Former Sales Manager Files Whistleblower Complaint Against Novartis

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Justice Department, 10 states join lawsuit alleging pharmaceutical giant ran massive kickback scheme with multiple pharmacies to boost sales of its patented drugs despite known side effects

WASHINGTON, D.C. (Feb. 10, 2014)—A former Novartis sales manager has filed a whistleblower complaint alleging that the pharmaceutical giant engaged in a massive kickback scheme to unlawfully induce CVS Caremark and other pharmacies to increase sales of five of its patented drugs, even as patients reported serious side effects from the drugs.

In the complaint filed Jan. 30 in federal court in Manhattan, David Kester alleges that Novartis used the kickback scheme to spur specialty pharmacies to boost sales of cancer medicines Exjade, Gleevec and Tasigna; the organ transplant drug Myfortic; and the cystic fibrosis drug TOBI. Kester claims the arrangements between Novartis and these specialty pharmacies violated the federal anti-kickback law, and that Medicare and Medicaid paid out hundreds of millions of dollars that they wouldn't have paid out had they known of the secret inducements. Medicare and Medicaid do not cover drug sales that result from violations of the anti-kickback law.

The lawsuit – which Kester originally filed under seal in 2011 – names pharmacies CVS Caremark, Accredo, Bioscrip and Curascript as participants in the alleged scheme. The U.S. Justice Department has joined in some of Kester's claims against Novartis related to sales of Exjade and Myfortic, and 10 states have joined claims based on Exjade.

Kester was employed for seven years as an account manager for Novartis, where his responsibilities included marketing the cystic fibrosis drug TOBI to clinics and physicians. He resigned from the company in April 2013 while his case was pending under seal. The case was unsealed in January 2014.

Kester's new complaint signals the claims on which he will proceed independently of the government, including claims based on Novartis' misconduct relating to TOBI and the targeted oncology drugs Gleevec and Tasigna. In 2013, the two cancer drugs had combined sales of more than $2.3 billion, with government programs accounting for more than 40 percent of Novartis' U.S. sales.

In April 2013, the New York Times reported that many cancer specialists have criticized Novartis and other pharmaceutical companies for "astronomical, unsustainable and perhaps even immoral prices" of drugs such as Gleevec and Tasigna. Like Exjade and Myfortic, Tasigna's label carries a black-box warning – the FDA's most serious warning – advising of the risk of fatal complications.

Alleged pharmacy kickback scheme

In the lawsuit, Kester alleges that Novartis agreed to pay special rebates and increase patient referrals to the participating pharmacies. In exchange, according to the complaint, the pharmacies agreed to set up special "High Touch Nurse Programs" that purported to provide unbiased "education" and "counseling" to patients about their medication regimen, or undertake other initiatives to start patients on Novartis's products. The lawsuit alleges, however, that the true purpose of these programs was simply to increase orders and refills of Novartis drugs in order to maximize profits.

> *"Our client's goal in filing this case is to protect patients from receiving tainted advice from pharmacies," said Shelley R. Slade of Vogel, Slade & Goldstein, LLP, which filed the complaint along with co-counsel Susman Godfrey LLP. "When patients ask a question at a pharmacy, they should feel confident that the answer they receive is both honest and coming from a trained professional – be it a pharmacist, nurse or pharmacy technician."*

Kester's complaint alleges that certain "High Touch Nurse Program" personnel contacting patients were no more than "call center" employees without the clinical skills needed to counsel patients. He also claims Novartis employees boasted that the "High Touch Nurse Program" was successful in keeping patients on the iron-chelating drug Exjade, even when the patients were experiencing side effects. Exjade's adverse effects can be so serious that in 2010 the FDA required the product label to include a boxed warning indicating that certain of these effects can be "fatal," and recommending "close patient monitoring."

Justice Department and 10 States join lawsuit

In April 2013, the United States joined certain of Kester's claims relating to the transplant drug Myfortic. The lawsuit alleges that the illegal kickback scheme led specialty pharmacies to sacrifice their professional independence and work to convert patients to Myfortic from competing drugs, without disclosing to patients and physicians that the pharmacies secretly were being paid by Novartis.

In January 2014, the U.S. Justice Department and 10 states filed additional complaints against Novartis in Kester's lawsuit, asserting that Novartis had paid illegal kickbacks to specialty pharmacy Bioscrip so that Bioscrip would recommend Exjade. According to the United States' complaint, a former Bioscrip manager explained under oath that "Novartis' system of 'tying rebates and patient referrals to the number of refill shipments cause [Bioscrip] to be focused exclusively on the number of orders and refill rates, rather than on patient care.'"

Bioscrip reached a settlement with the government and Kester in January, with the pharmacy agreeing to pay $15 million and to cooperate with the government's investigation of Novartis. A public statement of acknowledgement from Bioscrip admitted that Novartis would refer new patients to the pharmacy based on "scorecards," which measured how long patients would continue to order Exjade prescription refills. According to the statement, the pharmacy's score would go down if a patient stopped ordering Exjade, even if the reason was side effects or instructions from a doctor.

Kester's qui tam lawsuit was first filed in November 2011 in United States District Court in the Southern District of New York by Shelley R. Slade of the national qui tam whistleblower law firm, Vogel, Slade & Goldstein, LLP, located in Washington, D.C. High-stakes trial litigation firm Susman Godfrey LLP joined the legal team shortly before the filing of Kester's new complaint, with Susman Godfrey partners Bill Carmody and Arun Subramanian entering appearances in the case.