POLICY & PRACTICE

Mortality Warning on AneuRx Stent

The Food and Drug Administration has issued a public health warning on the AneuRx Stent Graft System. Patients who receive the graft to prevent abdominal aortic aneurysm rupture should be regularly monitored because they appear to have a higher mortality rate than patients who have an open repair, said the FDA in its March warning. Long-term data suggest that initial mortality is 2.3% (not the 1.5% originally calculated) and continues to rise 3 years after implant, hitting 1.3% in the fourth year and 1.5% in the fifth year. The agency recommended that the graft only be used in patients who fit criteria outlined in the product labeling. Medtronic said that several previously published studies have shown that the endovascular graft has an advantage in perioperative mortality over open repair. In a Lancet study there was a higher rate of late rupture in the AneuRx group, but it was balanced by increased reinterventions and hospitalization for open-repair patients, according to Medtronic spokesman Daniel Beach. He also said that FDA's higher late mortality figure is due to the agency adopting a broader definition of aneurysm-related death.

Supreme Court Limits Device Suits

The U.S. Supreme Court has bolstered medical device manufacturers' argument that Food and Drug Administration approval confers special protection against liability suits. The Justices voted 8-1 in finding that the Medical Device Amendments of 1976 supersedes state law. That FDA act regulates devices that have gone through the premarket approval process, the most rigorous path to approval. Plaintiff Charles Riegel's estate had sued Medtronic Inc., alleging that a catheter that ruptured during cardiac surgery was designed, labeled, and manufactured in violation of New York law. But the Justices said that FDA approval "bars common-law claims challenging the safety or effectiveness of a medical device …" They upheld two previous lower court decisions. Justice Ruth Bader Ginsburg was the sole dissenter. Only state law allows a plaintiff to recover damages from a manufacturer; that avenue now appears to be closed. Many pending cases could be dropped as a result. The device industry applauded the ruling. "The FDA—and not a patchwork of state regulations or multiple jury verdicts—should determine the safety and effectiveness of medical technology," said Stephen Ubl, president and CEO of AdvaMed in a statement. But members of Congress involved in crafting the original device amendments were not as pleased. "Congress never intended that FDA approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices," said Sen. Edward Kennedy (D-Mass.) in a statement. "Congress obviously needs to correct the court's decision," he said.

49,000 Enroll in Vioxx Settlement

Merck & Co. says that 93% of those eligible to receive a settlement as a result of a Vioxx-induced stroke or heart attack have enrolled in the company's payout program. That encompasses 44,000 of the 47,000 who registered initially; another 5,000 people are seeking to enroll, but their eligibility has not yet been determined, according to a company statement issued in early March. Merck has agreed to put an estimated $4.85 billion into the settlement fund.

Woodcock Named CDER Head

Dr. Janet Woodcock has been named director of the FDA's Center for Drug Evaluation and Research. Dr. Woodcock, a rheumatologist, served as director of CDER once before, in the 1990s, and has served as acting director since October 2007. The drug industry's chief lobbying group, PhRMA, welcomed the appointment. Dr. Woodcock "has demonstrated willingness to work with diverse partners, including researchers, Congress, the White House, patients, and pharmaceutical research companies," said a statement from the group. But Public Citizen's health research group director Dr. Sidney Wolfe said in an interview that he's "not terribly hopeful" that Dr. Woodcock will lead the center well, because she doesn't like conflict or controversy. "I don't think she's the kind of CDER director we need right now," Dr. Wolfe said. "She's aware of a number of drugs on the market that should be taken off the market, but I don't think she has the fortitude to do something about it." CDER is charged with ensuring that safe and effective drugs—including prescription, over-the-counter, and generic products—are available to Americans.

Physicians Respond to Medicare Pay

The current uncertainty about Medicare payments to physicians is causing practices to postpone hiring staff, postpone investments in new technology, or even stop accepting new Medicare patients, according to a survey from the Medical Group Management Association. For example, 46% of respondents said that in light of the 10.6% cut in Medicare payments expected in July, they will refuse to accept new Medicare patients or limit the number of new Medicare patients. Nearly 28% said they would limit the number of appointments for Medicare patients. The pending cut could also affect the implementation of health IT systems, including e-prescribing. More than 60% of respondents said that they were more likely to postpone purchasing decisions related to e-prescribing because of the Medicare payment situation. "The 6-month adjustment to payments only served to create further uncertainty and administrative burden to practices already scrambling to shield themselves from additional payment cuts looming in 2009," Dr. William F. Jessee, president and CEO of MGMA, said in a statement. The results are based on responses from more than 1,000 group practices, according to MGMA.

—Alicia Ault

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