

Abbott Laboratories To Pay \$25 Million To Settle Non-Intervened Whistleblower Lawsuit Alleging that it Illegally Promoted its Cholesterol Drug TriCor and Paid Kickbacks to Prescribing Physicians

PHILADELPHIA, PA - The United States Attorney's Office for the Eastern District of Pennsylvania announced on Friday, October 26, 2018, that global healthcare giant Abbott Laboratories ("Abbott") has executed a settlement agreement and will pay \$25 million to settle a non-intervened whistleblower lawsuit alleging that it illegally promoted its blockbuster cholesterol drug Tricor for off-label uses and paid kickbacks to prescribing physicians.

In September 2009, Amy Bergman, a former Abbott sales representative, filed a *qui tam* whistleblower lawsuit in federal district court before the Honorable C. Darnell Jones, II in Philadelphia alleging that Abbott violated the federal False Claims Act ("FCA") and numerous state false claims laws by:

- **ILLEGALLY PROMOTING TRICOR FOR OFF-LABEL USES SUCH AS COMBINATION THERAPY WITH STATINS AND AS A FIRST-LINE TREATMENT FOR PATIENTS WITH DIABETES; and**
- **VIOLATING THE FEDERAL ANTI-KICKBACK STATUTE BY PAYING KICKBACKS TO PHYSICIANS TO INCENTIVIZE THEM TO PRESCRIBE TRICOR**

In 2012, the United States, and all of the plaintiff states receiving payment from this settlement, declined to intervene in Ms. Bergman's lawsuit. Thereafter, Ms. Bergman and her legal team from Pietragallo Gordon Alfano Bosick & Raspanti, LLP, Nicholson & Eastin, LLP and Kelley/Uustal, continued litigating the case on behalf of federal and state taxpayers, as well as their client on their own. After years of litigation, including robust motion practice, discovery and depositions, they ultimately secured the global \$25 million settlement announced by the government. The federal government will receive \$23.2 million and state Medicaid programs will receive \$1.8 million. Ms. Bergman will receive a relator's share of over \$6,000,000, plus pro rata interest, for her efforts and those of her entire legal team.

The United States Attorney for the Eastern District of Pennsylvania William McSwain said in his press statement:

"We thank Ms. Bergman for coming forward and providing essential assistance to the government. Preserving government program funds would be far more difficult without relators who are willing to shine a spotlight on alleged illegal practices like the ones

involved in this case. Ms. Bergman's efforts, and those of her attorneys, were critical to our favorable resolution of this case."

Marc S. Raspanti, co-lead counsel for Ms. Bergman and founder of the False Claims Act practice at Pietragallo Gordon Alfano Bosick & Raspanti, commented that "Patients deserve to know that their medical professional is making decisions based on their best interests and not because a company is marketing its drugs for unapproved uses or offering incentives to steer patients to specific drugs." Michael Morse, co-lead counsel for Ms. Bergman, commented that "the significant recovery for federal and state taxpayers in this case was the result of Ms. Bergman's courage in stepping forward as well as the tremendous work, over many years, of her entire legal team who handled the case in a non-intervened posture."

The Off-Label Marketing Allegations

Under Food and Drug Administration ("FDA") rules, prescription drug manufacturers and marketers may only promote their products for approved uses. Physicians are free to prescribe drugs for conditions beyond those for which approval has been received but marketing to induce off-label, unapproved use is not permitted.

Ms. Bergman's Complaints alleged that, from 2000 through 2008, Abbott marketed TriCor for purposes not approved by the FDA, and not supported by relevant medical compendia. The alleged off-label uses included the use of Tricor in combination therapy with statins, as a first line treatment in diabetics, and to address cardiac risk factors in diabetics. Medicare, Medicaid and other federally-funded health insurance programs do not cover off-label uses of drugs. Therefore, insurance claims submitted for Tricor for the unapproved uses were not payable by these programs.

The Kickback Allegations

The federal Anti-Kickback Statute ("AKS") and similar state rules prohibit the offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by federally funded programs. The Anti-Kickback Statute is intended to ensure that a physician's medical judgment is not compromised by improper financial incentives and is instead based on the best interests of the patient.

Ms. Bergman's *Qui Tam* Complaints alleged that Abbott increased sales of Tricor by directly and indirectly providing remuneration to prescribing physicians in order to incentivize the physicians for prescribing Tricor. This remuneration included, but was not limited to, gift baskets and certificates and other items of value.

The Legal Team

The settlement announced today by the government was achieved through the significant efforts of Ms. Bergman's whistleblower legal team, including: Marc S. Raspanti, Michael A. Morse, and Pamela Coyle Brecht from Pietragallo Gordon Alfano Bosick and Raspanti, LLP; Robert N. Nicholson and Parker Eastin from Nicholson Eastin, LLP; and John J. Uustal and Cristina M. Pierson from Kelley/Uustal.

Ms. Bergman and her legal team would like to express their appreciation for the efforts by the team of federal and state government supervising lawyers, and, in particular the substantial efforts of Assistant United States Attorney Charlene Keller Fullmer, Deputy Chief of Affirmative Litigation for the United States Attorney's Office for the Eastern District of Pennsylvania, who helped steer this matter to its successful conclusion.

In executing the settlement agreement in this case, Abbott expressly denied liability, wrongdoing, or that it engaged in any improper or illegal conduct. Moreover, Abbott denied all the allegations raised in Ms. Bergman's complaints. The government did not file a complaint.

The lawsuit is styled as *U.S. ex rel. Amy Bergman v. Abbott Laboratories*, Civil Action Civil Action No. 2:09-cv-04264999 (CDJ), which has been pending in the United States District Court for the Eastern Pennsylvania before U.S. District Judge C. Darnell Jones.

A copy of Ms. Bergman's Complaints, along with other pleadings publicly filed in the case, can be found at www.FalseClaimsAct.com or on the Department of Justice's website.

Pietragallo Gordon Alfano Bosick & Raspanti, LLP is a regional litigation law firm with a national client base. In addition to its Pittsburgh and Philadelphia offices, the firm has offices in Sharon, Pennsylvania; Steubenville, Ohio; and Weirton, West Virginia. Lawyers in the nationwide whistleblower practice group of Pietragallo Gordon Alfano Bosick & Raspanti have served for more than 29 years as lead counsel in *qui tam* cases that have recovered over \$2 billion for federal and state taxpayers. For more information, visit our website at www.PIETRAGALLO.com or www.FalseClaimsAct.com.

###