

NEWS

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Five Companies in Hip and Knee Replacement Industry
Avoid Prosecution by Agreeing to Compliance Rules and Monitoring

(More)

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NEWARK – Five companies that account for nearly 95 percent of the lucrative market in hip and knee surgical implants have avoided criminal prosecution over financial inducements paid to surgeons to use their products by agreeing to new corporate compliance procedures and federal monitoring under 18-month agreements with the Department of Justice, U.S. Attorney Christopher J. Christie announced today.

Zimmer, Inc., Depuy Orthopaedics, Inc., Biomet Inc., and Smith & Nephew, Inc., have executed Deferred Prosecution Agreements (DPAs), which will expire in 18 months if they meet all of their respective reform requirements. Criminal Complaints were also filed today against those four companies, charging them with conspiring to violate the federal anti-kickback statute. Those Complaints will be dismissed at the conclusion of the DPAs if the companies comply with their terms.

The fifth company, Stryker Orthopedics, Inc., voluntarily cooperated with the U.S. Attorney's Office before any other company. Due to its cooperation, Stryker executed a Non-Prosecution Agreement (NPA) with the government, under which Stryker is required to implement all the reforms imposed on the other companies under the DPAs, including 18 months of federal monitoring.

The criminal Complaints accuse the four 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.

Additionally, the four companies executing DPAs have reached civil settlements with the Department of Justice and U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). The four companies have agreed to pay a total of \$311 million to settle government claims under the anti-kickback statute and the civil federal False Claims Act. They have also entered into five-year Corporate Integrity Agreements (CIAs) with HHS-OIG. Those agreements require additional reforms and monitoring under the supervision of HHS-OIG.

The financial settlements and CIAs release the four companies from any civil liability and prevent 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. The company has not been given any release from civil liability nor any release from HHS.

The five companies have all agreed to accept the appointment of federal monitors to

review compliance with the corporate reforms required of each of them. The companies, the amount of their respective settlements and monitors are as follows:

- Zimmer Inc., based in Warsaw, Ind., will pay \$169.5 million, and has agreed to be monitored by former United States Attorney General John Ashcroft, currently Chairman of the Ashcroft Group LLC of Washington, D.C.
- Depuy Orthopaedics, Inc., also based in Warsaw, Ind., a subsidiary of Johnson & Johnson Corp. of New Brunswick, N.J., will pay \$84.7 million, and has agreed to be monitored by Debra Yang, the former U.S. Attorney for the Central District of California in Los Angeles, and now a partner at Gibson, Dunn & Crutcher in Los Angeles.
- Smith & Nephew Inc., of Memphis, Tenn., will pay \$28.9 million and has agreed to be monitored by David Samson, the former Attorney General of the State of New Jersey, and now a partner at Wolff & Samson in West Orange, N.J.
- Biomet Orthopedics, Inc., also of Warsaw, Ind., will pay \$26.9 million, and has agreed to be monitored by David N. Kelley, the former U.S. Attorney for the Southern District of New York in Manhattan, and now a partner at Cahill, Gordon and Reindel in New York City.
- Stryker Orthopedics, Inc., of Mahwah, N.J., which has entered no civil settlement, has agreed to be monitored by John Carley, former Senior Vice President for Legal Affairs at Cendant Corp. and counsel to the Federal Trade Commission during the Reagan Administration.

“This industry routinely violated the anti-kickback statute by paying physicians for the purpose of exclusively using their products,” Christie said. “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. With these agreements in place, we expect doctors to make decisions based on what is in the best interests of their patients – not the best interests of their bank accounts.”

“Patients in federal health care programs deserve the best available treatment from physicians and surgeons without the corrupting influence of kickbacks from the medical device companies,” said Gary Heuer, Special Agent in Charge of the HHS-OIG in New York. “We will continue to work closely with our law enforcement partners to vigilantly investigate schemes meant to defraud Medicare, and to prosecute those individuals to the fullest extent of the law.”

The financial inducements in the form of consulting agreements were entered into with hundreds of surgeons throughout the 2002-2006 timeframe. The investigation revealed

instances in which physicians did little or no work for the financial inducements 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 companies to the hospitals where the surgeries were performed and, more importantly, to the patients that they treated.

The federal Department of Health and Human Services reports that more than 700,000 total hip and knee replacement surgeries are performed in the U.S. each year. The investigation revealed that approximately two-thirds are performed on patients who are covered by Medicare.

Among the key requirements common to the DPAs and NPA:

- A federal monitor will be in place at each company to review compliance with the DPAs and NPA and all new and existing consulting relationships with the companies;
- Each company is required to conduct a needs assessment to determine the reasonable needs for educational consulting services, and new product-development consultants.
- All new consulting agreements shall require physicians to disclose their financial engagements with any company to their patients and require the companies to disclose the name of each consultant and what they have been paid on the company website.

Compliance with the federal law by all of these companies going forward is the key element of these agreements. When devising the new compliance standard for this industry, the current Zimmer Corporate Compliance Program provided many of the requirements contained in the Agreements.

The complete cooperation by the management of Smith & Nephew also played a role in forming elements of the DPA. We appreciate the company's willingness to deal with these historical issues and, given its cooperation, we have complete confidence in the company's management, their commitment to compliance with the law through this new compliance standard and the will to make sure it is enforced throughout their company.

The government's willingness to enter into a DPA with Biomet was due, in part, to the initiative they recently developed to strengthen their compliance processes, procedures and controls. This evidence of commitment to strict compliance with the law and the providing of resources to make it companywide in scope shows Biomet's commitment to changing its previous practices and those of the industry.

During the course of this investigation, the government discovered DePuy's commitment to conducting comprehensive health care compliance training for its employees and independent sales force. We found that even before they knew of this investigation, Depuy had voluntarily implemented reforms. Indeed, the substance of the DPA reflects a number of Depuy's reforms.

The settlement monies paid by the companies are to resolve the covered conduct detailed in the Civil Settlement Agreements with the Department of Justice. The differential in the respective civil settlement amounts is reflective of market share and other related business factors during the relevant time period, and not the relative culpability among the companies.

Christie credited Special Agents of the Department of Health and Human Services Office of the Inspector General, New York Regional Office, under the direction of Special Agent in Charge Gary Heuer; 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 which led to these agreements.

The criminal case was investigated and prosecuted by Counsel to the U.S. Attorney Michele Brown and Assistant U.S. Attorney Kevin O'Dowd. AUSAs Brown and O'Dowd were also ably assisted by Assistant U.S. Attorneys Marc Ferzan, Chief of the Commercial Crimes Unit, and Grace Park. The civil case was handled by Assistant U.S. Attorneys Rudolph Filko, Deputy Chief of the Civil Division, and Stuart Minkowitz, Civil Health Care Fraud Coordinator.

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Defense Attorneys:

For Zimmer – Frederick Robinson, Esq. of Fulbright & Jaworski for Zimmer

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