GlaxoSmithKline’s (“GSK”) $3 Billion Whistleblower Settlement Has Paid for One Of America’s Most Expensive Failed Corporate Internal Investigations, Qui Tam Whistleblowers’ Attorneys Say

Philadelphia, July 2, 2012 – GlaxoSmithKline has just paid for one of the most expensive failed internal investigations in corporate history, qui tam whistleblower attorney Brian Kenney said today. His law firm, Kenny & McCafferty, P.C., represents the two whistleblowers who sparked the nine-year federal probe that ended with today’s $3 billion payment to settle off-label drug marketing allegations involving nine prescription drugs and allegations of best price violations.

“When our clients were forced out of their marketing positions, GlaxoSmithKline (“GSK”) had proof of illegal off-label prescription drug marketing. Our clients properly reported those marketing misdeeds to management in 2001. An ensuing GSK internal investigation verified their allegations, but the company took no action, choosing hefty profits over compliance and patient safety,” said whistleblower attorney Tavy Deming of Kenney & McCafferty.

“GSK could have saved hundreds of millions, perhaps a billion or more dollars of the $3 billion it paid today by following through on the combined Human Resources /Corporate Compliance investigation they launched. Instead they ignored evidence of improper marketing and physician kickbacks. When you look at the detail and accuracy of Greg Thorpe’s written complaints distributed to the highest levels of Glaxo (See “Document Links” Below) it’s almost surreal that the company took no corrective action. Now more than a decade later, GSK is essentially admitting that Thorpe had been right in 2001,” Kenney said. “It’s been a very, very, very long 10 years for whistleblowers Thorpe and Blair Hamrick.”

GSK’s top management was aware of illegal marketing schemes involving the drugs, according to filed court documents. When the two Kenney & McCafferty-represented whistleblowers reported their concerns about illegal marketing practices they were witnessing in the field, GSK’s top compliance executive, an attorney who now holds a similar position with another medical device manufacturer, became involved in and oversaw the ensuing internal investigation.

Instead of changing the illegal conduct, the Company retaliated against the whistleblowers and they became the first to file an off-label marketing qui tam whistleblower Complaint against GSK. The original Complaint is one of the first ever filed alleging prescription drug off-label promotion, Kenney said

When the whistleblowers’ Complaints were still under seal and being investigated by the government GSK allegedly falsified and concealed documents in connection with an FDA inquiry into whether GSK marketed the antidepressant drug Wellbutrin off-label for weight loss, a central allegation in the whistleblowers’ Complaints. That led to the indictment of a GSK associate corporate counsel,
said Deming. Federal charges against the former associate general counsel later were subsequently dismissed by the court. (U.S. v. Lauren Stevens, C.A. No 10-0694 District of Maryland.

Thorpe and Hamrick provided first-hand revelations of GSK’s pervasive marketing misconduct relating to the nine drugs identified in Kenney & McCafferty’s Complaint (See “Document Links” Below) and Exhibits (See “Document Links” Below) unsealed with today’s settlement. According to Emily Lambert of Kenney & McCafferty, the Government joined the whistleblowers’ case and filed a Complaint-in-Intervention adopting the whistleblower’s claims. (See “Document Links” Below).

Extremely persuasive proof exposing illegal marketing of the asthma drug Advair for mild asthma was included in the insider evidence that Thorpe and Hamrick provided to Government investigators, Deming said. GSK’s mild asthma marketing campaign contravened Advair’s approved asthma use, which was limited to moderate and severe forms of asthma, and a black box warning on the drug’s label, yet GSK’s marketing efforts continued unabated into 2010. As a result, Advair’s portion of taxpayers’ recovery represents nearly 70 percent of the Government’s total $1.017 billion civil settlement of our clients’ claims, Lambert added.

The nine prescription drugs covered by the settlement included Advair, Wellbutrin, Paxil, Lamictal, Zofran, Imitrex, Lotronex, Flovent and Valtrex.

GSK maintained an elaborate illegal marketing regime for the prescription drugs included in today’s settlement, including, according to filed documents:

- Paying physicians (who could be counted on to influence their peers) as much as $25,000 for being a GSK “advisory board” member;
- Enrolling 49,000 physicians and health professionals to be part of its speakers bureau;
- Identifying physicians in academia to pay to speak on behalf of one of the company’s drugs;
- Creating the PowerPoint “slide kits” that physicians would use to deliver canned presentations;
- Using an elaborate “FaxBack” system allowing drug marketing reps to suggest articles related to off-label uses. The physicians would order these off-label promotional materials by calling a toll-free number, and thus not appear to be responding to an illegal marketing effort by the drug marketing representative;
- Pushing Imitrex, an adult medicine for migraine, for mild headaches, as well as for use in children, despite the FDA’s rejection of GSK’s application for child use due to lack of efficacy;
Pushing Lamictal, a drug approved only for partial seizures, in adults for other diagnoses. In at least one case a patient died from a reaction that the company had evidence could occur;

Marketing Paxil, the antidepressant, to children under 18 when it had not been approved for youngsters, and despite GSK’s own clinical trails that had shown that the drug was ineffective for children and also heightened the risk of suicide or other self-harming behavior three-fold; and,

Marketing the antidepressant Wellbutrin as superior to other antidepressant alternatives due to increased sexual functioning and weight loss, pushing the drug as the “happy, horny, skinny drug,” to concisely encapsulate GSK’s off-label Wellbutrin marketing campaign.

Physicians are free to prescribe drugs for off-label uses, but pharmaceutical companies are prohibited from marketing the drugs for uses that have not been approved by the FDA. Federal laws also prohibit pharmaceutical companies from paying kickbacks to physicians to induce prescriptions. Generally, government-funded healthcare programs such as Medicare and Medicaid preclude reimbursement for off-label prescriptions. When a pharmaceutical company’s illegal marketing practices cause off-label prescriptions to be written by doctors, and those prescriptions are paid for by Medicare and Medicaid, the payment becomes an actionable False Claims Act (“FCA”) violation, according to Kenney, who is a former federal prosecutor.

Under the FCA, *qui tam* actions allow private citizens with knowledge of fraud to help the Government recover ill-gotten gains and additional civil penalties. The FCA allows the Government to collect up to three times the amount it was defrauded, in addition to civil penalties from $5,500 to $11,000 per false claim.

In successful *qui tam* whistleblower cases in which the Government intervenes, whistleblowers are entitled to receive a percentage of *qui tam* recoveries, typically 15-to-25 percent, generally known as, “the relator’s share.”

Under the terms of the settlement agreement, the Government and the whistleblowers did not concede that their respective claims are not well founded. In turn, as is typical in civil agreements, GSK expressly denied liability, except for those admissions GSK agreed to make in connection with connection with a criminal Plea Agreement. Specifically, according to the agreement, GSK has agreed to plead guilty to criminal charges that the company misbranded Wellbutrin and Paxil and it failed to report data relating to clinical experience, along with other data and information regarding the diabetes drug Avandia to the Food and Drug Administration (“FDA”) in mandatory reports, all in violation of the Food, Drug and Cosmetic Act (“FDCA”).

In addition to paying a $1.042 billion civil settlement to the federal and state Governments, as part of the Settlement Agreement GSK agreed to be bound by
a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS").

The federal investigation into GSK’s marketing practices was conducted through a collaborative effort of the U.S. Department of Justice, and the U.S. Attorney’s Offices for the District of Massachusetts and the District of Colorado. Massachusetts Assistant Attorney General Bob Patten led the investigation on behalf of the states and the National Association of Medicaid Fraud Control Units ("NAMFCU").

Civ. No.: 11-10398 (D.Mass)

About Kenney & McCafferty, P.C.:

Kenney & McCafferty, PC is the one of the most successful national law firms specializing in representing qui tam, tax, and SEC whistleblowers. Kenney & McCafferty’s qui tam lawsuits have resulted in cases in which more than $5 billion in civil and criminal fines and penalties have been recovered for federal and state Governments, resulting in the payment of hundreds of millions of dollars in whistleblower rewards.

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Document Links:  
Call the attorneys to obtain at-once copies of these documents. For not-breaking access, as they become available, filed documents can be accessed via the “GSK” link on the quitam-lawyer.com homepage “Cases Over $100 Million.”  

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