Department of Justice

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PHARMACEUTICAL MANUFACTURER DAIICHI-SANKYO TO PAY $39 MILLION TO RESOLVE ALLEGATIONS THAT IT PAID KICKBACKS TO PHYSICIANS

Boston – Daiichi Sankyo, Inc., a global pharmaceutical company with its U.S. headquarters in New Jersey, has agreed to pay the United States and state Medicaid programs $39 million to resolve allegations that it violated the False Claims Act by using lavish meals and speaker program honoraria as kickback vehicles to induce physicians to prescribe the drugs Azor, Benicar, Tribenzor, and Welchol.

"Drug companies are prohibited from using lavish entertainment and padded speaker program payments to induce physicians to prescribe their drugs for beneficiaries of federal health care programs," said Carmen M. Ortiz, U.S. Attorney for the District of Massachusetts. "Settlements like this one show that the government will continue to pursue health care companies that use kickbacks to promote their products."

The settlement resolves allegations that Daiichi caused the submission of false claims for Azor, Benicar, Tribenzor, and Welchol. The claims were false because they resulted from kickbacks that Daiichi provided to physicians who prescribed the drugs. Specifically, it is alleged that Daiichi's kickbacks took the form of honoraria payments, meals and other remuneration to physicians who participated, or supposedly participated, in Physician Opinion & Discussion programs (PODs) from Jan. 1, 2005, through March 31, 2011, and other speaker programs from Jan. 1, 2004, through Feb. 4, 2011. The United States contends that the honoraria, meals and other remuneration were kickbacks because Daiichi paid physicians who participated in the speaker programs even if, among other things: (1) the honoraria recipient spoke only to members of his or her own staff in his or her own office; (2) the physician participants in PODs took turns accepting a "speaker" honoraria for duplicative discussions; (3) the audience included the honoraria recipient's spouse; (4) the honoraria recipient did not speak at all because the event was cancelled beforehand; and/or (5) the associated dinners were lavish and at times even exceeded Daiichi's own internal cost limitations of $140 per person.

"The Anti-Kickback Statute prohibits payments intended to influence a physician's ordering or prescribing decisions," said Acting Assistant Attorney General Joyce R. Branda for the Department of Justice's Civil Division. "The Department of Justice is committed to preserving the independence and objectivity of those decisions, which is a cornerstone of our public health programs."

"This settlement is evidence of the continuing efforts of the Defense Criminal Investigative Service and our law enforcement partners to protect medical beneficiaries and assure integrity within the pharmaceutical industry," said Craig W. Rupert, Special Agent in Charge of the DCIS Northeast Field Office, the investigative arm of the Office of the Inspector General, Department of Defense. "The Department of Defense purchases substantial quantities of pharmaceuticals and is affected by fraud schemes within this industry. DCIS will continue to aggressively pursue allegations of fraud and corruption harmful to U.S. taxpayers and the Department."

"It is vital to veterans receiving care at the VA that they are prescribed safe and effective medications for the sole purpose of healing their ailments," said Special Agent in Charge Jeffrey Hughes. "The VA Office of Inspector General will continue to work with our partners in the law enforcement community to ensure that is the case."

"Schemes such as this are particularly abhorrent," said Inspector General Daniel R. Levinson for the U.S. Department of Health and Human Services. "Manufacturers and physicians who engage in them are cheating Medicare and Medicaid out of millions of dollars and threatening programs upon which many elderly and disabled Americans rely. My office will take whatever steps necessary to guard against improper alliances between manufacturers of drugs and those who prescribe them. Through our Corporate Integrity Agreement we will be closely monitoring Daiichi."

"This settlement is another example of the FBI's commitment to ensure those who refuse to play by the rules and provide illegal incentives to influence the decision-making of health care providers are held accountable," said Vincent B. Lisi, Special Agent in Charge of the FBI's Boston Division."

The Anti-Kickback Statute was enacted to ensure that physicians' medical judgment is not compromised by improper payments or gifts. The statute generally prohibits anyone from offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by federal health care programs, including Medicare and Medicaid.

As part of the settlement, Daiichi has agreed to enter into a Corporate Integrity Agreement with the Department of Health and Human Services, Office of Inspector General (HHS-OIG), which obligates Daiichi to undertake substantial internal compliance reforms for the next five years.

The settlement announced today stems from a complaint filed by Kathy Fragoules, a former Daiichi sales representative, under the whistleblower provisions of the False Claims Act, which authorize private parties to sue on behalf of the United States, and to receive a portion of any recovery. Ms. Fragoules will receive $6.1 million of the federal recovery.

This matter was investigated by the Department of Defense Criminal Investigative Service; the Department of Veterans Affairs, Office of the Inspector General; HHS-OIG; and the Federal Bureau of Investigation. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro, Lisa Asiaf, and Giselle Joffre of Ortiz' office; Department of Justice Trial Attorney Douglas Rosenthal; Zachary Cunha, currently an Assistant U.S. Attorney in the District of Rhode Island; and Kimberly Friday, currently an Assistant U.S. Attorney in the Northern District of California.

The case is captioned *U.S. ex rel. Fragoules v. Daiichi Sankyo, Inc.*, Civil Action No. 10-10420 (D. Mass.).

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