Published on *The National Law Review* https://natlawreview.com

Judge Dismisses FCA Claims Against Compounding Pharmacy and Private Equity Firm Owner but Allows the Government to Amend

Article By:

Karen S. Lovitch

Cassandra L. Paolillo

Last week, a U.S. district court judge in the Southern District of Florida upheld a magistrate judge's decision to dismiss False Claims Act (FCA) allegations against a compounding pharmacy, its private equity firm owner, and two individuals. As discussed in a previous post, DOJ filed its complaint in intervention last February against the pharmacy, Patient Care America (PCA); its private equity backer, Riordan Lewis & Haden, Inc.; and two individual executives. The government alleged that the parties engaged in an illegal kickback scheme that resulted in the submission of false claims to TRICARE for expensive compounded drugs. This case is reportedly the first in which the federal government intervened against a private equity firm owner.

The motions to dismiss filed by defendants were referred to a magistrate judge who issued a Report and Recommendations in November 2018. Although the magistrate judge upheld two of the government's claims, she recommended dismissal of the FCA allegations. The U.S. district court judge agreed.

The court's decision to dismiss the FCA claims turned on the government's failure to adequately allege FCA liability based on violations of the federal Anti-Kickback Statute (AKS). Quoting an earlier case, the court made clear that liability under the FCA does not arise solely from the "disregard of Government regulations or improper internal policies, unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." In other words, simply alleging a violation of the AKS is not enough to state a claim under the FCA; FCA liability arises from the submission and payment of a false claim and the express or implied false certification of compliance therewith.

The court held that the government failed to plead with the level of particularity required to sustain a theory of express or implied certification under the FCA. The government attempted to show that PCA's provider agreement with TRICARE's pharmacy benefit manager constituted an express certification because it included an agreement to comply with the law and with applicable program requirements. The court disagreed with this argument because PCA did not execute the provider agreement in connection with the submission of claims. The court also found that the government

failed to sufficiently state a claim under a theory of implied certification based on submission of misleading claims because the complaint included too little detail to meet the heightened pleading standard under the FCA.

Although last week's decision is a win for the defendants, victory may be fleeting because the court allowed the government to amend its complaint, and, as is often the case, the court's decision offers the government a roadmap for how to do so. The court was unpersuaded by the fact that the government had received five extensions in advance of its decision to intervene, which, according to the defendants, allowed the government ample time to develop its case. Noting that this complaint was the government's first, the court dismissed the FCA claim without prejudice and ruled that the government may file an amended complaint in intervention on or before March 18, 2019. We will continue to closely watch this qui tam case and any others involving private equity firms, including one recently unsealed case filed against another private equity firm and its principals, among others. The government declined to intervene, but the relator may choose to proceed with the case.

National Law Review, Volume IX, Number 72