

Whistleblower Alleges Shire Pharmaceuticals Neglected ADHD Monitoring

Whistleblower claims Shire Pharmaceuticals did not protect the public from Vyvanse and Adderall

OAKLAND, NEW JERSEY, UNITED STATES, October 11, 2023 /EINPresswire.com/ -- After paying out \$56.5 million as part of the settlement with federal and state governments in 2014 for allegedly misleading the public, U.S. and state agencies by claiming Adderall would “normalize” its users and Vyvanse would provide “less abuse liability,” a former Shire Executive who was the Head of Data Science has filed a lawsuit claiming Shire was not in compliance for many years with the Drug Enforcement Agency (DEA) regulations requiring Shire to monitor Suspicious Orders of those drugs and report them to the DEA. The Whistleblower, Dr. Vincent Polito, claims he was terminated for repeatedly blowing the whistle and ultimately informing the company's Chief Compliance Officer against the wishes of his management.

Dr. Polito claims that after being recruited from I.B.M. in 2014, and after only weeks on the job, he was asked to investigate and create a DEA-compliant suspicious order monitoring system (SOM) to monitor and report suspicious orders. Documents in the Court filings allege that several of Shire's key executives created roadblocks to prevent him from completing his work. Polito alleges his concerns of Shire being out of compliance with the DEA's regulations were repeatedly downplayed and ignored by his superiors. He claims other executives interfered with his work by changing his presentations to other key executives. He also claims he was terminated from his project in the summer of 2015, after he and a consultant, along with the head of the SOM project, Wes Graham, visited Shire's U.S. Distribution facility in Lexington Kentucky.

There he alleges they discovered drugs that were marked for destruction - which were contained in bottles marked 50% full as a default measurement – were not verified by either counting or weighing the pill bottles' contents. Dr. Polito also claims to have discovered that Shire's internal company sales data did not match sales data reported to the DEA. The Court filings state Dr. Polito reported his discovery to his superiors and other executives and was soon removed from the project.

In January 2016, he alleges that over the objection of his supervisor, Walter Mullikin, a named defendant, he again reported the alleged violations of the DEA regs to the then Chief Compliance Officer, Jeffrey Rosenbaum, a named defendant, who had no knowledge of the DEA regulation problems that the company was experiencing. Shortly after that, the Court documents show Dr.

Polito was forcibly placed on leave and was never allowed to return; ultimately being terminated in August of 2016. According to a letter sent by Shire to Polito, he was terminated for unprofessional conduct and for not cooperating in an internal investigation.

In April 2016 while on forced paid leave, Dr. Polito filed a qui tam suit which later was rejected by the US Attorney's Office in Washington DC over concerns that the alleged violations were not covered by the False Claims Act. In August 2018 he filed this wrongful termination suit in Massachusetts Superior Court alleging he was fired in violation of Public Policy for whistleblowing activities. In August 2018 he filed this wrongful termination suit in Massachusetts Superior Court alleging he was fired in violation of Public Policy for whistleblowing activities. The case is filed in the Middlesex County Superior Court and is Case Number 1881CV02440.

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