United States Attorney's Office
Southern District of New York

PRESS RELEASE

Manhattan U.S. Attorney Announces $54 Million Settlement Against Salix Pharmaceuticals For Using "Speaker Programs" As Mechanism To Pay Illegal Kickbacks To Doctors To Induce Them To Prescribe Salix Products

Thursday, June 9, 2016

For Immediate Release

U.S. Attorney's Office, Southern District of New York

Salix Admits to Paying Doctors to Serve as "Speakers" at Programs that Were Primarily Social in Nature and Where the "Speakers" Spent Little or No Time Discussing the Relevant Salix Product

Preet Bharara, the United States Attorney for the Southern District of New York, Scott J. Lampert, Special Agent in Charge of the U.S. Department of Health and Human Services, Office of Inspector General's New York Region ("HHS-OIG"), and Diego Rodriguez, Assistant Director-in-Charge of the New York Field Office of the Federal Bureau of Investigation ("FBI"), announced today a $54 million settlement in a civil fraud lawsuit against SALIX PHARMACEUTICALS, INC. ("SALIX"), a specialty pharmaceutical company based in Raleigh, North Carolina, that sells products used to treat various gastroenterology conditions. The settlement resolves claims that SALIX violated the federal Anti-Kickback Statute and False Claims Act by using its "speaker programs" as a mechanism to pay kickbacks to doctors to induce them to prescribe SALIX drugs and medical devices that were reimbursed by federal health care programs. Specifically, the United States' Complaint-in-Intervention alleges that SALIX held sham speaker programs, frequently at high-end restaurants, where doctors were paid substantial honoraria purportedly to educate other doctors about a Salix product, but in reality spent little or no time discussing the product. The settlement will also resolve numerous state law civil fraud claims.

Today, U.S. District Court Judge Denise L. Cote approved a settlement stipulation to resolve the Government's claims against SALIX. Under the settlement, SALIX is required to pay approximately $46.53 million to the United States and has made extensive admissions regarding its conduct. Further, as part of the settlement, SALIX will pay approximately $7.47 million to resolve the state law civil fraud claims.

Manhattan U.S. Attorney Preet Bharara said: "For years, Salix Pharmaceuticals unlawfully sought to increase prescriptions of its products by using its 'speaker programs' as a vehicle to pay kickbacks to doctors. Through these 'speaker programs,' which were frequently nothing more than social gatherings with little or no educational component, Salix found a way to pay doctors money and treated them to fancy meals to push their drugs. With today's settlement, Salix has taken responsibility for its conduct and agreed to pay a significant financial penalty. This action and settlement is part of our continuing effort to pursue health care providers who put their profits ahead of patient safety."

HHS-OIG Special Agent in Charge Scott J. Lampert said: "When Salix Pharmaceuticals paid doctors large sums of money to speak at programs that were primarily social events, the goal was to induce the doctors to prescribe Salix products and enhance the company's bottom line. We will continue to investigate such illegal arrangements that undermine impartial medical judgment and place company interests above those of patients."

FBI Assistant Director-in-Charge Diego Rodriguez said: "Salix used high priced meals at swanky restaurants to get doctors to push its products. Whether those doctors actually prescribed those medications, the simple idea behind the pitch eats away at the faith patients have in their doctors to put their health and wellbeing above the interests of a corporation. The FBI and our partners will do all that we can to keep these practices from doing more harm than good."

As alleged in the Complaint-in-Intervention filed in Manhattan federal court:

During the period January 2009 through December 2013 (the "Covered Period"), many of SALIX's speaker programs for Xifaxan, Apriso, Relistor, MoviPrep, OsmoPrep, Solesta, and Deflux (the "Covered Products") were nothing more than social events at which SALIX wined and dined doctors to induce them to write prescriptions for these products. These speaker programs included both in-person events (at which both the speaker and the attendees were present in person and the speaker was paid to provide an educational talk on a Covered Product to the attendees using a slide presentation), as well as pre-recorded events (at which a SALIX employee was supposed to use a laptop or other device to play for the attendees a pre-recorded video of a doctor delivering a slide presentation, and then call the paid speaker, who was to be available to answer any questions by telephone).

The speaker programs, which were typically held in restaurants, were supposed to be educational in nature and the cost of the meal was supposed to be modest. But in practice, SALIX held many speaker programs that were primarily social in nature, including events where it repeatedly invited the same doctors, who frequently were from the same practice or otherwise knew each other, to attend the same exact program on the same exact topic. With respect to the pre-recorded programs – which SALIX personnel internally referred to as "doc-in-the-box programs" – the pre-recorded video frequently was not played or was intentionally played in a manner so it could be ignored. SALIX also held many speaker programs at very expensive, high-end restaurants.

The doctors whom SALIX paid to be speakers and whom SALIX invited to its events were often the high prescribers of its products or were viewed as having the potential to be high prescribers. Many of these doctors increased their prescription-writing for the Covered Products after becoming speakers and/or repeatedly attending sham speaker programs. During the Covered Period, SALIX spent approximately $25 million on speaker payments and meals.

As part of the settlement, SALIX admitted, acknowledged, and accepted responsibility for the following conduct:

- Throughout the Covered Period, speaker programs were an important part of SALIX's strategy for increasing sales of the Covered Products.SALIX conducted approximately 10,000 speaker programs for the Covered Products, including approximately 8,000 programs alone for Xifaxan, Apriso, and Relistor.

- Speaker honoraria payments for a program ranged from $250 (for a doctor available on call to answer questions associated with a pre-recorded program) to $4,500 (for a doctor who spoke at an in-person program and had a specified level of experience and certain credentials).During the Covered Period, SALIX paid over 500 physicians honoraria for serving as speakers on the Covered Products, with dozens of physicians earning more than $50,000, and several earning more than $100,000.

- Throughout the Covered Period, SALIX did not have effective mechanisms in place to monitor adequately its speaker programs to ensure compliance with internal policies. For example, there were no effective mechanisms in place to audit speaker programs and insufficient efforts were made to review data and other information on speaker programs to ensure compliance with the company's internal policies.

- Throughout the Covered Period, numerous SALIX employees held speaker programs for the Covered Products that were primarily social in nature and/or otherwise did not comply with the company's internal policies.For example, there were programs where:

  - the designated speaker spent little or no time discussing the Covered Product;

  - the required slide presentation was not shown in its entirety or not at all;

  - doctors attended multiple programs on the same topic (at which the same slide presentation was supposed to have been shown) within a short period of time;

  - the programs were held in the main dining rooms of restaurants or other locations that were not conducive to an educational program;

  - the programs were held at high-end restaurants (such as Nobu and Le Bernardin in New York City), with per-person costs exceeding $200 and even $300;

  - the SALIX sales representative responsible for a program reported that certain physicians had attended the event even though they had not, in order to make the per-person cost of the event appear lower than it actually was;

  - attendees included individuals other than healthcare professionals with a legitimate interest in the scheduled topic, such as a physician's spouse; and/or

  - the programs were used as an opportunity to provide a physician's practice (in some cases including administrative staff) with a meal or a happy hour.

- Additionally, with respect to the pre-recorded speaker programs, there were numerous instances where:(1) the SALIX sales representative did not play the pre-recorded presentation; (2) the SALIX sales representative played the pre-recorded presentation but placed the laptop or other viewing device in a location where it could not readily be seen or at a volume at which it could not readily be heard; and/or (3) the designated approved speaker was not called at the end of the pre-recorded presentation but still received an honorarium payment.

In connection with the filing of the lawsuit and settlement, the Government joined two private whistleblower lawsuits that had previously been filed under seal pursuant to the False Claims Act.

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Mr. Bharara thanked HHS's Office of the Inspector General, the FBI, and the Medicaid Fraud Control Units for Ohio and New York for their investigative efforts and assistance with the case.

The case is being handled by the Office's Civil Frauds Unit. Assistant U.S. Attorneys Jeffrey K. Powell and Christopher B. Harwood are in charge of the case.

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HEALTHCARE FRAUD

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