CareFusion Pays \$40 Million In Healthcare Fraud Scheme Involving Alleged Payment Of Over \$11 Million In Kickbacks To A Single Doctor

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The Justice Department <u>announced last week</u> that CareFusion Corp, a California-based medical technology company, will pay the government **\$40.1 million to settle whistleblower allegations** of healthcare fraud. The lawsuit claims that CareFusion violated the <u>False Claims Act</u> by paying kickbacks to increase the sale of its pre-surgical skincare product, and promoting the product for uses that were not FDA approved. CareFusion develops, manufactures, and sells pharmaceutical products, including ChloraPrep, the brand name of the pre-surgical skin treatment. According to the FDA, ChloraPrep has only been approved for the preparation of a patient's skin prior to surgery or injection.

In the U.S., medical devices must be approved by the **FDA** before they can be sold to the public. Companies that sell pharmaceuticals or devices, however, often unlawfully promote the use of their products for non-approved, or "off-label," uses to increase profits. This off-label marketing leads to the submission of improper claims to the Medicare and Medicaid systems, which results in fraud. Under the False Claims Act, a whistleblower with information about this type of off-label marketing can bring a lawsuit in the name of the government – known as a qui tam lawsuit – to recover money fraudulently obtained from the government.

According to the lawsuit against CareFusion, the company paid \$11.6 million in kickbacks to a single doctor, Dr. Charles Denham, during his time serving as co-chair of the safe practices committee at the National Quality Forum, a non-profit organization that makes recommendations on healthcare practices. The lawsuit alleges that the purpose of those payments was to persuade Denham to recommend, promote and arrange for the purchase of ChloraPrep by healthcare providers.

The healthcare <u>whistleblower</u> in this case is Dr. Cynthia Kirk, a former vice president of regulatory affairs for the Infection Prevention Business Unit of CareFusion. In her qui tam lawsuit, Dr. Kirk further asserts that during the period between September of 2009 and August of 2011, CareFusion knowingly made unsubstantiated representations about the appropriate uses of ChloraPrep, and endorsed ChloraPrep to potential buyers for uses that were not approved by the FDA. Some of the claims were allegedly not even medically recognized.

Through a qui tam lawsuit, a whistleblower, also known as a "relator", helps the government recover

money that has been paid as a result of fraudulent claims. Federal and state governments have recovered billions of dollars as a result of information provided by qui tam whistleblowers, like Dr. Kirk, in healthcare fraud cases, whether the fraud is committed by hospitals, nursing homes, pharmaceutical companies, device suppliers or physician practices. A healthcare whistleblower who brings a successful qui tam lawsuit usually receives between 15% and 30% of the amount that the government recovers.

Pursuant to the CareFusion settlement, Dr. Kirk will receive \$3.26 million as her qui tam award for bringing her case under the False Claims Act.

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