Department of Justice

U.S. Attorney's Office

Eastern District of Pennsylvania

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Abbott Laboratories and AbbVie Inc. to Pay $25 Million to Resolve False Claims Act Allegations of Kickbacks and Off-Label Marketing of the Drug TriCor®

PHILADELPHIA – United States Attorney William M. McSwain announced today that pharmaceutical companies Abbott Laboratories and AbbVie Inc. ("Abbott") will pay $25 million to resolve allegations that it employed kickbacks and unlawful methods of marketing and promotion to induce physicians to prescribe the drug TriCor®.

The settlement resolves allegations that, between 2006 and 2008, Abbott knowingly paid kickbacks to physicians in order to induce TriCor® prescriptions. Abbott, through its sales representatives, allegedly provided physicians with improper gift baskets, gift cards, and other items to induce prescriptions of TriCor®. Abbott also engaged health care providers for consulting services and speaking engagements, where one purpose of the remuneration for the programs was to induce or reward physicians for TriCor® prescriptions.

In addition to the kickback allegations, the settlement also resolves allegations that Abbott engaged in unlawful methods of off-label marketing and promotion relating to the sale of TriCor® for unapproved indications. The FDA-approved indications for TriCor® during this time period were for use, in conjunction with diet, to treat patients with hypertriglyceridemia, mixed dyslipidemia, or hypertriglyceridemia. However, Abbott marketed the drug off-label for: (1) use in treating, preventing, or reducing cardiovascular events and other cardiac health risk; (2) use in combination with statin drugs, and (3) use as a first-line treatment of diabetic patients, including treatment to prevent or reduce cardiac health risks in diabetic patients. These uses were not FDA-approved and were not covered by federal healthcare programs.

"Federal law protects patients from medical providers who write prescriptions so they can enrich themselves, and from drug companies who do not play by the rules in their marketing and promotional efforts," said U.S. Attorney McSwain. "Kickback schemes are a form of illegal pay-to-play business practices that have no place in our health care system; they interfere with physician-patient relationships and drive up the cost of health care. Off-label promotion and marketing practices similarly prioritize drug companies' profits over patient care. We are proud to partner with HHS-OIG to protect the integrity of our health care programs."

"Pharmaceutical companies that ignore rules designed to protect patients will be held accountable. Patients must be able to trust that decisions made by their doctors are based on unbiased professional judgment and not personal gain," said Maureen R. Dixon, Special Agent in Charge of the Office of the Inspector General

for the U.S. Department of Health and Human Services in Philadelphia. “We will continue to work with the U.S. Attorney’s Office in this District to root out all forms of waste, fraud and abuse in our federal health care programs.”

As a result of today’s $25 million settlement, the federal government will receive $23.2 million, and state Medicaid programs will receive $1.8 million.

This settlement resolves allegations in a lawsuit filed in the Eastern District of Pennsylvania by Amy Bergman, a former Abbott sales representative, under the *qui tam*, or whistleblower, provisions of the False Claims Act. The *qui tam* provisions permit private parties to sue for false claims on behalf of the government and to receive a share of any recovery. Ms. Bergman will receive $6.5 million as her share of the recovery in the case.

“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,” said U.S. Attorney McSwain.

This case was a cooperative effort among the U.S. Attorney’s Office for the Eastern District of Pennsylvania, the Civil Division of the Department of Justice, the Office of the Inspector General of the Department of Health and Human Services, and the National Association of Medicaid Fraud Control Units. For the United States Attorney’s Office, Assistant United States Attorney Charlene Keller Fullmer and Auditor Dawn Wiggins handled the investigation and settlement.

The lawsuit is captioned *United States ex rel. Amy Bergman, et al. v. Abbott Laboratories*, Civil Action No. 2:09-cv-04264999 (E.D. Pa.). The claims resolved by the settlement are allegations only; there has been no determination of liability.

Component(s):
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