GlaxoSmithKline fined \$3bn after bribing doctors to increase drugs sales Sales reps in the US encouraged to mis-sell antidepressants Paxil and Wellbutrin and asthma treatment Advair

Simon Neville Tue 3 Jul 2012

The pharmaceutical group <u>GlaxoSmithKline</u> has been fined \$3bn (£1.9bn) after admitting bribing doctors and encouraging the prescription of unsuitable antidepressants to children. Glaxo is also expected to admit failing to report safety problems with the diabetes drug Avandia in a district court in Boston on Thursday.

The company encouraged sales reps in the US to mis-sell three drugs to doctors and lavished hospitality and kickbacks on those who agreed to write extra prescriptions, including trips to resorts in Bermuda, Jamaica and California.

The company admitted corporate misconduct over the antidepressants Paxil and Wellbutrin and asthma drug Advair.

Psychiatrists and their partners were flown to five-star hotels, on all-expenses-paid trips where speakers, paid up to \$2,500 to attend, gave presentations on the drugs. They could enjoy diving, golf, fishing and other extra activities arranged by the company.

GSK also paid for articles on its drugs to appear in medical journals and "independent" doctors were hired by the company to promote the treatments, according to court documents.

Paxil – which was only approved for adults – was promoted as suitable for children and teenagers by the company despite trials that showed it was ineffective, according to prosecutors.

Children and teenagers are only treated with antidepressants in exceptional circumstances due to an increased risk of suicide.

GSK held eight lavish three-day events in 2000 and 2001 at hotels in Puerto Rico, Hawaii and Palm Springs, California, to promote the drug to doctors for unapproved use.

Those who attended were given \$750, free board and lodging and access to activities including snorkelling, golf, deep-sea fishing, rafting, glass-bottomed boat rides, hot-air balloon rides and, on one trip, a tour of the Bacardi rum distillery, all paid for by GSK.

Air fares were also covered for doctors and spouses, in most cases, and speakers at the event were paid \$2,500 each.

Before one event, the compere said: "We have a wonderful and unforgettable night planned. Without giving it all away, I can tell you – you'll be experiencing a taste of luxury."

Not everyone was impressed, though. One psychiatrist complained: "The style of the conference would have been suitable for a convention of cosmetics sales reps; this is supposed to be a scientific meeting. To me, the music, lights, videos, emcees are offputting and a distraction, even demeaning."

GSK also published an article in a medical journal that mis-stated the drug's safety for children, despite the journal asking several times to change the wording.

Copies of the misleading article were given to sales representatives to pass on to doctors in the hope that it would secure more business. Tickets to sports matches were exchanged for discussions about Paxil, with one doctor writing: "Dinner and a Yankee game with family. Talked about Paxil studies in children."

Despite knowing that three trials had failed to prove its effectiveness on children, Glaxo published a report entitled "Positioning Paxil in the adolescent depression market – getting a headstart".

The second drug to be mis-sold was Wellbutrin – another antidepressant aimed only at adults.

The prosecution said the company paid \$275,000 to Dr Drew Pinsky, who hosted a popular radio show, to promote the drug on his programme, in particular for unapproved uses – GSK claimed it could treat weight gain, sexual dysfunction, ADHD and bulimia.

Pinsky, who had not declared his GSK income to listeners, said Wellbutrin could give women 60 orgasms a night. A study of 25 people using the drug for eight weeks was pushed by a PR firm hired by GSK, generating headlines including "Bigger than Viagra? It sounds too good to be true: a drug to help you stop smoking, stay happy and lose weight" and "Now That is a Wonder Drug".

When a GSK-funded doctor refused to remove safety concerns about the drug from an article he was writing, GSK removed his funding.

The investigation also found that sales representatives set up "Operation Hustle" to promote the drug to doctors, including trips to Jamaica, Bermuda and one talk coinciding with the annual Boston Tall Ships flotilla.

Speakers were paid up to \$2,500 for a one-hour presentation – up to three times a day – earning far more than they did working in their surgeries.

One speaker, Dr James Pradko, was paid nearly \$1.5m by GSK over three years to speak about the drug. He also produced a DVD funded by the company, which was claimed to be independent. It was shown more than 900 times to doctors.

The hope was that doctors would be persuaded to prescribe the drug to patients over its rivals.

The last drug under scrutiny was Advair, GSK's bestselling asthmatreatment.

The drug was launched to sales representatives in Las Vegas using images of slot machines, emphasising the bonuses they could make through sales. At the event, the then chief executive, Jean-Pierre Garnier, said: "What is the number one reason why you should love to be a GSK sales rep? Advair's bonus plan. Yeah!"

The company pushed the drug as the ultimate answer for tackling asthma, saying it should be the drug of choice for treating all cases. However, it had been approved only for treating severe cases, as other drugs were more suitable for mild asthma. GSK published material calling mild asthma a "myth" in an attempt to boost sales, according to the prosecution.

About \$600,000 a year was given to district sales representatives for entertainment, including regular golf lessons, Nascar racing days, fishing trips, and baseball and basketball tickets.

US attorney Carmin Ortiz said: "The sales force bribed physicians to prescribe GSK products using every imaginable form of high-priced entertainment, from Hawaiian vacations [and] paying doctors millions of dollars to go on speaking tours, to tickets to Madonna concerts."

GSK chief executive Andrew Witty said: "Whilst these [matters] originate in a different era for the company, they cannot and will not be ignored. On behalf of GlaxoSmithKline I want to express our regret and reiterate that we have learnt from the mistakes that were made."

Despite the large fine, \$3bn is far less than the profits made from the drugs. Avandia has made \$10.4bn in sales, Paxil took \$11.6bn, and Wellbutrin sales were \$5.9bn during the years covered by the settlement, according to IMS Health, a data group that consults for drug makers.