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U.S. Joins Whistleblower Suits Against J&J

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By SHIRLEY S. WANG and BRENT KENDALL

The U.S. Justice Department is joining two whistleblower lawsuits alleging that Johnson & Johnson marketed its cardiac drug Natrecor for a use that isn't approved by the Food and Drug Administration.

Prosecutors allege that the off-label marketing of Natrecor caused "false and fraudulent claims" to be submitted to federal health-care programs, which could have led to "damages in the hundreds of millions of dollars," according to Marcella Auerbach of Nolan & Auerbach PA, a plaintiff attorney in one of the whistleblower cases. J&J could pay triple damages if it loses.

"Our investigation showed what we believed to have been off-label usage," said Charles Miller, a spokesman for the civil division of the Justice Department. "As a result, we've joined the suit."

Doctors are allowed to prescribe medications for off-label use, however, the marketing of drugs is restricted to approved uses.

J&J spokesman Ernie Knewitz said the company had "reviewed the allegations thoroughly and will be prepared to address them through the courts."

The FDA approved Natrecor in 2001 for in-hospital use by patients with congestive heart failure. The government alleges, however, that Scios, a subsidiary of J&J, launched an aggressive campaign to market Natrecor for patients with less-severe heart failure in an out-patient setting, a use that wasn't included in the FDA-approved label for the drug.

According to court documents unsealed Thursday, the plaintiff in one of the suits alleges that "upper management has always permitted and encouraged active off-label marketing" and that off-label sales were tied to sales representatives' sales goals.

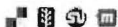
Whistleblower suits allow private citizens to provide the government with information involving fraud allegations. Both whistleblowers who filed the suits in the Northern District of California, Joe Strom and Jeffrey Smith, were former Scios sales managers.

"This is clearly a significant decision and we applaud the Department of Justice for deciding to make this commitment to this case," Ms. Auerbach said.


Write to Shirley S. Wang at shirley.wang@wsj.com and Brent Kendall at brent.kendall@dowjones.com

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