NOLAN AUERBACH & WHITE

Genentech & OSI Pharmaceuticals Made Misleading Representations to Physicians about Efficacy of Lung Cancer Drug Tarceva, According to Successful Whistleblower Case

Landmark Recovery Signals Next Wave of Whistleblower Cases

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SAN FRANCISCO – **Monday, June 6, 2016** –Whistleblower cases that expose pharmaceutical manufacturers making misleading representations to healthcare providers about the efficacy of their products are vital to the protection of citizens across the United States. Today, these allegations are in the national spotlight, as Nolan Auerbach & White announces the successful resolution of its client's landmark civil False Claims Act case against Genentech and OSI Pharmaceuticals.

This case involved Defendants' prescription drug Tarceva, initially approved in 2004 for the treatment of patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") in the second-line setting. In 2013, the FDA approved Tarceva to treat patients with certain EGFR mutations "first line" - i.e., before the failure of at least one prior chemotherapy regimen. One measure of health status of NSCLC patients may be expressed in terms of performance status ("PS") on the Eastern Cooperative Oncology Group ("ECOG") performance status scale, with the healthiest patients classified as ECOG PS 0 or 1.

The conduct covered under the Settlement Agreement provides the United States contentions that, through Defendants' distribution, marketing, and sale of the prescription drug Tarceva for NSCLC from 2006 through 2011, Defendants made misleading representations to physicians and other health care providers about Tarceva's effectiveness to treat certain NSCLC patients when there was little evidence to show that Tarceva was effective, unless the patients also had an EFGR mutation or unless they had never smoked; and that as a result, Defendants knowingly caused false or fraudulent claims for Tarceva to be submitted to, or caused purchases by, Federal Health Care Programs for Tarceva to treat NSCLC, as a first line of therapy, in current or former smokers classified as ECOG PS 0 or 1 who did not have a known EFGR mutation, when such first-line use was not approved by the FDA, was not a medically accepted indication as defined by applicable law, or was not covered by the United States and state Medicaid programs

To resolve these allegations, Genentech and OSI agreed to collectively pay over **$67 million**, making this False Claims Act settlement the largest pharmaceutical recovery involving allegations of misleading survival data claims.

The *qui tam* case was brought in February 2011 by client Brian Shields, a former Genentech product manager. "Our client was the lone relator behind this important *qui tam* recovery," explained Nolan Auerbach & White partner **Kenneth Nolan**. "As a West Point graduate and an Army helicopter pilot, Brian Shields served our country with distinction and honor. Now, as a successful *qui tam* relator, he continues to live a life of valor."

Mr. Shields's *qui tam* lawsuit alleged that Genentech and OSI supplied healthcare providers with inflated survival data that caused physicians to prescribe their lung cancer drug broadly in the first-line setting, including to patients who did not have a known EGFR mutation.

"Previous pharmaceutical *qui tam* cases have exposed manufacturers that marketed their drugs for unapproved uses," said Nolan Auerbach & White partner and former federal prosecutor **Marcella Auerbach**. "However, in this case, the manufacturers allegedly marketed their lung cancer drug with knowingly inflated survival data. As alleged in the *qui tam* complaint, the end result was a substantial boost in sales—both for the on- and off-label patient populations."

"As the son of a cancer survivor, I take the fight against cancer very seriously," explained successful whistleblower **Brian Shields**. "Sometimes in life you need to stand up and do the right thing, even if an entire corporation and industry may be against you."

The False Claims Act allows private citizens with detailed knowledge of fraud to bring an action on behalf of the government and to assist in the recovery of the government's stolen dollars. The statute allows the government to recover three times the amount it was defrauded, in addition to civil penalties of $5,500 to $11,000 per false claim. Successful whistleblowers can receive between 15 and 30 percent of the governments' recovery.

Defendants will collectively pay the federal government $62,645,000 plus accrued interest to settle the federal False Claims Act allegations. The participating States will receive $4,355,000 plus accrued interest as a result of a Medicaid State settlement. The relator share will be 17%, or over $11 million.

The settlement was achieved through the coordinated efforts of the U.S. Justice Department, state attorneys general and other law enforcement entities including Medicaid Fraud Control Units, and the Office of Inspector General of the U.S. Department of Health and Human Services. The government was represented by an exceptional team of government attorneys, led by Assistant United States Attorney Illa Deiss, U.S. Attorney's Office for the Northern District of California, and Trial Attorney Jennifer Cihon, U.S. Justice Department, Civil Division, Commercial Litigation Branch.

The case is *United States ex rel. Shields v. Genentech, Inc., et al.,* Civil Action CV 11-0822 MEJ (N.D. Cal.). For information about pharmaceutical fraud whistleblower cases, see www.whistleblowerfirm.com.

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