NEWS

Whistle-Blower Attorneys Credit Teamwork With DOJ in Achieving $390 Million Novartis False Claims Settlement

On Nov. 20, Novartis Pharmaceuticals entered into a $390 million settlement with the Department of Justice to settle False Claims Act allegations originally brought by qui tam whistle-blower and former Novartis sales manager David M. Kester (225 HCDR, 11/23/15).

The settlement was noteworthy not only for its large financial payout to the federal government and states involved in the lawsuit, but because Novartis made factual admissions that it doled out undesignated referrals for it drug Exjade as an incentive to specialty pharmacies for encouraging patients' continued use of the drug. Novartis also admitted to using rebates for the drug Myfortic as an incentive to specialty pharmacies to promote the drug over competitors' drugs.

Bloomberg BNA's Eric Topor spoke with Bill Carmody, a partner at Susman Godfrey LLP and one of the attorneys who represented Kester in the FCA litigation with Novartis and its co-defendant specialty pharmacies Accredo Health Group and BioScrip.

Bloomberg BNA: **Why do you think the Department of Justice chose to intervene in the Novartis FCA litigation?**

Bill Carmody: I think it's because of the size. It was a huge case, with huge consequences. And, I think because of the novelty of it. Typically what you see in these sorts of cases is doctors getting paid, typically getting paid in cash. Here, the unique circumstance was that a big pharmaceutical company was not paying medical doctors, but specialty pharmacies. And, paying them not cash, but by way of patient referrals. The scheme was much more elaborate and complex, a novel one that the government wanted to put a stop to.

Bloomberg BNA: **What factors elevated the final settlement amount to such a high-dollar figure? The number of claims processed during the time period covered by the settlement?**

Carmody: The fact of the matter is, the patient referral scheme was the big money in the case. There were a couple components of damages. There were improper rebates, but that was probably small potatoes compared to the patient referral aspect. That went on for over three years. If you take a look at the claims submitted by the specialty pharmacies, the claims Novartis caused them to submit in that three-and-a-quarter-year period, the numbers were huge.

Bloomberg BNA: **Do you think the two motions to dismiss that Novartis lost during the litigation contributed to the final settlement amount? Maybe some leverage they might have lost there? (Editor's Note: The court denied two separate motions to dismiss filed by Novartis in May 2014 (105 HCDR, 6/2/14) and in August 2014 (155 HCDR, 8/12/14).**

Carmody: Obviously we got great rulings in the motions to dismiss. Every defendant, Novartis in this case, wants to play the cards they have in their hand before they reach into their pocket, so they certainly tried to

play all the legal cards they had in the form of motions to dismiss. I think they realized, not only did they lose, but the judge saw the case the way we did. Novartis likely realized they would be just as unsuccessful in a motion for summary judgment. The judge kind of hinted that such a motion probably wouldn't be well taken, so Novartis surely realized that this is a case that's going to be tried. And any time any case is tried there is always a lot of uncertainty, a lot of risk. Here, with the numbers we were talking about, the evidence we developed, and what the depositions and documents bore out, it was compelling.

Bloomberg BNA: **I believe the DOJ was seeking billions in damages, correct?**

Carmody: Yes, exactly. The numbers in a worst case scenario for Novartis could have been in the billions of dollars. The theories here were pretty novel. And, if you take a look at the case law it's frankly pretty sparse. We felt pretty confident at the trial court and the jury level with the evidence that we elicited in pre-trial discovery that we would have in all likelihood a good day at the trial court. But there's no telling exactly what can happen because there's just not strong precedent right on point for this type of case.

Bloomberg BNA: **Can you talk about some of the risks that Mr. Kester, as a sales manager at Novartis, took as the lone whistle-blower plaintiff in this case?**

Carmody: The risk he took was maybe not having a chance to work in pharmaceuticals. He spent his years, his life, being very successful and being promoted within big pharmaceutical companies. But he saw this scheme unfolding before his own eyes. It was a point in his own life where the easy thing would have been, like some of the others, to just turn a blind eye to it and continue on because he was making great money. But he took a different path, and he reported what he saw. It's really amazing that one person could figure out exactly what was going on here in the drug he was selling, and other similar drugs. He brought it to the government's attention and took a big risk in that he would be blackballed from the industry.

Bloomberg BNA: **How do you prepare a client for the years-long process of FCA litigation?**

Carmody: I think the best thing that you can always do with a whistle-blower client, or frankly with any client, is just be brutally honest. Because litigation, by its nature, is incredibly uncertain, and it's incredibly time consuming. It's something that most humans who aren't trial lawyers really don't appreciate. How long the case can go on, the peaks and valleys in any case. Here was someone in David [Kester's] position who wasn't independently wealthy, or some big Fortune 500 company that in a worst case scenario could persevere forward. It was more difficult, but David is a strong guy, and he understood from the start the uncertainty and the risk involved. But he had such a strong moral compass that he knew in his heart that this was the only path that he could take.

Bloomberg BNA: **Once the DOJ intervenes in an FCA case, what is your role as relator's counsel, and how did you help the DOJ's investigation in this case after it intervened?**

Carmody: What we did in this case, and I think the government would probably confirm, is incredibly different from the typical case. Typically, the relator's lawyer, once the government intervenes, has very little to no role. The government is the 800-pound gorilla that handles the case from there. But because of the size of this case and because the government did not intervene in all of the case, only parts of the case—certain claims against certain defendants, but not all claims against all defendants—we in came in to the case [as well]. It was really novel on one hand, but on the other, it worked out just great, [because of] the team we formed. Shelley Slade and her firm, Vogel, Slade & Goldstein LLP, represented the relator, David Kester, and brought us into the case. Susman Godfrey provided trial horsepower and we probably had about 15 or so lawyers working on the cases. We assisted the government, the [U.S. Attorney's Office for the Southern District of New York], which had great lawyers, but not as many as we did. And then of course we had 11 states intervene. They had lawyers on behalf of the states who would attend some of the depositions, and at least one lawyer that I can think of who took the lead in certain depositions. It was a wonderful team effort as everyone realized we were all aligned together, and it worked out just fabulously.

Bloomberg BNA: **So the DOJ asked for your firm's assistance because they needed more manpower and based on the complexity of the issues involved?**

Carmody: No, it didn't occur like that. Before we got involved in the case, the government had intervened in part of it. Vogel, Slade & Goldstein was also involved, as were 11 states. By the time Susman Godfrey got to the case and it had become unsealed, there were a number of great lawyers involved. But I think everyone realized who our firm is and what we brought to the table. We have incredible horsepower and we try "bet the company" cases. We didn't come in and try to take over anything, but instead we wanted to help any way we could. I think that approach got the government comfortable with having us participate in a co-lead role in just about all of the discovery.

Bloomberg BNA: **I imagine the DOJ took the lead on the settlement negotiations with Novartis?**

Carmody: Absolutely. Ultimately there were three settlements in the case. The first with BioScrip which was the smallest at $15 million, which occurred just before we got involved in the case. Second, there was the settlement with Accredo [Health Group]. And that was one of the defendants that the government initially declined to intervene on. So the case against Accredo was prosecuted by Susman Godfrey. What happened then is, at the settlement process the government struck a deal with Accredo and intervened at the same time. So the bottom line was that we were indirectly involved in that settlement because we had done the work against Accredo, and the government appreciated our input. When it came to Novartis, the government had intervened early on. But, I think because of the respect they had for us, and because the government hadn't intervened in all claims brought by the relator, we were certainly involved in the [settlement] process, mediation, and follow-up discussions. But ultimately the case is the government's call.

Bloomberg BNA: **In a settlement like that, how do you protect your whistle-blower client's interests when you're not the primary party negotiating with the defendants?**

Carmody: All you can do is have a good relationship with the government, as we did, and make sure we're all working hand-to-glove together as we did. In that way, the whistle-blower is protected through the combined horsepower we brought to bear on his behalf, and the government did a wonderful job here. The settlement speaks for itself; as Novartis paid $390 million in addition to the other $75 million of previous settlements. My understanding is that this is the single biggest settlement ever for a single relator who only asserted violations of the anti-kickback statute.

Bloomberg BNA: **There were significant factual admissions in the settlement with Novartis, as there were in the settlements with Accredo and BioScrip as well. Can you explain a bit how those were negotiated into the settlement?**

Carmody: We were not involved with negotiating those factual admissions, the government was. But you've hit on something vitally important here. There have been a lot of big time qui tam settlements over the years. Yet, this is the first one that I know of where a company like Novartis, a big pharmaceutical player, not only pays a huge amount of money—all told they're paying almost $400 million—but importantly, they accepted responsibility for their wrongdoing. This is unusual, and the admissions you're talking about that Novartis made confirm the kickback scheme here, and ensure that neither Novartis or any big pharmaceutical company are going to do this sort of thing again.

If you take a look at those admissions, Novartis admitted that it incentivized these specialty pharmacies to push refills in return for referrals. Novartis was giving the patient referrals to specialty pharmacies. And, in return for getting kickbacks in the form of patient referrals, the specialty pharmacies recommended that patients stay on Exjade and pushed refills when patients didn't need them. That was the first thing that happened.

Second, vitally important, Novartis "scorecarded" (rated) these specialty pharmacies on their [patient] refill rates. That's part of the admissions.

And finally, Novartis admitted that it rewarded the specialty pharmacies that pushed the most refills, and penalized the other two [specialty pharmacies]. What I mean by that is that Novartis would give 60 percent of these unallocated referrals [to the specialty pharmacy with the best scorecard rate], and each of these unallocated referrals provided a whole lot of money to these specialty pharmacies, depending on reimbursement, per month and per drug anywhere from $3,500 to $11,000 per month.

What Novartis did is reward the big seller, and penalize the other two by allocating referrals on a 60/20/20 basis.

What it really turned out to be is a big pharma version of the TV show "Survivor," where the lowest scorecarded specialty pharmacies were facing the threat of being voted off the island. It was an elaborate and complex kickback scheme of which we don't know of any direct precedent.

It was an amazing case, and amazing that the government was able to get Novartis to accept responsibility here. And, by so doing, it's going to ensure that this sort of thing doesn't happen again.

Bloomberg BNA: **Tell me about the potential impact this settlement has on FCA litigation. What key points should other FCA plaintiff attorneys take from the litigation and settlement?**

Carmody: Teamwork to me was the most incredible part of this. We all got a wonderful result on behalf of the relator, the United States government and the states that participated here as well. Because of this incredible team, a team formed of private law firms, the DOJ, the [U.S. Attorney's Office for the Southern District of New York] folks who did a fabulous job, and we had all the states.

So I think the lesson harkens back to the old adage: "Pigs get fat and hogs get slaughtered." If you have a really big and important case, a client is best served by assembling the very best trial team—even if that means adding additional lawyers or firms.

There's always enough to go around and make all the participants happy when a great result is achieved. Here the government got a great result that really speaks for itself in terms of both the settlement amount and the admissions that were garnered by the government to make sure that this sort of practice doesn't happen again.

The real significance here is that big pharma will cease using patient referrals to corrupt the independence of specialty pharmacies, who are supposed to be acting in the best interests of patients.

Our lawsuit and settlement put a stop to big pharma co-opting the independence of the specialty pharmacies.

Bloomberg BNA: **Do you think that there are other pharmacy marketing schemes that other drugmakers are using, maybe not exactly like this, but with a similar goal of using referrals in a different way?**

Carmody: There sure could be. I'm certainly not aware of any as I sit here now, but there certainly could be.

But I think in light of the precedent here, and the admissions in our suit and how it all ended, the pharmaceutical companies are going to look real closely at what they are doing to ensure they're not violating the law and doing anything to compromise patient care.