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F.D.A. Plans Safety Check of 3 Drugs for Anemia

By [ANDREW POLLACK](#)

The [Food and Drug Administration](#) said Wednesday that it would review of the safety of the widely used [anemia](#) drugs sold by [Amgen](#) and [Johnson & Johnson](#) after another clinical trial suggested that high doses of one of the drugs might cause strokes.

In a [commentary](#) published online Wednesday by The [New England Journal of Medicine](#), agency officials wrote that the results of the new trial, as well as of previous trials, “raise major concerns” about the use of the drugs to treat the anemia caused by chronic kidney disease.

The officials said the agency would convene an outside advisory committee to re-evaluate the use of the drugs in patients with kidney disease and to consider new ways to control doses of the products.

Amgen, a large biotechnology company, was built on the sales of its anemia drugs, Epogen and Aranesp. Johnson & Johnson sells Procrit, which is manufactured by Amgen. The drugs raise the body’s level of red blood cells, which ferry oxygen to the body’s tissues.

But sales have been falling since 2007, when studies renewed concerns that the drugs might cause heart attacks and strokes and also might worsen the condition of patients with [cancer](#). The drugs are also used to treat the anemia caused by [chemotherapy](#).

Since 2007, the F.D.A. has held three advisory panel meetings on these drugs and has changed the labels of the drugs to warn of risks and lower the doses used.

Sales of Aranesp are expected to fall to below \$3 billion in 2009 from \$4.1 billion in 2006. Sales of Epogen, used only for kidney [dialysis](#) patients, have held steady at about \$2.5 billion a year.

Amgen said in a statement on Wednesday that the commentary in the medical journal “highlighted areas of incomplete understanding” regarding use of the anemia drugs.

Amgen’s shares fell 43 cents to close at \$56.79. Shares of Johnson & Johnson, which is less dependent on the anemia drugs, rose 52 cents to close at \$64.45.

The newest concern was prompted by results of a study called “Treat,” which were published Oct. 30 in The New England Journal of Medicine.

The trial, planned in 2004 before the safety concerns intensified, aimed to see if using Aranesp to increase the red blood cell levels of people with [diabetes](#) and kidney disease would prevent death and cardiovascular problems.

The trial found that there was no statistically significant difference in deaths and cardiovascular problems between patients who received Aranesp and those who received a placebo.

While that represented a failure of the original goal of helping people, that the drug did not kill people was considered somewhat reassuring in light of the safety questions that had arisen between the time the trial started and when it ended.

But those who took Aranesp had about double the rates of [stroke](#).

Dr. Ellis F. Unger, deputy director of the F.D.A. office that regulates renal and cardiovascular drugs, said in an interview that the agency published its commentary in the medical journal to inform doctors of the risks.

“One should not misinterpret Treat as being reassuring,” he said.

Others have also called for caution. Dr. Ajay K. Singh of Brigham & Women’s Hospital and Harvard Medical School said that avoiding the use of the drugs in kidney patients not undergoing dialysis “is now the soundest approach given the remarkable observations from the Treat study.” He made the remarks in a commentary published online recently by The Journal of the American Society of Nephrology.

An advisory panel to [Medicare](#) is also scheduled to meet in March to discuss coverage of the anemia drugs when they are used for patients with kidney disease. And Medicare is shifting how it pays for dialysis in a way that is expected to reduce the use of such drugs.

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