Implant makers make deal with prosecutors

Four major implant manufacturers made a deal with federal prosecutors to avoid prosecution related to kickbacks to surgeons. In the deal, announced Sept 27 by the US Attorney’s office in New Jersey, the companies, including Zimmer, DePuy Orthopaedics, Biomet, and Smith & Nephew, also agreed to pay a total of $311 million to settle civil claims. They also agreed to corporate reforms and federal monitoring for 18 months.

Stryker is subject to federal monitoring but not criminal charges because it cooperated with prosecutors before the others, the US Attorney’s office said. None of the companies admitted wrongdoing.

The companies are accused of using consulting agreements with surgeons to induce them to use their artificial hip and knee products. The investigation found this practice was common from at least 2002 through 2006.

US Attorney Christopher J. Christie said surgeons who had agreements with the companies were typically paid tens to hundreds of thousands of dollars per year for consulting contracts and were often lavished with trips and other expensive perks. The investigation also found situations in which physicians did little or no work for their payments but did agree to exclusive use of a company’s products. The US Attorney said the physician consultants failed to disclose these relationships to hospitals “and, more importantly, to the patients they treated.”

“This industry routinely violated the Anti-Kickback Statute by paying physicians for the purpose of exclusively using their products,” said Christie. “Prior to our investigation, many orthopedic surgeons in this country made decisions predicated on how much money they could make—choosing which device to implant by going to the highest bidder.”

The settlements release the 4 companies from civil liability and prevent them from being excluded from Medicare payments.

The US Attorney said the companies had cooperated in the reforms and taken initiative to develop and enforce new compliance standards.

Investigation began in 2005

The investigation began in 2005 when orthopedic implant companies acknowledged receiving subpoenas from the US Department of Justice requesting copies of all consulting contracts and other agreements with surgeons.

Hospitals, which pay the bills for implants, had said for years that implant vendors cultivate relationships with surgeons, who develop loyalties to a brand. They say these relationships have made it difficult to involve the surgeons in projects to standardize on implant brands and control rising implant costs.

From 2003 to 2004, for example, total hip and knee implant prices rose by 9%, while Medicare reimbursement was up by only 2.4%, according to Orthopedic Network News. About two-thirds of hip and knee replacements are performed on Medicare patients. The cost of the implant can consume 75% to 80% of the DRG payment.

In its agreement with the US Attorney, Biomet said it adopted a new code of conduct in 1999 and adopted the AdvaMed Code of Ethics (www.advamed.org) in 2004. It also agreed to pay consultants no more than $500 per hour for actual time spent consulting.

DePuy Orthopaedics, a unit of Johnson & Johnson, said that even before the
investigation was announced, it had made changes regarding physician relationships and said it will work with the government.

The chief executive for Smith & Nephew, David J. Illingworth, said that the company had worked closely with the Department of Justice to refine compliance procedures.

Zimmer’s president and CEO David Dvorak said he believed Zimmer is well positioned to abide by the settlement requirements because of a corporate compliance program implemented in 2005.

The companies account for nearly 95% of the market for hip and knee implants, the US Attorney’s office said. ✤