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Mallinckrodt Agrees to Pay $260 Million to Settle Lawsuits Alleging Underpayments of Medicaid Drug Rebates and Payment of Illegal Kickbacks

Pharmaceutical company Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc. (Questcor)) (collectively Mallinckrodt), has agreed to pay $260 million to resolve allegations that Mallinckrodt violated the False Claims Act by knowingly: 1. underpaying Medicaid rebates due for its drug H.P. Acthar Gel (Acthar); and 2. using a foundation as a conduit to pay illegal co-pay subsidies in violation of the Anti-Kickback Statute for Acthar. In 2019 and 2020, respectively, the government filed separate complaints detailing these allegations. 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.

"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."

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 (HHS-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.

"Mallinckrodt illegally reduced the amounts it paid to state Medicaid programs by improperly calculating the rebates it owed," said U.S. Attorney Rachael S. Rollins for the District of Massachusetts. "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."

"When pharmaceutical companies manipulate Medicare Part D by covering patient copays, the whole structure of the Part D program is undermined," said U.S. Attorney Jennifer Arbittier Williams for the Eastern District of Pennsylvania. "Our office is committed to maintain the financial integrity of taxpayer-funded programs like Medicare, and therefore we will continue to pursue fraud actions like this so that Medicare Part D and other federal healthcare programs remain viable for those who rely on the benefits."

"Drug company schemes to undermine Medicaid and Medicare payment rules harm these critical taxpayer-funded health programs," said Chief Counsel Gregory E. Demske of HHS-OIG. "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 Special Agent in Charge Joseph R. Bonavolonta of the FBI, 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."

Medicaid Drug Rebate Claims

Pursuant to the Medicaid Drug Rebate Program, drug manufacturers are required to pay quarterly rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs. The statute requires manufacturers 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 by comparing the drug's Base Date Average Manufacturer Price (AMP), which is the drug's price on the date that the "dosage form and strength" of the drug was first marketed or 1990, whichever is later, to its current price.

In its complaint filed on March 3, 2020, the government alleged that Mallinckrodt knowingly underpaid rebates due for Acthar from 2013 until 2020. According to the complaint, Mallinckrodt and its predecessor Questcor began paying rebates for Acthar in 2013 as if Acthar was a "new drug" first marketed in 2013, rather than a drug that had been approved since 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 alleged that Acthar's price had already risen to over $28,000 per vial by 2013, and 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 U.S. Food and Drug Administration and marketed prior to 1990, and agreed to correct Acthar's base date AMP and that it will not change the date in the future.

Kickback Claims

When a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may be required to make a partial payment, which may take the form of a copayment. Congress included copay requirements in the Medicare program, in part, to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration — which includes money or any other thing of value — to induce Medicare patients to purchase the company's drugs. This prohibition extends to the payment of patients' copay obligations.

In its complaint filed on June 5, 2019, the government alleged that Mallinckrodt knowingly used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar so it could market the drug as "free" to doctors and patients while increasing its price. Mallinckrodt allegedly paid these illegal subsidies through three funds that Mallinckrodt had a foundation set up to induce Medicare-reimbursed purchases of Acthar, and used the subsidies to counteract doctor and patient concerns about the drug's high cost.

The settlement provides for Mallinckrodt's payment of approximately $234.7 million to resolve the Medicaid rebate allegations and approximately $26.3 million to resolve the kickback allegations. Of the amount allocated to the Medicaid rebate claims, Mallinckrodt will pay approximately $123.6 million to the United States and approximately $110.1 million to the participating Medicaid 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 protections and this settlement with the government has been approved for payment by the U.S. Bankruptcy Court for the District of Delaware.

The allegations resolved by the settlement agreement were originally brought in cases 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 these cases, which are captioned: *United States of America et al. ex rel. Landolt v. Mallinckrodt Pharmaceuticals Inc.*; *United States of America ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*; and *United States of America ex rel. Clark v. Questor Pharmaceuticals, Inc.* The Strunck whistleblowers will receive approximately $4.9 million from the recovery for the kickback allegations and the Landolt whistleblower will receive approximately $24.7 million from the federal recovery for the Medicaid rebate allegations.

The government's pursuit of these matters illustrates the government's emphasis on combating healthcare fraud. One of the most powerful tools in this effort is the False Claims Act. Tips and complaints from all sources about potential fraud, waste, abuse and mismanagement can be reported to the Department of Health and Human Services, at 800-HHS-TIPS (800-447-8477).

These matters are being handled by Trial Attorneys Augustine Ripa, Michael Hoffman and Dan Schiffer of the Civil Division's Commercial Litigation Branch, Fraud Section; Assistant U.S. Attorney Evan Panich of the District of Massachusetts; and Assistant U.S. Attorneys Colin Cherico, Paul Koob and Matthew Howatt of the Eastern District of Pennsylvania. HHS-OIG assisted with the matters.

The claims asserted by the United States are allegations only and there has been no determination of liability.

Attachment(s):
Download DMA Mallinckrodt Settlement.pdf
Download EDPA Mallinckrodt Settlement.pdf

Topic(s):
False Claims Act

Component(s):
Civil Division
USAO - Massachusetts
USAO - Pennsylvania, Eastern

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