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Department of Justice

U.S. Attorney's Office

District of Massachusetts

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Sanofi Agrees to Pay \$11.85 Million to Resolve Allegations That it Paid Kickbacks Through a Co-Pay Assistance Foundation

BOSTON – The U.S. Attorney's Office announced today that pharmaceutical company Sanofi-Aventis U.S., LLC ("Sanofi"), has agreed to pay \$11.85 million to resolve allegations that it violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation, The Assistance Fund ("TAF").

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively "co-pays"). These co-pay obligations may be substantial for expensive medications. Congress included co-pay requirements in the Medicare program, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs.

Sanofi sells Lemtrada, a multiple sclerosis drug that costs nearly \$100,000 per patient per year. Medicare co-pays for Lemtrada can be many thousands of dollars per year. The cost of the drug often presents significant barriers to access for Medicare patients.

The government alleged that TAF, an entity claiming 501(c)(3) status for tax purposes, operates funds, including a fund for MS patients, that pay the co-pays of certain patients, including Medicare patients, who were prescribed Lemtrada. TAF allegedly raised its maximum per-patient grant allocation to \$20,000 specifically to accommodate Lemtrada patients. During the relevant time period, TAF's MS fund frequently ran out of funding and was closed to new patients. If any patients applied for co-pay assistance at a time when the MS fund was out of funding and closed to new patients, TAF did not maintain a wait list of such patients. As a consequence, whenever TAF's MS fund opened to new patients, the fund provided grants to the patients who applied immediately after the opening and did not provide grants to patients who had sought to apply earlier but at a time when the fund was closed.

The United States further alleged that Sanofi made payments to TAF not with a charitable purpose but rather with the intention of using TAF as a conduit to pay the financial obligations, including Medicare co-pay obligations, of patients taking Lemtrada, and that Sanofi's payment through TAF of Medicare co-pays for Lemtrada violated the Anti-Kickback Statute. To effectuate its scheme, Sanofi worked with its third-party reimbursement hub to identify Medicare patients for whom physicians had prescribed Lemtrada, but who had not yet received infusions of the drug because they lacked sufficient funds to afford the co-pays for Lemtrada. Sanofi made nine payments to TAF

during 2015 and 2016. At the times Sanofi made eight of these nine payments, TAF's MS fund had run out of funding, and was closed to new patients. In conjunction with its payments to TAF, and knowing that TAF's MS fund did not maintain wait lists and would fund the first patients who applied for assistance after the fund received new funding, Sanofi instructed its hub quickly to refer as many Lemtrada patients as possible to the TAF MS fund. As a result, when TAF's MS fund opened with funding from Sanofi, Lemtrada patients received a disproportionately large share of the Medicare co-pay grants TAF issued and patients taking MS drugs other than Lemtrada received a disproportionately small share of the Medicare co-pay grants TAF issued.

"According to the allegations in today's settlement agreement, Sanofi used a supposed charity as a conduit to funnel money to patients taking Sanofi's very expensive drug, all at the expense of the Medicare program," said United States Attorney Andrew E. Lelling. "This office will continue to pursue drug companies for violations of the anti-kickback laws. We commend Sanofi for swiftly resolving the government's allegations."

"Sanofi sought to undermine the Medicare program through its use of kickbacks disguised as routine charitable donations aimed at helping patients battling multiple sclerosis and who were struggling with costly copays," said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division. "They rigged the system so those taking its drug Lemtrada gained an unfair advantage over patients using other medications, and with today's settlement, they are finally being held accountable for their actions."

Sanofi has also entered into a corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA requires, among other things, that Sanofi implement measures designed to ensure that arrangements and interactions with third-party patient assistance programs are compliant with the law. In addition, the CIA requires reviews by an independent review organization, and compliance-related certifications from company executives and Board members.

A limited liability partnership formed by a former employee of Sanofi's predecessor, Genzyme Corporation, brought these allegations through a whistleblower lawsuit. Under the *qui tam* provisions of the False Claims Act, private individuals, known as relators, can sue on behalf of the government for false claims and share in any recovery. In connection with today's announced settlement, the partnership will receive approximately \$2.7 million of the recovery.

U.S. Attorney Lelling, HHS-OIG Chief Counsel Demske and FBI SAC Joseph Bonavolonta made the announcement today. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Evan Panich of Lelling's Office, with assistance from Kelley Hauser, Trial Attorney with Department of Justice's Civil Division.

Topic(s):

Health Care Fraud

Component(s):

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