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Amgen Workers Helped U.S. in Marketing Inquiry

By ANDREW POLLACK

“I hope no one is taping this,” the Amgen manager remarked at a company sales meeting in 2005.

The manager then boasted of how she had given a \$10,000 unrestricted grant to a pet project of a doctor who was an adviser to the local Medicare contractor. In turn, she said, the doctor would help persuade the contractor to provide reimbursement for an unapproved use of Amgen’s anemia drug, Aranesp.

Someone, it turned out, was taping it. Jill Osiecki, a longtime sales representative at Amgen, was wearing a recording device under her clothes, transmitting the proceedings to agents of the Department of Health and Human Services.

The result of Ms. Osiecki’s undercover work, and information provided by other whistle-blowers, led to Amgen’s agreement this week to pay \$762 million to settle federal investigations regarding the marketing of some of its top-selling drugs.

Judge Sterling Johnson Jr. of Federal District Court in Brooklyn accepted the settlement on Wednesday, clearing the way for 10 whistle-blower lawsuits to be unsealed.

Amgen, the world’s largest biotechnology company, will pay \$150 million in criminal penalties after pleading guilty to one misdemeanor count of marketing Aranesp for unapproved uses and in unapproved doses.

The rest of the money — \$612 million — will go to settle civil false claims lawsuits filed by the federal government, states and whistle-blowers. These contain accusations that go well beyond the off-label marketing of Aranesp.

They include off-label marketing of other drugs like Enbrel for psoriasis and Neulasta, which increases the levels of white blood cells. Amgen is also accused of offering kickbacks to doctors and clinics to induce them to use its drugs. These reportedly came as cash, rebates, free samples, educational and research grants, dinners and travel, and other inducements.

The government also accused the company of knowingly misreporting the prices of some of its drugs.

Except for those in the criminal count, Amgen denied the other accusations, though it did issue a statement on Wednesday acknowledging the settlement.

“The government raised important concerns in the criminal prosecution,” Cynthia M. Patton, chief compliance officer at Amgen, said in the statement. “Amgen acknowledges that mistakes were made, and we did not live up to our standards.”

Ms. Osiecki, 52, was one of the main whistle-blowers and will be entitled to a share of the settlement. The amount each whistle-blower will receive has not been determined or is being kept confidential, their lawyers said.

Ms. Osiecki worked as a sales representative for Merck for nine years before joining Amgen in 1990, soon after the biotechnology company won regulatory approval for its first product. The company, based outside Los Angeles, had “good science, good products, strong ethics,” Ms. Osiecki said in an interview.

But, she said, the corporate culture changed starting around 2000. That was when new management came in and Aranesp was approved, setting up a fierce marketing battle with Johnson & Johnson and its rival anemia drug, Procrit.

“It was more important to make your numbers than to follow the rules,” said Ms. Osiecki, who was based in Milwaukee and sold Aranesp.

In August 2004, with her concerns mounting, Ms. Osiecki called the Office of Inspector General of the Department of Health and Human Services and left a message. Within days, she was called back, and she went to see an agent, who persuaded her to secretly record meetings. She did that 13 times over about 15 months, mainly sales meetings.

Aranesp is used mainly in a hospital, clinic or physician’s office. It is bought by the medical practice, which can make a profit if the patient and insurers pay more for the use of the drug than the practice paid.

Ms. Osiecki said Amgen “marketed the spread,” trying to make it more profitable for doctors to use Aranesp rather than Procrit.

Such financial inducements could also spur greater overall use of a drug and can violate anti-kickback laws, said Ms. Osiecki’s lawyer, Brian P. Kenney of Kenney & McCafferty in Blue Bell, Pa.

Ms. Osiecki said the first sales meeting at which she wore the recording device, wrapped around her midriff under baggy clothes, was in October 2004 in a Milwaukee hotel. She could look down from the meeting room and see the car parked across the street containing the agent with the receiving device. She said she was not particularly nervous.

The speaker was a pharmacist from an oncology practice going through the numbers on how his practice could make a million dollars more a year using Aranesp rather than Procrit.

Ms. Osiecki said Amgen was careful to cover up such marketing. Spreadsheets showing doctors how much more money they could make using Aranesp were “homemade bread,” meaning they were created by each sales representative, not by the company. And representatives were told not to leave the presentations behind after showing them to doctors.

Her 107-page complaint, filed in late 2004, contains many other accusations.

Other whistle-blowers made other accusations. [REDACTED] a former sales representative, said Amgen overfilled vials of Aranesp, essentially providing free drugs to doctors. They could then bill Medicare or private insurers for the use of that drug, making an extra profit.

“Amgen was offering a kickback in the form of extra product subsidized by the taxpayers,” said Robert M. Thomas Jr., one of [REDACTED] lawyers.

Elena Ferrante and Marc Engelman, both former sales representatives, contended that Amgen promoted Enbrel’s off-label use for mild psoriasis when the drug was approved only for moderate or severe cases of the disease.

Lydia Cotz, one of their lawyers, said the two refused to go along with the off-label marketing. They are now pursuing wrongful termination claims against Amgen in arbitration proceedings that Amgen requires be kept confidential, she said.

“It’s been a very long heroic journey for my clients,” she said.

Ms. Osiecki is now also a former Amgen sales representative. She said that she was fired in December 2005 after she let slip that she had retained a company voice mail message that she thought provided evidence of illegal activity. Leaving the pharmaceutical industry, she moved to Amelia Island, Fla. She now works for a small business.

Mosi Secret and Barry Meier contributed reporting.

