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MALLINCKRODT TO PAY MORE THAN $230 MILLION TO SETTLE LAWSUIT ALLEGING UNDERPAYMENT OF MEDICAID DRUG REBATES

Nashville-Attorney General Herbert H. Slatery III announced that Tennessee will receive nearly $5 million dollars in a settlement with Mallinckrodt, which sells and markets pharmaceutical products throughout the nation.

The total value of the settlement is approximately $233 million, plus interest, to be paid over a period of seven years. The agreement settles allegations of fraud against Mallinckrodt with all 50 states, Washington, D.C., Puerto Rico, and the federal government.

The government alleged that from January 1, 2013, through June 30, 2020, Mallinckrodt knowingly underpaid Medicaid rebates due for its drug H.P. Acthar Gel (Acthar). That conduct violated the Federal False Claims Act and Tennessee's False Claims Act and resulted in the submission of false claims to TennCare, Tennesssee's Medicaid program.

"Mallinckrodt significantly increased the price of this particular drug, then tried to ignore that fact when calculating and paying Medicaid rebates to programs like TennCare," said General Slatery. "Let's just say- we brought it to their attention."

Under the Medicaid Drug Rebate Program, drug manufacturers are required to pay back the difference between a drug's price increase each year and the rate of inflation.

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 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.

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.

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