

Contracts With Doctors: Not Just a U.S. Compliance Issue Anymore

First International Medical Device
Compliance Congress and Best Practices Forum

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U.S. Hip and Knee Industry

- 5 companies (Zimmer, DePuy, Biomet, Smith & Nephew and Stryker) account for nearly 95% of market
- More than 700,000 total hip and knee replacement surgeries performed in U.S. each year (HHS)
- Approximately 2/3 of implant patients are Medicare beneficiaries
- Physicians control selection of devices, but typically do not bear the cost

Role of Surgeon Consultants

- Product Design
- Product Evaluation
- Surgeon Education and Training
- Sales Force Education
- Research

The Investigation

- Commencement:
 - Grand jury subpoenas issued to five largest orthopedics companies in late March 2005 by the U.S. DOJ through the U.S. Attorney's Office for the District of New Jersey (USAO)
- The Focus:
 - Consulting agreements with, and payments to, orthopedic surgeons
- Duration:
 - Two-and-a-half years

The Allegations

- According to the Office of Inspector General –
 - From 2002-2006, 4 manufacturers paid over \$800 million under 6,500 physician consulting agreements
 - Vague descriptions of services rendered, sometimes drafted by sales reps
 - \$5,000 per quarter for reports on market trends, OR activity and product issues that were “cursory...often duplicated from quarter to quarter” and “of little or no value”
 - Panel presentations at resorts; \$5,000 for a 10 minute presentation
 - Training for experienced sales reps; full day billed for 1-2 hour sessions
 - Product design teams with up to 20 physicians, some added after project more than halfway completed

Criminal Complaints:

- Filed against 4 of the 5 companies, alleging conspiracy to violate the federal anti-kickback statute, in violation of 18 U.S.C. § 371
- Alleged conduct: “[E]ntering into financial arrangements with orthopedic surgeons who were offered or who solicited payments from [Company], in part, for the surgeons’ use of [Company’s] hip and knee joint reconstruction and replacement products,” from in or about January 2002 to in or about December 2006.”

The Resolution

- Deferred Prosecution Agreements:
 - Prosecution of criminal complaints deferred for 18-month term of DPA, provided the Company does not breach a material provision of the DPA
 - Dismissal upon expiration of the DPA
 - No statement of facts or admission of wrongdoing
 - According to USAO press release, Stryker avoided DPA, and entered into NPA, due to early cooperation.
- Civil Settlement Agreements with payments totaling \$311 million
- 5-Year Corporate Integrity Agreements

Requirement: Monitor Duties & Authority

- Access to all non-privileged documents deemed reasonably necessary
- Authority to meet with any employee or agent
- Review and evaluate all policies, practices and procedures relating to retention and payment of consultants
- Approve annual needs assessment
- Veto power over any consulting arrangements or payments
- Quarterly reports to USAO, to include recommendations to enhance future compliance

Requirement: Consultant and Payment Disclosures

Website disclosures:

- DPA/NPA posting
 - Consultants, City & State
 - Payments in \$25k increments
 - In-kind compensation
- Consulting agreements must require consultant disclosures to patients and affiliated hospitals.

Requirement: Needs Assessment

- Annual needs assessment, as approved by the Monitor, to define and limit all consulting services
- Including written support for the needs
- Must also –
 - Include budget for educational grants, gifts and donations
 - Incorporate detailed protocols or procedures to be followed before a consulting agreement will be authorized

Requirement: Consulting Agreements

- In writing and executed by Compliance Officer, CEO, General Counsel and other senior managers
- No agreements through third parties, including distributors
- Limited to calendar year term, except for product development, clinical and research agreements
- Must identify specific services and rates

Requirement: Consultant Payments

- Hourly rates capped at \$500 for time actually expended, absent independent FMV analysis (i.e., no retainers)
- Company employee or representative present for all services, except with Monitor approval (e.g., data collection, travel or prep time)
- Company representative and consultant verifications under penalty of perjury as condition of payment

Requirement: Royalties

- Must be justified by contributions to development of intellectual property
- Product design teams limited to those reasonably necessary to achieve design and development needs
- Aggregate royalties under product development agreements may not exceed FMV expressed as percentage of sales
- Advance and minimum royalties prohibited
- No royalties beyond life of U.S. patent
- No royalties on a Consultant's own use of product
- Commercially reasonable fixed amounts permitted in lieu of royalties for the transfer of IP

Other Requirements

- No payments for research or collection of data without written protocol
- No funding of fellowships for fellows who work with health care professionals (HCPs), except to legitimate medical education institutions or foundations
- No charitable donations to organizations controlled by HCPs or their immediate family members, or where an immediate family member of a HCP is employed

Compliance Officer's Role

- Oversight, evaluation and approval of needs assessment
- Approval of consulting services budget and all payments
- Evaluation of each new proposed consultant
- Execution of all consulting agreements
- Approval of fellowships and charitable contributions, in consultation with the Monitor

The Aftermath

- SEC/Justice Foreign Corrupt Practices Act inquiries
 - Payments to government-employed physicians in foreign countries
- New Jersey USAO focus shifts from large to smaller orthopedic manufacturers
 - Subpoenas to Wright Medical and Exactech
- Individual surgeons also under scrutiny
- Association of American Medical Colleges Task Force recommends banning gifts, food and travel, and “strongly discouraging” speaker bureau participation
- Physician Payments Sunshine Act
- New Justice Department guidelines for monitor appointments

One Company's Response

- Zimmer Announces Comprehensive Compliance Reform Program
 - Ban on all gifts to health care professionals
 - No longer sponsoring physician presentations at professional society meetings
 - Eliminating satellite institutes at customer locations
 - Physicians receiving royalties may no longer serve as trainers
 - Annual donation to third-parties for all education and resident/fellowship funding
 - Standardizing compliance polices across all business units worldwide

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