

BRIEN T. O'CONNOR

ROPES & GRAY



Few criminal defense lawyers ever give an opening statement that delivers a knockout blow. But Boston attorney Brien T. O'Connor did exactly that in a high-profile federal fraud case last year.

O'Connor and his Ropes & Gray colleague Joshua S. Levy defended Hopkinton-based medical device manufacturer Stryker Biotech against charges that the company and three of its sales executives defrauded surgeons into combining Calstrux, a bone-void filler, with OP-1, a bone morphogenetic, for an off-label use that the Food and Drug Administration never approved.

The company faced massive fines and exclusion from federal health programs, while the sales execs — represented by attorneys from three other Boston firms — were looking at the possibility of serious prison time.

However, the defense team realized during discovery that the government never interviewed seven surgeons who allegedly had been victimized. The team sought and received the cooperation of the surgeons, who were prepared to testify that the defendants never deceived them in any way.

O'Connor revealed that fact to the jury in his opening statement. And before the government finished the direct examination of its first witness, it dropped all charges against the individual defendants and all felony charges against Stryker, accepting a guilty plea to a no-intent misdemeanor charge and a \$15 million fine.

Though the government was criticized in the media for the outcome, O'Connor, a former federal prosecutor himself, says he has nothing but respect for the prosecutors who handled the case.

"We give the government a lot of credit for responding very professionally and very immediately to some of the very significant points we made in our opening statement," he says. "The government made a very difficult and courageous decision to take a misdemeanor from the company and let the executives go."

Q. How did you get the surgeons to cooperate? After all, if they used the mixture with bad results,

wouldn't it be in their interest to maintain that the product was fraudulently marketed to them?

A. With some of them it was very difficult. Part of that is they didn't know us. They're very busy on significant patient health issues. Though it was hard, we were persistent and followed up. All told, we were very impressed with their willingness to talk to us because, in some respects, that's an act of courage and recognition that a trial is a search for the truth and we all have to play a role in the process to get the right result.

Q. If the surgeons weren't defrauded, how did they know to do the mixing to get the anticipated results without promotion from the company?

A. That's a really good question, and we worked hard in the opening [to address that]. ... We displayed scientific articles clearly demonstrating that surgeons had been mixing bone-void fillers with active bone-healing and bone-forming agents [for years]. ... The government's main concern was that on neither the Calstrux nor OP-1 label was there any approval for the use of the two together. But the government brought serious felony charges requiring the government to prove not just off-label promotion but fraud beyond a reasonable doubt. It's on that point that we focused our defense efforts.

Q. More broadly, the Department of Justice has been engaged in an intense effort over the past few years to crack down on the promotion of off-label uses of drugs and devices. How might a case like this impact that kind of campaign?

A. I hope a lesson from this case is that there's a big difference between fraudulent conduct and misdemeanor off-label promotion. The rules [regarding] off-label promotion are very complex and difficult to follow. And I think the government does need to be careful not to overcharge. ... Additionally, these surgeons are the meal ticket for salespeople. If they don't have the trust and confidence of surgeons, they're done in the medical community because surgeons talk to each other. So proving the company was trying to deceive is a huge undertaking.

— ERIC BERKMAN

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