NATIONAL ASSOCIATION OF MEDICAID FRAUD CONTROL UNITS

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

The National Association of Medicaid Fraud Control Units (NAMFCU) announced on March 7, 2022 that 50 states, Washington, D.C., and Puerto Rico, have joined 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. Mallinckrodt's U.S. headquarters is located in Bedminster, New Jersey. The total value of the settlement is $233,707,865.18, plus interest, to be paid over a period of seven years.

The settlement 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 and the (State False Claims Statute) and resulted in the submission of false claims to the (State) 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.

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.

A NAMFCU Team 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.