

New details have emerged regarding GlaxoSmithKline's acts of misconduct which led to a \$3 billion qui tam ("whistleblower") suit. GlaxoSmithKline ("Glaxo" or "GSK") recently agreed to pay \$3 billion to resolve claims that the drug giant unlawfully engaged in off-label marketing of nine prescription drugs. The Glaxo employees who became whistleblowers and helped institute the lawsuit against GSK first reported the evidence of unlawful off-label drug marketing to the company itself. GSK promptly launched an internal investigation which verified their employees' reports. However, instead of taking appropriate action to bring the company back into compliance with the law, Glaxo instead opted to allow the unlawful marketing to continue due to the hefty profits received through improper off-label marketing of the drugs. Those actions also came at the risk of patient safety.

In 2001, two GSK employees reported concerns about illegal marketing practices they learned of while working in the field for the drug company. GSK's lead compliance officer then launched an internal investigation. Rather than acting on the verified reports of unlawful marketing, Glaxo retaliated against the employees. At that point, the employees became whistleblowers and their charges became the basis of an off-label marketing whistleblower complaint against GSK. Details of the unlawful marketing campaign became public when documents were unsealed in connection with the early July 2012 settlement of the case.

Evidence presented in the case revealed the following misconduct by Glaxo:

- Glaxo improperly marketed the asthma drug Advair for mild asthma even though the drug was only approved for treatment of moderate to severe forms of asthma and the drug carried a "black box" warning, an FDA requirement for drugs with the most severe and dangerous potential side effects.
- Glaxo promoted Imitrex, an adult medicine for migraines, for use with children, despite the FDA's rejection of GSK's application for child use.
- Glaxo pushed the antidepressant Paxil for children under 18 even though the drug had not been approved for treatment of youths and despite GSK's own clinical trials showing the drug was ineffective for children and also heightened the risk of suicide and other self-harming behavior three-fold.
- Glaxo marketed its antidepressant Wellbutrin as superior to other antidepressant alternatives due to increased sexual functioning and weight loss, marketing the drug as the "happy, horny, skinny" drug, to capture in a phrase GSK's improper off-label marketing campaign for Wellbutrin.

GSK also paid physicians who could be counted on to recommend off-label drug uses to peers as much as \$25,000 for being a GSK “advisory board” member and added nearly 50,000 healthcare professionals to its “Speaker’s Bureau.” The evidence in the case documents an extensive campaign to market a number of prescription drugs for off-label uses. Doctors are permitted to prescribe drugs for off-label uses, but drug companies are not free to market the drugs for uses that were not approved by the FDA. Federal law also prohibits drug companies from paying kickbacks to physicians to induce prescriptions. Government-funded healthcare programs such as Medicare and Medicaid generally preclude reimbursement for off-label prescriptions.

The case was pursued under the False Claims Act which allows for whistleblower suits to be brought by private citizens with knowledge of fraud to help the government recover money out of which it was defrauded. The False Claims Act allows for civil penalties ranging from \$5,500 to \$11,000 per false claim, as well as an award to a whistleblower (“the relator’s share”) which is generally 15–25 percent of the amount recovered through the qui tam suit.