

How to Avoid Hazards When Investing in Medical Device Companies

It's likely the medical device industry will continue to face the same level of scrutiny it endured in late 2007 and early this year. Historically, companies focused on getting their device through the Food and Drug Administration (FDA) approval process so that they could begin marketing to providers and patients. Now, other departments within the umbrella of the Department of Health and Human Services are investigating device companies' relationships with physician consultants. Even Congress has gotten involved by investigating the FDA for failing to debar criminals who participate in the device-to-market process.

Prospective investors need to be aware of the increased regulatory oversight of the medical device industry. Investors who understand the regulatory environment can schedule due diligence early and avoid potential hazards before closing a transaction.

Relationships with Consultants and the Anti-Kickback Statute

The anti-kickback statute prohibits anyone from knowingly and willfully receiving or paying anything of value to influence the referral of federal health care program business. Violations are punishable by prison terms, criminal fines, administrative civil money penalties, and exclusion from participation in federal health care programs. Medical device companies can become a target for investigation under the statute. This is because device manufacturers are relationship dependent—they must have relationships with physicians in order to develop

and test new devices. In addition, device companies need to train physicians how to use newly marketed devices. Free meals and CME training often are used by device manufacturers to accomplish this.

The Medical Device Manufacturers Association (MDMA), a trade organization for medical device companies, published Guidelines for Interactions with Customers. "Customers" is broadly defined to include "clinical and non-clinical people who make decisions related to product purchase." MDMA Guideline #10 states that consulting arrangements provide valuable research to medical device companies. This Guideline addresses reasonable compensation based on factors that would keep such compensation within a safe harbor under the anti kickback statute.

Investigators, however, are finding some agreements between device manufacturers and consultants offer substantial payments for only vaguely defined duties. In January 2008, the *Boston Globe* reported a story about an Arkansas neurosurgeon who pled guilty to soliciting and accepting kickbacks from a salesman under a consulting agreement that provided cash and stock options for "fake research." The salesman worked for Orthofix International, a subsidiary of Blackstone Medical Inc. The physician settled the charges against him by agreeing to pay \$1.5 million. The U.S. Attorney for the District of Nevada and the Office of Inspector General (OIG) continue to investigate Blackstone. Orthofix acquired Blackstone in 2006 for \$333 million. It is reported that Orthofix set aside \$50 million, or nearly

one-sixth of the purchase price, to pay for settlements related to the improper payments to physicians.

The OIG and the Department of Justice (DOJ) continue to investigate improper remuneration or kickbacks between medical device manufacturers and physicians who consult with them. Recent OIG and DOJ activity within the medical device industry includes the following:

- On February 4, 2008, the New Jersey Attorney General issued a subpoena to Synthes Spine Inc., a medical device maker specializing in surgical spine implants, including ProDisc. The investigation apparently is focused on whether the surgeons, who were researching the device and also had an investment interest in the medical device maker, made the required disclosures when they endorsed ProDisc.
 - The New Jersey Attorney General in the Synthes investigation also issued a subpoena to Viscogliosi Brothers LLC, a venture capital and private equity firm that specializes in developing and financing companies that market and sell orthopedic and spinal products. The subpoena seeks information concerning the investment backing that funded the ProDisc's development.
- In December 2007, orthopedic device manufacturers Wright Medical Group Inc. and Exactech Inc. reported that they were the subjects of subpoenas from the U.S. Attorney for the District of New Jersey regarding company agreements with surgeons.
- In September 2007, the U.S. Attorney's Office for the District of New Jersey agreed to deferred prosecution agreements with Zimmer, Inc.; Deputy Orthopedics Inc.; Smith & Nephew Inc.; and Biomet Orthopedics Inc. The separate agreements with these four manufacturers of hip and knee implants include corporate reform provisions and federal monitoring for a period of 18 months in exchange for deferred prosecution of criminal complaints charging each of these companies with conspiring to violate the anti-kickback statute. If the companies comply with the terms of the deferred prosecution agreements, the complaints will be dismissed. The criminal complaints accuse the companies of using consulting agreements that include

tens of thousands to hundreds of thousands of dollars in payments yearly to orthopedic surgeons as inducements for the surgeons to use a particular company's artificial knee and hip replacement and reconstruction products. The DOJ's claim is that some physicians did little or no work for the compensation they received as consultants but agreed to use the paying company's product exclusively.

- The four companies also reached civil settlements with the DOJ and the OIG under which they agreed to pay a total of \$311 million (each company will pay an amount based on its market share) to settle government claims under the anti-kickback statute and the civil False Claims Act. In addition, the companies each entered into five-year corporate integrity agreements that require additional reforms and monitoring under OIG supervision. In exchange, the four companies are released from civil liability and exclusion from the Medicare program. Stryker Orthopedics Inc., which was the first to cooperate with federal prosecutors, entered into a non-prosecution agreement that requires it to implement the same reforms as the other four companies, including 18 months of federal monitoring.

New Medical Center Policies Created Regarding Relationship

In February, the University of Pittsburgh Medical Center (UPMC) began enforcement of a policy that prohibits gifting by pharmaceutical and medical device industries. The ban extends from *de minimis* gifts (e.g., pens, food, etc.) to personal gifts regardless of value, samples, and consulting contracts without substantial job duties. According to Barbara Barnes, vice president for contracts, grants, and continuing medical education at the University of Pittsburgh School of Medicine, the policy "is aimed at removing the improper influence of commercial interests on patient care and research, while recognizing industry's positive role in advancing the practice of medicine." In addition, UPMC requires sales representatives to complete a training program, register with the hospital, and be invited to visit personnel for a specific purpose. Other academic medical centers such as Stanford, Massachusetts General, and the University of Arizona have implemented or are drafting similar policies.

Marketing Practices

The FDA has jurisdiction over medical devices and approves devices for specified uses or treatments of specific medical conditions. The product manual that accompanies the device sets forth the FDA-approved uses for that product. Off-label marketing is a violation of the Food Drug and Cosmetic Act (FDCA) because the manufacturer would be marketing the device for a use that has not been approved by the FDA. An FDCA violation can be charged either as a felony or a misdemeanor under 21 U.S.C. § 333(a)(1)-(2).

A provision of the 1997 Food and Drug Modernization Act¹ allows manufacturers or their sales representatives to proactively provide physicians with peer-reviewed articles from scientific or medical journals or reference books and information about clinical trials of off-label uses of the product. This anomaly in the regulations leaves much uncertainty in actual marketing practices. On February 15, 2008, the FDA, with much Capitol Hill opposition, issued draft guidance on “good reprint practices” for distribution of scientific journal articles that involve unapproved uses of FDA approved medical devices.

The draft guidance states that manufacturers who disseminate information about off-label use should limit the reprints to journal articles that:

- are published by an organization with an editorial board that uses experts in the subject;
- are peer reviewed; and
- are not primarily distributed, written, or edited by a manufacturer or a party significantly influenced or having a financial relationship with such manufacturer.

The information should be distributed in an unabridged reprint or copy of the article without markup by the manufacturer, have a bibliography, and be separate from any promotional literature. The reprint should contain a prominently displayed statement disclosing that the information has not been approved by the FDA.

In light of the new draft guidelines and the opposition generated by its release, we expect further regulatory

¹ FDAMA § 401; 21 U.S.C. § 360aaa.

scrutiny of off-label marketing and distribution of reprints.

Prospective Investors

How can a prospective investor decrease its exposure to risks when the target is a medical device company?

Due Diligence

Conduct due diligence as early as possible. Such due diligence should include a review of your target’s consulting agreements to confirm that they are in writing and that the compensation is at fair market value. Consult your attorney to determine if other applicable anti-kickback safe harbor provisions are met.

Integrity Agreements and Compliance Programs

Ask if there is a strong compliance program in effect and ask to review compliance policies and procedures. Also, determine whether the target has a corporate integrity agreement.

Sales Force Considerations

In order to understand the target’s marketing practices, assess whether the size of the sales force is proportional to the company’s approved use products. Assess whether the providers identified by the sales force are those providers treating approved use conditions. Evaluate whether the sales staff is aware of various hospital no conflict policies and what measures the company takes to assess compliance. Review the distribution of promotional materials, leave behind material, seminars, and conferences to assess whether the focus is on approved use. Assess whether off label reprints are distributed within the regulatory guidelines.

Debarment Checks

Currently the FDA lacks authority to debar medical device companies. However, individuals who are convicted of felonies under Title 21 of the United States Code may be debarred. In addition, the OIG has the authority to exclude individuals and entities who have been sanctioned from participating in federal health care programs. Due diligence may include checking the FDA debarment list, the OIG web site, and other government exclusion lists as appropriate for sanctioned parties.

If you would like further information or assistance, please call the Dechert attorney with whom you regularly work or any of the attorneys listed below.

Practice group contacts

If you have questions regarding the information in this legal update, please contact the Dechert attorney with whom you regularly work, or any of the attorneys listed. Visit us at www.dechert.com/health.

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