FDA may limit anemia drug use for kidney disease

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(AP) -- The Food and Drug Administration is considering new restrictions on widely used anemia drugs that appear to double the risk of stroke in patients with kidney disease.

The FDA posted its safety review of the three blood-boosting medications from Amgen Inc. on Thursday, focusing on their use in patients with chronic kidney disease who are not yet sick enough to receive dialysis.

The medicines - Procrit, Aranesp and Epogen - are multibillion dollar sellers because of their ability to boost oxygen-carrying red blood cells, reducing the need for painful blood transfusions. But sales have fallen sharply since 2007, when the FDA added the first of several safety warnings to the drugs, based on evidence they can cause tumor growth and hasten death in cancer patients. The drugs are no longer used in patients with several types of cancers.

Anemia, which causes weakness and shortness of breath, is a side effect of chemotherapy and kidney failure.

Now the FDA is reviewing a study published last year that showed kidney disease patients taking Aranesp were twice as likely to experience stroke compared with those taking a dummy treatment. The goal of the study was to show that the drug could prevent heart attack, stroke and other heart-related problems, as had been assumed for years.

But FDA reviewers, using the chemical name for Aranesp, said in their posting that the "evidence raises considerable doubt about the safety and advisability of using darbepoetin in this manner."

Amgen has argued that its drugs should continue to be used because they help avoid blood transfusions, which carry their own risks. But the FDA's scientists point out that 15 percent of patients who took the company's drug still needed transfusions, compared with 25 percent of those taking a placebo treatment.

"Treatment did not eliminate the risk of requiring (red blood cell) transfusions," states the FDA review.

On Monday the agency will ask a panel of outside experts to review the data and make recommendations on how to safely use the drugs. Panelists could recommend bolstered warning labels, additional studies or lower doses of the drugs. The FDA is not required to follow the group's advice, although it often does.

Amgen, based in Thousand Oaks, Calif., makes all three drugs. Procrit is sold by Johnson & Johnson's Centocor Ortho Biotech division, under a long-standing agreement between the companies.

Last year the drugs - known as erythropoiesis stimulating agents - had combined sales of $6.3 billion, according to health data firm IMS Health.

Pre-dialysis kidney patients contributed 30 percent of Aranesp's revenue last year, estimates Robyn Karnauskas, an analyst at Deutsche Bank. New FDA restrictions would shave $86 million in sales off the drug, he estimates, which would have a minimal effect on Amgen's revenue. Amgen, one of the giants of the biotech drug industry, had total revenue exceeding $14.6 billion last year.