



Pharmaceutical Company Agrees to \$625 Million False Claims Act Settlement

The civil settlement is one of the largest FCA settlements in recent years.

The Department of Justice ("DOJ") recently announced that it agreed with AmerisourceBergen Corporation ("ABC") and several of its subsidiaries to resolve a False Claims Act ("FCA") case for \$625 million. The case stemmed from allegations that ABC's subsidiaries distributed prefilled syringes of cancer drugs that were not approved by the Food and Drug Administration ("FDA") and that risked introducing bacteria into otherwise-sterile medications. Although settlement agreements in FCA cases generally do not contain an admission of responsibility, ABC accepted responsibility for the underlying conduct set forth in the settlement agreement, which included:

- Operating a program that created prefilled syringes by opening sterile vials and transferring drugs into smaller prefilled syringes and then selling them to oncology practices;
- Selling extra vials that remained after the prefilled syringes were filled;
- Providing rebates to physicians for the purchase of prefilled syringes but not vials;
- Filling orders (i) without signed prescriptions and (ii) submitted with one individual's name in quantities exceeding the safe use of the drug product; and
- Failing to register the subsidiary that prepared the prefilled syringes with the FDA.

As a result of the settlement, one *qui tam* relator (a former employee) will receive a payment of more than \$93 million. In connection with the FCA settlement, ABC also entered into a Corporate Integrity Agreement. Further, ABC's subsidiary entered into a plea agreement in September 2017 and agreed to pay a total penalty of \$260 million to resolve criminal charges relating to the same conduct.

The settlement resolves allegations made in three *qui tam* cases filed against ABC between 2010 and 2013. Notably, the DOJ only partially intervened in each action, and the settlement agreement is limited to the particular covered conduct. For example, the settlement agreement did not include injectable drugs Aranesp and Taxotere, which were named in a complaint filed by Omni Healthcare Inc., or allegations made by a former ABC executive that a group purchasing organization owned by ABC violated the Anti-Kickback Statute by passing through price discounts to medical providers. Omni's complaint also brought claims against McKesson Corporation, which were severed in March 2018 and remain pending.



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