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Grant & Eisenhofer Represents Whistleblower Accusing Celgene Corp. of Off-Label Marketing of High-Risk Cancer Drugs Derived from Thalidomide

Unsealed federal lawsuit alleges that pharmaceutical giant engaged in unlawful marketing schemes involving blockbuster drugs Thalomid and Revlimid in cancer treatment, costing taxpayers hundreds of millions of dollars; charges of kickbacks to physicians in pushing for unapproved treatments

LOS ANGELES/WASHINGTON (February 6, 2014) – Leading whistleblower law firm **Grant & Eisenhofer P.A.** represents a key whistleblower in a false claims lawsuit unsealed today against one of the nation's largest pharmaceutical companies, **Celgene Corporation** (NASDAQ: CELG) involving charges of off-label marketing of two of its cancer treatment drugs.

The federal suit alleges that Celgene marketed its drugs **Thalomid** and **Revlimid** to cancer patients and their doctors for unapproved purposes, and paid kickbacks to physicians for prescribing the medications. Thalomid is a form of thalidomide, a drug notorious for causing severe birth defects in the 1960s, making the term "thalidomide baby" a shorthand for a generation of birth abnormalities; its usage led Congress to strengthen FDA oversight of pharmaceuticals. The suit alleges that Celgene engaged in unlawful marketing schemes of both Thalomid and Revlimid, costing the U.S. government and state healthcare payors hundreds of millions of dollars.

Filed in U.S. District Court for the Central District of California, the suit, *U.S. ex rel. Beverly Brown v. Celgene Corp.*, was originally filed under seal in 2007. The lawsuit was brought under both federal and state false claims acts, as well as the California Insurance Frauds Prevention Act, which mandate initial filing under seal.

Grant & Eisenhofer is representing **Beverly Brown**, a former top-performing sales representative at Celgene who worked heavily on marketing both Thalomid and Revlimid during her decade-long stint at the company (2001-11).

Ms. Brown's complaint alleges that Celgene preyed on a vulnerable patient population by aggressively marketing highly toxic drugs –Thalomid, and later Revlimid – for high-risk cancer treatments that had not been approved by the FDA. According to the suit, Celgene knowingly concealed the risks of venous thromboembolism and deaths associated with Thalomid use in cancer patients. The suit contends that when Celgene ultimately secured an indication for treatment of multiple myeloma with Thalomid, the approval was conditioned on a black-box warning on the drug's packaging, alerting doctors and patients of the significant risks of venous thromboembolism and fatality.

The suit claims that Celgene violated explicit FDA regulations prohibiting misbranding by promoting Thalomid and Revlimid for off-label use. Celgene is accused of flooding the market with sales representatives under heavy pressure to sell both drugs to oncologists for whatever cancers they were treating, including blood cancers as well as solid tumors, on the basis of minimal evidence. The complaint further alleges that Celgene sales reps encouraged physicians to switch patients from Thalomid to Revlimid, regardless of whether the patients were stable.

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The suit also accuses Celgene of paying kickbacks to physicians to prescribe Thalomid and Revlimid and encourage fellow doctors to prescribe the drugs. As a result of illegally marketing both medications for off-label usage, the lawsuit alleges that Celgene caused federal, state and local government health care programs, as well as private insurers, to pay for millions of prescriptions that never would have been submitted for reimbursement but for Celgene's activities.

The False Claims Act allows private citizens to seek redress in the name of the U.S. government, while a number of states and cities have enacted analogous statutes. The California Insurance Frauds Prevention Act allows whistleblowers to bring claims on behalf of private insurers operating in the state and regulated by the California Insurance Commissioner. In addition to the U.S. government, the case against Celgene seeks redress on behalf of 28 states, the District of Columbia, the City of Chicago and private health insurers in California.

Cases similar to the one against Celgene, including those brought against Abbott, Pfizer and GlaxoSmithKline, have resulted in the return of billions of dollars to government treasuries.

"Celgene's illegal marketing of these two extremely toxic medications, derived from a drug whose improper usage became an infamous lightning rod for pharmaceutical regulation a half-century ago, has jeopardized vulnerable patient populations," said **Reuben Guttman**, Director of the False Claims Litigation Group at Grant & Eisenhofer P.A.

"Honest medical information about treatment options includes direction on appropriate drug regimens," Mr. Guttman added. "Patients ravaged by cancer are among the most vulnerable and often desperate, and put extreme trust in their doctors that their regimens have been approved by the FDA for safety and efficacy. Unfortunately, we believe that this has not been the case in Celgene's promotion of Thalomid and Revlimid. The company consistently bypassed government regulations through its misbranding and marketing these two drugs for off-label usage, putting countless patients at risk, and burdening a health care system."

Grant & Eisenhofer is one of the nation's leading high-impact litigation firms. In the last two years, its False Claims Litigation Group has had unprecedented success representing lead whistleblowers in the government's $1.6 billion settlement with Abbott (2012); its $1.04 billion settlement with GlaxoSmithKline (2012); its $257 million settlement with Pfizer (Wyeth) (2013); and its $24.9 million dollar settlement with Amgen (2013).

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