

Amgen to pay record \$762 mn fine over anemia drug (Update)

December 18 2012

US pharmaceutical giant Amgen has pleaded guilty to illegally introducing a mislabeled drug for treating anemia onto the market and will pay a record \$762 million fine, officials said Wednesday.

The Justice Department said the guilty plea was part of a settlement with the United States that "represents the single largest criminal and civil False Claims Act settlement involving a biotechnology company in US history."

The \$762 million includes \$612 million to resolve False Claims Acts suits and \$150 million in criminal penalties and forfeiture, a statement said.

The drug in question is Aranesp, which the criminal plea agreement says Amgen—in an attempt to boost sales—illegally introduced for uses and at dosage levels that the Food and Drug Administration had specifically declined to approve due to insufficient clinical evidence linked to safety and efficacy.

"Instead of working to extend and enhance human lives, Amgen illegally pursued corporate profits while jeopardizing the safety of vulnerable consumers suffering from disease," said Marshall Miller, acting US attorney for the Eastern District of New York.

"Today's settlement demonstrates our vigilance in protecting America's healthcare consumers and pursuing any corporation that seeks to profit

by violating US law."

According to the criminal plea agreement detailed by the Justice Department, Amgen's internal sales and marketing materials "made plain" that its mishandling of Aranesp was the firm's "core business strategy" to gain market share from Procrit, sold by competitor Johnson & Johnson.

While Aranesp, launched in 2002, was approved by the FDA at calibrated doses for certain anemia patients, Amgen illegally sold it with the intention that it be used at "off-label doses" in order to increase sales, the Justice Department said.

As part of the civil settlement, Amgen has agreed to pay \$612 million to resolve claims that it caused false claims to be submitted to Medicare, Medicaid and other government insurance programs.

Under the terms of the criminal plea agreement, Amgen will pay a criminal fine of \$136 million and criminal forfeiture totaling \$14 million.

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