HLB Resolves False Claims Act Allegations Against Reliance Medical, Apex Medical Technologies, and Kronos Spinal Technologies

Case Studies 09.16.22

Patric Hooper and Bridget Gordon negotiate a $1 million settlement, ending eight years of civil litigation and criminal investigations against the spinal implant manufacturer, two distributorships, and their owners.

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The Client's Issues and Risks

In 2006, entrepreneurs Bret Berry and Adam Pike founded Reliance Medical Systems to produce spinal implant devices, then later launched two intermediaries, Apex Medical Technologies and Kronos Spinal Technologies, to distribute Reliance devices to hospitals. Apex and Kronos were owned, in part, by spinal surgeons who provided expert input to optimize Reliance's product designs. These surgeons received a share of the companies' profits based on their ownership interests. The surgeons' expert feedback not only improved the spinal implants' performance but also disrupted the industry by allowing innovative physician-owned companies (POCs) like Reliance and distributorships (PODs) such as Apex and Kronos to take market share from larger, more established medical device corporations.

Taking a different view of the POC/POD business models, the Department of Health & Human Services (HHS) Office of Inspector General (OIG) and the US Department of Justice (DOJ) believed Berry and Pike violated the Medicare and Medicaid Anti-Kickback Statute (AKS) and False Claims Act (FCA) by using PODs to illegally pay surgeons to use Reliance implants in medically unnecessary procedures, after which the surgeons and hospitals would submit fraudulent claims to Medicare. Subjected to a 2011 FBI wiretap involving a confidential informant posing as a physician and a 2015 search warrant, the companies and their two owners were targets of a nine-year criminal investigation—an investigation that was supposed to have been confidential but was widely covered by major news outlets, including the *Wall Street Journal*.

In 2014, DOJ sued the companies and their founders in a civil action, claiming the AKS prohibited remuneration such as POC/POD profit distributions to physicians. DOJ alleged Reliance paid at least four physicians more than $5.5 million to use Reliance devices in spinal fusion surgeries. DOJ Civil lawyers alleged that Medicare reimbursed $9 million for those spinal implant procedures and sought treble damages and civil penalties of more than $30 million from our clients under the FCA.

The HLB Difference

For nearly eight years, HLB attorneys Patric Hooper and Bridget Gordon vigorously defended Berry and Pike and their companies. Patric and Bridget also publicly challenged the political influence that large medical device manufacturers exerted on HHS through the manufacturers' significant lobbying activities and campaign contributions. They asserted these efforts by the large medical device companies were intended to compel HHS to stifle competition from Apex, Kronos, and other smaller competitors.

Ultimately, the matter went to trial, but not before Patric and Bridget scored several initial wins in a Los Angeles federal court:

- Judge Dean Pregerson insisted DOJ produce virtually all documents from its parallel criminal investigations, which it had not done despite numerous previous requests; once produced, the documents revealed substantial exculpatory information.
- The Court planned to instruct the jury that OIG fraud alerts and sub-regulatory guidance are not law, and failing to follow them would not be a violation of the law.
- The court indicated it would not include DOJ's requested instruction on the "one purpose rule" (from *U.S. v. Greber* and other decisions) in the jury instructions.
- The court was prepared to include a "good faith/advice of counsel" jury instruction, acknowledging the years of sound legal advice the client had relied upon.

The parties agreed to a settlement after the first day of trial on May 5, 2022.

The Result and Its Implications

Through their tireless representation, Patric and Bridget achieved multiple procedural and substantive victories for the clients:

- The $1 million resolution is not an ability-to-pay settlement and is a fraction of the $30 million in damages prosecutors initially demanded, as well as a small fraction of the $9 million in single damages prosecutors alleged.
- There was no admission of wrongdoing by Reliance, Apex, Kronos, Berry, or Pike, and all were released from liability for the alleged conduct at the center of the litigation through the entering of settlement in June of 2022, providing finality to the matter.
- OIG has stated it will pursue no administrative action against the clients.
- Although their three companies were the focus of a prolonged criminal investigation, the two founders were never charged with any criminal wrongdoing; in fact, DOJ informed them in February 2019 it would not pursue criminal charges against them or any of their businesses.

The settlement ended almost a decade of our clients having to defend costly, time-consuming investigations and litigation. The resolution highlights for providers, manufacturers, distributors, and other health care industry participants the importance of challenging DOJ and the OIG when they are not well founded and not capitulating to excessive government demands.

Client Testimonials:

> "Thanks Pat and Bridget. There's no way we could've survived these past 8 years, and the last few months, without you. We are forever grateful, and I mean that from the bottom of my heart."
>
> – Bret M Berry

> "We still can't believe it. Bret and I are very grateful for both of you. We're honored to have been in the trenches together and to spend such pressure time with you guys. We care a lot about you."
>
> – Adam Pike

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