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In June 2006, the United States Justice Department, acting through its Newark, New Jersey office, issued subpoenas to the following major manufacturers of artificial joints: Biomet; DePuy; Smith & Nephew; Stryker; and Zimmer. Each of these subpoenas demanded consulting contracts, professional services agreements, and related documents which could evidence the corporation's arrangements with orthopedic surgeons.

Clearly, the thrust of the Justice Department's subpoenas is to establish whether the device companies are in some way offering "remuneration" to orthopedic surgeons to use their products. While neither a physician nor a major corporation would engage in such an unseemly action as offering or taking cash for the use of a given product, companies are becoming more and more "creative" with ways to provide remuneration to physicians. The government apparently feels this way, as they are focusing on consulting contracts and professional services agreements. Typically, it is through such consulting contracts and professional services agreements that ways are found to compensate physicians for ordering a given company's products. Educational seminars at "resort areas" where the "free time" exceeds the "seminar time" as well as stipends for research and educational programs that require little or no work by the physician only serve to confirm the government's belief that violations of the anti-kickback statute are occurring.

Under the Medicare/Medicaid anti-kickback statute, it is illegal "to offer" or "to accept" remuneration in return for a referral of a patient or services paid for by Medicare. Not only does the acceptance or payment of such remuneration constitute a federal felony (with a maximum of

5 years imprisonment), it can also result in civil federal false claims violations and exclusion from the Medicare/Medicaid program. According to recent reports, the action by the Justice Department constitutes a second round of subpoenas that were issued to the same five device makers. This can only lead one to conclude that the first round of subpoenas led the government to believe that further inquiry was required.

To avoid being charged with violating the anti-kickback statute, one should strive to meet the "safe harbor" requirements. While several safe harbors apply to the relationship between a surgeon and a device maker, many of the safe harbor agreements have the following common elements:

- (1) they are set out in writing and signed by the parties;
- (2) the services provided are specified;
- (3) the term is of not less than one year; and
- (4) the compensation is set in advance, is consistent

with fair market value in an arms-length transaction and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.

In the event that you or your practice receive a subpoena from the Justice Department or are asked to be interviewed by FBI agents, you should immediately seek legal counsel, as the visit or request you are receiving is definitely not "ROUTINE."

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