

Holding Big Pharma Accountable

Whistleblower was fired by Shire Pharmaceuticals after reporting violations

Boston, Massachusetts Oct 16, 2023 ([Issuewire.com](https://www.issuewire.com)) - Dr. Vincent Politio, a former Shire Pharmaceuticals employee, filed a Whistleblower complaint after being terminated by Shire Pharmaceuticals. Dr. Politio was fired by Shire on August 24, 2016, immediately after he reported the violation of laws to the United States Attorney's Office in Washington, D.C.

Dr. Politio claims he was asked to investigate and create a DEA-compliant Suspicious Order Monitoring system (SOM) to monitor and report suspicious orders. Dr. Politio alleges his concerns of Shire being out of compliance with the DEA's regulations were repeatedly downplayed and ignored by his superiors. He claims executives interfered with his work by changing his presentations to other key executives.

Dr. Politio claims he was terminated from his project in the summer of 2015, after he, a consultant, and 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 were not verified by either counting or weighing the pill bottles' contents.

Dr. Politio 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. Politio 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, he again reported the alleged violations of the DEA regulations to the then Chief Compliance Officer, Jeffrey Rosenbaum. Court documents show Dr. Politio was then forcibly placed on leave and was never allowed to return.

Dr. Politio was ultimately terminated on August 24, 2016, immediately after meeting with the U.S. Attorney's office in Washington, D.C. to report numerous violations of laws and Shire's failure to monitor Suspicious Orders of drugs and report them to the DEA.

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 was originally filed in August 2018 with an amended complaint filed in December 2018. Shire Pharmaceuticals filed a Motion to Dismiss which was rejected by the Court.

Shire Pharmaceuticals filed a Motion for Summary Judgment in early 2023. The Motion was heard on July 11, 2023. The case is in the hands of Judge Christopher K. Barry-Smith, Middlesex County Superior Court in Massachusetts under case number 1881CV02440.

<https://www.masscourts.org/eservices/searchresults.page>

What's the Importance of DEA Regulations and Potential Consequences for Violation?

The public's health is at stake. At the time of the Complaint, Shire manufactured and distributed Adderall and Vyvanse. Considered amphetamines, both drugs are listed as Scheduled II controlled substances because they have a "high potential for abuse" and can cause "severe psychic or physical and or psychological dependence."

Under Federal law, Shire is required to maintain "effective control" against these drugs from falling into

the wrong hands. For that reason, Shire and other organizations in the pharmaceutical industry are required under the Controlled Substances Act (CSA), to create internal automated systems to monitor and track suspicious orders of drugs like Adderall and Vyvanse and report them to the DEA.

What's the importance of the corporate integrity agreement? Was this a corporate Coverup?

In September 2014, as Dr. Polito began his work on Suspicious Order Monitoring, Shire agreed to pay \$56.5 million as part of a settlement agreement with the Federal Government for alleged violations in their promotion of Adderall and Vyvanse. As part of the settlement, Shire entered into a five-year Corporate Integrity Agreement (CIA).

According to Section III of this Agreement Shire was required to establish and maintain a U.S. Compliance Program. The Agreement requires the chief compliance officer to be responsible for monitoring the day-to-day compliance activities as well as reporting obligations under the CIA. The CIA was signed by then Chief Compliance Officer Caroline H. West.

What was the economic environment at the time of Polito's employment? (mergers and inversions)

In 2014 Shire was engaged with Abbvie in a reverse acquisition for \$54 billion. The deal fell through with Shire receiving \$1.6 billion for Abbvie's failed attempt. In February 2015 Shire acquired NPS Pharmaceuticals for \$5.2 billion. And in June 2016, just as Shire decided to terminate Dr. Polito, Shire acquired Baxalta for \$32 billion. Shire was acquired by Takeda in 2019 for \$62 billion.

Does this create SEC problems?

The Securities and Exchange Commission (SEC) requires public companies to report information on significant pending lawsuits. An initial review of Shire's 10-k filings for the years 2018- 2021 is silent on Dr. Polito's lawsuit. Whether a lawsuit that alleges violations of DEA's Suspicious Orders regulations and exposes Shire to the type of fines or potential for loss of license qualifies as significant under SEC regulations is something for the SEC to consider.

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