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FDA-CMS May Expanding Parallel Review Program to Device Types

A pilot program that allows devicemakers to simultaneously gain U.S. FDA approval and Medicare coverage may expand to evaluate device classes, rather than individual products, when it becomes permanent at the end of the year.

The parallel review pilot program operates on a device-by-device basis. However, the Centers for Medicare & Medicaid Services' national coverage decisions traditionally apply to device classes, rather than specific products. The most likely way to fix the mismatch would be to expand the program so that coverage decisions reached through parallel review would stand for all similar products, says Murray Sheldon, associate director for technology and innovation in the FDA's Center for Devices and Radiological Health.

Early Meetings Encouraged

Manufacturers interested in pursuing a parallel review path should meet with the FDA and CMS during the pre-IDE stage. While candidates conducting early feasibility studies may be considered, the "sweet spot" is right before a pivotal trial launches, FDA-CMS liaison Rochelle Fink says. Devices subject to parallel review must be PMA or de novo eligible; 510(k) products cannot participate.

The goal of the early meetings is to ensure that the trial design incorporates a representative sample of CMS beneficiaries, Fink explains. "The worst that can happen is that a manufacturer gets through the FDA review process, but then CMS says, 'great, this works on 40-year-olds, but what about our 65-year-olds?' and asks for more trial data," she says. A manufacturer that works with CMS from the beginning can avoid these setbacks by knowing what endpoints would be needed for CMS to consider coverage.

CMS' staffers may not always be available for presubmission meetings due to resource constraints, Fink admits. When that happens, the FDA will give the devicemaker materials on CMS' NCD requirements and stress the importance of testing products on Medicare recipients.

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CMS will devote whatever resources it has to ensure that devices can complete parallel review, says Tamara Syrek Jensen, director of the agency's coverage and analysis group. She adds that CMS is trying to be flexible regarding information requirements on parallel review products.

Sheldon and Fink, who spoke during a Tuesday session at the FDLI annual conference, stressed that the review will remain voluntary after the pilot phase ends on Dec. 18 — meaning CMS won't get involved in the presubmission process without a manufacturer's explicit request. Fink acknowledged that some devicemakers may not think a national coverage determination is appropriate for their product.

The agencies plan to launch a parallel review website soon. Questions may be directed to parallel-review@fda.hhs.gov. — Elizabeth Orr

Increase in Overseas Device Trials Spurs FDA Draft Guidance

The U.S. FDA is advising devicemakers that plan to use data from clinical studies conducted outside the U.S. to support an FDA premarket submission to meet with the agency before finalizing their trial design.

Meeting with the FDA early in the trial design process can help manufacturers ensure that the FDA will accept their OUS study data as valid scientific evidence, a draft guidance issued Wednesday states. Otherwise, the agency may request additional or duplicative U.S. trials.

While the agency has long accepted such data, provided it conforms to national and international laws governing clinical trials, a growing trend toward conducting device trials outside the U.S. has created the need for clearer guidance on FDA policies toward use of overseas studies. A separate rule is being finalized that will require overseas trials to be conducted according to good clinical practices, the draft notes.

Trial models that meet the FDA's standards for valid scientific evidence include well-controlled investigations, partially controlled studies, objective trials without matched controls, well-documented case histories and reports of significant human experience with a device, the agency says.

Devicemakers should consider whether the clinical conditions in the country where the trial is being conducted — such as standard of care — match those in the U.S., to enable the FDA to more accurately look at benefits and risks. Level of clinical skill among caregivers may also make a difference, the guidance says.

Sponsors should try to recruit study populations that match the U.S. patient population in areas such as race, gender, ethnicity and age.

Consider Variables

Other variables that may need to be considered include prevalence of smoking, diabetes and obesity, and cultural or language differences that may affect the interpretation of study results.

If differences exist between the OUS study subjects and the intended U.S. patient population, sponsors should either find a way to mitigate those differences or explain why they believe they don't affect the device's safety and effectiveness, the FDA says.

Sponsors should also consider the possibility that FDA requirements will differ from those where the OUS trial is conducted — for example, a foreign regulator may require proof of safety and performance, while the FDA standard is safety and effectiveness.

The draft guidance includes examples of seven cases where OUS data was used to support a device application and why the agency accepted or rejected its use.

Comments may be submitted to Docket No. FDA-2015-D-0975 through July 20. View the draft guidance at www.fdanews.com/04-27-15-trials.pdf. — Elizabeth Orr

European Court to Consider Whether NBs are Liable on Failed Devices

A European court will decide whether notified bodies can be held liable for failed devices.

A German court referred a liability case involving Poly Implante Prosthèse to the Court of Justice of the European Union earlier this month. PIP became notorious in 2010 when former executives and managers were charged with fraud for selling breast implants filled with industrial silicone instead of the medical silicone used in the CE- marked implants.

The plaintiff in the current case had filed suit against German notified body TÜV Rheinland for US $43,000 in damages suffered after receiving breast implants made by the company, plus liability for any future injuries. She argued that the notified body had not fulfilled its duty to audit PIP's quality management system or examine the design and surveillance of the company's implants. She also alleged that an adequate review of TÜV Rheinland would have stopped tainted implants from reaching the market much earlier.

Previous rulings on the issue in Europe have been mixed. Patients in France have successfully sued TÜV Rheinland in French courts. The notified bodies argued it was systemically deceived by PIP as well, but the French Commercial Court in Toulon ruled in 2013 that TÜV Rheinland is liable to French PIP implant victims. German courts have held that TÜV Rheinland can't be held responsible.

The current German case has been appealed to the German Federal Court of Justice, which is asking the CJEU for clarification on several points of the medical device directive. In particular, the court wants to know whether notified bodies are responsible for protecting potential patients and can be sued for damages if they are injured. The court also asked whether notified bodies have a responsibility to test finished products and whether they are obligated to review devicemaker's business records or carry out unannounced audits. The questions address Class III devices only.

The outcome of the case could have significant implications for the relationship between notified bodies and devicemakers in Europe, Covington & Burling attorneys say in a blog. If the plaintiff wins, German courts will need to reconsider whether devicemakers should be held solely responsible when their products fail. This could lessen the liability devicemakers face.

The decision could also help to create unified law on this point across EU nations. U.S. devicemakers could be affected if they place devices in the European market, says Adem Koyunco, head of Covington & Burling's German life sciences division.

He anticipates the court will issue a verdict in 12 to 18 months. — Elizabeth Orr

Proposed Medicare Payment Update Won't Hurt Devicemakers: Analysts

Devicemakers aren't likely to see their bottom lines hurt by hospital payment updates proposed by Medicare, an investment analyst says.

The Centers for Medicare & Medicaid Services issued a fact sheet April 17 discussing major provisions of the proposed rule, which would affect some 3,400 acute care and 435 long-term care hospitals.

Reimbursement for devices such as implantable cardioverter defibrillators, pacemakers and drug-eluting coronary stents are all up by low single-digits, says Leerink Partners, an investment bank specializing in healthcare.

Among the companies listed in a Leerink report are Advanced Biomedical Technologies (heart assist systems), Boston Scientific (coronary stents, pacemakers), Medtronic (coronary stents, pacemakers) and Abbott Laboratories (coronary stents).

The proposal sets goals and a timeline to move Medicare toward paying providers based on quality rather than volume of care they give patients.

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The CMS fact sheet discusses proposed fiscal year 2016 payment updates for inpatient stays at general acute care hospitals under the inpatient prospective payment system and long-term care hospitals under the long-term care hospital prospective payment system.

Total Medicare spending on inpatient hospital services will increase by about $120 million in fiscal 2016, CMS predicts.

The proposed rule would provide a 1.1 percent payment rate increase for general acute care hospitals that successfully participate in the Hospital Inpatient Quality Reporting Program and use electronic health records.

That rate increase and other proposed changes to IPPS payment policies will increase IPPS operating payments by 0.3 percent, CMS says.

Other payment adjustments include penalties for readmissions and for hospitals in the worst-performing quartile under the Hospital Acquired Condition Reduction Program.

The proposed rule also updates payments to hospitals for inpatient services based on performance of an announced set of measures.

CMS is proposing to add a care-coordination measure to the FY 2018 program year and a chronic pulmonary disease mortality measure.

For long-term care hospitals, CMS projects that PPS payments would decrease by 4.6 percent or about $250 million, based on proposed fiscal 2016 payment rates.

Cases meeting certain clinical criteria will see a 1.9 percent payment rate increase, the agency says.

The proposal will be published in the April 30 *Federal Register*, with a public comment period running through June 16. — Charlotte Astor

GVS Filter Technology Gets Warning Letter on Testing, Quality Violations

The FDA has warned the UK branch of GVS Filter Technology for failures in product-testing and quality control.

The Bologna, Italy-based company has branches worldwide and manufactures air and liquid filters for medical devices such as anesthesia machines and nebulizers.

Quality control failures cited in the Jan. 23 letter included three cases where nonconforming products required reworking and re-evaluation, but device history records did not document that the work was performed.

The FDA said the company's quality control procedure doesn't describe requirements for documenting how nonconforming products are handled, and doesn't require documentation of justification and approval for use of nonconforming products.

The letter said five nonconformance reports didn't adequately document disposition of nonconforming products. Records showed discrepancies in the number of devices determined to be "scrap" or for "use-as-is."

Following inspection, GVS Filter updated its nonconformance procedure to document disposal actions. But the company's response didn't include corrections to faulty nonconformance reports or evidence that records created before the update were reviewed, the letter states.

FDA also criticized the company for process validation failures. A test report listed a batch of sample filters as "pass" after they failed to meet the specification of 99.97 percent. In another instance, a sampling plan for sodium-chloride efficiency testing was described with no documentation of the statistical technique used to verify product characteristics.

Although the company later updated its lot history record forms, it didn't show evidence of retrospective review of other lot history records to determine that all acceptance tests were conducted properly. It also didn't analyze "the potential risks to safety and effectiveness of the filters" that might result from deficient tests that weren't recorded.

The company's CAPA violations include failure to adequately document all corrective activities.

FDA noted two CAPA records for customer complaints and three nonconformance related CAPAs. It said the company didn't document validation of the corrective actions to ensure that these actions didn't adversely affect the devices in question.

The company is actively working to address all topics in the warning letter and is committed to providing the highest quality products in compliance with FDA regulations, a spokesman told *IDDM*.

Read the warning letter at www.fdanews.com/04-16-15-GVS.pdf. — Charlotte Astor

FDA Approves Corneal Implant To Improve Close-Up Vision

The FDA has approved AcuFocus' KAMRA inlay, the first implantable device to help improve vision in patients with presbyopia who have not had cataract surgery.

The implant is intended for patients ages 45 to 60 who don't need assistance with distance vision but have trouble seeing close objects or small print and need reading glasses with plus-1.00 to plus-2.50 diopters of power.

The ring-shaped device works by blocking unfocused light rays from entering the eye while allowing central light rays to pass through a small aperture, removing blurriness. Results from clinical trials showed that 83.5 percent of 478 patients had vision clarity of 20/40 or better after one year.

The FDA, which announced the approval April 17, stresses that the implant's safety is unknown in patients who have had LASIK procedures. Use is contraindicated in patients who have had cataract surgery or have severe dry eye.

The KAMRA inlay is already marketed in Europe and 33 other countries. AcuFocus has set up a global registry to monitor and share clinical outcomes with surgeons and advance the surgical procedure, the company said. — Charlotte Astor

Taiwan Plans Changes to Device Registration Process

Effective July 1, devicemakers seeking to register products in Taiwan will need to have their quality system documents approved before submitting an application.

Under the program, applicants will need to undergo a review of administrative documents within 10 days of submission, including application forms, QSD approval letters, authorization letters, and certificates to foreign governments or certificates of free sale, says Stewart Eisenhart, senior regulatory analyst with Emergo Group.

Applicants sometimes are accepted without QSD approval letters, he says. The Taiwan Food and Drug Administration's new process will involve review of preclinical safety and performance tests for Class II and III devices, and facility quality control documentation.

The changes bring the system closer in line with the Asian Harmonization Working Party, says Seth Goldenberg, director of global regulatory strategy at NAMSA. Most importantly for innovative companies, the new process will let them leverage overseas approvals, he tells *IDDM*.

Registration fees will increase, but figures are not available. — Jonathon Shacat

FTC Health Claims Crackdown Leads to More Data Requests

Ongoing Federal Trade Commission demands for more scientific information to back marketing claims may affect some devicemakers, experts said Tuesday at the Food & Drug Law institute in Washington, D.C.

The U.S. FDA has primary regulatory authority over drug and device marketing. However, some products – such as most mobile apps and certain types of exercise equipment – may not be considered devices by the FDA. When that's the case, the FTC comes in to ensure marketing is fair and accurate. The Commission has recently taken action against several mobile app manufacturers, including the makers of an app said to detect melanoma (*IDDM*, April 20).

Richard Cleland, assistant director of the FTC's advertising practices division, says specific health claims made in marketing require specific substantiation, including randomized clinical trials. Peer-reviewed literature may be acceptable if it allows the FTC to assess the reliability of the original study.

The FTC frowns on scientific evidence gathered in foreign clinical studies if the original trial results cannot be subpoenaed, Cleland says.

"We've seen fabricated data submitted," he explains. "There's no way for us to detect fraud unless we can get to the underlying data."

The evidence standards aren't entirely new, Ivan Wasserman, a partner with Manatt, Phelps & Phillips law firm, told *IDDM*. But the FTC is being more specific in explaining what it wants. "It used to be that consent orders were written more generally," he says. "Now they tend to include more specific language with regard to what kind of substantiation companies need to make specific claims."

The FTC has taken some prominent actions regarding unsupported health claims recently, including administrative claims against pomegranate juice manufacturers Pom Wonderful that led to an ongoing court case. The company included claims on its website that the juice could cure heart disease, prostate cancer and erectile dysfunction.

In January, the U.S. Court of Appeals for the D.C. Circuit upheld the FTC's order on the grounds that Pom Wonderful had mischaracterized the scientific evidence.

In a similar case, Bayer and the FTC are involved in a dispute as to whether FTC requests for information on a probiotic supplement constitute an unfair attempt to hold the

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product to the same standards as a drug. The Department of Justice is seeking a civil contempt order against Bayer for violating court orders to change its marketing.

While neither of those cases involves a device, they help to indicate current FTC concerns, Wasserman says. And when finalized, the law they create will apply to all products whose manufacturing is subject to FDA scrutiny.

To prepare, devicemakers should make sure they're doing their own scrutiny of any external research they use to build marketing claims, he says.

"Manufacturers should make sure they have access to underlying data and procedures," he says. "They should consider doing a deep dive themselves, rather than relying on published studies." — Elizabeth Orr

China Issues 90 Industry Standards for Devices

The China Food and Drug Administration has issued 90 industry standards – 14 mandatory and 76 recommended – covering implants for surgery, medical electrical equipment, in vitro diagnostic reagents and dentistry.

The standards will improve the medical device standards system of China, help improve the quality of medical devices and promote the sound development of medical device industry, the CFDA says in an announcement posted earlier this month.

The 14 mandatory standards will take effect Jan. 1, 2017, while the 76 recommended standards will take effect Jan. 1, 2016, says John Balzano, special counsel for Covington & Burling's food and drug practice group.

The standards are part of the CFDA's ongoing device regulatory reform, which aims to increase the quality of devices in the Chinese market, he tells *IDDM*.

Jack Wong, director of regulatory affairs for Asia Pacific in TerumoBCT's Singapore branch, says it is difficult to describe the impact to industry, but recommends that companies identify any standards related to their products to determine whether they are in compliance.

China's device regulations were adopted in March 2014 and took effect Oct. 1 (*IDDM*, April 3).

Read the standards, in Chinese, here: www.fdanews.com/04-15-CFDA-Standards.pdf. — Jonathon Shacat

FDA Recalls Ebola Virus Test Kits Due to Lack of Efficacy

LuSys Laboratories is recalling all lots of its Ebola Virus One-Step test kits because the kits haven't been shown to be accurate for the disease.

A false positive result could be life-threatening by placing a patient in isolation with Ebola-infected patients, according to a March 13 recall notice posted to the FDA's website last week. By contrast, a false negative test could cause a lack of or delay in treatment and risk infecting healthcare providers, family and close contacts.

The Class I recall affects devices sold in California and exported to Sierra Leone, Canada and Denmark between October 2014 and January 2015.

Individual items listed include: Ebola VP 40 IgX Serum/Plasma/Blood Cassette; Ebola GP IgX Blood, Serum/Plasma Cassette; Ebola VP IgG/IgM (Dual Strip) Blood/Serum/Plasma Cassette; Ebola VP IgX Blood, Serum/Plasma Cassette; Ebola VP IgG/IgM (Dual Strip) Blood/Serum/Plasma Cassette; Ebola Virus Antigen Blood; and Ebola Virus Antigen Nasal.

LuSys advised customers to stop using the tests and return them to the company.

View the recall notice at www.fdanews.com/04-27-15-lusys.pdf. — John Bechtel

IN BRIEF

St. Jude Medical Seeks Spinal Modulation

St. Jude Medical plans to acquire Spinal Modulation and add several new therapies to its chronic pain treatment portfolio, the company said. The buyout will give St. Jude access to the CE Mark-approved Axium neurostimulator system for relief from dorsal root ganglion pain. The FDA is reviewing a PMA on the product. A deal was made possible by St. Jude's $40 million equity investment in Spinal Modulation, which granted the devicemaker an exclusive option to distribute the Axium system worldwide as well as buyout options. Upon the closing of the deal, St. Jude will pay $175 million, with additional payments due upon FDA approval of the Axium system and other sales-based milestones. St. Jude expects to finalize the acquisition in the second quarter of 2015.

Boston Sci Seeks China Alliance

Boston Scientific has entered into a strategic alliance with Frankenman Medical Equipment Co. to develop and manufacture endoscopic products in China, the Marlborough, Mass., devicemaker said. The alliance lets Boston Scientific take advantage of Frankenman's entrenchment in the China surgical devices market. The two companies plan to accelerate medical training and implement less invasive procedures in China. The agreement stipulates that Boston Scientific will become a Frankenman shareholder and provide services and expertise to the company. Frankenman was established in 2003 and is based in Suzhou, China, serving more than 100 hospitals in the country.

Roche Buys Cancer Screening Startup

Roche has acquired CAPP Medical, a genomics research startup focused on cancer screening and monitoring, the Switzerland-based company said. CAPP Medical's disruptive liquid noninvasive technology works by isolating and quantifying small amounts of circulating tumor DNA in the bloodstream. Through a blood draw, health professionals have the potential to monitor tumor response and resistance to cancer therapy. The Palo Alto, Calif., company's next-generation sequencing assays could significantly speed up cancer diagnosis and prove to be more cost effective than the current standard of care, says Roland Diggelmann, COO Roche Diagnostics.CAPP Medical's technology has been designated for Research Use Only by the FDA.

Heartware IDE Study Finds Success

Heartware's first destination therapy clinical trial has achieved its primary endpoint, the devicemaker says. The investigational device exemption study tested the HVAD Pump as long-term therapy for patients with end-stage heart failure ineligible for a heart transplant. The HVAD system treatment yielded a higher stroke rate, but device malfunction was evidenced more frequently in the control arm, says Dr. Joseph Rogers, a co-principal investigator. Of the 200 patients who were implanted with the device with a sintered inflow cannula — a 2011 FDA-approved modification that enables better tissue adhesion — 57.5 percent of patients reached the primary endpoint.

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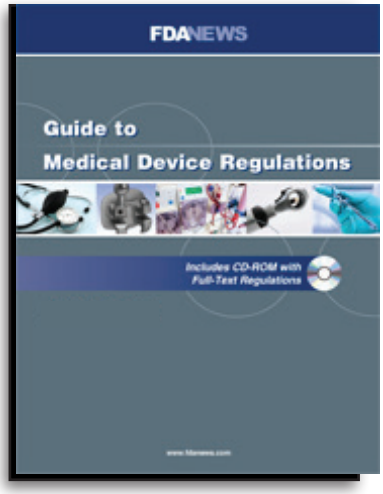

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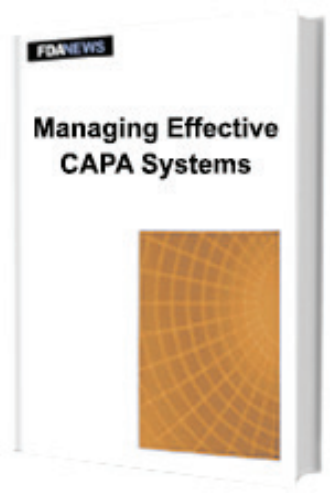

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