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Devicemaker-doctor relationships ripe for fraud litigation

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The number of healthcare whistleblower cases has swelled over the the past decade as settlements have yielded nearly $23 billion, and medical device companies are likely to be a prime target.

A recent False Claims Act lawsuit claiming that a medical device company paid kickbacks to doctors illustrates an increasingly tenuous arrangement that may spur more whistleblower cases.

The Department of Justice intervened in the whistleblower suit against Life Spine seeking millions of dollars of damages for allegedly paying kickbacks in the form of consulting fees, royalties and intellectual property acquisition fees to induce physicians to use the manufacturer's spinal implants, devices and equipment.

The doctors who received these payments accounted for about half of the Huntley, Ill.-based company's domestic sales of spinal products from 2012 through 2018, the lawsuit claims. Life Spine would allegedly recruit surgeons who could use a high volume of its products and pay them to train other doctors, provide input on products and transfer their patents to Life Spine. The device manufacturer tied the payments to utilization, according to the suit.

Life Spine said in a statement that both parties are engaged in discussions and look forward to resolving the matter.

"This may be the tip of the iceberg for spinal FCA cases," said Mark Silberman, a partner in Benesch's healthcare and life science group who has served as a state and federal prosecutor. "I feel confident this is not the last notable case we will see."

Life Spine is one of a wave of cases that reinforced that an anti-kickback violation can also be an FCA violation, said Adam Tarosky, partner in Nixon Peabody's government investigations and white collar defense practice.

"That is a big area where the definition of fraud has been broadened," the former DOJ attorney who worked FCA cases said, adding that was set in motion by a provision of the Affordable Care Act.

More FCA lawsuits have been filed over the past decade, with the vast majority targeting the healthcare sector, a trend that is not expected to slow as the federal government and whistleblowers recover billions of dollars a year. Device manufacturers and pharmaceutical companies are often prime targets given the potential windfall for the federal government and whistleblowers, who can **reap up to 30%** of the total settlement depending on if the government intervenes. It joins about a quarter of the cases, a ratio that has dipped slightly as more FCA suits have been filed, according to the **DOJ**.

The number of healthcare-related whistleblower cases reached 446 in fiscal year 2018, up from 231 in 2008, DOJ **data** show. That accounted for more than two-thirds of all so-called qui tam lawsuits, which are filed by a private citizen, or relator. Non-qui tam cases are brought by an investigative government agency and may include civil fraud matters outside of the FCA.

Of the $2.11 billion in total qui tam settlements and judgments recovered by the DOJ in fiscal year 2018, $1.95 billion involved the healthcare industry. That compared to $969.3 million recovered in 2008; healthcare qui tam settlements have eclipsed $1 billion per year since then.

In total, qui tam healthcare cases yielded close to $23 billion over that 10-year span, while relators netted almost $4 billion of that sum.

"Every aspect of healthcare has seen a notable increase in False Claims Act cases," Silberman said.

There is no reason to think that the number of FCA cases will significantly decline, Tarosky said.

"(Qui tam and non-qui tam) settlements are north of $2 billion every year," he said. "The government makes a lot of money from FCA cases."

Notably, Congress allocated $745 million in discretionary funding to the Health Care Fraud and Abuse Control Program in fiscal year 2018 while the HHS secretary and attorney general earmarked $286 million in mandatory funding, according to HHS' Office of Inspector General. Discretionary funds are available for two years.

Regulators and the general public have more access to payment data, which has invited more scrutiny. Companies paid physicians and teaching hospitals $9.35 billion in 2018 in general payments such as

consulting fees, gifts, grants, and travel and lodging; research; and ownership and investment interest in companies, according to CMS' Open Payments data.

While many compensation arrangements are not improprietous, the stigma and worry that regulators and whistleblowers will take notice has changed behavior, Silberman said.

"I have seen the full spectrum of organizations that say I am going to stop providing spinal surgery for those on Medicare and Medicaid because of the risk," he said. "Some will close up shop or quality providers will be exhausted from proving they didn't do anything wrong."

There is some gray area: What happens when a business has ulterior motives but a doctor thinks it is a legitimate arrangement, Silberman asked.

Also, the government tends to take notice of one instance of bad conduct and then search for others that mimic that action, he said.

"Then a quality provider is having to spend a lot of time, energy and effort to prove they are innocent, which is not how the system should work," Silberman said, adding that the DOJ issued guidance in May that outlines compliance strategies, but more clarification is needed.

Meanwhile, the Justice Department has sent mixed signals on how they oversee FCA cases.

Whistleblowers have up to four year of additional time to bring FCA cases where the government has declined to intervene, per a recent Supreme Court ruling that will likely lead to more qui tam cases. The justices unanimously held in *Cochise Consultancy v. U.S. ex rel. Hunt* that FCA claimants can sue up to three years after the responsible federal official knew or should have known the relevant facts, but not

more than 10 years after the alleged violation.

But the department issued two policy memos last year with the goal of dismissing more whistleblower cases and narrowing the types of federal policy documents whistleblowers can cite to support their claims.

The former was the Granston Memo, indicating that the government is supposed to be more selective about what cases are being brought in its name. Although Silberman has yet to see any real impact to that end.

Both Nixon Peabody's Tarosky and Kathleen McDermott, a partner at Morgan Lewis, disagreed, noting an anecdotal increase in the number of dismissals.

"Extending the statute of limitations exacerbates other procedural inequities of the FCA related to the amount of time that cases remained sealed and partial intervention efforts," the former assistant U.S. attorney and DOJ healthcare fraud coordinator said. "It's a good time to reset the statute."

The FCA is a punitive, inefficient statute that is costly and burdensome, McDermott added.

William Horton, a partner at the law firm Jones Walker, said that he is seeing more cases where the government doesn't intervene and relators continue with the case and sometimes win big settlements. Those victories have allowed FCA lawyers to take on more cases, he said.

"Our system is not getting any less complex," Horton said, citing the requirements for Medicare to cover inpatient hospital stays and the two-midnight rule.

Some of his clients previously left unintentional mistakes untouched —"no harm, no foul."

"Now, they are tracking them down and changing their system to minimize the risk of occurrence," Horton said.
