

November 30, 2006

## Treatment of Anemia Questioned

By [ALEX BERENSON](#)

An expert panel of doctors for the National Kidney Foundation plans to assess whether hundreds of thousands of patients with kidney disease are being dangerously overtreated with drugs for [anemia](#).

The decision to convene the panel comes two weeks after studies in [The New England Journal of Medicine](#) suggested that kidney patients whose anemia was more aggressively treated were more likely to die or suffer heart problems than those who were allowed to remain more anemic.

As a result, the panel, which will meet early next year, may recommend less aggressive treatment of anemia, potentially hurting sales for Amgen and Johnson & Johnson, which market the drugs, which are among the world's best-selling prescription medicines.

"There are substantial sums of money involved here," said Kerry Willis, vice president for medical and scientific activities of the National Kidney Foundation. The foundation, in response to a reporter's question, confirmed the panel's plans to meet. The panel's recommendations would not have the force of law. But they are certain to be closely watched by kidney doctors as well as administrators of the federal Medicare program, which is by far the largest buyer of the drugs worldwide.

Sold under the brand names Epogen, Procrit, and Aranesp, the anemia drugs will reach almost \$10 billion in sales worldwide in 2006. Medicare will spend \$2 billion on them for kidney dialysis patients alone, and a similar amount for [cancer](#) patients and patients with kidney disease not yet on dialysis.

Nearly one million Americans, including 500,000 kidney patients, receive the drugs every year.

But some independent scientists say they believe that kidney patients are receiving too much of the drugs, in part because dialysis clinics make bigger profits for providing higher doses. The clinics make little profit on the actual dialysis services they provide for Medicare enrollees, who are the vast majority of dialysis patients.

The foundation's panel will probably meet in January or early February and could release new treatment recommendations for public review a few weeks later, the foundation said.

The anemia panel consists of 15 nephrologists who meet under the auspices of the foundation, a private nonprofit group based in New York that provides financing for kidney researchers. The panel is one of several panels sponsored by the foundation that make recommendations about how to improve treatment for kidney patients.

But some scientists complain that Amgen has until now had too much influence on the creation of the foundation's guidelines. The most recent version of the anemia guidelines, released earlier this year, encourages more aggressive treatment than the [Food and Drug Administration](#) recommends.

“The guidelines are funded through the National Kidney Foundation by industry, by and large,” said Dr. Daniel Coyne, professor of medicine at [Washington University](#) in St. Louis. “They write guidelines that are opinion-based, by and large, and favor industry or would appear to favor industry.”

While Amgen sponsors the creation of the guidelines and donated \$4 million to the foundation last year, both the foundation and the company say that the company does not control which doctors are chosen for the panel or influence their choice of treatment.

Dr. Rob Brenner, senior director of medical affairs at Amgen, said the company had always promoted use of its drugs in accordance with the more cautious F.D.A. label, not the more aggressive guidelines created by the foundation.

The anemia drugs are proteins that stimulate bone marrow cells to produce hemoglobin, the main component of red blood cells. They must be given via injection, either intravenously or through the skin.

The original drug, called epoetin, is made by Amgen, which markets it under the brand name Epogen. Johnson & Johnson sells the identical drug, also produced by Amgen, as Procrit.

The other drug, darbepoetin, is sold under the name Aranesp. It was introduced in 2001 by Amgen and is a slightly modified version of epoetin that can be given less frequently.

Neither the National Kidney Foundation panel nor the F.D.A. suggest how much of the drugs patients should receive. Instead, they have guidelines for hemoglobin targets in the blood.

In general, healthy adults have hemoglobin levels of 14 grams or more per deciliter of blood, while patients are considered to need treatment if their levels are below 10 grams. Severe anemia can be devastating, leaving patients unable to work, walk for more than a few minutes, or even think clearly, while also increasing their risk of infection and [heart disease](#).

But high levels of hemoglobin can cause high [blood pressure](#), strokes and heart attacks, even in healthy adults. Now some scientists say they believe that kidney doctors need to become more conservative about treating anemia, which probably means using less of the drugs.

The prescribing label for Epogen, as approved by the F.D.A., says dialysis patients should have a target hemoglobin level of 10 to 12 grams per deciliter of blood. In its most recent guideline, the panel of doctors overseen by the kidney foundation said a target of 11 to 13 grams was appropriate. It is that target that will now be under review.

In practice, almost all dialysis patients receive the drugs, and almost none have hemoglobin levels below 11 grams after treatment. About half have levels of more than 12 grams, according to data from the United States Renal Data System, a federally sponsored group that monitors kidney patient care. Almost 20 percent of patients have levels above 13 grams.

The differences may seem small, but one of the studies published in *The New England Journal* found that patients treated to an average hemoglobin level of 12.6 grams had a 34 percent higher risk of death or serious heart problems than those treated to a level of 11.3 grams.

And the average patient at the higher level required about twice as much of the anemia drug to get to that

level.

[Copyright 2006 The New York Times Company](#)

[Privacy Policy](#) | [Search](#) | [Corrections](#) | [RSS](#) | [First Look](#) | [Help](#) | [Contact Us](#) | [Work for Us](#) | [Site Map](#)

---