

## NEWS RELEASE

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## Ventura County-based Amgen Inc. Pays Over \$15 Million to Resolve Allegations that it Illegally Marketed Cancer Drug with Kickbacks

LOS ANGELES – Biopharmaceutical company Amgen Inc. today paid the United States more than \$15 million to resolve allegations that the Ventura County company provided illegal financial incentives to physicians and physician groups to induce them to prescribe the cancer drug Xgeva.

Amgen, which is headquartered in Thousand Oaks, paid the money today pursuant to a settlement agreement with the United States to resolve allegations that it violated the Medicare Anti-Kickback Statute and the federal False Claims Act. The Medicare Anti-Kickback Statute prohibits anyone from offering, paying, soliciting or receiving anything of value to generate referrals for items or services payable by any federal health care program.

Xgeva, which is the brand name of the drug denosumab, was approved by the Food and Drug Administration in late 2010 for use with certain cancer patients undergoing chemotherapy. It is most commonly prescribed for patients with metastatic bone disease in order to prevent skeletal-related adverse events.

In order to increase sales of Xgeva, Amgen used data purchase agreements — which the company called the "Deep Dive" contracts — to provide financial incentives to oncologists and urologists to prescribe Xgeva. The original plan for the Deep Dive contracts called for Amgen to pay doctors to fill out a short survey on the Internet on how they were treating patients with bone cancer, including which drugs were used — whether or not Xgeva was prescribed. However, Amgen altered the original Deep Dive

program design by increasing the amount of money it would pay doctors, and by offering such payments only to doctors who prescribed Xgeva for their patients. Amgen's Xgeva marketing team also was not supposed to know the identities of the doctors who received Deep Dive contracts, but team members had access to that information. Additionally, in a further effort to influence doctors to prescribe Xgeva, Amgen provided cash payments characterized as honoraria to oncologists and urologists for participating in audience response sessions, data market research surveys, and "treatment trends" advisory board programs which touted the benefits of Xgeva.

This settlement resolves a lawsuit filed under the *qui tam*, or "whistleblower," provisions of the False Claims Act, which allow private citizens with knowledge of fraud to bring civil actions on behalf of the United States and share in any recovery. The case, which was filed last year in federal court in Los Angeles by two Amgen employees – *United States ex rel. Davis et al. v. Amgen Inc., et al.*, CV12-00570-R (MRWx) – was unsealed Tuesday after the United States elected to take over part of the case and negotiated the settlement with Amgen. The two men who originally filed the lawsuit, William Davis and Spencer Miller, will collectively receive \$2.75 million as part of the settlement.

The United States Attorney's Office for the Central District of California, and the Justice Department's Civil Division, handled the civil settlement. This matter was investigated by the U.S. Department of Health and Human Services, Office of Inspector General.

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