

Amgen, Inc. (“Amgen”) to pay \$762 million in fines and damages.

Whistleblower Kassie Westmoreland finds vindication after hard-fought litigation alleging “overfill” kickback claims against Amgen and AmerisourceBergen subsidiary Integrated Nephrology Network (“INN”).

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Brooklyn, NY, December 19, 2012. Biotech giant Amgen was sentenced today, after pleading guilty in Brooklyn federal district court to a criminal misdemeanor federal Food Drug and Cosmetic Act violation. Amgen admitted “misbranding” in its marketing of the drug Aranesp and agreed to pay a total of \$762 million in criminal fines, forfeitures, and civil damages to the United States and affected states. The settlement includes Amgen’s pattern of fraudulent marketing of Aranesp through schemes including: off-label marketing, pricing fraud, kickbacks in many forms, and conspiring with a purported group purchasing organization, INN, to help carry out these frauds.

AmerisourceBergen subsidiary INN has entered a separate agreement to pay \$15 million to the government in settlement of Ms. Westmoreland’s claims that INN had conspired with Amgen in illegally marketing Aranesp.

Whistleblower Kassie Westmoreland played a critical role in the success of the government’s prosecution, which involved her complaint, as well as several other whistleblower-filed suits against Amgen. Ms. Westmoreland, a Pharmacist and former Amgen employee, filed suit against her former employer and INN (then known as International Nephrology Network) in 2006 in federal district court in Boston alleging a variety of national fraud schemes involving Amgen’s drug Aranesp. Her case was assigned to Judge William G. Young, who denied transfer to Brooklyn and ordered the case unsealed in 2009, while other suits against Amgen remained under seal, mostly in Brooklyn, where the government’s investigation was based through the United States Attorney’s Office for the Eastern District of New York.

“Judge Young’s decision to unseal Ms. Westmoreland’s complaint against Amgen and INN was a critical moment in the history of not only this case but the government’s overall investigation,” her attorneys said. “With the federal government electing at that juncture to remain on the sidelines of the litigation in the District of Massachusetts, Kassie Westmoreland showed incredible courage and determination in pressing on with the litigation with her own team and with the State governments who intervened. In the end, after defending her claims from various defense motions to dismiss and motions for summary judgment and obtaining powerful evidence for trial through discovery, the imminent trial date in Ms. Westmoreland’s case as of October 2011 brought Amgen and INN to the table in negotiations with the government.”

Amgen announced its agreement in principle to settle Ms. Westmoreland's and the other relators' claims with the government and that it had reserved \$780 million just days before the Westmoreland trial was to begin.

Ms. Westmoreland's case centered around allegations that Amgen, in manufacturing single use vials of its drug Aranesp, had intentionally manipulated the amount of "overfill" to increase the vial volume beyond that needed to ensure delivery of the labeled dosage. Amgen had then encouraged doctors to bill Medicare and Medicaid for the overfill, which typically was more than the indicated or prescribed dose. Amgen provided and marketed the extra Aranesp overfill to encourage the purchase and use of Aranesp and to distinguish Aranesp from a competing drug, Procrit, which Amgen also manufactured, but which was sold by Ortho Biotech/Johnson & Johnson under a licensing agreement. By providing extra Aranesp in every vial and encouraging doctors to bill insurers – including Medicare and Medicaid and other government programs– for that overfill, Amgen presented an economic inducement for doctors to purchase Aranesp rather than Procrit, thereby increasing Aranesp's market share and Amgen's own profits. Such conduct that is intended to affect the conduct of medical practices violates the federal Anti-Kickback Statute, a criminal statute. Ms. Westmoreland, with the assistance of her attorneys, alleged that Amgen and INN had systematically promoted overfill billing as an inducement to change doctors' prescribing patterns. During discovery, documents and deposition testimony confirmed that Amgen, in conspiracy with INN, had used overfill to entice physicians to choose Aranesp based on the promise of increased Medicare and Medicaid reimbursement for the overfill. Five Amgen employees at all levels of the company – from sales representative to National Sales Director – elected to stand on their Fifth Amendment rights against self-incrimination rather than provide any testimony regarding their time at Amgen. "I wish we had been able to put our evidence into the record at trial so American taxpayers would know the full extent of the fraudulent activity," Ms. Westmoreland said. "The evidence was so clear. But ultimately I feel vindicated by the fact that Amgen was forced to admit their guilt based upon the irrefutable evidence against them."

The Westmoreland litigation in Boston involved a massive amount of work performed on a demanding schedule. The efforts required of Ms. Westmoreland and her legal team before Judge Young included amending her complaint four times, litigating more than 20 motions on legal and discovery issues, taking and defending more than 115 depositions, preparing and addressing more than 20 expert reports and depositions, and reviewing more than 6 million pages of documents. This required Ms. Westmoreland's attorneys to commit substantial time and resources to the litigation, without any guarantee of recovery. Throughout this process, Ms. Westmoreland and her counsel were convinced that their efforts would be vindicated.

Ms. Westmoreland's case also significantly impacted the development of False Claims Act case law. When Judge Young initially dismissed the complaints of Ms. Westmoreland and several intervening states, Ms. Westmoreland's attorneys found themselves litigating in both the District Court and the U.S. Court of Appeals for the First Circuit. Ms. Westmoreland amended her complaint and pressed forward in the District Court and gathered valuable discovery from Amgen and INN. Meanwhile, several states elected to appeal Judge Young's ruling to the First Circuit, and Ms. Westmoreland joined them on behalf of certain states. The unanimous judgment of the First Circuit Court of Appeals not only reinstated the dismissed claims but also substantially clarified an area of the law relevant to claims under the False Claims Act.

Ms. Westmoreland's legal team was comprised of firms from three different cities, Los Angeles, Boston, and Washington, D.C. Her first attorneys were Los Angeles litigators Charles Kester and Lawrence Isenberg of Kester & Isenberg, who partnered with Boston whistleblower specialists Bob Thomas and Suzanne Durrell and their then colleague Rory Delaney who is now in private practice in Boston. In 2009, when the case was unsealed and greater litigation resources were needed, attorneys from the Washington, D.C. firm of Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C., including Silvija A. Strikis, Joseph S. Hall, Wan J. Kim, Derek T. Ho, and Andrew C. Shen, joined the effort on behalf of Ms. Westmoreland. All of the lawyers maintained an active role in the case until its completion.

Ms. Westmoreland is grateful for the tireless efforts of her attorneys and expert witnesses, as well as to those individuals who stepped forward with evidence supporting the government's investigation and her claims. She would also like to thank the many members of federal and state law enforcement who worked on the investigation, litigation, and today's settlement, including: the United States Attorneys' Offices for the Eastern District of New York, who led the federal investigation and settlement effort, and the District of Massachusetts; the Department of Justice; the National Association of Medicaid Fraud Control Units led by the Attorneys General of several states, including New York, Massachusetts, California, Indiana, and Illinois who intervened in her case and supported her throughout the litigation; the Federal Bureau of Investigation; the Food and Drug Administration; and the Offices of Inspector General of the Department of Health and Human Services and the Office of Personnel Management.

Case Captions: *United States, et al., ex rel. Westmoreland v. Amgen, et al.*, Civil Action No. 06-10972-WGY (D. Mass.); *New York, et al., ex rel. Westmoreland v. Amgen, et al.*, Nos. 10-1629, 10-1630, 10-1633, 10-1634, 10-1635, 10-1636, 10-1954, 10-1955 (1st Cir.).