

## Son of POD: New FCA Challenge to Latest Variation on Physician-Owned Distribution

Emphasizing the continued and growing interest of federal enforcement authorities against Physician-Owned Distributors of implantable medical devices (“PODs”), a federal district judge recently denied a motion to dismiss a False Claims Act case. The case, *U.S. ex rel. Cairns v. D.S. Med. LLC*, alleges that ownership of a spinal implant distributor by the referring physician’s fiancée, and operation by the two of them as a joint venture, resulted in Anti-Kickback Law violations by the physician and his fiancée. In the case, the United States alleges that the physician instructed the hospital at which he practiced to purchase spinal implants from the distributor D.S. Medical, LLC (“DS Medical”) for use on his patients, including Medicare and Medicaid beneficiaries. Interestingly, the complaint does not even allege that the physician was the legal owner of DS Medical; instead, it relies on a less direct financial relationship that has only some of the indicia of ownership to show that profits from the physician’s self-referral constituted kickbacks:

- The physician and the person identified in the complaint as the sole investor and owner of DS Medical had been engaged to be married since at least 2008, implying that they should be treated, for remuneration purposes, as family members.
- The physician operated DS Medical as a joint venture with his fiancée, although the term does not appear to be employed to indicate any legal ownership interest by the physician. Rather, the character of the joint venture arose from facts such as the physician’s participation in management of DS Medical, his sharing of employees and contractors with DS Medical, and the lease of space by DS Medical from the physician’s practice.
- Further, funds from DS Medical were utilized to purchase multiple items for the physician and the fiancée, including a home, multiple other properties, and cars.

Demonstrating that that the government is thinking about this action as a POD case, the allegations of kickbacks read as if taken from the OIG’s [2013 Special Fraud Alert on Physician-Owned Entities](#) (“SFA”):

- DS Medical was the physician’s nearly exclusive source of spinal implants.
- The physician was the only “true” physician customer.
- DS Medical had little financial risk when it began operations, and few startup costs; it allegedly had profit margins of 95 percent.
- The physician allegedly began using more spinal implants after DS Medical began operations.
- DS Medical allegedly helped the physician profit from decisions about choice of implants.
- The physician maintained significant influence over his hospital regarding choice of implants.

The case underscores that the federal government’s concern with PODs will not be limited to the OIG’s interpretive guidelines, but is of growing interest to the Department of Justice as a new application of the False Claims Act to Anti-Kickback Law enforcement. It is particularly notable that the government applied the SFA’s analysis of the problems with self-referring POD owners to what might be described as a quasi-ownership situation, indicating that the government will not be fooled by form-over-substance changes to the POD business model. It is also significant that this case comes out of Missouri: the only prior POD-related FCA cases that have been widely reported arose out of California. (See prior Ropes & Gray alerts [“U.S. Department of Justice Files False Claims Action Against 3 PODs and Physician Investors for Physician and Hospital Claims”](#); and [“Justice Department Filing Makes Clear That Current False Claims Act Investigation Focuses on POD, Associated Hospital and Individual Doctor”](#).) That a regional U.S. Attorney

from another jurisdiction has now brought this case is yet another warning to those who continue to ignore the SFA's teachings on the risks of owning, selling to, and buying from PODs (or, now, their progeny).

If you have any questions, please do not hesitate to contact [Thomas N. Bulleit](#), or your usual Ropes & Gray contact.

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