarket program for medical devices — most significantly the establishment of an expedited pathway for breakthrough, innovative technologies — which will increase the efficiency, predictability and transparency of the agency's review process and improve patient access to the best in medical progress," he said in a prepared statement.

However, while the group applauds the legislation's passage, it continues to express concern about a provision that would apply Medicare rates for durable medical equipment to Medicaid.

*(See* **21st Century**, *Page 2)*

## MHRA Updates Progress on Reforms In Response to Critical Findings

After receiving a less-than-favorable review on engagement with the clinical community, the UK's Medicines and Healthcare products Regulatory Agency says it has made progress on this front — including forming an independent Devices Expert Advisory Committee and hiring clinical staff capable of peer-to-peer dialogue with healthcare leaders.

But, as the agency notes, challenges remain.

Published July 3, the MHRA report touches on 12 recommendations by Professor Terence Stephenson, chair of the General Medical Council, who led an independent team to assess the agency's access to expert advice on devices, and found it lacking. The agency has identified the initial 14 stakeholder groups whose expertise would be needed for the DEAC, and a kickoff meeting is expected to take place this month.

*(See* **MHRA Report**, *Page 4)*

**21st Century,** *from Page 1*

Mark Leahy, president and CEO of the Medical Device Manufacturers Association, also expressed appreciation for the House's work, saying in a prepared statement that his organization will cooperate with Congress to improve the measure.

During a Rules Committee meeting ahead of the vote, two device-related amendments were adopted. One proposed by Rep. Mike Fitzpatrick (R-Pa.) encouraged recording unique device identifiers at the point of care in electronic health record systems to enhance the availability of data for postmarket surveillance. The House voted to include this amendment in the final bill.

Fitzpatrick had offered seven other amendments that focused on getting unsafe devices off the market, particularly power morcellators. These devices are used to remove uterine fibroids and have been linked to spreading cancer in women. "What happened with the power morcellator … should never be allowed to happen again," he said on the floor. All the other amendments were rejected before the House considered the bill.

Another amendment, offered by Rep. Jared Polis (D-Colo.) called for a report on the risks and benefits of a two-tiered approval process that would allow medical devices to come to market provisionally if they've demonstrated safety but not efficacy. "This solves a real problem in the world," Polis said, adding that the long period of review by the FDA makes bringing devices to market very expensive.

Polis ultimately withdrew the amendment after concerns were voiced. "I believe it's got merit," said Rep. Fred Upton, (R-Mich.), author of the bill, who said he would work with Polis to flesh out the idea.

Now all eyes have turned to the U.S. Senate. "The U.S. Senate Health, Education, Labor & Pensions Committee is working in a bipartisan manner on a similar initiative," says a spokesperson for the HELP Committee. "The Senate hopes to have legislation by the end of the year." — Elizabeth Hollis

## FDA Outlines Label, Test Expectations For Products Containing Heparin

To reduce dosing errors that have resulted in deaths and patient adverse events, the FDA is providing manufacturers with labeling and safety testing recommendations for medical devices and combination products containing the blood thinner heparin.

Patient safety organizations such as the Institute for Safe Medication Practices have maintained that confusing labels on heparin vials were responsible for inadvertent medication errors. And as a July 9 draft guidance notes, heparin products span a wide range of doses and concentrations based on the indication and the intended patient population.

Following high-profile incidents involving heparin overdoses — including actor Dennis Quaid's newborns receiving 1,000 times the prescribed dose — the U.S. Pharmacopeial Convention revised its labeling expectations for the drug in 2012.

### Updated Labels

Heparin vials now must display the strength per vial, followed by the strength per milliliter. The draft guidance provides examples of this labeling format and recommends that this information be provided in the instructions for use. In addition, the labels must identify the organ and animal species from which the product is derived. The draft guidance also provides labeling expectations for heparin-bonded products.

In terms of safety testing, the FDA urges manufacturers to follow the 2013 guidance document, *Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality*. Manufacturers also should verify and document that the drug product has been tested to the current USP monograph, as well as manufactured and tested consistent with existing FDA guidance.

Premarket submissions should document compliance with heparin safety testing and include the following information:

- Heparin source-tissue and species, e.g., porcine intestinal mucosa;
- Confirmation of the species origin; and
- Name, address and contact information of the heparin active pharmaceutical ingredient manufacturer, as well as that of any repacker or distributor that handled the product prior to receipt.

Another topic addressed in the draft guidance is heparin containing oversulfated chondroitin sulfate. In 2008, heparin contaminated with this substance from a Chinese plant was linked to adverse events. The FDA says that between Jan. 1 and May 14, 2008, 11 deaths and 86 nonfatal adverse events were reported in patients using heparin-containing devices.

Both the FDA and USP have testing recommendations for OSCS. In their premarket submissions, manufacturers should demonstrate conformance with testing parameters from the 2013 guidance on monitoring the quality of crude heparin and show that the testing methods used can detect low levels of OSCS.

To read the draft guidance, visit www.fdanews.com/071315-heparin-draft-guidance.pdf. — Elizabeth Hollis

## Ireland Proposes Funding Model For Medical Device Regulatory Activities

Starting in 2016, medical devicemakers supplying or manufacturing products in Ireland would be subject to a proposed fee-based system to cover the cost of the Health Products Regulatory Authority's market surveillance activities.

HPRA developed the system at the request of Ireland's Department of Health, which had been providing the majority of the authority's funding, according to a public consultation document announcing the proposal. It comes as health authorities in other European countries, including Austria, Germany, Portugal and Spain, have turned to user fees to recover the costs of their regulatory activities.

*(See* **Ireland Pricing**, *Page 6)*

## Indian Regulators Seek Details On Orthopedic Implant Pricing

India's National Pharmaceutical Pricing Authority is asking several orthopedic implant manufacturers to provide details on cost increases that potentially may violate drug pricing laws.

In a letter addressed to executives at pharmaceutical associations and device manufacturers, NPPA asks for a brief description of the products, the maximum retail price and the percent increase in the MRP for each of the last three years. The regulator is looking into possible violations of the Drug Pricing Control Order of 2013, which states that no manufacturer, importer or distributor may raise the MRP of a nonscheduled drug more than 10 percent during the preceding 12 months.

According to the letter, the companies had sought clarification on whether DPCO 2013 provisions apply to medical devices, something NPPA confirms. "Orthopedic implants along with other medical devices are notified as 'Drug' under the Drugs & Cosmetic Act 1940 and rules thereunder," the letter states.

The rules authorize the government to inspect price list records, including those of 14 notified medical devices. NPPA asks the associations to encourage their member companies to provide the information within seven days of receipt of the letter.

The authority previously asked for this information in a May 15 notice that highlighted media reports alleging orthopedic implants have been sold at exorbitant prices with high profit/trade margins.

The letter comes as industry continues its ongoing push for a distinct definition of medical devices and a pricing and reimbursement system separate from that of drugs. The government took a step in that direction last month by announcing the creation of a dedicated authority to oversee the regulation and production of medical devices. Industry groups may comment on the government proposal through July 15 (*IDDM*, June 12).

The latest NPPA letter is available here: www.fdanews.com/071315-NPPA-request.pdf.
— Elizabeth Hollis

**MHRA Report**, *from Page 1*

The DEAC is expected to play a prominent role in helping the MHRA assume a more proactive role in building relationships and exchanging information with clinical groups within the UK. In fact, the agency already has contacted the Royal Colleges and specialist societies to help develop and manage a structured network of clinical advisers, rather than relying on an ad hoc group.

In terms of hiring clinical staff, the MHRA notes it has a full complement for the devices division — three medically trained positions and a senior nurse. In addition, the agency has developed a career pathways group to address recruitment and retention issues within the division.

However, recruitment, training and development of clinical staff remain critical challenges, the MHRA notes.

The report also touches on steps taken to support the safe introduction of innovative technologies in clinical practice, particularly in the wake of the Poly Implant Prothèse breast implant scandal (*see story, page 7*). The agency says it has been active in a range of areas, including regenerative medicine and software as a medical device.

Still, work remains. "Current resource constraints severely limit our ability to provide more support and communication to companies, particularly considering the regulatory processes for novel devices and those that span the regulatory environments for both devices and pharmaceuticals, such as combination products and diagnostics supporting personalized medicine," the agency says.

To read the full progress report, visit www.fdanews.com/07-13-15-MHRA-update.pdf.
— Elizabeth Hollis

## Court Eliminates Hurdle For Whistleblowers to Collect

A federal appeals court has made it slightly easier for whistleblowers to collect awards after it nixed one of three requirements for being considered an original source in a *qui tam* lawsuit. The ruling also overturns the dismissal of a consolidated *qui tam* lawsuit against Kinetic Concepts, now known as Acelity.

In the July 7 ruling involving two former KCI employees, Steven Hartpence and Geraldine Godecke, the U.S. Court of Appeals for the Ninth Circuit determined that there are two requirements whistleblowers must meet to recover under the False Claims Act: they must voluntarily inform the government of the facts underlying the allegations, and they must have independent knowledge of the allegations.

The decision tosses out precedent set in a 1992 case, *Wang ex rel. United States v. FMC Corp.*, which added a third requirement: that the whistleblower also played a role in the public disclosure of the allegations.

### Courts Drop Third Prong

In its decision, the court notes that many other circuits have declined to apply the third prong, saying it "impermissibly grafts onto the statute a requirement nowhere to be found in the statute's text," according to court documents. "Today, we join our sister circuits; after reviewing the statutory text, we conclude that *Wang*'s hand-in-the-public-disclosure requirement has no textual basis, and we give it a respectful burial," the circuit says.

Hartpence and Godecke separately accused KCI, which manufactures wound-healing products, of fraudulently collecting reimbursements from Medicare. The district court found the two didn't qualify as an original source because neither had a hand in the public disclosure under the third prong of *Wang*. It also barred Godecke's claims because she was not the first to file.

In its decision, the circuit court says the district judge erred because some of Godecke's claims were materially distinct from those of Hartpence.

As a result of the ruling, *U.S. Ex Rel., Steven J. Hartpence v. Kinetic Concepts, Inc.; KCI-USA, Inc.,* and *U.S. Ex Rel, Geraldine Godecke v. Kinetic Concepts, Inc.; KCI-US, Inc.*, have been remanded to the U.S. District Court for the Central District of California for further proceedings. — Elizabeth Hollis

## Advocacy Group Calls for Recall, Approval Withdrawal of Seprafilm

Public Citizen has filed a petition urging the FDA to rescind its approval of the Seprafilm bioresorbable membrane, which is used to prevent postoperative adhesions, citing adverse patient events, including at least 21 deaths.

The consumer advocacy organization maintains that Seprafilm, which was developed by Genzyme, has not been shown to be safe and effective. In addition to the reported deaths, the FDA's MAUDE database includes 524 adverse events — such as bowel obstruction, abscess, peritonitis, fever, fluid collection and inflammatory reaction — linked to Seprafilm, the group says.

The FDA approved the device in 1996 on the condition that Genzyme, which was acquired by Sanofi in 2011, would conduct a postmarket safety study. The agency had concerns about the number of serious adverse events in the Seprafilm arm of one of two pivotal efficacy studies, according to the petition. These events included abscesses and pulmonary emboli.

Public Citizen alleges both the pre- and postmarket studies "were plagued by a host of serious issues," including protocol violations and problematic reanalysis of data. According to the petition, agency inspectors sent a warning letter to a principal investigator who failed to maintain blinding throughout the study. In addition, the

*(See* **Seprafilm Petition**, *Page 6)*

## Seprafilm Petition, *from Page 5*

investigator failed to report some adverse event data and lacked informed consent documentation.

The group also maintains that the postmarket study, dubbed Study 601 and conducted to assess the device in reducing the incidence of bowel obstruction following abdominopelvic surgery, failed to meet its primary endpoint. Further, patients in the Seprafilm group were significantly more likely to experience anastomotic leak, peritonitis, vomiting and fistula versus those in the control group.

"Rather than accept these results — which were potentially disastrous with respect to the continued marketability of Seprafilm — Genzyme, in coordination with the Study 601 Steering Committee, engaged in several extensive post hoc re-analyses of the data designed to re-characterize the failed trial as a success," the petition maintains. For example, Genzyme allegedly created a new definition for bowel anastomosis, a term that had been interpreted different ways by investigators. The U.S. National Library for Medicine defines anastomosis as a surgical connection between two structures.

As a result of the redefinition, the steering committee reclassified an unknown number of subjects as having a bowel anastomosis.

### Off-Label Problems

The petition also points to dangers related to off-label use of the device, including with Cesarean sections and pediatric surgery, the petition states. It notes that in December 2013, Genzyme agreed to pay $22.28 million to settle false claims allegations related to Seprafilm. Whistleblowers came forward accusing Genzyme sales representatives of improperly showing doctors and other staff how to create Seprafilm "slurry."

To make this slurry, Seprafilm sheets were cut into small pieces, dissolved in saline and ultimately used in laparoscopic surgery — an unapproved use. Genzyme was accused of knowingly causing healthcare organizations to submit false and fraudulent claims for reimbursement.

In an e-mailed statement to *IDDM*, Sanofi and Genzyme say they are committed to the safe and effective use of Seprafilm. "We stand behind the clinical trial results and nearly 15 years of postmarketing surveillance data reported to the FDA for Seprafilm. We continue to advise physicians to follow the approved product labeling, including directions for general use."

To read the citizen petition, visit www.fdanews.com/071315-Seprafilm-petition-pdf.pdf.
— Elizabeth Hollis

## Ireland Pricing, *from Page 3*

HPRA considers this a suitable approach in terms of equity and minimizing burden, in advance of a wider solution at the European level.

Taking company size into consideration, the proposed fee structure is as follows:

- Manufacturers with more than 150 employees would pay about US $33,000;
- Manufacturers with 50 to 150 employees would pay about US $27,500;
- Manufacturers with 15 to 49 employees would pay about US $16,500;
- Manufacturers with five to 14 employees would pay about US $5,500; and
- Manufacturers with fewer than five employees or turnover of less than US $557,800 would pay about US $275.

Other fees apply to distributors and authorized representatives for medical devices in Ireland. The fee for export certifications, also known as certificates of free sale, would rise to about US $275. As a result of this fee increase, HPRA says it will introduce an expedited service for issuing these certificates.

Interested parties may e-mail feedback about the consultation to MDConsultation@hpra.ie through Aug. 6.

The consultation is available by visiting www.fdanews.com/071315-HPRA-funding.pdf.
— Elizabeth Hollis

## French Court Overturns Ruling in Implant Suit

TÜV Rheinland has scored another victory in a French court in a case involving faulty breast implants. However, its fate in another case is up in the air as it awaits a decision from the European Court of Justice.

At issue was whether TÜV properly conducted its role as a certification body after it awarded safety certificates to Poly Implant Prothèse. The now-defunct French manufacturer ignited an international scandal when it was exposed for using industrial-grade silicone in breast implants. More than 400,000 women received the implants in 68 countries before they were pulled from the market in 2010.

After PIP dissolved, six distributors of the implant, along with 1,700 women, brought suit against the notified body based on allegations of negligence. France's Toulon Commercial Court found in favor with the plaintiffs and ordered TÜV to pay about US $3,300 to each woman involved in the case. An additional 1,600 plaintiffs joined the case on appeal.

The Aix-en-Provence Court of Appeal disagreed with the lower court's ruling, determining that TÜV was not obliged to take samples of the product or initiate tests on marketed prostheses. The ruling followed favorable decisions for the notified body in the Paris Civil Court and Marseille Criminal Court, according to a company statement.

"This decision is in line with a long series of positions taken in favor of TÜV Rheinland by courts and authorities to date and constitutes an important step in the court disputes as a result of the fraud perpetrated by PIP to the detriment of the women concerned but also of TÜV Rheinland," company spokesman Frank A. Dudley tells *IDDM*. He adds that TÜV always has worked to perform its inspection duties "in compliance with all applicable laws and regulations."

The furor over PIP prompted calls for more unannounced audits of medical device manufacturers. Prior to the scandal, notified bodies could conduct these audits, but it was not a routine practice (*IDDM*, April 23).

In September 2013, the European Commission recommended unexpected audits every two years for manufacturers of high-risk devices, and every three years for those making low- and moderate-risk products.

David Clerk, founder of Ganymede Consulting in Zug, Switzerland, says he has had extensive discussions with devicemakers about the PIP case, and many in industry think TÜV was following regulations. "However, the discussion usually finishes with the question of whether the regulations in Europe are not stringent enough, and if such a situation could happen with a company operating on American soil," he explains.

"An unannounced inspection from a notified body in Europe — this is simply not something a device manufacturer needs to worry about," Clerk adds. "The general consensus, however, is that any company that deliberately doctors products for financial gain could do so no matter how stringent the quality system regulations are."

### Awaiting ECJ Clarification

A case involving a woman who sued TÜV after receiving the defective implants remains pending in the German Federal Court of Justice after she suffered defeats in lower court rulings. Until now, the courts have held that notified bodies are not liable if a person is injured, as they act in the public interest and not in the interest of individuals, Wolfgang Rehmann, international head of life sciences & healthcare at the law firm Taylor Wessing in Munich, tells *IDDM*.

The woman's appeal went to Germany's highest court, which is seeking clarification from the ECJ on points of law. The European court's decision will give guidance as to whether a notified body is negligent, says Rehmann.

"The European Court, therefore, will have an impact on the question whether there can be liability as such, or whether it has to be ruled out for legal reasons," he explains. "The court will rule on the principle. Whether there was negligence in a given case needs to be assessed by the respective national court deciding on the specific case." — Elizabeth Hollis

# BRIEFS

## Blockage Leads to Resuscitator Recall

Teleflex Medical has recalled its Hudson RCI Lifesaver single-patient use resuscitator after reports of oxygen intake ports becoming blocked, preventing the delivery of breathing support. The disposable medical device is intended to provide temporary breathing support for patients experiencing acute ventilatory failure. The company initiated the recall May 15 for products manufactured and distributed between June 2014 and April 2015. The FDA has deemed it a Class I recall. Teleflex says it has not received any reports of injuries or deaths related to the recall.

## Allergan to Buy Oculeve

Allergan has signed an agreement to acquire South San Francisco, Calif.-based Oculeve for $125 million upfront in an all-cash deal, plus commercialization milestone payments related to the development program of OD-01. Oculeve's OD-01 is a nasal neurostimulation device that boosts tear production in patients with dry eye disease. The company has completed four clinical studies of the device in more than 200 patients. Allergan plans to conduct two more pivotal trials prior to FDA submission, which is expected next year. Allergan anticipates the deal will close the third quarter of the year.

## SculpSure Snags Expanded Indication

Cynosure's SculpSure lipolysis laser treatment has won an expanded FDA indication for noninvasive fat reduction in the abdomen. The hands-free device uses a laser to treat the desired area in about 25 minutes, and patients can achieve results without downtime or surgery, the company says. The technology is expected to be launched in the U.S. in the second half of the year. In May, the FDA cleared the laser treatment for noninvasive lipolysis of the flanks.

## FDA Green Lights Herpes Test

Theranos has gained FDA 510(k) clearance for its herpes simplex 1 virus IgG test system. The test uses finger stick and venous blood testing technology, the Palo Alto, Calif.-based company says. Unlike conventional tests that are cleared for venous samples, the system can be used for venous, venous plasma, capillary plasma and capillary whole blood samples, the consumer healthcare technology company claims. This is the company's first FDA clearance.

## Quantidex Pan Cancer Kit Launched

Austin, Texas-based Asuragen has launched its Quantidex pan cancer kit, a next-generation sequencing oncology panel that classifies mutations on 21 genes associated with different cancers. The assay, which provides analysis of both formalin-fixed paraffin embedded and fine-needle aspiration tissues, features sample multiplexing, high analytical sensitivity and the ability to profile a large number of biomarkers in a single test, according to the company. The Cancer Prevention and Research Institute of Texas helped fund the kit's development. The assay is intended for research purposes only.

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

**Editor:** Elizabeth Hollis
(703) 538-7639
ehollis@fdanews.com

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

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
www.fdanews.com

**Reporters:** Kellen Owings, Jonathon Shacat; Jason Scott
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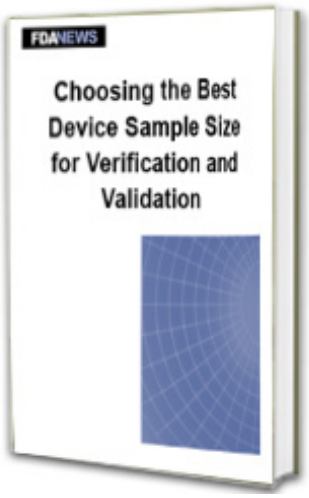


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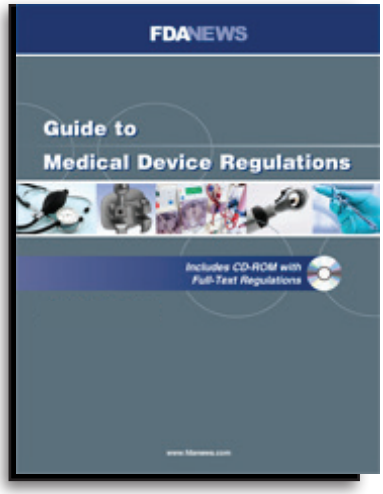


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