



December 8, 2015

MADIGAN ANNOUNCES SETTLEMENT WITH NOVARTIS PHARMACEUTICALS CORPORATION FOR KICKBACK ALLEGATIONS

Chicago — Attorney General Lisa Madigan today announced that Illinois reached an agreement to settle kickback claims against Novartis Pharmaceuticals Corporation ("Novartis"). The settlement will resolve allegations that Novartis provided kickbacks to certain specialty pharmacies in exchange for recommending the drug Exjade to Medicaid and Medicare patients. Under the settlement, Novartis has agreed to pay \$390 million to the United States and more than forty states. Illinois will receive nearly \$4.5 million under the settlement.

In their court filings, the government plaintiffs alleged that Novartis paid kickbacks to the pharmacies to corrupt the pharmacies' interactions with patients by inducing the pharmacies to exaggerate the dangers of not taking Exjade, emphasize Exjade's benefits, and downplay the severity of Exjade's side effects. The scheme began after Exjade failed to meet Novartis' internal sales goals and Novartis discovered that refill rates for Exjade were lower than anticipated.

Novartis, which is headquartered in East Hanover, New Jersey, is a subsidiary of the Swiss pharmaceutical company Novartis AG. In late 2005, Exjade was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of chronic iron overload due to blood transfusions. After launching the drug, Novartis marketed Exjade as a treatment for patients with a number of underlying conditions that affect blood cells or bone marrow.

"This scheme deceived vulnerable patients with exaggerated and inaccurate medical information that played with their well-being and their wallets," said Madigan. "Any company that tries to benefit from misleading its customers will be held responsible in Illinois."

The settlement stems from a whistleblower lawsuit, *U.S. ex rel. Kester, et al. v. Novartis Pharmaceuticals Corporation, et al.*, No. 11-CIV-8196, which was filed in the United States District Court for the Southern District of New York. Two of the specialty pharmacies named as defendants in the case, BioScrip, Inc. and Accredo Health Group, Inc., previously agreed to pay \$15 million and \$60 million, respectively, to resolve claims that they accepted kickbacks from Novartis to promote Exjade. Illinois received more than \$750,000.00 under those settlements.

The settlement specifically resolves allegations that between 2007 and 2012 Novartis paid kickbacks to three specialty pharmacies – BioScrip, Accredo, and US Bioservices. The pharmacies were selected by Novartis to be part of a closed distribution network through which most Exjade prescriptions in the United States were filled. Novartis created the distribution network, which it called EPASS, and therefore had significant control over how many patient referrals each pharmacy received. The pharmacies shipped most Exjade prescriptions to patients by mail and were supposed to call patients to set up the shipments and obtain consent for refills. The pharmacies billed themselves as specialty pharmacies that could arrange for these shipments and run educational programs for patients.

In the course of the scheme, Novartis pressured the specialty pharmacies by threatening to exclude them from the EPASS network or to reduce the number of patient referrals they received from EPASS. In addition, Novartis set up a contest in which the pharmacy that kept patients on Exjade the longest would receive additional patient referrals from EPASS. The contest winner was determined by scorecards created by Novartis that were sent to each of the three pharmacies. Novartis also paid rebates to the specialty pharmacies, which made each patient referral valuable and incentivized the specialty pharmacies to encourage patients to stay on Exjade. The contest and the rebates were not disclosed to Exjade patients or their caregivers.

In their filings, the government plaintiffs also alleged that lawyers for Novartis raised concerns about the contest for nearly a year before it was implemented. According to the filings, Novartis went forward with the contest after one senior executive challenged

the legal advice and another determined that the benefits of the scheme to Novartis outweighed the risk of violating the federal Anti-Kickback Statute.

To appease Novartis, all of the pharmacies put together plans to increase refill rates that included nurses placing phone calls to patients or caregivers. BioScrip told Novartis that it would make claims about Exjade preventing organ damage even though the FDA had told Novartis it should not make these claims in promotional materials. Another pharmacy, Accredo, showed Novartis a call protocol that directed nurses to tell patients it was "extremely important" to take Exjade and to describe the common side effects of the drug but not the more severe side effects, such as kidney or liver problems.

Novartis admitted many aspects of the scheme in a stipulation filed in federal court in connection with the settlement. Among other things, Novartis admitted that it indicated to BioScrip that it might terminate its distribution agreement or reduce the number of patient referrals it received from EPASS. Similarly, Novartis admitted that it told Accredo and US Bioservices that Novartis might reduce the number of patient referrals they received from EPASS and "pushed" Accredo and US Bioservices to implement plans in which nurses would call patients and encourage them to stay on Exjade. Novartis also admitted that it used the scorecard results to allocate EPASS patients to the specialty pharmacies.

Assistant Attorney General Elisa Hamilton handled the case for Illinois.

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