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The *Medical Devices Law & Industry Report* is interested in publishing analysis articles by attorneys and other experts on subjects of concern to the devices industry, as well as reporting on significant settlements, pending lawsuits, and other developments. If you are interested in writing an article or alerting us to developments that might be of interest, please contact Brian Broderick, the managing editor, at (703) 341-5701 (e-mail: bbroderick@bna.com), or submit your idea in writing to: Medical Devices Law & Industry Report, Bloomberg BNA, 1801 S. Bell St., Arlington, VA 22202.

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Regulatory News

Combination Products

Industry Input Sought for Combo Products Guidance Development, FDA Official Says

The Food and Drug Administration wants guidance input from the combination medical product industry, according to an agency official.

John Weiner, the FDA Office of Combination Products' associate director for policy, said Oct. 29 that the agency is actively developing guidance and sees this as a time ''for industry and the FDA to work together.''

Weiner said this signals that the combination products industry will get the regulatory clarification needed to move products to market faster, adding the FDA is committed to helping companies bring innovative products to patients.

Speaking to a combination products summit in Cincinnati, Weiner said the office plans to issue further guidance later this year to inform premarket reviews, focusing on clear guidance for the review of common combination product types.

Citing a document issued earlier in October by FDA Deputy Commissioner for Medical Products and Tobacco Robert Califf (9 MELR 659, 10/28/15), who has been nominated to head the agency, Weiner said clear guidance is a stated priority, as is substantial engagement by both agency staff and the regulated community.

Trade associations are being asked to give OCP ''real world'' collective information the agency can use, said Weiner, and to view OCP as a resource committed to helping industry.

The OCP's website says combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

Consistent Decisions. OCP Director Thinh Nguyen said combination products are growing in importance, blurring the therapeutic distinction between medical device and drugs.

As the market grows, so does the need for consistent decisions by the FDA, he said.

Classifying a product as a device means a $5,000 user fee is paid by the manufacturer, said Nguyen, whereas a drug determination carries with it a $260,000 user fee. The difference could make or break a small company's ability to bring its product to market, he said; as a result, some manufacturers gamble, apply as a device and hope to qualify.

Every combination product needs to be assessed on a case-by-case basis, Nguyen said, adding that combination products by their nature are ''human products.''

While industry tends to view FDA interactions as somewhat adversarial, Nguyen said his office genuinely wants to help companies bring state-of-the-art products to market by assisting them whenever it can.

Consequently, he said, companies should feel free to contact his staff and ask for help without any fear of reprisal.

Xavier Health, a collaborative initiative of Xavier University that brings the drug and medical device industries together with government regulators, sponsored the combination product summit, its first.

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Additional information about Xavier Health and the summit is available at http://xavierhealth.org/.

Enforcement

FDA Data Show International Efforts; China Tops List of Foreign Inspection Sites

The FDA's most recent data on inspectional observations and warning letter citations issued to medical device manufacturers, posted on the agency's website Nov. 4, showed an increasing focus on foreign-based facilities, particularly in China.

The report, ''2014 Annual FDA Medical Device Quality System Data,'' was issued by the Center for Devices and Radiological Health (CDRH). It shows a steady increase in the number of international inspections performed by the agency, with China topping the list of locations.

The number of foreign quality system surveillance inspections rose to 594 in 2014 from 460 in 2013, with 190 inspections occurring in China, the report said. Germany was next on the list for calendar year 2014, with 72 inspections, followed by Japan with 37.

In similar data the agency released last year, Germany topped the list, with China coming in second (8 MELR 672, 10/15/14).

And with regard to foreign-based companies, the data from 2008 to 2014 revealed that the agency has found a higher percentage of foreign-based device manufacturers—58 percent—not fully compliant with the FDA's Quality System Regulation (QSR)—compared to 48 percent of domestic manufacturers. The QSR governs FDA inspections of medical device manufacturing facilities.

Attorney Sonali Gunawardhana, of Wiley Rein LLP in Washington, told Bloomberg BNA Nov. 5 that the data also show that foreign inspections are more likely to result in some type of QSR violation than are domestic inspections.

And ''some of that discrepancy may be explained by the learning curve for foreign manufacturers,'' attorney Keith Barritt, of Fish & Richardson P.C. in Washington, said.

''It will be interesting to see if that levels out,'' Barritt told Bloomberg BNA Nov. 5.

The data bear out the agency's increased international focus.

Although the total number of routine medical device quality system surveillance inspections has remained relatively steady from 2010 to 2014, the percentage of foreign inspections has steadily increased. In 2011, there were 341 inspections of foreign companies compared with 594 international inspections in 2014, according to information in the report.

China Numbers. While China accounted for more than 30 percent of all international inspections in 2014, attorney Linda D. Bentley, of Mintz, Levin Cohn, Ferris, Glovsky and Popeo, P.C. in Boston, told Bloomberg BNA that figure isn't surprising, given the large number of facilities there. ''It's probably just a drop in the bucket,'' she said.

Bentley said that because the FDA now has an office in China, the agency is likely to be able to inspect Chinese facilities more regularly than in the past. Nevertheless, she said, the agency focus on China also may relate to overall quality concerns.

''My sense is the FDA is concerned about quality issues coming out of China,'' Bentley said. Accordingly, device firms that are outsourcing manufacturing to China should make sure they do ''more than adequate due diligence'' on those facilities, she said.

Most Cited Quality Violations Remain Consistent. And with regard to the types of QSR violations most frequently cited by the FDA, attorneys say the most recent data is consistent with data the agency published in the past.

The QSR includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing and servicing medical devices intended for human use.

The two quality system areas that are most heavily reviewed and cited by the FDA in inspections—corrective and preventive action (CAPA) violations, and production and process controls (P&PC)—were also the top areas most frequently cited in the agency's data for recent years, Bentley told Bloomberg BNA. ''So my advice about quality system issues would be the same as in the past,'' she said.

''Things are pretty much status quo in the world of QSR inspections,'' Gunawardhana agreed. ''The big area remains inadequate CAPAs across the board for both domestic and foreign facilities.''

Edward C. Wilson Jr., of Hogan Lovells US LLP in Washington, also said the FDA is continuing to find companies falling short in the same areas. ''P&PC and CAPA continue to be areas where FDA is finding a lot of perceived noncompliance,'' Wilson told Bloomberg BNA Nov. 5. ''Neither of those are big surprises but industry should be aware of them,'' he said.

The FDA issued the report, which includes FDA Form 483 (inspectors' observations) and warning letter citations, in connection with its Case for Quality Initiative (8 MELR 647, 10/1/14). The initiative also seeks to enhance the transparency of quality-related data for devices.

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A copy of the FDA's report is at http://src.bna.com/V4.

Safety

GAO Report Highlights Safety Concerns On New Medical Devices, DeLauro Says

A report released by the GAO Oct. 29 shows that the FDA ''must do more to ensure the safety of medical devices,'' Rep. Rosa DeLauro (D-Conn.) said.

The report also shows that new medical devices aren't being proved safe or effective before being released for use by consumers, DeLauro said in an Oct. 29 statement.

People aren't ''guinea pigs,'' she also said, and the Food and Drug Administration shouldn't be rushing devices to market.

DeLauro asked the Government Accountability Office to study the characteristics and status of device postmarket studies. In particular, the GAO found that 88 percent of postmarket surveillance studies, which the FDA can order after it becomes aware of a potential device safety issue, were inactive as of February 2015.

The data were included in a report, ''FDA Ordered Postmarket Studies to Better Understand Safety Issues, and Many Studies Are Ongoing.''

Postapproval and Postmarket Studies. In her statement, DeLauro said there are two kinds of studies conducted after a device has been cleared for sale: postapproval, which are ordered simultaneous to when a device goes on the market, and postmarket surveillance, which is usually ordered after a device has already been on the market for a period of time.

Postapproval studies are ordered to obtain information not available before devices are marketed, such as a device's performance over the course of long-term use, the report said.

The GAO found 56 percent of the 313 device postapproval studies the FDA ordered from Jan. 1, 2007, through Feb. 23, 2015, were for cardiovascular devices and most were making adequate progress.

Unlike postapproval studies, the FDA may order postmarket surveillance studies at the time or after a device is approved or cleared for marketing. For example, if the FDA becomes aware of a potential safety issue it may order a postmarket surveillance study, according to the report.

The FDA conducted ordered 392 postmarket surveillance studies from May 1, 2008, through Feb. 24, 2015, the study said, and 90 percent of them were for orthopedic devices and devices such as certain kinds of implantable surgical mesh following concerns with these types of devices. As of February 2015, 88 percent of the postmarket surveillance studies GAO analyzed were inactive, according to the report.

The report said inactive studies include those that were consolidated (108 studies), meaning that a manufacturer was able to combine an order for a postmarket surveillance study with other related study orders into a single study, such as combining studies of multiple de-

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vice models into a single study; and those that were inactive for other reasons, such as if the order was for a device that is no longer marketed.

The remaining 12 percent of the postmarket surveillance studies were either ongoing (40 studies) or completed (8 studies), the report said.

Of the 40 ongoing studies, more than half were progressing adequately, according to the FDA, and had been ongoing for an average of a little less than three years. The remaining were delayed and had been ongoing for an average of about four years as of February 2015, the GAO said.

DeLauro: Device Laws 'Weak.' The GAO's findings demonstrate that ''the laws governing medical devices are weak'' and are allowing medical products onto the market without rigorous study, De Lauro said.

In addition, the findings also show that postmarket and postapproval studies often take a long time to be completed, and that companies lack incentive to find participants for their studies, contributing to the reality that devices can be sitting on the market without anyone having to prove that they are safe and effective, DeLauro said. For example, she said the average length for postapproval studies is about three years, with the longest study taking almost seven years.

She also vowed to continue to monitor this situation closely to determine whether Congress should be taking action.

Industry Response. Janet Trunzo, senior executive vice president, technology and regulatory affairs at the Advanced Medical Technology Association (AdvaMed), a device trade group, told Bloomberg BNA Oct. 30 that the industry welcomes the GAO study, calling postmarket surveillance an important part of oversight.

''We appreciate GAO's overview of FDA's medical device postmarket studies program,'' Trunzo said. ''As the report notes, the agency's postmarket studies program is part of a robust set of pre- and postmarket authorities FDA employs to ensure the continued safety and effectiveness of medical technologies. Medical technology manufacturers take their postmarket responsibilities very seriously as these programs provide important information on the continued safety and effectiveness of marketed medical devices. It is important to note that medical devices and diagnostics save and improve the lives of millions of American patients every day while boasting an enviable safety record.''

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The GAO report is at http://www.gao.gov/assets/680/672860.pdf.

Quality

FDA Official Announces Plans for Eight Medical Device Quality Guidances

The FDA plans to issue several guidance documents on medical device quality, an agency official said Oct. 27.

William MacFarland, with the Food and Drug Administration's Center for Devices and Radiological Health (CDRH), announced the agency's intention to issue eight guidance documents on various device quality issues.

A presentation delivered by MacFarland revealed the guidances would likely cover quality characteristics related to specific devices or parts of devices, such as catheter coatings, ventilators, infusion pumps, defibrillators leads and implantable cardioverter defibrillators, among other topics.

MacFarland spoke the guidances during a session of the Regulatory Affairs Professionals (RAPS) Society annual conference in Baltimore. He is the director of manufacturing and quality, which is part of the Office of Compliance at the CDRH.

Critical to Quality Initiative. The guidance documents are being developed through the Critical to Quality, or CtQ, Initiative. According to the conference program, the concept behind the program is for the FDA to work with industry to define what device features and characteristics are most important to the safety and effectiveness of devices.

The CtQ Initiative, in turn, is part of a broader CDRH program known as the Case for Quality, the aim of which is to foster device quality by collaborating with industry, providers, patients, payers and investors.

During his presentation, MacFarland explained he didn't want the FDA to release the eight documents as guidances.

However, MacFarland told conference attendees that he was advised that the documents had to be released as guidances. The eight documents are ready to go, MacFarland said, but the guidance writing process will mean that their release will now be delayed.

After his presentation, MacFarland told Bloomberg BNA that there's no timeline for releasing the guidances. ''This information is as new as last Thursday [Oct. 22], and I can't commit to a timeframe,'' MacFarland said.

Indicators. The documents that will become guidances tend to have six to eight CtQ indicators, MacFarland explained to the RAPS meeting. These are six to eight characteristics ''that are most important'' for the quality of a specific device, MacFarland said.

MacFarland also said the CtQ indicators aren't meant to describe all the features that are important for device quality. Instead, they are intended to get everyone internal to the FDA and external to the agency on the same footing regarding what constitutes a quality device, he said.

The format for each indicator is basically the same and consists of four key pieces, MacFarland said. First, he said there needs to be a defined quality characteristic for the device.

Describing what happens to the device user when the defined quality characteristic isn't met is the second

part of each CtQ indicator, according to MacFarland. The third piece of the indicators is accounting for how the characteristic is controlled, he said, adding this could mean industry may need to account for the defined quality aspect during the design phase and not just during the manufacturing phase.

The final part of each CtQ indicator would describe how the control is audited or investigated, MacFarland said.

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Slides from MacFarland's presentation are at http://src.bna.com/MB

Oversight

Drugs, Devices on HHS Inspector General's Radar Screen in FY 2016

Several drug- and device-related items will be the subject of HHS inspector general reviews in the coming year, according to a work plan released Nov. 2.

The topics include Medicaid drug pricing, the protection of personal health information on certain medical devices, cost savings from the 340B drug discount program and oversight of a reporting program for drug and device company payments to doctors. The items are part of the Department of Health and Human Services Office of Inspector General's work plan for FY 2016. The plan summarizes new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations during the current fiscal year and beyond.

A new item is the specialty drug pricing and reimbursement in Medicaid. The OIG said it'll determine ''how State Medicaid agencies (States) define specialty drugs, how much States paid for specialty drugs, how States determine payment methodologies for specialty drugs, and the differences in reimbursement amounts for these drugs among the States.'' The OIG said specialty pharmacies dispense prescription drugs that often require special handling or administration. Specialty drugs ''are often expensive and are used to treat rare conditions, such as Hepatitis C, HIV, and certain cancers,'' the OIG said.

The states use the Centers for Medicare & Medicaid Services' national average drug acquisition cost to set Medicaid pharmacy reimbursement amounts. ''However, this average does not include the cost of drugs sold at specialty pharmacies,'' the work plan said, adding that states that use the national average drug acquisition cost data to assist in setting Medicaid pharmacy reimbursement amounts ''may have difficulty determining Medicaid pharmacy reimbursement amounts for specialty drugs.'' The expected issue date of this work is fiscal year 2017.

Devices. In another new item, the OIG said it'll examine whether the Food and Drug Administration's oversight of hospitals' networked medical devices ''is sufficient to effectively protect associated electronic protected health information (ePHI) and ensure beneficiary safety.''

Computerized medical devices—such as dialysis machines, radiology systems and medication dispensing systems—that are integrated with electronic medical records (EMRs) ''and the larger health network'' pose a ''growing threat to the security and privacy of personal health information,'' the OIG said.

Such medical devices use hardware, software and networks to monitor a patient's medical status and transmit and receive related data using wired or wireless communications. The OIG said device manufacturers provide ''Manufacturer Disclosure Statement for Medical Device Security (MDS2)'' forms to assist health-care providers in assessing the vulnerability and risks associated with ePHI that is transmitted or maintained by a medical device. The expected issue date of this task is FY 2016.

340B Program. In an ongoing project, the OIG said it'll look at cost savings for Medicare and its beneficiaries as a result of the 340B drug discount program for safety-net providers. The OIG also said it will calculate the amount by which average sales price-based payments exceed 340B prices. Average sales price is used in Medicare Part B.

The 340B program enables eligible health care providers ''(generally those that serve a disproportionate share of needy patients) to purchase prescription drugs at statutorily discounted prices while charging paying patients and insurers (including Medicare and, in some cases, Medicaid) full price for the drugs,'' the OIG said. Previous OIG work found that some Medicare payments to providers for 340B-purchased drugs ''substantially exceeded'' the providers' costs.

Under the 340B program design and Part B payment rules, the difference between what Medicare pays and what it costs to acquire the drugs is fully retained by the participating 340B entities, ''allowing them to stretch scarce Federal dollars,'' the OIG said. ''However, policymakers have questioned whether some of the savings mandated through the 340B Program should be passed on to Medicare and its beneficiaries.'' The expected issue date for this review is FY 2016.

Other areas the OIG will review include the oversight actions that the CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria, and the financial interests that were reported to the CMS under the Open Payments Program. Open Payments was created under the ''sunshine'' provisions of the Affordable Care Act and requires drug and device companies to report on payments to doctors.

In addition, the OIG said it plans to review the education and enforcement actions that states have taken ''on the basis of information generated by their drug utilization review (DUR) programs related to inappropriate dispensing and potential abuse of prescription drugs, including opiates.''

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The HHS OIG work plan is at http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current.

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Safety

FDA Outlines Info Needed for Device Electromagnetic Compatibility Claims

A Nov. 2 draft guidance describes the information that should be provided to support a claim of ''electromagnetic compatibility'' in premarket submissions for electrically powered medical devices.

Deborah Kotz, a Food and Drug Administration spokeswoman, told Bloomberg BNA Nov. 3 the ''guidance affects any electrically powered device, whether battery operated or AC powered. These include electric wheelchairs, pace makers, cochlear implants,'' and spinal cord stimulators, among others.

Electromagnetic compatibility (EMC) refers to the ability of a device to function properly in its intended electromagnetic environment, including immunity to electromagnetic disturbance, without introducing excessive electromagnetic disturbances (emissions) that might interfere with other devices, the draft document said.

A spokesman for the Advanced Medical Technology Association (AdvaMed) told Bloomberg BNA Nov. 3 that the group is still reviewing the document. However, ''we are pleased that FDA has documented their current expectations for information to support claims of electromagnetic compatibility that must be provided in a premarket submission,'' the AdvaMed spokesman said.

The FDA outlined nine types of information that are needed to substantiate EMC claims in medical device approvals and clearances.

The draft guidance is titled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices.'' A Nov. 2 Federal Register notice (80 Fed. Reg. 67,411) announced the document's availability.

Comments (FDA-2015-D-3787) are due Dec. 17.

Interference Problems. Electromagnetic disturbance is electronic product radiation that may interfere with the performance of an electrically powered medical device in its intended environment (i.e., cause an electromagnetic interference (EMI)), the notice said. EMI is a hazard with risks for electrically powered medical devices, the notice said, adding, ''EMC assessment can help to ensure that the risks associated with performance degradation of electrically powered medical devices due to EMI are adequately mitigated.''

The types of premarket submissions covered by the document include premarket approvals (PMA) or premarket notification clearances, Kotz told Bloomberg BNA Nov. 3. A premarket approval application is filed typically for high-risk, or class III devices, and requires a demonstration that a device is safe and effective, often through clinical data.

A premarket notification clearance, or 510(k), demonstrates that a device is substantially equivalent to another device already on the market. Clinical data typically aren't generated for a 510(k). The 510(k) process is how the FDA allows most devices on the U.S. market. The agency says it generally reviews 510(k) submissions for class II, or moderate-risk, devices.

Other types of premarket submissions covered by the document include a de novo application, Kotz said. A de novo is a premarket request for the FDA to classify a novel device into class I (lowest risk) or class II (moderate risk). In addition, humanitarian device exemptions (HDEs), which are used for approving devices for conditions affecting fewer than 4,000 patients in the U.S. per year, would be covered by the guidance, Kotz said. HDEs are similar to PMAs, but they don't require device companies to demonstrate effectiveness.

Consensus Standards. Manufacturers of electrically powered devices often reference FDA-recognized consensus national or international standards for EMC, like the International Electrotechnical Commission (IEC) 60601-1-2 standard or the equivalent U.S. version in premarket submissions, the draft guidance said.

According to the document, there are other device-specific consensus standards, or ''particular'' standards, under the IEC 60601-1 family. ''These particular standards may augment or supersede the requirements in the IEC 60601-1-2 standard,''the FDA guidance said, adding, ''There are also other consensus standards for electrically-powered medical devices'' that include information on EMC (e.g., International Organization for Standardization (ISO) 14708 for active implantable devices).

To facilitate premarket submissions and reviews, a claim of EMC for a device should be accompanied by the following information:

- a summary of the testing that was performed to support EMC;
- the specifications of the standard that were met (including immunity test levels);
- the device-specific pass/fail criteria used (this includes how the pass/fail criteria were derived);
- the specific functions of the device that were tested and how these functions were monitored; and
- the performance of the device during each test, indicating if the device met the 115 emissions and immunity pass/fail criteria.

The draft guidance also said manufacturers should submit an identification of and a justification for any of the standard's allowances that were used in the premarket submission and a description of and justification for any deviations from the specifications of the referenced standard. ''The justification should explain how the deviations would not compromise the safety and effectiveness (performance) of the device,'' according to the draft guidance.

Moreover, claims of EMC should contain the device labeling and evidence of compliance with the reference standard's labeling (identification, marking and documents) specifications, the FDA document said. Detailed descriptions of all changes or modifications that were made to the device in order to pass any of the EMC tests should also be included. If modifications were made, the document said, a statement should be included indicating that the changes or modifications will be incorporated into the final production model and documented in the design history file in accordance with design controls.

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The draft guidance is at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM470201.pdf.

The notice is at http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27818.pdf.

Enforcement

Surgical Instruments Company Gets FDA Warning About Quality, Marketing

The Food and Drug Administration warned a California-based surgical instrument maker that its products are adulterated and misbranded due to quality violations and lack of marketing clearance, according to a letter posted to the agency's website Oct. 27.

The FDA letter was addressed to Aros Surgical Instruments Corp. of Newport Beach, Calif., but the letter also calls the company AROSurgical. The letter, signed by Alonza E. Cruse, director of the FDA's Los Angeles district, listed eight categories of violations that FDA inspectors found during an inspection at a facility in February.

The Sept. 25 letter said that the company didn't establish and maintain procedures to control device design to ensure that specified requirements are met. For example, the agency said the company didn't maintain design control documentation for the design of its surgical sutures. The design documentation the company submitted for the sutures was inadequate, the agency said, adding that Aros hadn't ''addressed the fundamental deficiency or lack of proper design control processes and procedures which should have been in place before these devices were placed into interstate commerce.''

Other quality violations included inadequate purchasing control procedures and the failure to establish and maintain data that clearly describe or reference the requirements, including quality requirements, that purchased or otherwise received product and services must meet.

''For example,'' the FDA's Cruse wrote, ''you do not maintain records that clearly describe or reference specified requirements, including quality requirements that the contract manufacturer of your surgical sutures and micro anastomosis clamps must meet.''

Anastomosis clamps are often used to control blood flow from the carotid artery, aorta and inferior vena cava during surgery.

Also, the letter said, the device maker didn't have procedures to notify contract manufacturers of changes in the products manufactured under its brand name.

In addition, Aros didn't keep complete device master records, the letter said. The device master records submitted didn't include complete device specifications, and didn't reference production process specifications, quality assurance procedures and specifications or packaging and labeling specifications, the agency said.

Quality audit procedures were also lacking, the FDA told Aros, and didn't ensure that individuals conducting quality audits didn't also have direct responsibility for the matters being audited.

Clamps Lack Marketing Clearance. In addition to the quality violations detailed in the letter, Cruse said that Aros's micro anastomosis clamps are adulterated because the company didn't have an approved application for premarket approval (PMA) or an approved application for an investigational device exemption (IDE) in effect. The clamps are also misbranded, the agency said, because the company commercially distributed the device with a change or modification that could significantly affect its safety or effectiveness.

The company didn't notify the agency of those changes before selling the devices, the letter said.

Among other things, Aros modified the micro anastomosis clamp by changing its sterilization method, changing its component materials, changing its closing force and changing the clamp's design from straight to curved.

Biocompatibility. ''The change in sterilization method and change in materials may have affected the biocompatibility of the device,'' Cruse wrote, and the other enumerated changes—including adding curved design and changing the closing force of the clamps without any testing—could significantly affect safety and effectiveness.

''Therefore, a new 510(k) is required for these changes,'' the letter said. ''Our office requests that AROSurgical Instruments Corporation immediately cease activities that result in the misbranding or adulteration of the above-referenced surgical sutures and micro anastomosis clamps, such as the commercial distribution of the device for the uses discussed above,'' the agency said.

Cruse advised Aros to take prompt action to correct the violations addressed in the letter.

The FDA didn't post any new letters to device companies Nov. 3.

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Full text of the FDA's warning letters is at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm#recent.

Medicare

OMB Receives Final Rule Establishing Payment Model for Hip, Knee Replacements

The White House Office of Management and Budget has received for review a final rule establishing a new Medicare payment model for hip and knee replacements.

Under the proposed rule (80 Fed. Reg. 41,197), hospitals would be held accountable for the quality of care they deliver to Medicare fee-for-service beneficiaries for hip and knee replacements from surgery through recovery. The Centers for Medicare & Medicaid Services issued the proposal in July (9 MELR 451, 7/22/15). Comments (CMS-5516-P) were due Sept. 8 (9 MELR 545, 9/16/15).

The Federation of American Hospitals and the Association of American Medical Colleges have recom-

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mended the CMS delay the start of the proposal, while the American Hospital Association asked the Department of Health and Human Services to issue waivers of the applicable fraud and abuse laws that inhibit care coordination.

Device makers also criticized the proposal. The Advanced Medical Technology Association said the financial arrangements in the rule would cause providers to select low-cost devices when a patient's medical condition could be better treated with more costly products. Furthermore, many devices provide benefits over multiple years, which aren't adequately reflected in delivery reform models with short episode windows, the association told the CMS in a comment letter.

The payment model is scheduled to take effect Jan. 1.

Hip and knee replacements are some of the most common surgeries that Medicare beneficiaries receive, according to the HHS. In 2013 there were more than 400,000 inpatient procedures costing Medicare more than $7 billion for hospitalization alone, the HHS said.

The OMB received the final rule Oct. 28.

BY STEVE TESKE

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The final rule is at http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/html/2015-17190.htm.

Quality

FDA Inspection Finds Theranos Has Flaws in Product Validation

Blood-testing startup Theranos Inc., under fire after reports that the company overstated the ability of its tests to accurately perform several dozen types of measurements, has flaws in the process it uses to validate its products, Food and Drug Administration inspectors found.

Heavily redacted inspection reports, posted Oct. 27 by the FDA, said that Theranos's ''design validation did not ensure the device conforms to defined user needs and intended uses.'' The name of the device was redacted. In addition, ''the design was not validated under actual or simulated use conditions.''

The inspections were conducted Aug. 25 through Sept. 16 at Theranos's Palo Alto and Newark, Calif., offices.

Theranos claims its technology can run finger-stick samples for tests that have typically required an entire vial of blood. ''We are confident in the reliability of our tests, because we comprehensively validate the accuracy of every test we run,'' Theranos said in a statement Oct. 22. While the company lists about 200 tests on its online menu, the company said this month that it is using its new technology on only one, a herpes test (9 MELR 673, 10/28/15).

Theranos wasn't able to immediately comment on the FDA inspection reports. The FDA didn't immediately respond to questions asking for more information on the reports.

Working With FDA. In a previous statement, Theranos said it was working with the FDA to validate its tests. ''We initiated filings with FDA two years ago—by choice, not necessity—because we are seeking to create a new model for laboratory testing standards,'' Theranos said. ''In our discussions with FDA, we determined that it was appropriate to temporarily pause use of the Nanotainer tubes for all tests.''

The FDA reports also said Theranos's blood-collection device, which Theranos describes as a capillary tube nanotainer, is a class II medical device, which is considered higher-risk than the class I Theranos had categorized it as.

''You are currently shipping this uncleared medical device in interstate commerce, between California, Arizona, and Pennsylvania,'' the FDA document said.

After limiting the technology's use, the company has said it will resume using the nanotainers and associated testing technology once the FDA reviews and clears more types of tests offered by Theranos and using its technology. In the meantime, Theranos is using traditional vein draws for everything but the herpes test, which was cleared by the FDA in July.

Accuracy Questioned. The accuracy of Theranos's technology was questioned in a Wall Street Journal article in October. Theranos has disputed the article's claims, and the Journal has said it stands behind the story.

The FDA also listed inspection observations that many startup testing companies unfamiliar with U.S. regulations get slapped on the hand for, including inadequate procedures for evaluating complaints and documenting corrective actions.

The latest company to receive such a notice was Merge Healthcare Inc., which was purchased by IBM for $1 billion earlier this month. Merge received a warning letter Sept. 30 for failing to show it had adequately reviewed or evaluated complaints (9 MELR 657, 10/28/15).

—With assistance from Caroline Chen in San Francisco.

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More information on the FDA form 483 inspection reports is at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.htm.

Medicare

Medicare Drops Proposed Coverage Changes On Lower Limb Prosthetics After Opposition

The CMS said Nov. 2 it won't finalize changes proposed on its coverage policy for lower limb prosthetics that had been strenuously criticized by groups representing manufacturers and users of orthotics and prosthetics.

''Both CMS and its contractors have heard your concerns about access to prostheses for Medicare beneficiaries,'' the agency said in a statement. The four durable medical equipment Medicare administrative contractors won't finalize their draft local coverage determination (LCD) at this time.

Workgroup Will Look at Issue. Instead, the Centers for Medicare & Medicaid Services said it will convene a workgroup in 2016 ''to develop a consensus statement that informs Medicare policy by reviewing the available clinical evidence that defines best practices in the care of beneficiaries who require lower limb prostheses.''

A coalition of amputee, beneficiary and prosthetic industry groups had charged that the proposal by the four local DME contractors would limit access to modern prosthetic technology and care.

Opponents argued that the proposed changes were concerning because they contained a long set of requirements a beneficiary must satisfy before being eligible to receive prosthetic care and would eliminate access to certain prosthetic components if the amputee uses a cane, crutch or walker to assist in ambulating or cannot achieve ''the appearance of a natural gait'' while using a prosthesis, among other requirements.

According to the coalition, the changes were drafted as a result of recommendations in a 2011 Department of Health and Human Services Office of Inspector General report that had questioned billing for prosthetics.

Advocates Pleased. The decision not to finalize the proposed coverage policy was applauded by the Center for Medicare Advocacy.

The proposal would have ''unfairly and illegally restricted Medicare coverage for beneficiaries in need of lower limb prostheses,'' Kathy Holt, associate director of the center, said in a statement.

The LCD would have ''ignored potential function, eliminated coverage for best-fitting prostheses, and required a 'normal gait' for coverage of prostheses—requirements that few, if any, could meet,'' Holt said.

She said the group had filed a complaint with the HHS Office for Civil Rights on behalf of a beneficiary who wouldn't have been able to obtain coverage for the prostheses under the proposed LCD.

The CMS said the workgroup will comprise clinicians, researchers, policy specialists and patient advocates from different federal agencies.

It will identify areas where ''evidence gaps exist related to the prescription of lower extremity prostheses, and make recommendations concerning the study designs and outcome measures that best inform patient oriented function, quality of life and service satisfaction in this realm.''

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Approvals

Bayer Birth Control Device Would Lose FDA Approval Under Republican Lawmaker's Bill

The FDA would be forced to pull its approval for a Bayer AG birth control device under a bill (H.R. 3920) introduced by a Republican lawmaker Nov. 4.

Rep. Michael G. Fitzpatrick (R-Pa.) sponsored the E-Free Act, which would revoke the Food and Drug Administration's premarket approval (PMA) of Bayer's Essure medical device.

A PMA is filed typically for high risk, or class III devices, and requires a demonstration that a device is safe and effective, often through clinical data. Essure is a permanent female sterilization device, with a nickel-based metal coil designed to be inserted in the fallopian tube. The FDA approved the device in 2002.

William A. Garvin, an attorney who specializes in device and drug approval issues at Buchanan Ingersoll & Rooney PC in Washington, told Bloomberg BNA in a Nov. 4 e-mail that the FDA is in a much better position to review the studies supporting whether a device is safe and effective than Congress.

Garvin said that ideally, patient groups would work within the FDA system to have the agency re-review the safety and efficacy of devices and even remove approval of a device if needed.

''Many drugs and devices come with risks of serious injury or even death, but that does not mean that these products should always be barred from the market in all cases,'' Garvin said. ''I do think this bill is indicative of patient groups being more willing to bring Congressional pressure on FDA when they feel like their concerns are falling on deaf ears.''

Deaths and Injuries. A bill summary from Fitzpatrick's office said the FDA has received over 5,000 formal complaints related to Essure. The device has caused the deaths of four women as well as five fetal deaths in women who became pregnant after the device was placed, Fitzpatrick's summary said.

Moreover, tens of thousands of others reported other symptoms, including extreme pelvic and abdominal pain, bleeding, migraines, allergic and hypersensitivity reactions to nickel, autoimmune reactions, loss of teeth and hair, the metal coil breaking and migrating throughout the body and the coil cutting into the uterus and other organs in the abdominal cavity, according to the summary.

In September, an FDA advisory panel said Bayer should do more studies on Essure to better determine causes of pain and other severe side effects (9 MELR 603, 9/30/15).

Bayer's Response. Responding to a request to comment on Fitzpatrick's legislation, a Bayer spokewoman provided a statement to Bloomberg BNA that said the company stands by the positive benefit-risk profile of Essure. The product '' is an important option for women who have completed their families and want a permanent form of birth control,'' the statement said.

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Furthermore, Essure's safety and efficacy ''is supported by more than a decade of science, as well as real world clinical experience—with the product having been studied with more than 10,000 women since it was first developed,'' Bayer said.

The FDA recently held a meeting of its Obstetrics and Gynecology Panel of the Medical Devices Advisory Committee to discuss the benefits and risks of Essure, Bayer's statement said, adding, ''It is critical that the scientific, data driven process already in place at FDA continues to guide the path forward.''

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The bill is at http://src.bna.com/UH.

The bill summary is at http://src.bna.com/UI.

Medicare

Device Group Applauds Pass-Through Changes in 2016 Hospital Outpatient Rule

Changes to a medical device reimbursement program outlined in a Medicare payment rule received praise from an industry group.

DeChane Dorsey, the vice president for payment and health-care delivery at the Advanced Medical Technology Association (AdvaMed), told Bloomberg BNA Nov. 3 the group is generally pleased with changes to the device pass-through program.

The 2016 hospital outpatient final rule (CMS-1633-FC, CMS-1607-F2) (RIN 0938-AS42; RIN 0938-AS11) specified the changes to the device pass-through program.

Under the rule, issued Oct. 30, the Centers for Medicare & Medicaid Services said it will evaluate applications through annual rulemaking, in addition to the quarterly subregulatory review process. Device pass-through payments are intended to enable initial access to certain new medical devices. The CMS currently accepts and reviews applications for device pass-through on a quarterly basis through a subregulatory process, a CMS fact sheet said Oct. 30.

A health-care consultant told Bloomberg BNA in July that currently, communication about approved or denied pass-through applications only takes place between the CMS and the applicant (9 MELR 452, 7/22/15). However, the 2016 payment rule modifies the pass-through process in a way that changes the types of information that will be available in future hospital outpatient proposed and final rules.

For instance, Dorsey said that with the changes, the CMS will provide some information on whether it's leaning toward approving or denying submitted pass-through applications in future outpatient proposed rules. With that change, device makers will have a bit more perspective on what the CMS is thinking on their individual applications, Dorsey said. In addition, that change provides manufacturers the opportunity to submit additional information or comments to support their pass-through applications, she said.

However, Dorsey told Bloomberg BNA that the final rule's changes aren't as transparent as AdvaMed wanted. Ideally, the CMS would provide a rationale for why it didn't approve a device for pass-through payments, Dorsey said. Not having this information makes it difficult to know approval/denial rates over time, according to Dorsey.

Auditing Changes. The rule also modified a controversial payment policy for short-term hospital stays, which a trade group for recovery audit contractors blasted Nov. 3.

The Council for Medicare Integrity criticized changes to the CMS's so-called two-midnight policy. Under the old policy, Medicare Part A generally wouldn't pay for hospital stays that weren't expected to span at least two midnights. Changes to the policy included in the 2016 hospital outpatient final rule will allow inpatient admissions that span fewer than two midnights to be payable under Medicare Part A on a case-by-case basis based on the judgment of the admitting physician. Also, the CMS said that, starting in 2016, certain quality improvement organizations (QIOs), and not auditors, will review two-midnight cases.

Kristin Walter, a spokeswoman for the CMI, told Bloomberg BNA, ''It's astonishing that Medicare oversight is decreasing at a time when financial losses due to provider misbilling are rapidly increasing.''

RAC Review Moratorium. RACs haven't reviewed short inpatient hospital stay claims in two years and in that time, ''we've seen the Medicare billing error rate climb to a high of 12.7 percent, which equates to a program loss of $46 billion annually,'' Walter said.

In August, the CMS said it won't allow RACs to conduct patient status reviews of short-term hospital admissions through the end of 2015. The enforcement delay had been set to expire Sept. 30.

Sean Brown, the vice president of communications at the Federation of American Hospitals (FAH), a trade association of for-profit hospitals, told Bloomberg BNA Nov. 3 that the group supports the CMS changes to the two-midnight policy, as these changes will allow more discretion for physician judgment in determining whether a patient should be admitted to a hospital.

Quality Improvement Organizations. As part of its changes to the two-midnight rule, the CMS also announced modifications to how RACs will operate. Under the rule, Medicare's QIOs will oversee the majority of patient status audits, beginning in 2016.

A QIO is a group of health quality experts, clinicians and consumers organized to improve the care delivered to people in Medicare. Part of the mission for QIOs is protecting the Medicare trust fund by ensuring that the program pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting.

QIOs will refer providers to RACs based on patterns of practices, such as ''high rates of claims denial after medical review or failure to improve after QIO assistance has been rendered,'' the agency said in a separate Oct. 30 fact sheet. ''Accordingly, we do not expect substantial Recovery Auditor medical review activity for such claims for several months.'' The RAC program identifies improper Medicare payments to providers, such as hospitals. The change ''complements a number

of changes CMS has already made to the Recovery Audit Program,'' the agency said.

Brown said the FAH supports moving from RACs to QIOs for the primary review of patient-status issues. This is a big step forward and can help minimize incentives by the RACs to deny inappropriately inpatient claims, Brown told Bloomberg BNA.

The final rule will be published in the Federal Register Nov. 13 and will take effect Jan. 1. The agency also is asking for comment on certain payment classifications by Dec. 29.

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The final rule is at http://src.bna.com/Q2.

A fact sheet is at http://src.bna.com/Wc.

Research and Development

FDA Says Identifiability, Leftover Remnants Not Basis to Waive Consent for Biospecimens

Device studies that use leftover biospecimens or samples that have been stripped of their identifying information are still subject to the FDA's informed consent requirements, the agency clarified in an information collection notice published in the Oct. 23 Federal Register (80 Fed. Reg. 64,422).

The clarification and request for comment makes a distinction between the Food and Drug Administration's human subject protection regulations (21 C.F.R. Part 50) and the Department of Health and Human Services' corresponding regulations known as the Common Rule (45 C.F.R. Part 46). Under the Common Rule, biospecimens that have been stripped of identifiable, private information don't meet the definition of a human subject. The proposed rule issued in September to modernize the Common Rule seeks to change that criterion, and all biospecimens would be considered human subjects, regardless of identifiability.

FDA Aligning With HHS Proposal. In the Oct. 23 information collection notice, ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable,'' the FDA's language appears to be more in line with the proposed change to the Common Rule.

''FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded,'' the notice said. ''Nor do FDA regulations allow IRBs [institutional review boards] to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.''

The notice builds on a guidance document on using leftover human specimens in in vitro diagnostic studies. The FDA said in the notice that that guidance ''outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.'' That guidance document is titled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable,'' issued under the Good Guidances Practices regulation, 21 C.F.R. § 10.115.

''[I]nformed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial,'' the FDA said.

Public comments on the proposed collection of information are due Dec. 22 and should be submitted at http://www.regulations.gov using the docket number FDA-2012-N-0560. Written comments may be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md., 20852, using the same docket number.

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The guidance document is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm.

The Federal Register notice is available at http://www.gpo.gov/fdsys/pkg/FR-2015-10-23/html/2015-26985.htm.

International Trade

Cholesterol Test Strips Probed By ITC for Patent Infringement

Imports of blood cholesterol test strips will be investigated to determine whether they infringe upon a U.S. patent, the International Trade Commission announced Nov. 2 (Inv. No. 337-TA-696).

The investigation is based on a complaint filed by Polymer Technology Systems, Inc., of Indianapolis, which alleged that the strips infringe upon a patent held by the company, in violation of Section 337 of the Tariff Act of 1930. The company asked the ITC to issue an exclusion order and a cease and desist order to prevent the allegedly infringing products from being imported, marketed or sold in the U.S.

The respondents for the investigation are Infopia Co., Ltd., of Anyang-si, Korea; Infopia America LLC of Titusville, Fla.; and Jant Pharmacal Corp. of Encino, Calif.

The case will be assigned to an administrative law judge, who will schedule and hold an evidentiary hearing. The judge's initial determination as to whether there has been a violation of Section 337 will be subject to review by the commission.

The ITC's announcement is available at http://www.usitc.gov/press_room/news_release/2015/er1102ll517.htm.

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Industry News

Mergers and Acquisitions

Challenge of Steris' $1.9 Billion Bid For Synergy Health Is Over, FTC Says

The Federal Trade Commission's challenge of Steris Corp.'s proposed $1.9 billion acquisition of Synergy Health plc was formally ended by a unanimous vote and statement released Oct. 30.

The agency's request for an injunction to block the deal was denied Sept. 25 by the U.S. District Court for the Northern District of Ohio (9 MELR 608, 9/30/15).

The parties moved to withdraw the case from adjudication before an administrative law judge on Oct. 1. The ALJ withdrew the action and stayed all proceedings after complaint counsel failed to respond to the withdrawal motion (9 MELR 646, 10/14/15).

On Nov. 2, Steris, now called Steris plc, said it had completed the ''combination'' with Synergy Health plc. ''This combination marks a significant milestone for STERIS, creating a stronger global leader in infection prevention and sterilization, better-positioned to provide comprehensive solutions to medical device companies, pharmaceutical companies, hospitals and other healthcare facilities around the world,'' Walt Rosebrough, the president and chief executive of Steris, said in the statement.

Steris is now incorporated in the United Kingdom, with U.S. offices in Mentor, Ohio.

FTC Dismisses Administrative Complaint. While the commission could have still pursued its challenge, it declined to do so. Instead, itdismissed its administrative complaint. Despite ongoing ''competitive concerns'' with the deal, it concluded that ''further adjudication would not serve the public interest.''

The denial of injunctive relief from the district court ''would render it difficult for us to craft meaningful relief were we to find the merger unlawful at the conclusion of the administrative proceeding,'' it said.

The agency's complaint alleged the merger was anticompetitive because it would likely eliminate ''competition between Steris' gamma sterilization facilities and Synergy's planned x-ray sterilization facilities in certain regional markets in the United States, thus depriving customers of an alternative sterilization service and additional competition.''

The commission vote to approve its statement and dismiss the administrative complaint was 4-0.

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The administrative complaint is at http://src.bna.com/Q4.

The order withdrawing the complaint is at http://src.bna.com/Q6.

Mergers and Acquisitions

Smith & Nephew Agrees to Buy Blue Belt To Expand Robotics Surgery Business

British medical device maker Smith & Nephew Oct. 28 said it will purchase Blue Belt Technologies, a Minnesota-based company that makes the Navio surgical drill, for $275 million.

The deal, which is expected to be completed by year-end, is seen by Smith & Nephew as a strategic move, giving it the know-how to compete in robotics-assisted surgery.

Blue Belt, which is based in Plymouth, Minn., has been working on the Navio system for more than 10 years, according to Joe Metzger, spokesman for Smith & Nephew. He said the system provides robotics assistance in partial knee replacement surgeries through navigation software and a hand-held robotic bone-shaping device. The system is noteworthy, Metzger said, because it uses robotic technology for bone-shaping applications, while not requiring any preoperative imaging. He added that Navio's software provides intraoperative feedback to size and position implants, assess joint laxity, and achieve soft-tissue balance throughout the range of motion.

He said while only a small portion of surgical cases are partial knee replacements, the purchase of Blue Belt is important because it is expected that the Navio system soon will be used for other procedures, including total knee replacements, revision knee surgeries and bi-cruciate retaining knee arthroplasty. Metzger said revision knee surgery isn't served by robotics now, while bi-cruciate retaining knee arthroplasty is expected to be a major market that could offer patients more natural motion and greater stability by preserving cruciate ligaments.

The company expects that the Navio system soon will be used for other procedures, including total knee replacements, revision knee surgeries and bi-cruciate retaining knee arthroplasty.

Enhanced Platform for Expansion. In a press release, Smith & Nephew and Blue Belt said combining Smith & Nephew's developing products with robotic technology would give the company an enhanced platform for expansion.

The release also said that Blue Belt has been working on programs targeting total hip arthroplasty and sports medicine.

It said additional opportunities could develop through Smith & Nephew's global commercial infrastructure. The company has a presence in more than 100 countries.

In a statement, Olivier Bohuon, chief executive officer of Smith & Nephew, said his company's work with Blue Belt and customer insight convinced the London-based company that robotics will be used more often in orthopedic reconstruction in the near future. He said the combination of products and research should create a platform that helps the company shape this area of surgery.

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Legal News

Fraud and Abuse

Nearly 500 Hospitals to Pay $250M To Resolve False Cardiac Device Claims

The Department of Justice has reached 70 settlements involving 457 hospitals in 43 states for more than $250 million related to cardiac devices that were implanted in Medicare patients in violation of Medicare coverage requirements.

An implantable cardioverter defibrillator (ICD) treats chaotic, extremely fast, life-threatening heart rhythms by delivering a shock to the heart, restoring the heart's normal rhythm. Only patients with certain clinical characteristics and risk factors qualify for an ICD covered by Medicare, the DOJ said Oct. 30. Medicare coverage for the device costs approximately $25,000.

Attorney Joseph E. B. ''Jeb'' White, with Nolan Auerbach & White PA in Philadelphia, told Bloomberg BNA that ''while the number of hospitals involved in this settlement announcement is noteworthy,'' there are likely many more that filed similar false claims.

''In terms of the number of defendants, this is one of the largest whistleblower lawsuits in the U.S. and represents one of this office's most significant recoveries to date.''

—Wifredo A. Ferrer, U.S. attorney, Southern District of Fla.

According to a national coverage determination (NCD) issued by the Centers for Medicare & Medicaid Services, an ICD shouldn't be implanted in patients within 40 days of suffering a heart attack, or within 90 days of having a bypass or angioplasty operation, subject to certain exceptions, in order to allow the patient's heart a chance to recover on its own. The DOJ alleged that the settling hospitals implanted ICDs in patients during the prohibited waiting period from 2010 through 2013.

''In terms of the number of defendants, this is one of the largest whistleblower lawsuits in the U.S. and represents one of this office's most significant recoveries to date,'' U.S. Attorney Wifredo A. Ferrer of the Southern District of Florida said in a statement.

''Guided by a panel of leading cardiologists and the review of thousands of patients' charts, the extensive investigation behind the settlements was heavily influenced by evidence-based medicine,'' he said.

Kirk Ogrosky, an attorney with Arnold & Porter LLP in Washington, told Bloomberg BNA Oct. 30 that ''[a] notable feature of this settlement is the fact that certain professional guidelines conflicted with Medicare's coverage decisions.'' Ogrosky said ''physicians were treating the patients before them doing what they thought best, and the hospitals are stuck paying the bill.''

'Everybody Is Doing It' Defense. ''In recent years, we have seen the Justice Department recover from hundreds of hospitals that improperly billed for kyphoplasty procedures. Now, the Justice Department has set its sights on improper defibrillator billings,'' said White, adding that ''the 'everybody else is doing it' defense is not working.''

Thomas S. Crane, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC in Boston, was more circumspect in his view of the scope of the settlements.

''The large number of hospitals involved indicates this was much more of an overpayment recovery action addressing ambiguous regulations rather than anything to do with fraud,'' Crane told Bloomberg BNA.

Ogrosky cautioned that ''[e]very provider who files claims that rely on a professional's medical judgment needs to understand that they may be on the hook where claims are submitted that do not comply with coverage rules.'' Ogrosky added, ''While large in the aggregate, the average hospital paid about half a million dollars to settle. Yet the years of legal fees, expert costs and other expenses make this a significant matter for the entire hospital community.''

The DOJ said it was ''continuing to investigate additional hospitals and health systems.''

White said, ''This statement is a clear shot across the bow to other hospitals that they should self-disclose similar improper billings.''

Principal Deputy Assistant Attorney General Benjamin C. Mizer said in a statement, ''While recognizing and respecting physician judgment, the department will hold accountable hospitals and health systems for procedures performed by physicians at their facilities that fail to comply with Medicare billing rules.''

Mizer added that the DOJ was ''confident that the settlements announced today will lead to increased compliance and result in significant savings to the Medicare program while protecting patient health.''

Another notable aspect of the investigations was the use of ''evidence-based medicine,'' according to the DOJ, which involved a panel of cardiologists that reviewed ''thousands of patients' charts.''

Many of the hospitals that settled the ICD allegations were named defendants in a whistle-blower lawsuit filed by relators Leatrice Ford Richards and Thomas Schuhmann, a cardiac nurse and health-care reimbursement consultant, respectively (*United States ex rel. Ford Richards v. Abbott Northwestern Hosp.*, S.D. Fla., No. 08-cv-20071-PCH, *settlement announced* 10/30/15).

The whistle-blowers received more than $38 million of the total settlement amount as successful relators un-

der the False Claims Act, and could receive portions of any additional settlements.

Health Systems Involved. Some of the notable hospital systems involved in the settlement include:

- Adventist Health System Sunbelt Healthcare Corp.: 11 affiliated hospitals settled for $5.5 million;
- Ascension Health: 32 affiliated hospitals settled for $14.9 million;
- Catholic Health East: 13 affiliated hospitals settled for $11 million;
- Catholic Health Initiatives: 17 affiliated hospitals settled for $7.8 million;
- Community Health Systems: 31 affiliated hospitals settled for $13 million;
- Hospital Corporation of America: 42 affiliated hospitals settled for $15.8 million;
- Health Management Associates Inc.: 27 affiliated hospitals settled for $7.2 million; and
- Tenet Healthcare: 19 affiliated hospitals settled for $12.1 million.

Bryan A. Vroon in Atlanta represented the whistleblowers.

BY ERIC TOPOR

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The full list of settling hospitals and settlement amounts is at http://src.bna.com/QJ.

The Hospital Corporation of America settlement is at http://src.bna.com/Rf.

Product Liability

Wright Medical Limited in Bellwether Trial; Plaintiff's Medical Expert Also Restricted

Hip implant maker Wright Medical Technology can't warn a jury in the first test case to be tried in federal multidistrict litigation that an assessment of punitive damages would have a ''chilling effect'' on the development of new medical devices (*In re Wright Med. Tech. Inc., Conserve Hip Implant Prods. Liab. Litig.*, 2015 BL 359373, N.D. Ga., No. 1:12-md-02329-WSD, 10/30/15).

''To allow evidence that an award of punitive damages might stifle or chill innovation in the development of medical devices generally, and hip implant devices specifically, would require a distracting departure in the trial of the core issues in this case,'' the U.S. District Court for the Northern District of Georgia said Oct. 30.

''This would delay the trial of this case and likely waste considerable time,'' the court said.

Trial is scheduled to start Nov. 9 in the bellwether suit in which plaintiff Robyn Christiansen alleges the Wright Conserve Hip Implant System failed about six years after it was implanted in Christiansen's right hip in 2006.

Physician Testimony Limited. Judge William S. Duffey Jr. also partially blocked Christiansen's attempt to offer the testimony of a surgeon who removed numerous hip implants allegedly compromised by ''metallosis.''

This theorizes that metal debris—from metal parts that touch each other and abrade—leach into the body, harming soft tissue and causing product failure.

Dr. Lynn G. Rasmussen sought to testify that out of 328 implant procedures she participated in involving Wright devices, she needed to ''revise,'' or repair, the devices in 43 cases due to metallosis and/or cup loosening, and is monitoring an additional 41 patients for similar concerns.

The court said Rasmussen's testimony about her experience with metallosis and revision surgeries must be substantially related to the facts of this case.

''Any testimony regarding prior revision surgeries and signs of metallosis thus must involve the Conserve Hip Implant System, and not a different metal-on-metal device, and it must involve patients who required revision surgery due to metallosis,'' the court said.

The ruling entirely barred comments about cases the surgeon is monitoring because it is ''unknown whether any design defect is present in these monitored devices and it is unknown whether the devices will require revision as a result of metallosis,'' the court said.

The judge's rulings cleared the way for trial in the suit.

In August, the court allowed most of the claims to go forward, including one for punitive damages (2015 BL 281293).

There are 539 actions pending in the multidistrict proceedings (MDL No. 2329), according to an Oct. 15 statistics report.

Pope McGlamry Kilpatrick Morrison & Norwood in Atlanta represents the plaintiff.

Duane Morris, in Philadelphia and Atlanta, represents Wright and related defendants.

BY BRUCE KAUFMAN

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The opinion is available at http://www.bloomberglaw.com/public/document/Christiansen_et_al_v_Wright_Medical_Technology_Incorporated_et_al/1.

Product Liability

$20M Judgment Wrongly Axed In Knee Implant Video Gone Wrong

A Pennsylvania appeals court wrongly tossed a $20 million judgment against a knee implant maker and a video producer in a suit by a woman who said her knees were seriously hurt while riding an exercise bike in a promotional video for the implant maker, a divided Pennsylvania Supreme Court said (*Polett v. Public Communications, Inc.*, 2015 BL 352793, Pa., No. 18 EAP 2014, 10/27/15).

The trial court acted within its discretion on two evidentiary points in the suit against Zimmer Inc. and producer Public Communications Inc., the majority said in

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an Oct. 27 opinion by Justice Debra Todd. She said the trial court appropriately instructed the jury that a cause other than the bicycle ride must be supported by medical evidence.

The court remanded Margo and Daniel Polett's suit to the Pennsylvania Superior Court, directing it to consider whether the trial judge properly denied Zimmer and PCI's motion to reduce the jury verdict. The appeals court didn't reach that issue when it threw out the judgment and granted the defendants a new trial.

''We are gratified by the Supreme Court's thorough and perceptive analysis and decision,'' Shanin Specter, one of the plaintiffs' attorneys, told Bloomberg BNA in an interview Oct. 28. ''We look forward to returning to the Superior Court to address the remaining issue of remittitur.''

Remittitur is a procedure through which a judge can lower the amount of damages granted by a jury in a civil case.

The issues in the case were ''garden variety evidentiary and instructional issues, decided well within the trial court's discretion. The Supreme Court saw that,'' Specter said.

Attempts to reach counsel for the defendants weren't successful.

Knee Replacement in 2006. Margo Polett's right knee was replaced in 2006 with Zimmer's ''Gender Solutions Knee,'' a device designed specifically for women. She also underwent surgery to replace her left knee.

There were no complications from the surgery and Polett was pleased with the outcome, the opinion said.

Polett later agreed to appear in a promotional film for the Zimmer implants. During the filming, she rode a stationary bicycle and walked on a treadmill. The producers didn't consult her surgeon, Dr. Robert Booth, about whether she was cleared for this exercise, the opinion said.

Polett began to feel pain and discomfort immediately after the filming. The pain worsened over time, and Polett required additional surgical treatments that resulted in significantly limited function and loss of mobility, the court said.

The couple sued Zimmer and PCI.

The couple didn't sue Booth, but executed a tolling agreement that suspended the statute of limitations for a possible suit against him, the opinion said.

A jury heard the plaintiffs' claims that Zimmer and PCI were negligent in having Polett ride the exercise bike in the video without first determining whether she was medically cleared to do so.

Doctor Says Bike Ride Caused Harm. Booth testified that the bicycle ride caused the inflammation that led to Polett's cascade of problems. He rejected the notion that any other activities Polett engaged in after the surgery, including walking on the beach or foreign travel, could have caused her post-operative problems, the court said.

The defendants presented evidence that although Polett's bicycle ride in the video was a factor in her inflammation, several other factors also contributed, the opinion said.

The jury was told in a supplemental instruction that a finding that something other than the exercise bike caused Polett's injuries must be based on medical testimony, and that jurors must not speculate on what else could have caused her harm, the top court said.

Verdict. The jury returned a $26.6 million verdict for Polett, allocating 34 percent of the fault to Zimmer, 36 percent to PCI and 30 percent to Polett.

Polett's share of the award was reduced by her comparative negligence. After computing delay damages, the court entered judgment of $19.6 million for her and $700,000 for her husband.

The defendants appealed.

The intermediate court said the trial court abused its discretion in barring the tolling agreement between Booth and the Poletts from being admitted into evidence.

Additionally, the appeals court said the trial court abused its discretion in allowing Booth to provide expert testimony, and erred in giving the ''no speculation'' injury supplemental instruction to the jury.

The Poletts appealed.

Tolling Agreement Properly Out. The trial court was within its discretion to conclude that the agreement's probative value was outweighed by its potential to confuse the jury and delay the trial, the supreme court said.

Nor did the lower court abuse its discretion in allowing Booth to testify as an expert—not excluding his expert causation testimony under Pa. R. Civ. P. 4003.5, which provides that experts whose opinions were ''acquired or developed in anticipation of litigation'' must be identified prior to trial.

The trial court was within its discretion to find that Booth developed his causation opinion during the course of his treatment relationship with Polett, which predated the litigation, the supreme court said. The court also said the defendants' contention that they were prejudiced by the lack of a formal expert report from Booth, or the introduction at trial of his opinion as to causation, was meritless.

And the state's top court said the trial court didn't err in giving the supplemental instruction to the jury, after a defense attorney gave a closing argument enumerating various proposed causes for Polett's medical problems, which hadn't been addressed by experts.

The trial court found there was no medical evidence presented by PCI and Zimmer to permit the jury to speculate on an alternative causation theory, the supreme court said.

The supplemental instruction was an integrated part of the trial court's overall instructions ''properly apportioning the burden of proof between the parties and ensuring that the jury's findings would be based on the evidence of record before it,'' the court majority said.

A dissenting opinion by Justice Michael Eakin said the tolling agreement was improperly allowed, the trial court's supplemental instruction regarding alternative causes wasn't permissible, and Booth was inappropriately allowed to testify as an expert.

Specter and Charles L. Becker of Kline & Specter represented the Poletts.

Brian Ercole, Troy Brown and James Pagliaro of Morgan, Lewis & Bockius represented the defendants.

BY JULIE A. STEINBERG

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Majority opinion is at http://www.bloomberglaw.com/public/document/Polett_v_Public_Communs_No_18_EAP_2014_2015_BL_352793_Pa_Oct_27_2

Dissenting opinion is at http://www.bloomberglaw.com/public/document/MARGO_POLETT_AND_DANIEL_POLETT_Appellants_v_PUBLIC_COMMUNICATIONS

Off-Label Uses

Court Again Stays Proceedings in Amarin Off-Label Case Against FDA Until Dec. 17

A federal court Oct. 30 extended a stay of proceedings in Amarin Pharma Inc.'s lawsuit against the FDA challenging agency regulations concerning the promotion of drugs for unapproved uses (*Amarin Pharma, Inc. v. FDA*, S.D.N.Y., No. 15-cv-3588 (PAE), *order*, 10/30/15).

The court extended the stay in the case until Dec. 17 to give the parties more time to engage in settlement discussions. The stay had been scheduled to expire Oct. 30 (9 MELR 569, 9/16/15).

The court order comes after a lawyer for Amarin told Judge Paul A. Engelmayer of the U.S. District Court for the Southern District of New York in an Oct. 30 letter that the parties, who had been granted an earlier stay, were continuing to engage in settlement discussions to resolve the matter. Amarin requested additional time to continue negotiations with the agency, and the judge granted the request.

Suit Brought in May. In May, Amarin Pharma and a group of doctors sued FDA, challenging the constitutionality of FDA regulations that prohibit Amarin from making completely truthful and nonmisleading statements about its high-triglyceride treatment Vascepa, a pure omega-3 fatty acid known as EPA (9 MELR 320, 5/13/15).

Under long-standing policy at the FDA, companies can be subject to criminal prosecution and civil liability if they promote their products for uses for which the FDA hasn't specifically approved them. Amarin wants to be able to tell doctors about how Vascepa can be used safely and effectively off-label without fear of prosecution or liability.

In June, the FDA, responding to issues Amarin raised in its lawsuit against the agency, told Amarin in a letter that it didn't object to many of the off-label statements the company wants to make about Vascepa.

In August, Engelmayer granted preliminary relief to Amarin and the physician plaintiffs, finding that Amarin had established a likelihood of success on the merits (9 MELR 533, 8/19/15).

Amarin Pharma has U.S. offices in Bedminster, N.J., and is part of Ireland's Amarin Corp. Plc. The four plaintiff doctors are from New York.

Amarin and the physician plaintiffs are represented by attorneys with Cahill Gordon & Reindel LLP, New York.

BY DANA A. ELFIN

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The one-page order signed by the district court judge is at http://src.bna.com/RE.

Patents

Medtronic Doesn't Infringe Atlas Wireless Network Patent; St. Jude May Escape Anyway

The Federal Circuit gave mostly bad news on Oct. 29 to Atlas IP LLC in its attempts to enforce a wireless network patent against medical technology companies (*Atlas IP, LLC v. Medtronic, Inc.*, Fed. Cir., No. 2015-1071, 10/29/15; *Atlas IP, LLC v. St. Jude Med., Inc.*, Fed. Cir., No. 2015-1190, 10/29/15).

The appeals court affirmed a ruling that device maker Medtronic Inc. did not infringe, and more importantly, reversed a judgment that puts the validity of the patent in question. That may still help device maker St. Jude Medical Inc., even though the court vacated the district court's judgment that St. Jude did not infringe the patent.

The Federal Circuit's two decisions include more rules for how district courts should construe patent claim terms, particularly as to the doctrine of claim differentiation.

The court also distinguished when a losing party in district court can appeal that decision if the case involves patent law, compared to what ''finality'' means in other appellate courts.

Different Infringement Arguments in Two Cases. Atlas's U.S. Patent No. 5,371,734 describes a ''protocol'' for wireless network devices to communicate with one another. The advantage of Atlas's protocol is that it includes instructions by a hub device to a number of remote devices that allow the latter to conserve battery power.

Atlas sued Medtronic and St. Jude alleging patent infringement by their wireless-implemented medical products for monitoring a patient's condition. For example, Atlas contended that Medtronic's cardiac defibrillators and insulin pumps infringed claim 21 of the '734 patent because of how certain components communicated with each other.

The infringement issues in the two separate cases depended on whether Atlas could get a broad enough interpretation of when the hub's instructions were sent or what specifically the instructions contained.

In the *Medtronic* case, the Federal Circuit agreed with the U.S. District Court for the Southern District of Florida on the meaning of ''establishing'' communication cycles with the remote devices—i.e., so they could power down between cycles. Setting up those cycles had to take place before the remote device was allowed to transmit, the court said, and Atlas conceded that Medtronic's implementation didn't do that.

But St. Jude's infringement of claims 11 and 14 of the patent turned on whether ''transmitting'' the starting time and duration of a communication cycle had to be ''in advance'' of the cycle—i.e., even earlier than when a remote device had powered on again.

The lower court ruled that it had to be in advance, and again Atlas conceded noninfringement under that construction. But the Federal Circuit saw no such re-

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quirement in either the claims or the patent's specification.

But since the district court had not yet considered St. Jude's infringement if ''in advance'' didn't apply, the appeals court vacated the noninfringement judgment rather than reversing it.

Claim Differentiation Limited. The doctrine of claim differentiation assumes different claims have different scope. It applies when a term is ambiguous and, if it is construed a certain way, would effectively be the same as another claim. Such a construction is generally to be avoided, but the Federal Circuit allows several exceptions:

> [W]e have been cautious in assessing the force of claim differentiation in particular settings, recognizing that patentees often use different language to capture the same invention, discounting it where it is invoked based on independent claims rather than the relation of an independent and dependent claim, and not permitting it to override the strong evidence of meaning supplied by the specification.

Atlas's argument in the ''establishing'' context was that other claims specifically required cycle-setting in advance—so claim 21 could not have meant that. The argument failed here for the further reason that there were other differences between those other claims and claim 21.

Validity Judgment Sent Back. In the *Medtronic* decision, the court reversed the district court's interpretation of an ambiguous term. That construction drove the lower court to find no invalidity for being anticipated by or obvious in light of earlier network technology, so the appeals court vacated that decision.

The question was whether at least one of the remote devices had to transmit something back to the hub for the network protocol to work. The claim language in question is: ''the hub establishing repeating communication cycles, each of which has intervals during which the hub and the remotes transmit and receive frames.''

The court said that had no ''plain meaning'' that necessitated a transmission, just as '' 'each school day has classes during which the teacher and students ask and answer questions' could easily be understood to describe what the classes are set up to permit, even what generally goes on, rather than that some student must ask a question in each class.''

The court sent the case back to the district court with the construction requiring ''that each cycle have one or more intervals in which remotes are *allowed* to transmit.''

Despite its continuing liability for infringement, St. Jude still can win if the district court finds the claims invalid under that interpretation of the claims' scope, since claims 11 and 14 include the same language.

Federal Circuit's Unique Jurisdiction Rule. Federal Circuit appeals are frequent under the scenario that Atlas faced: Claim construction is so one-sided that the disadvantaged party would rather appeal right away without resolving other issues—but leaving the other issues available for later review if necessary.

The court acknowledged in the *Medtronic* decision that, under the law in sister circuits—the Eleventh Circuit here—''the district court's decision strongly appears not to be final,'' and thus non-appealable.

But 28 U.S.C. § 1295(a)(1) ''sets out the exclusive jurisdiction of our circuit, and only our circuit,'' the court said. And in the Federal Circuit, it said, ''the district court's order dismissing all pending counterclaims without prejudice, after fully adjudicating some of the claims, is final.''

Judge Richard G. Taranto wrote the court's opinions, which were joined by Judges Kimberly A. Moore and Jimmie V. Reyna.

George C. Summerfield Jr. of Stadheim & Grear Ltd., Chicago, represented Atlas. John C. O'Quinn of Kirkland & Ellis LLP, Washington, represented Medtronic. Mark A. Perry of Gibson, Dunn & Crutcher LLP, Washington, represented St. Jude.

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Text of Medtronic decision at http://www.bloomberglaw.com/public/document/Atlas_IP_LLC_v_Medtronic_Inc_Docket_No_1501071_Fed_Cir_Oct_22_201.

Text of St. Jude decision at http://www.bloomberglaw.com/public/document/Atlas_IP_LLC_v_St_Jude_Medical_Inc_Docket_No_1501190_Fed_Cir_Dec_.

Product Liability

Full 5th Cir. to Hear Suit Over Joined Medical Malpractice, Product Claims

The full Fifth Circuit will decide whether health care providers were properly sued together with medical device makers by a Louisiana man who alleges both sets of defendants harmed him (*Flagg v. Stryker Corp.*, 5th Cir., No. 14-31169, *rehearing en banc* 11/5/15).

The court Nov. 5 granted a petition for rehearing en banc by Stryker Corp. and Memometal Inc., makers of a toe implant that allegedly caused injury to plaintiff Kale Flagg.

In September, a divided, three-judge panel of the Fifth Circuit said Flagg's medical malpractice claims against his Louisiana health care providers were properly joined in the suit with product liability claims against the device companies, neither of which was a citizen of Louisiana.

Whether health care providers are properly joined with product liability defendants is a question that often arises as plaintiffs fight to keep their suits in state court, and defendants seek to remove them to the federal system, which requires complete diversity of citizenship between the parties.

But here, Judge Catharina Haynes, who wrote the majority panel ruling, said the case marked the first time the appeals court had examined the intersection between the Louisiana Medical Malpractice Act and joinder, diversity jurisdiction (9 MELR 579, 9/16/15).

In this instance, the panel said, because the health care providers were properly named as defendants in the suit, diversity of citizenship didn't exist and the U.S. District Court for the Eastern District of Louisiana lacked jurisdiction to hear Flagg's case.

The Fifth Circuit panel then reinstated the case, which had been dismissed by the district court, and ordered the district court to remand the suit back to the Louisiana state court where it was originally filed.

Administrative Review Proceedings. Here, the district court erroneously discounted the citizenship of the Louisiana health care providers on the ground that Flagg sued them in court a week after starting medical review proceedings required by Louisiana law as a prerequisite to a malpractice suit, the majority said in the panel ruling.

The fact that the medical review board still had to issue an opinion didn't mean Flagg had no possibility of recovery against the health care providers, the standard for showing they were improperly joined in the suit, the majority said.

In dissent, Judge W. Eugene Davis advocated a rule that. if the statute creating a cause of action requires exhaustion with an administrative agency before suit can be filed, a plaintiff can't maintain a court action on the unexhausted claim. Such a suit should be dismissed and the defendants disregarded for diversity jurisdiction purposes, the dissent said.

Jurisdictional fights are common in civil litigation. Defendants often argue they would prefer to litigate in federal court to avoid inconsistent state-court rulings, but plaintiffs may view state courts as better positioned to enforce state law protections.

Ohlmeyer & Ohlmeyer, LLC represents Flagg.

Roach & Newton and Irwin Fritchie Urquhart & Moore, LLC represent Stryker and Memometal.

BY JULIE STEINBERG

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The order is available at http://www.bloomberglaw.com/public/document/Kale_Flagg_v_Denise_Elliot_et_al_Docket_No_1431169_5th_Cir_Oct_10/1.

The defendants' petition for rehearing is at http://www.bloomberglaw.com/public/document/Kale_Flagg_v_Denise_Elliot_et_al_Docket_No_1431169_5th_Cir_Oct_10/2.

The plaintiff's response to the petition is at http://www.bloomberglaw.com/public/document/Kale_Flagg_v_Denise_Elliot_et_al_Docket_No_1431169_5th_Cir_Oct_10/3.

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BNA Insights

Value-Based Contracting: A (Critical and Solvable) Rubik's Cube for Manufacturers

BY DONIELLE MCCUTCHEON AND TREVOR WEAR

In recent years—as a result of statements made by the President and others in his administration, government initiatives, and the increasingly competitive healthcare market that is focused on value-based (rather than fee-for-service) arrangements—medical device manufacturers have experienced an interest in responding to this change in environment by offering customers arrangements that involve performance-driven, outcomes-based, or risk-share concepts rather than traditional sales and discount arrangements. However, medical device manufacturers who wish to showcase the benefits of their newest innovation, or who simply want to stand out in a crowded field by pursuing such novel arrangements, face challenges in implementing these arrangements given the current (and rigid) legal framework under the federal healthcare fraud and abuse laws, in particular, the federal Anti-Kickback Statute (''AKS''),[1] which were enacted and implemented decades before this current industry shift. The AKS is particularly relevant to value-based arrangements because it is a very broad, intent-based statute that prohibits medical device manufacturers from providing anything of value (*e.g.*, discounts and services) to their customers with the intent to induce such customers to make referrals or recommendations for the manufacturer's products that may be reimbursed by a federal healthcare program (''FHCP''), such as Medicare or Medicaid.

Given the government's drive to transition its FHCPs toward reimbursement regimes that are based on performance-driven, outcomes-based, and risk-share concepts, the government needs to modernize the existing healthcare fraud and abuse laws to more fully accommodate the government's healthcare agenda, the changing healthcare environment, and industry practices. It seems unfair of the government to establish waivers and other safe harbors that apply only in the narrow context of the government's specific initiatives, *e.g.*, the Medicare Shared Savings Program, and not more broadly to other commercial arrangements, when value-based arrangements are beneficial to healthcare as a whole. As further explained below, such changes need not be dramatic. In fact, a few tweaks to the current regulatory structure would have a significant impact on the types of arrangements that manufacturers could more readily execute with customers. However, recognizing that any meaningful regulatory change

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Trevor Wear is a partner in the Chicago office of Sidley Austin LLP. He is a healthcare lawyer with more than fifteen years of experience in healthcare administration and law. Trevor's practice covers much of the healthcare industry, although he devotes much of his time to counseling pharmaceutical and medical device manufacturers on fraud and abuse and other compliance matters and on coverage, reimbursement, and other strategic issues, both in the U.S. and abroad.

[1] 42 U.S.C. § 1320a-7b(b).

would take significant time and that the industry's value-based focus is not going away, we also offer below considerations that manufacturers should keep in mind when evaluating and pursing such arrangements under the current legal framework.

The Government's Value-Based Initiatives

Based, in part, on the view that fee-for-service reimbursement systems ''contribute to waste in health care by encouraging unnecessary utilization and fragmented, poor quality care,''[2] the government has implemented a number of value-based initiatives. For example, the Centers for Medicare and Medicaid Services (''CMS'') Innovation Center was established by the Affordable Care Act (''ACA'') with the express purpose of ''test[ing] innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care.''[3] The Innovation Center solicits input from interested parties and selects models based on a variety of criteria, including reducing costs and improving quality of care.[4] One Innovation Center initiative is the Bundled Payments for Care Improvement (''BPCI'') initiative, which consists of four models that categorize patient services into episodes of care.[5] Medicare's reimbursement practices differ by model, but generally, Medicare pays hospitals based on episodes of care, rather than on a fee-for-service basis, and depending on the model, the hospital can receive further payments if its care is delivered at a lower cost than CMS estimates.[6] Another Innovation Center model is the Comprehensive Care for Joint Replacement program, which ''hold[s] participant hospitals financially accountable for the quality and cost of'' a hip or knee joint replacement surgery and recovery by comparing the hospital's actual fee-for-service expenses for the episode against Medicare's episode price and issuing an extra payment to the hospital or requiring that the hospital repay Medicare for any difference.[7] The Secretary of the Department of Health and Human Services (''HHS'') has authority to waive certain requirements under the Medicare and Medicaid programs to facilitate these innovative initiatives.[8] These initiatives are part of the Obama administration's goal of tying 50% of Medicare payments to quality and value through alternative payment methods by 2018.[9] CMS reports that it is actively analyzing data from these initiatives with the aim of, among other things, identifying quality and process improvements.[10] The data gleaned from these programs will likely lead to broader implementation of bundled and episode-based payment methodologies under FHCPs.

Similarly, the ACA established the Medicare Shared Savings Program, which permits groups of providers to collaborate in providing care for Medicare fee-for-service beneficiaries through Accountable Care Organizations (''ACOs'') and to receive certain shared savings that may result from the coordinated care.[11] In connection with this program, Congress has permitted the HHS Secretary to waive requirements of specific fraud and abuse laws as necessary to facilitate the ACOs.[12] Accordingly, on November 2, 2011, CMS and the HHS Office of Inspector General (''OIG'') jointly published an interim final rule establishing specific waivers and acknowledging the tension between the ACA's value-based initiatives and the pre-existing fraud and abuse laws: ''the Secretary has determined . . . that it is necessary to waive certain provisions of the Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing [Civil Monetary Penalty], and the Beneficiary Inducements [Civil Monetary Penalty] in some circumstances to carry out the Shared Savings Program.''[13] The rule established five waivers to address different circumstances, such as a pre-participation waiver applying to the start-up phases of an ACO, a broad waiver that applies to ACO-related arrangements during the ACO's participation under the Shared Savings Program, and a waiver applying to the distribution and use of shared savings payments earned under the Program.[14] On October 29, 2015, CMS and OIG finalized the Medicare Shared Savings Program waivers with the exception of the waivers of the application of the Civil Monetary Penalty law provision relating to ''gainsharing,'' as the HHS Secretary determined that this was no longer necessary in light of legislative changes that occurred after the publication of the interim final rule.[15] According to CMS, as of April 2015, the Medicare Shared Savings Program included 404 Shared Saving Program ACOs and 7.3 million assigned beneficiaries in 49 states plus Washington, D.C. and Puerto Rico.[16]

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[2] OIG, MANAGEMENT CHALLENGE 2: TRANSITIONING TO VALUE-BASED PAYMENTS FOR HEALTH CARE, https://oig.hhs.gov/reports-and-publications/top-challenges/2013/challenge02.asp.

[3] Pub. L. No. 111-148, 124 Stat. 389 (codified at 42 U.S.C. § 1315a (2012)).

[4] 42 U.S.C. § 1315a(a)(3) & (b)(2). *See also* CMS, MODEL DESIGN FACTORS, http://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf.

[5] CMS, BUNDLED PAYMENTS FOR CARE IMPROVEMENT (BPCI) INITIATIVE: GENERAL INFORMATION, http://innovation.cms.gov/initiatives/bundled-payments/.

[6] *Id.*

[7] CMS, COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL, http://innovation.cms.gov/initiatives/ccjr/.

[8] 42 U.S.C. § 1315a(d)(1).

[9] Press Release, CMS announces additional participants in pilot project to improve care and reduce costs for Medicare, Aug. 13, 2015, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-08-13.html.

[10] *See, e.g.*, CMS, BPCI FACT SHEET, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-13-2.html. In fact, in February 2015, the agency published report detailing the first year of the BPCI. LewinGroup, CMS BPCI INITIATIVE MODELS 2-4: YEAR 1 EVALUATION & MONITORING ANNUAL REPORT (prepared for CMS), Feb. 2015, https://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf.

[11] Pub. L. No. 111-148, 124 Stat. 395 (codified at 42 U.S.C. § 1395jjj (2012)).

[12] 42 U.S.C. § 1395jjj(f) (2012).

[13] CMS and OIG, Medicare Program; Final Waivers in Connection With the Shared Savings Program; Interim Final Rule, 76 Fed. Reg. 67992, 67993 (Nov. 2, 2011).

[14] *Id*. at 67993.

[15] CMS and OIG, Medicare Program; Final Waivers in Connection With the Shared Savings Program; Final Rule, 80 Fed. Reg. 66726 (Oct. 29, 2015).

[16] *See* CMS, MEDICARE SHARED SAVINGS PROGRAM FAST FACTS (April 2015), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/All-Starts-MSSP-ACO.pdf.

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Overview of Manufacturer Initiatives

Medical device manufacturers' customers, typically hospitals and other providers, are often subject to the government's growing number of value-based reimbursement initiatives. Additionally, the products manufactured by medical device companies are usually paid for by FHCPs through packaged or bundled reimbursement models. For these reasons, and in light of the myriad of government value-based and risk-sharing initiatives, medical device manufacturers should be (and several forward-thinking manufacturers are) developing novel contracting strategies that align with and leverage these performance-driven concepts. Such contracting strategies offer manufacturers a way to negotiate with customers on something other than greater discounts and rebates, and they can take many forms. For example, there are two basic models for manufacturer risk-share offerings. Under the first model, the ''downside'' model, the manufacturer agrees to return a portion of the product purchase price to the customer in the form of a rebate if the customer fails to achieve certain expected cost savings or clinical performance goals through the use of the manufacturer's product. Under the second model, the ''upside'' model, in exchange for reduced upfront pricing on a product, the customer will remit additional payment to the manufacturer (perhaps even in an amount that results in the customer paying the full, undiscounted amount of the product), if the customer achieves certain cost savings or clinical performance goals, or both. These arrangements may or may not involve the manufacturer also providing information and analysis designed to improve the function of the customer's clinical or cost control systems, *e.g.*, care pathway development and episode-based performance analysis. Under some contemplated arrangements, the manufacturer may also provide services in the form of on-site assessments and implementation support, which, in many cases, are intended to ensure the customer realizes improved results through the use of the manufacturer's technology. For purposes of illustration, a manufacturer may offer a large hospital system a significant discount on one of its medical technologies that is used in the hospital inpatient setting and has been proven to reduce patients' length of hospital stay associated with certain admissions, under an agreement that requires the customer to make additional payment to the manufacturer, if the customer achieves reduced inpatient stays for the applicable admissions as a result of the arrangement with the manufacturer.

Other value-based or risk-share arrangements include, for example, contracting arrangements where the manufacturer offers a customer a ''per procedure'' bundled fee on all of the devices needed in the service related to a particular Diagnosis Related Group (''DRG''). For example, this might include all of the devices needed for a total joint replacement. Similarly, a manufacturer may offer a customer a cap on the amount the customer will spend with respect to certain procedures if the customer agrees to almost exclusively use the manufacturer's products for the selected procedure. Pursuant to other arrangements, a customer may only pay for a product if the patient has a positive response to the therapy. Like those discussed above, these arrangements may also involve a service component, such as a requirement that the customer provide certain data to the manufacturer or that the manufacturer analyze certain aspects of the customer's operations and make cost-savings recommendations, which better ensures that the performance or outcomes goals of the arrangement will be met.

Misalignment with Current Legal Framework

While it is clear that many medical device manufacturers are ready and willing to implement (and a number of manufacturers have already implemented, albeit in a more limited fashion) these novel arrangements that align incentives across the industry and are responsive to the government's stated goals of moving toward value-based healthcare, there is misalignment between the policy goals and programs and the underlying legal framework, which potentially creates risk for medical device manufacturers exploring these arrangements.

From an AKS perspective, given the breadth of the statute, there are a number of statutory exceptions and regulatory safe harbors to protect arrangements in the marketplace that the government wants to encourage but that would otherwise implicate the law (*e.g.*, discounts and warranties), but the more innovative, cost-saving arrangements that the industry should be moving towards do not often fit well within the currently available exceptions and safe harbors. Specifically, a trilogy of recent enforcement actions involving pharmaceutical manufacturers[17] have left many in the industry wondering whether it is now the government's view that discount arrangements that involve a service or performance component fall outside the AKS discount safe harbor, despite the fact that such a position would be a significant departure from longstanding government guidance. Given that many of these novel arrangements include the provision of data and/or consulting services, which are often tied to the discounts and rebates offered by the manufacturer and may also include discount or rebate triggers that are tied to something other than product purchases (*e.g.*, a patient health outcome), many are concerned that the government might fail to recognize discount safe harbor protection for such arrangements.

Further, similar to the government programs discussed above, much of the cost-saving achieved under these risk-share and value-based programs is due to the manufacturer bundling a suite of items and services and offering the entire package at a reduced price to the customer. However, the ''same methodology'' limitation under the AKS discount safe harbor, which limits bundled discounts only to arrangements where the items or services at issue are ''reimbursed by the same [FHCP] using the same methodology,''[18] also creates a hurdle for manufacturers, as these arrangements often tie together products and services that are used in different procedures or different settings, which makes compliance with this safe harbor requirement challenging.

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[17] *See, e.g.*, *U.S. ex rel. Lisitza and Krammerer v. Johnson & Johnson*, Nos. 07-10288, 05-11518, Compl. of the U.S. (D. Mass Jan. 15, 2010); *U.S. ex rel. Lisitza and Krammerer v. Johnson & Johnson*, Nos. 07-10288, 05-11518, Transcript of Motion to Dismiss, at 25, 27, 59-60 (D. Mass Oct. 7, 2010); *see also U.S. ex rel. Banigan and Templin, et al. v. Organon*, No. 1:07-cv-12153-RWZ, 3rd Am. Compl., (D. Mass. Sept. 7, 2010); *see also U.S. v. Novartis Pharmaceuticals Corp.*, No. 1:11-cv-08196-CM, Amended Complaint-in-Intervention (S.D.N.Y. Jan. 8, 2014).

[18] *See* 42 C.F.R. § 1001.952(h)(5)(ii).

While usually addressable, many manufacturers also struggle with how to make the price concessions under these arrangements transparent to the FHCPs, consistent with the reporting and disclosure requirements under the discount safe harbor.

Manufacturers may also look to structure their innovative arrangements to satisfy other AKS safe harbors, such as the personal services, equipment rental, or one of the managed care safe harbors, but it is often difficult to design an arrangement that meets all of the technical elements of any safe harbor, and the government has previously advised that ''multi-purpose'' arrangements will need to be structured so that each purpose meets a safe harbor.[19]

Given the severe penalties under the AKS, and the related liability under the False Claims Act, it is no surprise that many manufacturers have been reluctant to implement these arrangements, and as a result, the healthcare system fails to realize the potential efficiencies and cost-savings that can be achieved. While there are existing value-based and risk-share arrangements that are structured to comply with current law, absent a modification to the legal and/or regulatory regime, it is likely that many manufacturers will continue to refrain from proceeding with such arrangements or will resign themselves to implementing only limited versions of such arrangements, leading to lost cost-saving opportunities for the system, minimal improvement in patient care, and, very likely, fewer sales for manufacturers.

A Possible Legal or Regulatory Fix?

While we believe that value-based and risk-share arrangements can be designed to comply with current law, they can be further encouraged and even more readily adopted, if adjustments are made to the current regulatory structure. Addressing the legal challenges manufacturers face in implementing value-based and risk-share arrangements would not require an overhaul of the healthcare fraud and abuse laws. Rather, as the government has already done with respect to its own programs, namely the CMS Innovation Center and Medicare Shared Savings Program, the government could simply implement limited waivers to the existing fraud and abuse laws and regulations to provide additional flexibility to manufacturers. Another possible consideration is for OIG to issue a new safe harbor under the AKS for certain value-based arrangements among industry stakeholders. Specifically, such a safe harbor could resemble other safe harbors and permit arrangements where, among other things, (i) the terms of the arrangement are set forth in a written agreement executed between the parties, (ii) all remuneration exchanged between the parties is documented and reviewable by the government upon request, (iii) the arrangement is consistent with current standards of medical care and protects against both inappropriate reductions in services and overutilization, (iv) written disclosure of the arrangement is provided to all patients whose care may be affected by the arrangement, and (v) no reimbursement is sought from a FHCP for any ancillary services offered in connection with the arrangement. Such an approach would align with many of the safeguards articulated by OIG in the numerous advisory opinions the agency approved with respect to gainsharing between hospitals and providers.[20] Like other existing safe harbors, this safe harbor could be narrowly tailored to permit only those arrangements that present a low likelihood of fraud and abuse.

Considerations for Working under the Current Regime

Recognizing that a legal fix, if implemented, will take some time, there are a number of considerations medical device manufacturers should keep in mind as they evaluate such arrangements, including those listed below. However, each arrangement requires a case-by-case analysis to ensure the arrangement is structured to align as closely as possible with existing law and guidance.

- Structure the arrangement to fit within an available AKS exception or safe harbor, which could mean, for example, defining the value at issue as a discount or rebate tied to the purchase of the product that meets the discount safe harbor, even if the discount or rebate is triggered by a clinical or economic outcome.
- Include robust ''compliance with laws'' language in the applicable agreement, including a provision that preserves the provider's independent clinical judgment and protects the best interest of patients, in part, to address potential corporate practice of medicine issues and tort theories of liability, as well as healthcare fraud and abuse concerns.
- To the extent the contemplated arrangement will include the provision or receipt of ancillary data, analysis, or other service components that are directed to the customer, consider designing such aspects of the arrangement as a separate service arrangement, consistent with the AKS personal services safe harbor.[21]
- Arrangements that involve, or could be perceived as involving, switching (*i.e.*, transitioning from a competitor's product to the manufacturer's product) should be carefully considered, particularly if the manufacturer's product is more expensive and/or less clinically appropriate for certain patients.
- Consider the inclusion of robust audit rights to permit the manufacturer to validate the accuracy of any data or other information provided under the arrangement, and where such audit rights exist, exercise the right when and if there are questions or concerns about the data and performance under the arrangement.
- Consider launching the arrangement on a pilot basis, particularly if this is the first such arrangement entered into by the manufacturer, that provides a means for the manufacturer to get out of the arrangement after a specified time period in case there is any issue from a compliance, business or other perspective.

[19] OIG, Anti-Kickback Provisions; Final Rule, 56 Fed. Reg. 35952, 35957 (July 29, 1991).

[20] *See, e.g.*, OIG Ap. Op. No. 07-21 (Dec. 28, 2007); OIG Ap. Op. No. 05-1 (Jan. 28, 2005), OIG Ad. Op. No. 01-1 (Jan. 11, 2001).

[21] 42 C.F.R. § 1001.952(d).

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- Depending on the arrangement, a manufacturer may wish to seek an advisory opinion from OIG. This was the approach many took with respect to gainsharing arrangements prior to OIG's 2014 proposed rulemaking in which the agency stated that gainsharing arrangements were not an enforcement priority for the agency unless the arrangement lacked sufficient patient and program safeguards.[22]
- Evaluate other legal considerations, including, but not limited to, laws impacting product promotion, insurance, and patient privacy.

[22] OIG, Revisions to Safe Harbors Under the AKS, and Civil Monetary Penalties Rules Regarding Beneficiary Inducement and Gainsharing; Final Rule, 79 Fed. Reg. 59717, 59729 (Oct. 3, 2014).

There is strong momentum throughout the industry to transition to value-based compensation for healthcare items and services. This is something that payors (particularly, the government) are demanding and others in the industry are expecting. Medical device manufacturers are not exempt from this industry-wide shift. While there are legal hurdles that the government should address, the healthcare industry is already moving to value-based arrangements, in large part, at the hands and encouragement of the government. Therefore, to compete successfully in this evolving industry, medical device manufacturers should carefully consider whether such arrangements make sense for them, given their products and customers, and evaluate how best to implement value-based and risk-share arrangements in a manner that meets their business objectives and minimizes the potential fraud and abuse risk.

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