

MEDICAL EQUIPMENT COMPANY AGREES TO RECORD-SETTING ANTI-KICKBACK SETTLEMENT

On March 1, 2016, the Department of Justice ("DOJ") released a statement describing a settlement with the United States' largest endoscope distributor ("Company") to resolve civil claims and criminal charges connected to payments and kickbacks made to physicians and hospitals. The Company agreed to pay a total of \$623.2 million to settle the criminal penalties and civil complaints. In addition, the Company agreed to enter into a three-year deferred prosecution agreement ("DPA") allowing the Company to avoid conviction if it complies with the terms of the DPA.

AKS VIOLATIONS

The criminal complaints against the Company, which the Company admitted to in its criminal settlement for \$312.4 million, stated that the Company gave kickbacks to hospitals and physicians in violation of the federal Anti-Kickback Statute ("AKS"). The kickbacks were in the form of consulting payments, international travel, expensive meals, grants and free endoscopes intended to reward sales and new business. The pattern of kickbacks helped the Company realize profits of more than \$230 million. During the period that the improper conduct occurred, the Company did not employ a compliance officer and its employees were not properly trained in compliance. As a result, the Company has agreed to DPA terms including the following:

- Employ an experienced compliance officer;
- Maintain an effective compliance program and augment its compliance training;
- Maintain a confidential compliance hotline and website for reporting wrongdoing;
- Obtain annual certifications from the CEO and board of directors that the compliance program is effective; and
- Require that executives who are involved in future wrongdoing forego up to three years of performance-based compensation.

The DPA will be enforced and evaluated by an independent monitor. The three-year DPA has the option to be extended for an additional two years if the Company violates the terms of the DPA.

ADDITIONAL ALLEGATIONS

The Company also agreed to settle the civil complaints for \$310.8 million. The kickbacks described above allegedly caused false claims to be submitted to federal health care programs, resulting in violations of the AKS as well as federal and state False Claims Acts. These potential false claims violations were brought to light by a whistleblower who was the former chief compliance officer of the Company.

A subsidiary of the Company also settled with the DOJ for \$22.8 million to resolve a criminal complaint that it violated the Foreign Corrupt Practices Act.

CORPORATE INTEGRITY AGREEMENT

Along with the monetary settlements and DPA, the Company agreed to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General. The corporate integrity agreement establishes certain requirements of the Company's compliance program, including:

- Compliance responsibilities for Company management and board members;
- A health care compliance code of conduct;
- Training and education;
- Requirements for consulting arrangements, grants, charitable contributions, review of travel expenses and management of certain assets;

- Risk assessment and mitigation process; and
- Procedures for testing the compliance program.

PRACTICAL TAKEAWAYS

This settlement marks the largest amount paid for AKS violations by a medical device company. In its statement regarding the settlement, the DOJ reiterated its concerns about improper relationships and payments between medical device manufacturers and the health care providers who use their products. Medical device companies and other health care entities, particularly those that market and sell directly to physicians and hospitals, should ensure that:

- The marketing department is working alongside the company's legal department and/or outside counsel to properly structure promotions and other incentive programs;
- Their financial relationships are set forth in accordance with relevant anti-kickback statutes; and
- A proper compliance plan is being followed by all company departments.

If you have any questions or would like assistance submitting a comment, please contact:

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