

3 New Settlements Highlight DOJ Scrutiny Of Device Makers

By **John Bentivoglio and Jennifer Bragg** (April 4, 2018, 5:30 PM EDT)

Three recent settlements between the U.S. Department of Justice and medical device makers highlight how health care fraud prosecutors are using the civil False Claims Act to target a wide range of marketing, distribution and manufacturing practices in the medical device sector. While at first blush the pace of settlements in the first quarter of 2018 seems relatively high, a more thorough look shows that device companies, as well as individual executives and employees, have been the target of criminal and civil enforcement officials for years.

Abiomed — DOJ Pursuing Small-Dollar Financial Relationships

On March 8, 2018, the DOJ announced a \$3.1 million civil False Claims Act settlement with Abiomed relating to alleged misconduct in connection with the company's speaker program. Notably, the settlement and accompanying press release made no mention of payments to the speakers themselves. Rather, the settlement and release focused exclusively on the number and backgrounds of the attendees and the value of the food and beverages provided to such attendees. According to the DOJ, Abiomed sought to induce physicians to use its devices, which cost more than \$20,000 each, by buying meals for them at expensive restaurants. The government further alleged that Abiomed paid for meals in instances where attendees ordered alcohol in amounts inconsistent with legitimate scientific discussion, paid for meals where spouses were in attendance, paid for meals that exceeded Abiomed's guidelines and held programs in which their employees misrepresented the number of physicians in attendance in order to make the program appear to comply with company expense guidelines.

Although the qui tam complaint that prompted the DOJ investigation alleges broader misconduct, the DOJ press release references only noncompliance regarding speaker program attendees as the basis for the settlement, asserting that providing doctors with lavish meals or meals accompanied by entertainment can impair a physician's independent medical judgment. In announcing the resolution, Abiomed filed an 8K in which it noted that "the government inquired about thousands of business and educational engagements the company conducted with physicians. The investigation revealed that less than 2% of those meals exceeded Abiomed's internal guidelines." The company also noted that the director of clinical operations who filed the qui tam complaint was an employee for less than a month.



John Bentivoglio



Jennifer Bragg

DJO Global — Aggressive Sales Tactics Focus of False Claims Act Settlement

A second recent settlement involved DOJ scrutiny of sales practices that, while common in many industries, can trigger health care fraud allegations when applied in the health care industry. On Jan. 23, 2018, the DOJ announced a \$7.62 million civil False Claims Act settlement with Empi, a subsidiary of global medical equipment supplier DJO Global. The government alleged that Empi submitted false claims to TRICARE for transcutaneous electrical nerve stimulation (TENS) electrodes that were excessive and unnecessary. The settlement alleged that Empi used a technique called "assumptive selling" to persuade TRICARE beneficiaries to seek and accept unjustifiable quantities of TENS electrodes. Assumptive selling is described as a technique wherein company employees would contact TRICARE beneficiaries and induce them to order excessive TENS electrodes by acting as though the beneficiaries had indicated a need for them, when that may not have been the case. The direct-to-patient nature of the interactions may have heightened the DOJ's scrutiny of the company's selling techniques. In entering into the FCA settlement, the company denied liability and agreed to cooperate fully and truthfully with DOJ's continuing investigation of individuals and entities not released in the settlement. The company also agreed to provide the DOJ with complete and unredacted copies of all nonprivileged documents, reports, memoranda of interviews and records concerning any investigation of the covered conduct.

Alere — Manufacturing Problems Result in Civil Health Care Fraud Settlements

Most recently, a Massachusetts-based medical device manufacturer and its subsidiary agreed to pay the United States \$33.2 million to resolve allegations that it caused hospitals to submit false claims to Medicare, Medicaid and other federal health care programs by knowingly selling materially unreliable point-of-care diagnostic testing devices. According to the DOJ, between January 2006 and March 2012, Alere sold materially unreliable rapid point-of-care testing devices marketed under the trade name Triage[®]. The devices were used to diagnose a wide range of medical conditions, including acute coronary syndromes, heart failure and drug overdose, as well as being used in time-sensitive emergency room settings.

The DOJ further alleged that Alere had received customer complaints that put it on notice that certain devices it sold produced erroneous results that had the potential to create false positives and false negatives that adversely affected clinical decision-making. The DOJ claims that while the company eventually took corrective actions, it did so only after U.S. Food and Drug Administration inspections prompted a nationwide product recall in 2012. The company denied liability in entering into the civil settlement agreement.

The Alere settlement is significant in that it involves the use of the civil False Claims Act to address product quality problems. The issue of FCA liability for FDA manufacturing or quality violations is a hotly contested and closely watched issue. While no circuit has directly contravened the Fourth Circuit's holding in *United States ex rel. Rostholder v. Omnicare*,^[1] at least two circuits have since allowed cases to proceed where plaintiffs have shown more than mere technical violations of FDA regulations.^[2]

New Era of Scrutiny — or Continued Focus on Medical Device Makers and Suppliers

The pace of recent device settlements might lead one to conclude that the DOJ is newly energized in its scrutiny of this sector, but a broader review shows that medical device makers and suppliers have been in the DOJ's crosshairs for some time. Since the beginning of 2015, at least 24 device makers and medical equipment suppliers have settled criminal and civil health care fraud cases with the DOJ for amounts above \$1 million. Practices that have drawn scrutiny run the gamut from the sale of

unapproved products (Shire's Advanced BioHealing), to overly aggressive sales tactics (DJO Global), payment for promotional programs to steer patients to particular suppliers (Coloplast), violations involving speaker program attendees (Abiomed), and quality deficiencies (Alere).

Collectively, these 24 settlements have resulted in approximately \$1.3 billion in criminal and civil fines and penalties. Eleven of these settlements included corporate integrity agreements ("CIA") with the Office of Inspector General, U.S. Department of Health and Human Services, or involved companies already under a CIA. One company agreed to CIA-like provisions in a nonprosecution agreement. In several instances, DOJ press releases and later court filings indicate that, despite corporate settlements, prosecutors were continuing to scrutinize the conduct of individual employees and executives.

The Role of Whistleblowers in Recent Device Cases

Mention should be made of the role whistleblowers played in prompting the DOJ inquiries discussed above. Based on publicly available records, at least 16 of the device settlements since Jan. 1, 2015, involved whistleblower complaints under the qui tam provisions of the False Claims Act. Many of the whistleblowers were current or former employees, including a member of the sales force, a director of clinical operations and a senior quality control analyst. Public records from 15 of these cases indicate qui tam relators received approximately \$78 million (not including the fees and expenses defendant companies had to pay to relator's counsel).

Compliance Programs Have Improved, But More Focus May Be Needed

The life sciences industry in general, and the medical device sector in particular, has made great strides to strengthen company compliance programs, and the AdvaMed Code has set higher standards of conduct in key areas. But a close read of the settlements makes clear that AdvaMed Code compliance, alone, is not enough. DOJ prosecutors scrutinizing speaker programs have moved well beyond the requirements in the AdvaMed Code (a written contract, payment of FMV, no explicit tie between speaker payments and use or referrals of a company's product) to examine whether companies are complying with their own internal policies, and whether the number and type of attendees are consistent with the need for and legitimacy of speaker programs (regardless of whether the speaker actually made a presentation and was paid FMV for his or her services). The AdvaMed Code doesn't address a broad array of sales and promotional practices that are common in the device and medical supply industries (such as the practices at issue in the DJO Global and Coloplast cases) and the code does not — and was never intended to — cover quality system and manufacturing compliance.

What should companies do? Companies often start by creating the basic infrastructure of a comprehensive compliance program, including identification of a senior compliance officer with the ability to set and enforce standards of conduct subject to oversight by the CEO and ultimately the board of directors. Second, companies identify key risks in the areas of sales, marketing, promotion and manufacturing, and develop clear policies and procedures for conduct within those areas. Many companies look at the AdvaMed Code as a floor — not a ceiling — for sales and marketing practices, and key areas not addressed by the code are separately addressed in company policies. Training and education are key components of a compliance program, and frequent, short training modules are often perceived to be more effective than lengthy, once-annual compliance training programs.

Finally, companies should consider devoting significant resources to monitoring and auditing compliance with applicable laws and company policies. It is important to have clear lines of authority and responsibility for the intake, review and resolution of internal allegations of misconduct, whether those

are discovered in the course of informal monitoring activities, formal audit programs, internal ethics lines or external complaints from competitors or other sources. Many companies have come to understand that compliance programs don't have to stifle innovation or curtail otherwise effective sales and marketing practices. Rather, targeted and effective compliance programs can result in a commercial advantage to the extent that they prevent or mitigate criminal investigations, costly civil settlements and burdensome OIG-imposed compliance controls.

John T. Bentivoglio and Jennifer L. Bragg are health care and life sciences partners with Skadden Arps Slate Meagher & Flom LLP.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] 745 F.3d 694 (4 Cir. 2014) (cGMP violations alone are insufficient to establish FCA liability)

[2] See United States ex rel. Campie v. Gilead Sciences Inc., 862 F.3d 890 (9 Cir. 2017) (alleged failure to provide information about use of an ingredient manufactured at an unapproved facility was actionable under FCA); and United States v. Nargol v. Depuy Orthopaedics Inc., 865 F.3d 29 (1 Cir. July 26, 2017) (allegation of significant manufacturing defects resulting in the product not meeting conditions of approval was sufficient to survive motion to dismiss under FCA).