

How A Drug Co.'s Misreporting Earned A Whistleblower \$40M

By **Al Barbarino**

Law360 (March 14, 2022, 10:23 PM EDT) -- A whistleblower receiving a more than \$40 million cut of the recent \$233.7 million settlement between the U.S. Department of Justice and drugmaker Mallinckrodt had flagged his concerns internally, but resigned after lacking "confidence" the company would pay back hundreds of millions in Medicaid rebate underpayments, according to court documents and the tipster's attorneys.

James Landolt, a former Mallinckrodt director, resigned in 2017 and filed a qui tam action in 2018 alleging Mallinckrodt ARD LLC knowingly failed to pay the correct rebates for its drug Acthar, an anticonvulsant for children.

"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," Landolt said in a statement last week after the DOJ announced the settlement.

Landolt — Mallinckrodt's director of internal controls, gross-to-net accounting and government reporting from November 2015 to July 2017 — learned in 2016 the company had been misreporting the so-called base average manufacturer price for Acthar to the Medicaid Drug Rebate Program, he claimed in his 2018 suit. That reduced the amount of rebates Mallinckrodt paid to the program by hundreds of millions of dollars.

"For each and every quarter from the beginning of 2013 through the present and continuing, Mallinckrodt has knowingly paid the [Medicaid Drug Rebate] Program less than it owes in rebates for Acthar and instead retained and used for its benefit funds that belong to the government," Landolt claimed.

The government took up the case in March 2020, concurring Mallinckrodt knowingly underpaid the rebates between 2013 and 2020, and highlighting in its complaint a yearslong effort from the company to brush off requests from the Centers for Medicare & Medicaid Services, or CMS, to fix the issues.

The CMS had notified Mallinckrodt in 2016 that the company had been reporting an incorrect base average manufacturer price for Acthar and directed the company to correct its data reporting, according to the DOJ complaint.

But after Mallinckrodt received a CMS follow-up letter in March 2017 and did not correct Acthar's base average manufacturer price, Landolt "lacked confidence that its senior leadership would address the issue to his satisfaction," said Linda Severin, one of Landolt's attorneys at the Whistleblower Law Collaborative and an ex-assistant U.S. attorney in the Southern District of New York, in an emailed statement to Law360.

Landolt declined to comment for this article, but court documents, the DOJ settlement and his attorneys chronicled an alleged yearslong internal compliance failure as the company refused to correct the problems and didn't take Landolt's concerns seriously.

For instance, in spring 2017, Landolt spoke with his supervisor "to express his concerns that Mallinckrodt was not responding appropriately to CMS," according to an amended complaint.

But his supervisor "analogized the rebate issue to a taxpayer who realizes he has filed an incorrect tax return and owes back taxes," according to the complaint.

The supervisor, "in essence," had stated a taxpayer in that situation "would not voluntarily repay the money but instead wait until the Internal Revenue Service demanded it," according to the complaint.

Landolt resigned in early July 2017.

"When Mr. Landolt came to us with his concerns, we immediately recognized the significance of this matter because our firm had handled the Mylan EpiPen rebate case," Severin said, referring to a 2016 case where Mylan paid \$465 million for misclassifying the emergency allergy EpiPen shot as a generic drug to avoid paying the higher rebates. "We were able quickly to bring his concerns to the [DOJ] so the authorities could take action."

Mallinckrodt had underpaid \$258 million as of the first quarter of 2016, according to the DOJ complaint.

"Rather than take corrective action to address its underpayments then, Mallinckrodt dug in further on a position it knew the company's own regulatory department did not support," the DOJ said.

Mallinckrodt allegedly continued to report the incorrect average manufacturer price and the underpayment rose to \$650 million for the 2013 through 2020 period, according to an announcement from the Whistleblower Law Collaborative last week.

According to the DOJ, Mallinckrodt and its predecessor company Questcor began paying rebates for Acthar in 2013 as if Acthar was a "new drug" first marketed in 2013, when in fact it had been approved since 1952.

The company underpaid hundreds of millions of dollars in Medicaid rebates between 2013 and 2020, the DOJ said. Acthar's price had risen to more than \$28,000 per vial by 2013, the DOJ said, but "ignoring" all pre-2013 price increases for rebate purposes significantly lowered Medicaid rebate payments for Acthar.

"Congress enacted the Medicaid Drug Rebate Program to protect Medicaid programs from excessive price increases for drugs," said Suzanne Durrell of the Whistleblower Law Collaborative, who also represented Landolt and is the ex-chief of the civil division of the Boston U.S. attorney's office.

"State Medicaid programs are financially strapped and serve the poorest people in the country," Durrell said in an emailed statement to Law360. "We feel it's vitally important that the Medicaid programs not be defrauded and that drug companies live up to their reporting obligations. When companies fail to fulfill those obligations, it's essential to hold them accountable."

Mallinckrodt did not respond to requests for comment on Monday. Under the DOJ settlement agreement, the company admitted Acthar was not a new drug as of 2013, and agreed to correct the drug's base date

average manufacturer price and to not change the date in the future, the DOJ said.

The company also settled with a number of individual U.S. states participating in Medicaid, Washington, D.C. and Puerto Rico as part of the False Claims Act case brought by Landolt against Mallinckrodt plc and its subsidiary Mallinckrodt ARD LLC.

Of the roughly \$233.7 million settlement, the U.S. government will receive about \$123.6 million and the states will receive \$110 million, according to the DOJ.

Severin confirmed Landolt's payout will exceed \$40 million.

Compliance Responsibilities

In connection with the settlement, Mallinckrodt also entered a five-year corporate integrity agreement with the U.S. Department of Health and Human Services' Office of Inspector General.

The 76-page agreement contains drug price transparency and monitoring provisions focused on Medicaid rebate and patient assistance program activities. It also requires Mallinckrodt to establish a risk assessment program, assign a chief compliance officer, and obtain compliance-related certifications from company executives and board members.

Mallinckrodt also must appoint an employee and a member of senior management of Mallinckrodt as CCO to develop and implement the policies and procedures to comply with the corporate integrity agreement and federal health care program requirements, and to file at least quarterly reports to the company's board.

The compliance chief will also chair a new compliance committee that must meet quarterly. And any changes in the identity of the compliance officer must be reported to the HHS within five business days of the change.

The agreement notes that all reports related to the corporate integrity agreement must be submitted both to the HHS and to Mallinckrodt's current chief compliance officer, Kassie Harrold.

It was not immediately clear who the designated CCO will be, whether Harrold or some other individual. Harrold did not immediately respond to a request for comment on Monday.

In addition, Mallinckrodt had filed a voluntary petition for Chapter 11 bankruptcy on Oct. 12, 2020, which included an operating injunction requiring the company retain an outside, independent monitor to evaluate, monitor, and submit periodic compliance reports, the integrity agreement also notes.

As part of last week's settlement, Mallinckrodt also agreed to pay approximately \$26.3 million to resolve separate allegations for allegedly paying illegal kickbacks to doctors and patients in order to induce Medicare-reimbursed purchases of Acthar.

--Editing by Kelly Duncan and Lakshna Mehta.