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# Teva Pharmaceuticals Agrees to Pay $450 Million to Resolve FCA Claims

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Headlines that Matter for Companies and Executives in Regulated Industries

## Teva Pharmaceuticals Agrees to Pay $450 Million to Resolve FCA Claims

On October 10, the US Department of Justice (DOJ) announced that Teva Pharmaceuticals USA Inc. and Teva Neuroscience Inc. will pay $450 million to resolve two claims alleging Teva violated the Anti-Kickback Statute (AKS) and False Claims Act (FCA).

The first settlement arose out of a complaint filed in the District Court of Massachusetts. That complaint alleged that from 2006 through 2017, Teva violated and conspired to violate the AKS and FCA by paying Medicare patients' copays for the multiple sclerosis drug Copaxone. According to the complaint allegations, Teva coordinated and conspired with a specialty pharmacy and two copay assistance foundations to make donations specifically to cover the copays of Medicare patient prescriptions for Copaxone. The government alleged that Teva knew that using third-party charitable foundations to unlawfully offer copay assistance for patients using their drug is prohibited by the AKS and rendered its claims for reimbursement from Medicare false under the FCA. Teva agreed to pay $425 million, payable over a five-year schedule through 2029, to resolve this allegation — the DOJ's largest copay assistance settlement to date.

This case was closely monitored because Teva had a pending appeal before the First Circuit Court of

Appeals on the appropriate causation requirement in FCA cases arising out of violations of the AKS,see *US v. Teva Pharmaceuticals USA Inc. et al*., No. 23-1958. Teva argued that the 2010 amendment to the AKS required the government to prove that "but for" the donations to charitable foundations, the claims would not have been submitted for reimbursement to government health care programs. The Massachusetts district court disagreed and held that the government only needed to prove a "sufficient causal connection" between the alleged kickback under the AKS and the FCA. Separately, a different judge in the same federal district court held in favor of the "but for" causation standard in a similar kickback case, see *U.S. v. Regeneron Pharmaceuticals Inc.*, No. 23-2086. Both *Teva* and *Regeneron* were scheduled to argue the causation standard before the First Circuit, however, Teva and the government agreed to pause that appeal to allow the now finalized settlement discussions to develop. *Regeneron* proceeded to oral argument before the First Circuit in July 2024.

Our previous summaries of *US v. Teva Pharmaceuticals USA Inc. et al.*, No 23-1958 and *US v. Regeneron Pharmaceuticals Inc.*, No. 23-2086 are here and here.

Teva's second settlement arose out of a complaint filed in the Eastern District of Pennsylvania alleging that Teva conspired with other generic drug manufacturers to fix prices for the drugs pravastatin, clotrimazole, and tobramycin. Under this civil settlement, Teva agreed to pay $25 million to resolve allegations that the benefits it received under the price fixing scheme resulted in illegal kickbacks in violation of the AKS and FCA.

Previously, Teva entered a deferred prosecution agreement with the DOJ's Antitrust Division to resolve criminal charges related to the price fixing scheme. As part of the criminal settlement, Teva paid a criminal penalty of $225 million, which is separate from the $450 million it agreed to pay to settle the civil allegations.

The DOJ's press release is available here.

## Magellan Diagnostics Ordered to Pay Over $42 Million in Sentencing of Food, Drug, and Cosmetic Act Claims

On October 9, a Massachusetts federal court sentenced Magellan Diagnostics, Inc. on two counts of introducing a misbranded medical device in interstate commerce in violation of the Food, Drug, and Cosmetic Act. Magellan agreed to plead guilty to criminal charges related to the concealment of device malfunctions that resulted in inaccurate low lead test results for children and other patients. Magellan was ordered to pay a $21.8 million fine, $10.9 million in forfeiture, and a minimum of $9.3 million to compensate patient victims.

According to court documents, Magellan concealed from the US Food and Drug Administration (FDA) malfunctions in its LeadCare line of products which were used to detect and measure lead levels and lead poisoning in the blood of children and adults. One of those products, LeadCare II, accounted for more than half of all blood lead tests in the United States conducted from 2013 to 2017. The malfunction allegedly led to test results that reported falsely low lead levels and the FDA ultimately found that LeadCare devices could not accurately test venous samples and required a recall of all such devices.

Previously, three c-suite level executives of Magellan – the CEO, COO, and the Director of Quality Assurance and Regulatory Affairs – were indicted on various charges of wire fraud and conspiracy to commit wire fraud, and introduction of misbranded medical devices into interstate commerce with intent to defraud and mislead. We previously covered their indictments here. The individuals have

pled not guilty and are awaiting trial.

The United States Attorney's Office of the District Court of Massachusetts' press release is available here.

## Pharmaceutical Distributor Executives, Sales Representatives, and Brokers Criminally Charged for Unlawful Sales of Opioid Pills

On October 3, the DOJ announced unsealed charges against five pharmaceutical distributor executives, five pharmaceutical sales representatives and brokers, and three pharmacy operators in connection with the unlawful distribution of almost 70 million opioid pills and over 30 million doses of commonly abused prescription drugs. According to the DOJ, this is the largest criminal enforcement action targeting executives, brokers, and pharmacy owners, spanning four federal judicial districts in Texas, Florida, Missouri, and North Carolina.

The charging documents allege that the pharmacy distributors — located outside of Texas — sold oxycodone, hydrocodone, and hydromorphone to Houston-area pharmacies at above-market prices, specifically targeting so-called "pill-mill" pharmacies knowing that these prescription drugs would be diverted and end up on the black market. The same pharmacy distributors also allegedly sold prescription drug potentiators which purportedly enhance the high from opioids, including alprazolam, carisoprodol, and promethazine with codeine syrup. The DOJ announced the drugs represent a black-market value of over $1.3 billion.

The government also alleged that the distributors developed sophisticated techniques for avoiding detection from the US Drug Enforcement Administration, including compliance measures that appeared strong but were ineffective. The distributors were also far removed from the Houston-area pharmacies that purchased and unlawfully distributed the opioids to the community.

Nine of these individuals have pled guilty to various criminal counts, including unlawfully distributing and dispensing controlled substances, conspiracy to unlawfully distribute and dispense controlled substances, and possession with intent to district and dispense controlled substances. The sentences range from four to twenty years in prison.

The DOJ's press release is available here.

*Roberto Martinez also contributed to this article.*



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