

Report on Medicare Compliance Volume 33, Number 20. June 03, 2024 Spine Device Maker Settles FCA Case for \$12M; Self-Disclosures 'Are a Calculated Risk'

By Nina Youngstrom

Innovasis Inc., a spinal device manufacturer, and two executives have agreed to pay \$12 million to settle false claims allegations that they paid kickbacks to certain spine surgeons to get them to use Innovasis spinal devices, the U.S. Department of Justice (DOJ) said May 29.^[1] According to the settlement, Innovasis allegedly funneled money to the physicians with “lavish dinners” and travel, excessive consulting fees and intellectual property acquisitions that didn’t go anywhere in some cases.^[2]

The False Claims Act (FCA) lawsuit was set in motion by a whistleblower, former Innovasis regional sales director Robert Richardson. In his complaint, Richardson alleged Innovasis and the executives—founder and president Brent Felix, an orthopedic surgeon, and his brother, CFO Garth Felix—tried to memorialize the physician arrangements in a way that would comply with the law, but the implementation “actually violated the Anti-Kickback Statute because the arrangements and associated payments were tied to and intended to cause the surgeons’ choice of Innovasis products over competing devices.”^[3] The Felix brothers allegedly had “house accounts” they used for payments to referring physicians that were kept secret from most employees.

Before the whistleblower filed his FCA lawsuit, Innovasis and the Felix brothers had applied to the HHS Office of Inspector General’s (OIG) Health Care Fraud Self-Disclosure Protocol (SDP), said their attorney, Patric Hooper. “We had reported this to the OIG well in advance of the relator’s lawsuit being filed and we believe that the relator’s lawsuit should have been dismissed because the government was already investigating this pursuant to our self-disclosure,” said Hooper, with Hooper, Lundy & Bookman. “But we got into negotiating this and they wouldn’t go away unless we gave them \$6 million in single damages, and they doubled that. I’m not a big fan of the self-disclosure protocol because of things like this. We should have gotten credit.”

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