Executive Summary

CMS pushes back sunshine data collection date. Conceptus and Hologic settle contraception patent dispute. More news briefs.

CMS pushes back sunshine data collection

CMS will not require collection of data on physician payments from manufacturers under the Physician Payments Sunshine Act before Jan. 1, 2013, the Medicare agency announced in a May 3 blog post. The move follows receipt by CMS of over 300 comments on its December 2011 proposed rule to implement the Act, which was included in the 2010 health care reform law, and the agency says it wants to allow time to address the input received and for organizations to prepare for data submission. CMS affirms that it intends to release the final rule "later this year." Sunshine Act sponsors Sens. Herbert Kohl, D-Wis., and Chuck Grassley, R-Iowa, had sent a letter to CMS Acting Administrator Marilyn Tavenner in early April asking her to issue a final sunshine rule no later than June so that partial data collection could begin that month. (See "News In Brief" - "The Gray Sheet," Apr. 9, 2012.) "It's disappointing that CMS won't even collect data at all this year," said Grassley in a May 4 statement. "Consumers need to know more about the financial relationships between their doctors and companies sooner rather than later."

Conceptus v. Hologic

Hologic Inc. agrees to cease worldwide marketing of its Adiana permanent contraception system by May 18 to settle a May 2009 patent infringement suit filed by competitor Conceptus Inc. In exchange, Conceptus has agreed to forgive $18.8 million in damages owed by Hologic under an October 2011 jury award. (See "News In Brief" - "The Gray Sheet," Apr. 9, 2012.) The settlement, announced April 30, "resolves all outstanding litigation" between the companies, said Conceptus, which makes the Essure permanent birth control system. The pact also gives Conceptus a non-exclusive license to the Adiana technology for permanent birth control, though the firm says it does not intend to market the Adiana system. As a result of the agreement, Conceptus raised its 2012 sales expectations by $5 million, to a range of $140 million-$144 million. "We believe that the settlement with Hologic will allow us to expand our
distribution and increase the overall availability and usage of Essure," said Conceptus CEO D. Keith Grossman.

Teleflex tech acquisitions

Specialty medical device maker Teleflex Inc. gains access to the EFx family of laparoscopic fascial closure system products through its acquisition of Axiom Technology Partners for undisclosed terms in a deal announced May 1. The 510(k)-cleared devices are designed for closure of abdominal trocar defects. The purchase will broaden Teleflex’ general surgery product line and provide access to new sales channels, the company says.

Separately, Teleflex also announced May 1 that it has acquired EZ-Blocker disposable catheter technology for lung isolation procedures from an anonymous seller for undisclosed terms. The disposable catheter products incorporate a unique bifurcated distal end and novel bronchial blocker for lung isolation and one-lung ventilation, the firm explains. Lung isolation is used to achieve one-lung ventilation to facilitate a variety of thoracic surgical procedures and treatment of conditions of the lungs, heart, chest wall and diaphragm, the company notes. The firm is gearing for a European launch of the CE-marked device by June 30. The technology also is pending 510(k) clearance in the U.S., Teleflex notes. The purchase builds on Teleflex’ current anesthesia product offerings.

Teleflex simultaneously reported its financial results for its fiscal first quarter (ended April 1), including sales of $387.8 million - up 9.5% from the same quarter last year.

Covidien buys PolyTouch

Diversified device maker Covidien PLC gains PatchAssist laparoscopic surgical instrument device maker PolyTouch Medical for undisclosed terms in a deal announced April 30. The 510(k)-cleared PatchAssist enables accurate and rapid delivery and placement of soft tissue prosthetics for a variety of procedures including laparoscopic ventral hernia repair. In March, Covidien launched AccuMesh, which was developed from the PatchAssist technology to facilitate placement of mesh during laparoscopic ventral hernia repairs.

USPSTF recommendation for kidney disease

The Agency for Healthcare Research and Quality’s U.S. Preventative Services Task Force released its draft recommendation statement on screening for chronic kidney disease. The group concluded that evidence is insufficient to assess the balance of benefits and harms for routine screening for chronic kidney disease in asymptomatic adults. Common tests considered for screening the disease include creatinine-derived estimates of glomerular filtration rate and urine testing for albumin. The draft recommendation is posted on USPSTF’s website for public comment until May 29.