Medical Device Enforcement:
Recent Settlements and Strategies to Reduce Risk

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Webinar Takeaways

On July 18, 2013, Skadden hosted a webinar to provide insights into medical device enforcement with a focus on recent settlements and strategies to reduce risk. The webinar provided participants with practical tactics for assessing and mitigating risks in light of the government's current approach to enforcement.

DOJ Enforcement Update

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Since 2011, the Department of Justice (DOJ) has entered into settlement agreements with nine medical device companies for a combined total of $180 million. Although this figure pales in comparison to the settlements garnered in the pharmaceutical space, a review of recent settlements provides valuable insight into DOJ's approach to medical device enforcement. Bragg highlighted three recent settlements:

- **TranS1 (now Baxano Surgical)** – July 2013
  - DOJ alleged that the company counseled health care providers to bill using improper codes, engaged in off-label promotion and made improper payments to health care providers in the form of speaker programs and consulting fees.
  - The company settled for $6 million.
  - There have been no criminal charges, and the civil settlement remains under seal.
- **C.R. Bard** – May 2013
  - The government alleged that between 1998 and 2006 the company violated the Anti-Kickback Statute and the False Claims Act by making improper payments to customers and health care providers in the form of grants, guaranteed rebates, free medical equipment, conference fees and marketing assistance.
  - In addition to the $48 million civil settlement, the company and DOJ entered into a non prosecution agreement.
  - DOJ acknowledged that the company began taking remedial measures to enhance compliance prior to the initiation of the government's criminal investigation.

- **Orthofix** – December 2012
  - The company paid $42 million to resolve civil and criminal allegations of paying kickbacks by offering fitting and referral fees to health care providers, failing to advise patients of the opportunity to rent rather than buy the products, forging Certificates of Medical Necessity and improperly waiving patient copayments resulting in violations of the False Claims Act.
  - The subsidiary company pleaded guilty to a felony for allegedly obstructing a Medicare audit.
  - Six company employees and one health care provider have also been prosecuted for their roles in these activities.

Panelists noted that the government is applying a lower threshold when pursuing Anti-Kickback Statute cases against companies. Accordingly, the Anti-Kickback Statute is no longer reserved for actions involving extravagant gifts and vacations.

Although enforcement actions in the medical device space are less likely than those in the pharmaceutical arena to result in large financial payments, they are more likely to result in prosecutions of individual officers, executives and employees. These divergent enforcement results stem from some fundamental differences in the two industries. Some of these key differences include:

- Medical device reimbursement is significantly more complicated than pharmaceutical reimbursement. Additional compliance risks arise when companies allow sales representatives to play a role in the reimbursement process.
- There was a tremendous consolidation of pharmaceutical companies that has not occurred in the medical device industry. In these smaller medical device companies, more decisions are made by individuals than by committees, making individuals the more likely subjects of investigations and enforcement actions.
- The product life-cycle in the medical device field is much shorter than in the pharmaceutical field. This places increased pressure to generate sales, recoup expenses and create profits on a short horizon.

Focus on Individuals in Device Investigations

Michael Loucks | Boston

The recent cases against Orthofix employees — ranging from the vice president of sales to territory managers — alleged that these individuals falsified patient medical records, made false declarations to a grand jury and offered kickbacks to health care providers.

- Neither the company nor any of its employees were alleged to have engaged in off-label promotion. Instead, these cases suggest a trend toward "off-coverage" prosecutions. In "off-coverage" prosecutions, the alleged conduct includes attempts by the company to falsely cause Medicare to pay for uses of the device that are not within the specified coverage criteria.
- DOJ often develops cases against a company's employees or customers as a way to encourage the company to settle. In the Orthofix case, the government's claim that this was a problem of company culture was supported by evidence that the same violative behavior — namely, forging medical records — was occurring in several territories across the country.

- Companies should be wary of allowing employees to aid health care providers in obtaining or assuring Medicare or insurance coverage for their devices. Engaging in this activity only serves to enhance compliance and legal concerns for the company. If a company does allow this activity, the company should have a compliance focus on the routine employee activities that may create opportunities for off-label promotion, the submission of false claims to Medicare or Medicaid, and kickbacks to health care providers.

- It is noteworthy that several Orthofix employees pleaded guilty to felonies and were given sentences of home detention and probation. By contrast, Synthes employees pleaded guilty to misdemeanors and were given prison sentences. Panelists suggested that one possible explanation for the disparity is the element of patient harm alleged in the Synthes cases, which was not alleged in the Orthofix cases.

The panel counseled medical device companies to create front-end and back-end controls around interactions between company personnel and health care providers. Additionally, the panel emphasized that the government will focus on drivers of behavior such as incentive compensation, call plans and sales training. Companies are advised to have sufficient checks in place to ensure that the employees are following company guidelines and compliance procedures.

Focus on Reimbursement Differences in Device Investigations

Greg Luce | Washington, D.C.

The government's prosecution of off-label pharmaceutical promotion is widely seen as the playbook used for similar enforcement actions in the medical device industry. Medical device cases, however, present unique considerations that merit careful analysis, particularly when the government alleges violations of the federal False Claims Act.

- In these cases, the government has the difficult task of demonstrating that a medical device manufacturer's actions caused the submission of a false claim and, moreover, that the medical device was material to the government's decision to pay that claim.

- Device reimbursement is not fixed and varies by site of service. Accordingly, the profit motive often cited by the government in off-label cases may be diminished or even eliminated depending on where a device is used. For example, because the Inpatient Prospective Payment System (IPPS) pays a standard rate based on the patient diagnosis, itemized charges on a patient's bill are often immaterial to the amount of reimbursement a provider receives from Medicare.

- Courts recognize that off-label use of a medical device is distinct from a medically unnecessary use of that device. Indeed, the Supreme Court has stated that "'[O]ff-label' usage of medical devices ... is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

- The government has the burden of demonstrating that promotional activity caused the submission of a claim for payment. Even if the government can demonstrate that a device manufacturer's marketing or promotion activities violated FDA regulations, the government may not be able to establish that the manufacturer caused physicians or hospitals to submit false claims for reimbursement.

- Unlike drug sales, medical device manufacturers often provide technical support for their devices, which makes it difficult for the government to parse the difference between sales activity and product support. The ability to provide objective, accurate advice is something that companies should be able to do. However, companies take on too much risk by empowering personnel to submit claims on behalf of health care providers or patients.