

Mallinckrodt Agrees to Pay \$234 Million to Settle False Claims Act Case Brought by Whistleblower Law Collaborative Client for Unpaid Acthar Medicaid Rebates

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BOSTON, March 7, 2022 /PRNewswire/ -- The Whistleblower Law Collaborative LLC is pleased to announce that the United States, individual states, the District of Columbia, and Puerto Rico have settled a False Claims Act case brought by its client James Landolt against Mallinckrodt plc and its subsidiary Mallinckrodt ARD LLC for knowingly underpaying Medicaid rebates for its drug Acthar. Mallinckrodt will pay a total of \$233,707,865 (plus interest) in eight installments: the United States will receive \$123,642,146 and the Medicaid Participating States will receive \$110,065,718. In addition, Mallinckrodt has entered into a Corporate Integrity Agreement.

Mr. Landolt served as Mallinckrodt's Director of Internal Controls, Gross to Net Accounting and Government Reporting from November 2015 until July 2017. In that position, he learned that Mallinckrodt had been misreporting the base Average Manufacturer Price ("AMP") for Acthar to the Medicaid Drug Rebate Program (MDRP), which reduced the rebates Mallinckrodt paid to the MDRP by hundreds of millions of dollars.

Acthar was first approved by the FDA in 1952. In 2001, it cost approximately \$50 per 5 ml vial. Since then, Mallinckrodt has increased its price to approximately \$40,000 per vial. As a drug approved prior to 1990, Acthar's base AMP should have been reported using its price in 1990. Starting in 2013, however, Mallinckrodt began reporting data to the MDRP as if Acthar had been approved in 2010 (after the enormous price hikes).



The Centers for Medicare & Medicaid Services (CMS) notified Mallinckrodt in 2016 that it had been reporting an incorrect base AMP for Acthar and directed the company to correct its data reporting. Mallinckrodt, however, continued to report an improperly high base AMP, which deprived the MDRP of approximately \$650 million in rebates from 2013 until 2020.

Mr. Landolt resigned from Mallinckrodt in 2017 and filed a *qui tam* action in 2018 alleging that Mallinckrodt's knowing failure to pay correct rebates for Acthar violated federal and state False Claims Acts. In March 2020, the United States intervened in his lawsuit; in June 2020, twenty-eight states, the District of Columbia, and Puerto Rico also intervened.

In October 2020, Mallinckrodt filed for bankruptcy. On March 2, 2022, the bankruptcy court issued an order confirming Mallinckrodt's reorganization plan. Because of Mallinckrodt's bankruptcy, federal and state governments were not able to recoup the full amount of the unpaid rebates. However, Mallinckrodt finally began reporting Acthar rebates properly in 2020.

Mr. Landolt will receive a 20% share of the settlement amount. In reflecting on his experience, he noted: "It is easy to feel powerless in these types of situations. But individuals have a voice and the power to do something about wrongdoing, thanks to whistleblower laws like the False Claims Act." Mr. Landolt added, "I am very grateful to my attorneys Linda Severin and Suzanne Durrell for their legal guidance and moral support throughout the process. I also deeply appreciate the hard work and commitment that government attorneys and investigators brought to this case."

Mr. Landolt's attorneys applauded their client. Attorney Severin declared that "it was an honor to pursue this case on his behalf," noting that "Mr. Landolt's moral compass would not allow him to stand by and do nothing as Mallinckrodt continued to underpay its Medicaid rebate obligations by hundreds of millions of dollars."

Attorney Severin also praised the outstanding efforts of the government: "This case was fought on multiple fronts – in Massachusetts, where our client's *qui tam* case was filed; in D.C., where Mallinckrodt unsuccessfully sued CMS to avoid having to report Acthar's correct base AMP; and, finally, in bankruptcy court in Delaware. The Department of Justice and state Attorneys General Offices worked enormously hard to hold Mallinckrodt accountable and secure this victory for taxpayers." Ms. Severin especially commended the efforts of Assistant U.S. Attorney Evan Paníĉh

and former Assistant U.S. Attorney Gregg Shapiro of the District of Massachusetts and Department of Justice Civil Fraud Trial Attorneys Augustine Ripa and Michael Hoffman, as well as Katie Wilson of the Wisconsin Attorney General's Office and C. Ian Garland of the Florida Attorney General's Office, who coordinated the efforts of the State Attorneys General.

The United States' press releases can be viewed here (District of Massachusetts) and here (DOJ). Further information about the case is available here.

This is the second major success for the Whistleblower Law Collaborative in a Medicaid rebate fraud case. In 2017, Mylan paid \$465 million for misclassifying EpiPen as a generic drug to avoid paying the higher rebates owed on brand name drugs.

The Whistleblower Law Collaborative LLC devotes its practice entirely to representing whistleblowers. For more information, contact the firm at 617.366.2800 or email Linda Severin at linda@whistleblowerllc.com.

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