HONOLULU – Hawai‘i Attorney General Holly T. Shikada announced that the State of Hawai‘i joined 49 other states, Washington, D.C., Puerto Rico, and the federal government to settle fraud allegations 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 settlement is $233,707,865.18, plus interest, to be paid over a seven year period. The State of Hawai‘i will receive $86,164.40.

“The Medicaid Drug Rebate Program ensures that prescription medications are available to those in need, “ Attorney General Shikada said. “Companies that engage in deceptive practices harm the program and those that rely on it. These companies must be held accountable for their fraudulent activity.”

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), thereby violating the Federal False Claims Act and the Hawai‘i False Claims Act resulting in the submission of false claims to the Hawai‘i 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.

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 average manufacturer price and that it will not change the date in the future.

The Medicaid Fraud Control Unit receives 75 percent of its funding from the U.S. Department of Health and Human Services under a grant award totaling $1,811,916.00 for the fiscal year (FY) 2022. The remaining 25 percent, totaling $603,968.00 for FY 2022 is funded by the State of Hawai‘i.

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 lead states included California, Florida, Massachusetts, Michigan, Nevada, New York, Texas, and Wisconsin with the Department’s Medicaid Fraud Control Unit Director, Landon M.M. Murata, and the Department of Human Services’ Med-QUEST Division Administrator, Dr. Judy Mohr Peterson are representing the State of Hawai‘i in entering into the settlement agreement.

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