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Department of Justice

U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE

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Mallinckrodt Agrees to Pay Nearly \$234 Million to Resolve Allegations Related to Price Increases

Settlement resolves allegations that company avoided paying hundreds of millions of dollars in Medicaid rebates due to significant drug price increases

BOSTON – Pharmaceutical company Mallinckrodt ARD, LLC (formerly known as Mallinckrodt ARD, Inc. and previously Questcor Pharmaceuticals, Inc.), has agreed to pay \$233,707,865 as part of a settlement to resolve allegations that from 2013 until 2020, it knowingly underpaid Medicaid rebates that resulted from its price increases for the drug H.P. Acthar Gel (Acthar), in violation of the False Claims Act. [In March 2020](#), the government filed a complaint detailing these allegations and how Mallinckrodt unlawfully required Medicaid programs to foot the bill for an increase in price from \$50 per vial to \$28,000 per vial, as though a new version of Acthar came on the market in 2013, when in fact, it did not.

Mallinckrodt's payment of approximately \$233.7 million includes approximately \$123.6 million to the United States and approximately \$110.1 million to several states, pursuant to the terms of separate settlement agreements Mallinckrodt has or will enter into with those states. In October 2020, Mallinckrodt filed for bankruptcy protection and the United States Bankruptcy Court for the District of Delaware has approved Mallinckrodt's settlement with the government.

In connection with the settlement, Mallinckrodt also entered a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (OIG). The CIA contains unique drug price transparency provisions and monitoring provisions focused on Medicaid rebate and patient assistance program activities. The CIA also requires Mallinckrodt to establish a risk assessment program, implement executive recoupment provisions and obtain compliance related certifications from company executives and board members.

Pursuant to the Medicaid Drug Rebate Program, drug manufacturers are required to pay quarterly rebates to state Medicaid programs in exchange for Medicaid coverage of the manufacturers' drugs. The statute requires pharmaceutical companies to pay inflation-based rebates for drugs, which are designed to insulate the Medicaid program from drug price increases outpacing inflation. These rebates are calculated as the difference between the drug's current price and the price the drug would have had if its price had increased at the rate of inflation since 1990, or the date when the drug was first marketed, whichever date is later.

The government alleges that Mallinckrodt knowingly underpaid rebates due for Acthar from 2013 until 2020. Acthar is a specialty drug that has been approved for various indications, including multiple sclerosis and infantile spasms. Specifically, the government alleges that Mallinckrodt and its predecessor, Questcor, began paying rebates for Acthar in 2013, as if Acthar was a new drug first marketed in 2013. In doing so, Mallinckrodt and Questcor ignored all pre-2013 price increases when calculating and paying Medicaid rebates for Acthar.

The government also alleges Mallinckrodt received an unlawful and improper windfall as a result of these practices, because the company raised the price of Acthar significantly – from approximately \$50 per vial in 2001 to \$40,000 per vial today. In particular, the government alleges that Acthar’s price had already risen to over \$28,000 per vial by 2013. Mallinckrodt’s decision to disregard all pre-2013 price increases for Medicaid rebate purposes significantly lowered Medicaid rebate payments for Acthar. The government further alleges that the Centers for Medicare and Medicaid Services repeatedly warned Mallinckrodt against this practice in 2016, 2017, 2018 and 2019. Mallinckrodt, however, refused to take corrective action. Under the settlement agreement, Mallinckrodt admits and agrees that there is only one Acthar, that FDA approved Acthar in 1952 and that Acthar was first produced, distributed and marketed prior to 1990.

“Mallinckrodt illegally reduced the amounts it paid to state Medicaid programs by improperly calculating the rebates it owed,” said United States Attorney Rachael S. Rollins. “Today’s settlement vindicates the interests of the American taxpayer by ensuring that no pharmaceutical manufacturer can illegally boost its profits at the expense of state Medicaid programs, and the people and families those programs serve. This company unlawfully siphoned money out of the Medicaid program which poor people depend on for their medical care.”

“The Department is committed to protecting tax-payer funded health care programs and their ability to supply reasonably priced pharmaceutical products to elderly and vulnerable populations” said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Department of Justice’s Civil Division. “As this settlement demonstrates, the department will pursue those who seek to undermine these protections.”

“The Medicaid Drug Rebate Program relies on drug manufacturers to report accurate pricing information in order to calculate appropriate Medicaid rebates,” said Phillip Coyne, Special Agent in Charge with the Office of Inspector General of the U.S. Department of Health and Human Services. “Taxpayers rightly expect that pharmaceutical companies will play by the rules rather than falsely report prices to boost profits. Any drug company shirking that responsibility can expect to be held accountable for its deception.”

“Drug company schemes to undermine Medicaid and Medicare payment rules harm these critical taxpayer-funded health programs,” said Chief Counsel Gregory E. Demske of the Office of Inspector General. “Under this CIA, OIG will scrutinize Mallinckrodt’s Medicaid rebate practices and Mallinckrodt will be required to provide advance public notice of price increases for Acthar and other drugs.”

“This settlement resolves allegations that Mallinckrodt cheated the Medicaid program, and ultimately taxpayers, out of hundreds of millions of dollars, by exploiting a system that was set up to keep a check on rising drug prices to ensure that our most vulnerable citizens are able to receive medical treatment,” said Joseph R. Bonavolonta, Special Agent in Charge of the Federal Bureau of Investigation, Boston Division. “It also illustrates how the FBI and our partners will not allow pharmaceutical companies to dodge their obligations in order take advantage of federal health insurance programs at the expense of those who need them the most.”

The government’s allegations were originally alleged in a case filed under the whistleblower, or qui tam, provision of the False Claims Act. The act permits private parties to sue for fraud on behalf of the United States and to share in any recovery. The act also permits the government to intervene in such actions, as the government has done in this case.

U.S. Attorney Rollins; Principal Deputy AAG Boynton; HHS-OIG Chief General Counsel Demske; and FBI SAC Bonavolonta made the announcement today. Assistant U.S. Attorney Evan Panich of Rollins' Affirmative Civil Enforcement Unit; Raquelle Kaye of Rollins's Asset Recovery Unit; and Trial Attorneys Augustine Ripa and Michael Hoffman of the Justice Department's Civil Division handled the matter.

Attachment(s):

[Download US v. Mallinckrodt - Settlement Agreement.pdf](#)

Component(s):

[USAO - Massachusetts](#)

Updated March 7, 2022