

Last week, biotechnology giant Amgen agreed to pay some \$762 million to resolve claims involving unlawful marketing of the anemia drug Aranesp. Federal prosecutors charged Amgen with illegally marketing Aranesp for unapproved uses even after the Food and Drug Administration (“FDA”) expressly ruled them out. The federal charges were made public as Amgen pleaded guilty to unlawful marketing of the drug. Physicians are permitted to use drugs for unapproved uses, but companies are not permitted to promote such uses. In recent years, the federal government has collected billions of dollars from drug companies for unlawful off-label marketing to physicians. Amgen agreed to pay \$136 million in criminal fines, a forfeiture of \$14 million, and to pay \$612 million to resolve civil litigation stemming from a number of whistleblower suits.

Prosecutors asserted that Amgen had unlawfully promoted the use of Aranesp to treat anemia in cancer patients who were not undergoing chemotherapy, even though the drug’s approval was only for patients receiving chemotherapy. A study sponsored by Amgen showed that use of Aranesp by those non-chemotherapy cancer patients actually increased the risk of death. Amgen sought approval for use with non-chemotherapy patients, but the FDA rejected that request, reporting that Amgen’s studies were inadequate. Nonetheless, Amgen continued to promote the off-label use with physicians, relying on the same studies the FDA had deemed inadequate.

According to the federal investigation, Amgen sales representatives were trained to elicit questions from doctors about off-label uses as a way to initiate discussion and circumvent the prohibition on off-label use promotion. Those questions would provide the “necessary cover” for sales representatives to provide the doctor with studies supporting the off-label use, according to a document summarizing the charges against Amgen. The drug company also was able to list the unapproved uses in a reference called a compendium. The compendium system is intended to make drugs more easily available to cancer patients. Medicare is required to pay for off-label uses of cancer drugs listed in an approved compendium.

Aranesp was once Amgen’s biggest product, with sales of more than \$4 billion per year. Sales have steadily declined since 2007 because studies have shown that high doses of the drug can lead to blood clots and the worsening of cancer.