



National Medical Device Audioconference:
How the Recent Landmark \$311 Million Device Settlements Will Change Industry Practices

Insights Into Federal Investigations of Medical Device Manufacturers from a Former DOJ Attorney

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- Partner, Patton Boggs LLP (Washington, D.C.), practice exclusively in area of health care fraud and abuse.
- Represent major medical device and pharmaceutical companies, and individual corporate officers, in government investigations.
- 1997-2004: Assistant Director, Fraud Section, Civil Division, U.S. Department of Justice.
- 1991-1997: Trial Attorney, Fraud Section, Civil Division, U.S. Department of Justice.

Topics

1. Pending Enforcement Efforts
2. Medical Device Settlements and Investigations
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Pending Federal Enforcement Efforts

- Civil and even criminal cases driven largely by *qui tams*.
- High level of coordination between Criminal and Civil, federal and state.
- Over 150 federal *qui tam* (whistleblower) actions in many judicial districts against device and pharmaceutical manufacturers.
 - Criminal prosecutor is typically assigned.
 - Likely state False Claims Act allegations and thus one or more state Medicaid Fraud Control Units will review allegations.

Pending Federal Enforcement Efforts

- Typical allegations against device manufacturers:
 - Financial relationships,
 - Off-label marketing,
 - Unapproved or adulterated devices,
 - Reimbursement manipulation.
- Other potential allegations:
 - Clinical trials,
 - Safety issues.

Medical Device Settlements and Investigations

- Investigation of Zimmer, Stryker, Biomet, Smith & Nephew, and DePuy (March 2005) (New Jersey) (financial relationships with orthopaedic surgeons for hip and knee replacements).
- Resolved in September 27, 2007
 - “This industry routinely violated the anti-kickback statute by paying physicians for the purpose of exclusively using their products.” Christopher J. Christie, U.S. Attorney.
 - Civil settlement amounts reflected market share and other related business factors, not relative culpability

Medical Device Settlements and Investigations

Company	Criminal	Civil	Monitor
Zimmer	DPA	\$169.5	John Ashcroft
Depuy	DPA	\$84.7	Debra Yang
Smith & Nephew	DPA	\$28.9	David Samson
Biomet	DPA	\$26.9	David Kelley
Stryker	Non-pros	None	John Carley

Medical Device Settlements and Investigations

- Investigation of device maker Blackstone Medical for allegedly paying kickbacks to doctors who use its equipment.
- Issue involves Blackstone, which makes and sells devices used in spinal surgery, payments or gifts provided to physicians since 1999.
- An Arkansas neurosurgeon has pleaded guilty to soliciting and accepting kickbacks from a salesman for Orthofix International, Blackstone's parent company.
 - Dr. Patrick Chan agreed to pay \$1.5 million to settle the charges, which resulted from a whistle-blower suit. Among other things, Dr. Chan was accused of receiving stock options in Blackstone for using its equipment, and also, for doing unnecessary surgery just to use a Blackstone device.

Medical Device Settlements and Investigations

- Civil settlement announced in July 2006 with Medtronic Sofamor Danek.
 - Allegation of kickbacks to doctors to induce them to use company's spinal products.
 - The settlement resulted from the investigation of a civil action which was filed by a private whistleblower on behalf of the United States, according to the government.
 - The government alleged that between 1998 and 2003, Medtronic paid kickbacks to physicians in several ways, including sham consulting fees, sham royalty payments and extravagant trips to top tourist destinations.

Medical Device Settlements and Investigations

- U.S. v. Baylor University Medical Center; Yale-New Haven Hospital v. Leavitt (Nov. 2006) (Second Circuit).
- U.S. v. Caputo (October 2006) (N.D. Illinois)
Medtronic (July 2006) (Memphis).
- Serono (Oct. 2005) (Boston).
- Guidant (June 2003) (San Francisco).
- LifeScan (December 2000) (San Francisco).

Analysis

- DPAs may increase.
- Judicial guidance is scarce but may increase.
- Pressure for Executive Branch guidance, especially in area of off-label.
- Medical device investigations may rise, if not explode, in areas of kickbacks and off-label use.
- Clinical trial, safety issues may emerge as basis for False Claims Act allegations.

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