

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General



Inspector General
September 25, 2013

AMGEN, INC. TO PAY \$612 MILLION IN SETTLEMENT

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with other states and the federal government and reached agreement with Amgen, Inc. (“Amgen”) to settle allegations that Amgen engaged in various illegal marketing practices to promote sales of the drugs Aranesp, Enbrel, Epogen, Neulasta, Neupogen, and Sensipar and inaccurately reported and manipulated prices for these drugs, causing the submission of false claims. Amgen will pay the states and the federal government a total of \$612 million in civil damages and penalties to compensate Medicaid, Medicare, and various federal health care programs for harm suffered as a result of its conduct.

In addition, Amgen has agreed to plead guilty to an information to be filed by the government in the United States District Court for the Eastern District of New York that will allege a violation of 21 U.S.C. §§ 331(a) and 333(a)(1) and 18 U.S.C. §§ 2 and 3551, namely, the introduction into interstate commerce of a drug (Aranesp) that was misbranded within the meaning of 21 U.S.C. § 352(a) in violation of the Food, Drug and Cosmetic Act.

The government entities alleged that Amgen engaged in several improper marketing and pricing practices that included the following:

- Amgen illegally marketed the drugs Aranesp, Enbrel, and Neulasta;
- Amgen illegally offered, paid, or caused to be paid kickbacks for the purpose of influencing health care providers’ selection and utilization of Aranesp, Enbrel, Epogen, Neulasta, Neupogen, and Sensipar for Medicaid recipients;
- Amgen knowing reported inaccurate Average Sales Prices for Aranesp, Epogen, Neulasta, and Neupogen;
- Amgen knowingly reported inaccurate Best Prices and Average Manufacturing Prices for Aranesp, Enbrel, Epogen, Neulasta, Neupogen, and Sensipar by failing to include remuneration that was paid to health care providers and that was

conditioned on the purchase of Amgen products, in violation of the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8.

As a condition of the settlement, Amgen will enter into a Corporate Integrity Agreement with the United States Department of Health and Human Services, Office of the Inspector General, which will closely monitor the company's future marketing and sales practices.

This settlement is based on 10 *qui tam* cases that were filed in the United States District Court for the District of Massachusetts, the United States District Court for the Eastern District of New York, and the United States District Court for the Western District of Washington by private individuals who filed actions under state and federal false claims statutes. As part of the settlement, the District will receive \$739,226 in restitution and other recovery.

A National Association of Medicaid Fraud Control Units team participated in the investigation and conducted the settlement negotiations with Amgen on behalf of the settling states. Team members included representatives from the Offices of the Attorneys General for the states of California, Massachusetts, Indiana, Illinois, New York, and North Carolina.

Mr. Willoughby acknowledged the D.C. Department of Health Care Finance for its assistance in providing drug utilization data, and attorney Elaine Block and auditor LaShawn Brooks for their work on the investigation.