

Whistleblower Files Amended Complaint Against Biotech, Amgen and Marketing Partners

By Thomas & Associates, Kester & Isenberg

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Amgen and its Marketing Partners International Nephrology Network and ASD Healthcare, Both Owned by AmerisourceBergen Corporation, Offered Kickbacks to Medical Providers in Order to Increase Sales of Blockbuster Anemia Drug Aranesp.

Boston attorneys Suzanne E. Durrell, Robert M. Thomas, Jr., and Rory Delaney, and Los Angeles attorneys Charles F. Kester and Lawrence M. Isenberg of the law firm Kester & Isenberg, announced today the filing of an amended complaint against biotechnology company Amgen Inc. and others, in a case pending before United District Court Judge William G. Young in Boston.

The amended complaint, filed pursuant to federal and state False Claims Acts by Relator Kassie Westmoreland, a former Amgen employee, is filed the same day as a consolidated complaint in intervention brought by fifteen state Attorney General offices. These state plaintiffs recently filed notices of intervention in Ms. Westmoreland's lawsuit. (The federal government has not yet intervened in her lawsuit but has indicated that its investigation into her allegations is ongoing.)

Ms. Westmoreland's suit alleges, among other claims, that Amgen engaged in a variety of illegal kickback schemes the effect of which was to cause millions of dollars of overbillings to government health insurance programs. She has alleged, for example, that Amgen illegally induced physicians to prescribe its anti-anemia drug Aranesp by encouraging physicians to bill insurers for the "overfill" placed in the pre-packaged vials of the drug.

The suit also alleges that in some instances patients were given more Aranesp than medically indicated, because of the "overfill" billing potential, notwithstanding a "black box warning" from the FDA about the health risks of Aranesp, and the need for minimal dosing.

Aranesp (darbepoetin alfa) is an erythropoiesis-stimulating agent (ESA) and injectable drug product developed and manufactured by Amgen to stimulate and boost the production of red blood cells in the body. It was approved by the FDA in 2001 to treat anemia associated with chronic renal failure and in 2002 to treat chemotherapy-induced anemia in certain types of cancer patients.

Aranesp has been a lucrative product for Amgen with total sales reaching over \$11 billion dollars since the drug was first introduced into the marketplace. To date, the federal Medicare program and the state Medicaid programs have paid billions of dollars for Aranesp treatments. However, Aranesp is not without risk to patients. In 2007, the FDA issued "black box" warnings (the most serious warning on a drug's label) that Aranesp treatment could increase the risk of death, serious cardiovascular events and increased tumor growth and cautioned physicians to use the lowest effective dose to achieve blood counts in a range to avoid blood transfusions, but not higher.

Both Ms. Westmoreland's complaint and the multi-state complaint allege that the Amgen sales force offered free Aranesp product to medical providers and encouraged medical providers to bill third party payers including the state Medicaid programs for the free Aranesp.

Amgen also allegedly conspired with its partners International Nephrology Network and ASD Healthcare, both owned by AmerisourceBergen Corporation, to offer illegal kickbacks to medical providers, such as sham "honoraria" to attend all-expense paid meetings with the intention and effect of increasing sales of

Aranesp and converting new providers from competitor drugs to Aranesp.

Ms. Westmoreland, through her attorneys, issued a brief statement:

"I am extremely gratified that these allegations are getting the attention they deserve and that the fifteen states intervening in my case have investigated these matters and joined my lawsuit. I want to acknowledge the extraordinary work that has been done to date, as reflected in the detailed allegations of the multi-state complaint."

"In the months ahead, I will continue to assist law enforcement in this case – both the intervening states as well as the federal government in its ongoing investigation. I am committed to the truth coming out, and to the successful prosecution of this case."

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Launched in April of 2000, Thomas & Associates (www.ThomasandAssoc.net) is a boutique litigation practice concentrating in the areas of whistleblower litigation, white-collar criminal defense, and special prosecution of labor racketeering cases.

Founder, Bob Thomas, is a 1985 cum laude graduate of Harvard Law School and a former Assistant United States Attorney

In connection with its growing whistleblower practice, the firm is affiliated with Suzanne E. Durrell (of counsel, www.DurrellLaw.com), the former Chief of the Civil Division of the Boston United States Attorney's Office.

Thomas & Associates now has an active docket of False Claims Act (qui tam) cases filed in federal and state courts around the country. This now constitutes a significant portion of the firm's practice.

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