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Ex-Aegerion execs to pay \$6.5+ mln to settle drug promotion case

Caroline Spiezio

(Reuters) - Eight former Aegerion Pharmaceuticals Inc executives and employees have agreed to settle a whistleblower lawsuit that accused them of marketing a cholesterol drug meant for patients with a rare condition for off-label purposes, according to a filing on Thursday in Boston federal court.

The defendants will pay the U.S. government \$6.5 million and also cover attorney's fees and costs for the three individual whistleblower plaintiffs as part of the settlement, according to a copy of the agreement obtained by Reuters on Thursday.

The settlement said the former Aegerion executives and employees denied the allegations and did not admit liability.

The defendants' lawyers did not immediately respond to request for comment.

Plaintiffs' lawyer Patrick Egan of Berman Tabacco and U.S. Attorney's Office for the District of Massachusetts spokeswoman Elizabeth McCarthy declined comment on Thursday.

The U.S. Justice Department had intervened in the whistleblowers' lawsuit against Aegerion, a unit of Novilion Therapeutics Inc, but left the plaintiffs, who were ex-sales representatives, to pursue claims against the individual defendants on their own.

Those claims were the only ones remaining in the case after Cambridge, Massachusetts-based Aegerion agreed to pay \$40.1 million in 2017 to resolve the government's probes into its marketing practices of Juxtapid and plead guilty to two misdemeanor counts of misbranding the cholesterol drug.

While developing Juxtapid, Aegerion estimated that only 300 people nationally had homozygous familial hypercholesterolemia (HoFH), a rare condition for which the U.S. Food and Drug Administration approved the drug in 2012, U.S. District Judge Indira Talwani, who oversaw the case, said in April when she rejected the individual defendants' bid to dismiss the claims against them.

Yet the whistleblowers presented evidence that by 2015, Medicare had received claims for at least 2,511 patients, Talwani said, signaling not all of them had HoFH, a genetic disorder that causes a buildup of bad cholesterol and leads to premature heart disease.

The whistleblowers claimed the large number of prescriptions were due to Aegerion's aggressive marketing of Juxtapid for the off-label purpose of treating people with typical high cholesterol, rather than people with HoFH.

Ex-Aegerion sales representatives Michele Clarke, Tricia Mullins and Kristi Winger Szudlo had filed the lawsuit in 2013 under the False Claims Act. That law allows whistleblowers to sue companies on the government's behalf to recover taxpayer money paid out based on fraudulent claims.

For bringing the case, Clarke, Mullins and Szudlo were awarded \$4.7 million as part of the 2017 settlement.

They are now also entitled to a cut of any recovery from the settlement announced Thursday.

The defendants include ex-Aegerion chief executive officer Marc Beer; ex-chief financial officer Mark Fitzpatrick; ex-chief operating officer Craig Fraser; and ex-chief medical officer Mark Sumeray.

Other defendants include former sales representatives Melanie Detloff and James Frigge and former sales directors William Dull and Greg Fenner.

The case is U.S. ex rel Clarke et al v. Aegerion Pharmaceuticals In, et al, U.S. District Court, District of Massachusetts, No. 13-cv-11785.

For Clarke, Mullins and Szudlo: Bryan Wood, Patrick Egan and Stephen Ryan of Berman Tabacco and Royston Delaney of Delaney Kester

For the U.S.: Gregg Shapiro of the U.S. Attorney's Office for the District of Massachusetts

For Beer: R.J. Cinquegrana of Choate Hall & Stewart

For Frigge and Detloff: Peter Levitt of Donnelly Conroy & Gelhaar

For Dull: Frank Libby of LibbyHoopes

For Fenner: Michael Pineault of Clements & Pineault

For Fitzpatrick and Sumeray: Jonathan Kotlier and Ian Roffman of Nutter McClennen & Fish

For Fraser: William Kettlewell, Gregory Noonan and Julia McLetchie of Hogan Lovells

---- **Index References** ----

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