

Dept. of Justice: DOJ announces Mallinckrodt to pay \$230 million agreement in underpayment of Medicaid drug rebates lawsuit

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MADISON, Wis. – Wisconsin Department of Justice (DOJ) announced today that Wisconsin has joined with 49 other states, Washington, D.C., Puerto Rico, and the federal government to settle allegations of fraud against Mallinckrodt ARD, LLC (formerly known as Questcor Pharmaceuticals, Inc.), a U.S. subsidiary of the Irish pharmaceutical company Mallinckrodt plc (collectively Mallinckrodt), which sells and markets pharmaceutical products throughout the nation. The total value of the agreement is \$233,707,865.18, plus interest, to be paid over a period of seven years. Of this amount, Wisconsin will receive \$1,391,803.20, plus applicable interest.

“When companies break the rules of the Medicaid system, the Wisconsin Department of Justice works to hold them accountable and get restitution for taxpayers,” said AG Kaul. “Thank you to the team in our Medicaid Fraud Control and Elder Abuse Unit whose work ensured that Medicaid dollars will be recouped.”

The agreement resolves allegations that from January 1, 2013, through June 30, 2020, Mallinckrodt knowingly underpaid Medicaid rebates due for its drug H.P. Acthar Gel (Acthar). The government alleges that Mallinckrodt’s conduct violated the Federal False Claims Act, the Wisconsin False Claims Act, Wis. Stat. § 20.931 (repealed 2015), the Wisconsin Medical Assistance Act, Wis. Stat. § 49.49(4m), and resulted in the submission of false claims to the Wisconsin Medicaid program.

Under the Medicaid Drug Rebate Program, when a manufacturer increases the price

of a drug faster than the rate of inflation, it must pay the Medicaid program a per-unit rebate of the difference between the drug's current price and the price of the drug if its price had gone up at the general rate of inflation since 1990 or the year the drug first came to market, whichever is later.

However, the government alleges that Mallinckrodt and its predecessor Questcor began paying rebates for Acthar in 2013 as if Acthar was a "new drug" just approved by the U.S. Food and Drug Administration (FDA), rather than a drug that was first introduced to market in 1952. Allegedly, this practice meant the companies ignored all pre-2013 price increases when calculating and paying Medicaid rebates for Acthar from 2013 until 2020. In particular, the government alleges that Acthar's price had already risen to over \$28,000 per vial by 2013; therefore, ignoring all pre-2013 price increases for Medicaid rebate purposes significantly lowered Medicaid rebate payments for Acthar. Under the settlement agreement, Mallinckrodt admitted that Acthar was not a new drug as of 2013 but rather was approved by the FDA and marketed prior to 1990. Mallinckrodt agreed to correct Acthar's base date AMP and that it will not change the date in the future.

As part of the settlement, Wisconsin will receive \$1,391,803.20 in restitution and other recoveries. This settlement results from a whistleblower lawsuit originally filed in the United States District Court for the District of Massachusetts. The federal government, twenty-six states, the District of Columbia, and Puerto Rico intervened in the civil action in 2020. The settlement, which is based on Mallinckrodt's financial condition, required final approval of the U.S. Bankruptcy Court for the District of Delaware, which approved the settlement on March 2, 2022.

The Wisconsin Medicaid Fraud Control and Elder Abuse Unit, within the Wisconsin Department of Justice Division of Legal Services, receives 75 percent of its funding from the U.S. Department of Health and Human Services under a grant award totaling \$1,617,392 for the fiscal year 2022. The remaining 25 percent, totaling \$539,126 for fiscal year 2022 is funded by the State of Wisconsin.

A team from the National Association of Medicaid Fraud Control Units participated in the litigation and conducted settlement negotiations on behalf of the states. The team included representatives from the Offices of the Attorneys General for the states of California, Florida, Massachusetts, Michigan, Nevada, New York, Texas, and Wisconsin. Wisconsin Assistant Attorney General Katie M. Wilson served as the co-team lead for the states.

The requirements of 2017 Wisconsin Act 369 do not apply because this resolution is part of a bankruptcy proceeding and is not a “compromise or discontinuance of a civil action.”

Find this press release [here](#).