

NEWS

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Monitoring and Deferred Prosecution Agreements Terminated with Companies in Hip and Knee Replacement Industry

(More)

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NEWARK – Eighteen-month Deferred Prosecution Agreements (DPAs) with four companies in the lucrative hip and knee surgical implant industry expired today upon satisfactory completion of terms designed to reform industry practices involving payment of financial inducements to surgeons who use their products, Acting U.S. Attorney Ralph J. Marra, Jr., announced.

Also today, criminal conspiracy complaints filed on Sept. 27, 2007, at the time the DPAs were entered were dismissed against the companies – Zimmer, Inc., Depuy Orthopaedics, Inc., Biomet Inc., and Smith & Nephew, Inc. – at the request of the United States. The complaints alleged criminal violations of the federal anti-kickback statute, but were dismissed as a result of the companies’ successful completion of the DPAs.

A fifth company, Stryker Orthopedics, Inc., had cooperated in the criminal investigation and was not the subject of a criminal complaint or DPA. Stryker, however, entered into a non-prosecution agreement (NPA) in which it was subject to the same reform requirements as the other companies. Stryker too has satisfactorily completed terms of its agreement with the United States.

Monitors who enforced and oversaw compliance with the DPAs and NPA recently issued their final recommendations to the U.S. Attorney’s Office on the status of the companies’ progress and compliance. They are now released as monitors of the companies.

As a result of the government’s intervention and the DPAs and NPA, consulting payments to surgeons by all of the companies combined for ongoing consulting activity went from \$272 million in 2007 to \$105 million in 2008 – a 61 percent reduction. The total number of physicians receiving payments from the companies went from 1,693 in 2007 to 628 in 2008, a drop of 63 percent.

“We are confident that the industry, which had been engaged in illegal kickback practices to secure market share, has made significant changes in their practices to strengthen compliance programs, increase compliance staffs, and enhance internal compliance policies and procedures,” said Marra. “We expect they will continue these measures beyond the expiration of the agreements and commit to a continued culture of openness, accountability and compliance.”

“The monitors engaged by the companies were a critical driving force in fully integrating the goals and requirements of the agreements into the companies’ business practices,” Marra said. “These changes will ensure that physician consultants are retained not for the volume of their business but for the legitimate consulting services they can provide. All of these changes were achieved at no cost to taxpayers. Finally, and most importantly, patients will be better served, knowing that their doctors will be making decisions in the patients’ best interests rather than in the doctors’ financial self-interest.”

The five companies account for nearly 95 percent of the market in hip and knee surgical implants, which had annual combined sales in 2008 of \$6.5 billion. More than 700,000 total hip and knee replacement surgeries are performed in the U.S. each year, with approximately two-thirds of those surgeries performed on patients who are covered by the federal Medicare program.

On Sept. 27, 2007, the government accused the companies of using consulting agreements with orthopedic surgeons as inducements to use a particular company's artificial hip and knee reconstruction and replacement products. The investigation revealed that this was a common practice by the companies from at least 2002 through 2006. 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 perquisites.

The investigation revealed instances in which physicians performed work of little or no value for the financial inducements they received but did agree to exclusively use the paying company's products. The physician consultants also failed to disclose the existence of these relationships with the hospitals where the surgeries were performed and, more importantly, to the patients that they treated.

At the time the DPAs began and the criminal complaints were filed, Zimmer, Depuy Biomet Inc., and Smith & Nephew entered into civil settlements with the Department of Justice and U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), and paid a total of \$311 million to settle government claims under the anti-kickback statute and the civil federal False Claims Act. They also entered into five-year Corporate Integrity Agreements (CIAs) with HHS-OIG. Those agreements remain in effect and require additional reforms and oversight under the supervision of HHS-OIG.

The financial settlements and CIAs released the four companies from civil liability and prevented them from being excluded from the Medicare reimbursement program by HHS based on the conduct revealed in the investigation. Stryker did not enter into any civil settlement with the Department of Justice or HHS and was not released from civil liability.

Among the notable achievements and reforms:

- The companies overhauled their practices concerning the selection and engagement of consultants and moved to disengage and reduce the influence of their sales and marketing functions from the process;
- The companies have reorganized and added staff in their compliance departments in order to establish compliance policy, conduct compliance training, audit compliance

performance, and take corrective action as necessary;

- The companies disclosed the names of all their consultants on their company web sites, and the amounts paid to each of them, updated quarterly. A number of the companies intend to continue these postings;
- They adopted policies requiring consultants to certify under penalty of perjury that a bonafide services were performed;
- The practice of posting consultant identities, together with the amount of payments made to each such consultant, on a company's web site has also been adopted by some other companies in the medical device and pharmaceutical industry and may represent a trend that continues more broadly across the health care industry;
- The companies established confidential hotlines for complaints about improper behavior, which a number of the companies will maintain;
- The companies made improvements in their consultant payment approval processes in order to verify the appropriateness, necessity and lawfulness of payments;
- The companies conducted fair market value studies to determine appropriate compensation rates and structures to be used in future agreements with consultants to reduce subjectivity in payment rates;
- They established objective procedures for determining whether intellectual property has been contributed by individual consultants on any given development project;
- The companies began funding medical education programs, including medical fellowships and residency programs, through third-party administrators in an effort to eliminate any conflict of interest or perceived conflict of interest. This change will extend beyond the expiration of the DPAs and NPA;
- The companies improved ethics and compliance training and education programs, and trained thousands of employees, directors, contractors, consultants, distributors, sales agents, and other individuals who do business with or on behalf of the companies on federal health care laws and compliance requirements;
- The companies have prepared Annual Needs Assessments to plan, define, budget, and track all consultant activity. These assessments have caused the companies to reduce the number of consultants used, saving millions of dollars annually in consulting expenditures.
- The companies have moved to eliminate gifts to health care professionals, regardless of

value;

- In December 2008, the Advanced Medical Technology Association (“AdvaMed”) revised its Code of Ethics on Interactions with Health Care Professionals. The revisions in Code were driven by the companies under the DPAs, and many were based on provisions set forth in the DPAs. All the companies have committed to adopt the revised Code. For example, the companies have committed to submitting an annual certification to Advamed that each company has adopted the revised Code and implemented an effective compliance program; furnishing information regarding its compliance department and hotline reporting system to Advamed; and requesting that its affiliates, agents, dealers, and distributors provide Advamed with similar certifications and information concerning their compliance departments.

Marra credited Special Agents of the Department of Health and Human Services Office of the Inspector General, New York Regional Office, under the direction of Acting Special Agent in Charge Anna Coschignano; Special Agents of the United States Postal Inspection Service, under the direction of Special Agent in Charge David C. Collins; and Special Agents of the FBI, under the direction of Special Agent in Charge Weysan Dun, for their tireless work in the investigation of the hips and knees orthopedic industry.

The criminal case was investigated and prosecuted by First Assistant U.S. Attorney Michele Brown and Assistant U.S. Attorney Kevin O’Dowd. Brown and O’Dowd were assisted by Assistant U.S. Attorneys Marc Ferzan and Grace Park.

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Defense Attorneys:

For Zimmer – Seth Lundy, Esq. of King & Spalding

For Depuy – Walter Timpone, Esq. of McElroy, Deutsch, Mulvaney & Carpenter

For Smith & Nephew – David Vicinanza, Esq. of Nixon, Peabody

For Biomet – Steven Immelt, Esq. of Hogan & Hartson

For Stryker – Herbert Stern, Esq. of Stern & Kilcullen