



Service to those affected by chronic kidney disease

September 11, 2007

Dear Chairman & Members of the Advisory Committee:

My name is Lori Hartwell and I have lived with chronic kidney disease for the past 39 years. My kidney failure was caused by the e-Coli bacteria infection. Since then, I've survived 12 years of dialysis including 3 kidney transplants and 2 rejections.

I also founded and represent the Renal Support Network. Our patient-run nonprofit organization is devoted to helping improve the lives of people with chronic kidney disease and providing hope to fellow patients.

The Renal Support Network is **deeply concerned** that patients will suffer tremendously if the FDA limits the hemoglobin to a level that is below what is recommended in the National Kidney Foundation's KDOQI guidelines. This concern was accentuated by the recent National Coverage Decision for oncology, which determined that treatment of anemia could not be initiated until hemoglobin levels fall below 10 g/dl.

Patients with chronic kidney disease are **permanently** affected by anemia because kidneys produce the hormone that helps create red blood cells. As a result, effective anemia management is **key** to a kidney patient's ability to survive and thrive.

I would like to urge the committee to consider how your decision will affect the **patient's** quality of life. I will let the clinicians **speak** about the **clinical data** that show the relationship between hemoglobin levels and patient quality of life.

For my part, I would like to tell you about how patients actually feel. I currently have a kidney transplant, but rely on EPO to feel well - since without it my hemoglobin would be extremely low and it would be impossible for me to continue working and performing the normal activities of daily life.

An illness is too demanding when you don't have hope!

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In my case, I do not feel “normal” and cannot function as well if my hemoglobin level is below 12.0 g/dl. Many studies have shown that treatment outcomes and quality of life suffer when hemoglobin levels fall below 11.0 g/dl - and my own experience confirms this data. At a hemoglobin at 11.0 g/dl - I **can feel the** difference.

Daily activities become difficult or impossible to perform. Shortness of breath and fatigue are constant reminders that I have chronic anemia.

Many people who have chronic kidney disease have related similar experiences of how anemia has affected them. We **received** many letters from patients, but here is a sampling of quotes from Renal Support Network members.

Heather Powell stated “When I was first diagnosed I had to have blood transfusions every month in order to fight anemia. EPO did not exist at this time. The introduction of EPO had a huge impact on my life. I was healthier, more productive. I was able to complete college, work full time and enjoy life.”

John Garcia stated that “When I was anemic I was always tired, listless and cold. My family couldn’t get me to do anything.”

Kathe LeBeau says, “When I have a Hemoglobin below 10, I can’t walk as far as the mailbox, grocery shop, do much housework or find the energy to go to work.”

There are currently hundreds of thousands of other patients with chronic kidney disease, and we have had the benefits of hemoglobin levels above 11 g/dL for almost twenty years. I urge the committee to consider how the quality of kidney patients life will suffer if your decision forces us to ignore twenty years of progress **and regress** to hemoglobin levels where it is near impossible for us to remain productive citizens. I would contend that **regaining our quality** of life is as important as **preserving our lives**.

Quality of life is centered on the **foundation of hope** and the belief that life is still worth living. Initiating any of the healing arts has at its core a belief that life is still worth living and an expectation of improving quality of life. Otherwise, it is pointless. Everything from replacing a limb for an injured soldier or providing physical or occupational therapy for an elderly person with a fractured hip to taking an aspirin for a headache, is done to improve quality of life. Failure to consider **quality of life** as a goal in managing anemia is **tantamount** to ignoring the patient.

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Renal Support Network is also **concerned** that lowering the patient's target hemoglobin will result in a dramatic increase in the number of patients with low hemoglobin levels, resulting in the **increased need** for patients to receive blood transfusions and to be hospitalized.

Blood transfusions can have a **significant and long-lasting negative** impact on our health, and even increase our risk for death. Blood transfusions can severely affect a patient's ability to receive a kidney transplant. The **reactive antibodies** received from blood transfusions result in fewer potential kidney matches from donors.

Melissa Daniels has had chronic kidney disease since she was a **small child**, and received a number of blood transfusions before EPO was available. Even though she has not received a blood transfusion in some time, the effect of those transfusions continues to **haunt her**, and she currently has a reactive antibody percentage level of 81%.

As a result of blood transfusions, the number of potential kidney donors that are a compatible match is severely limited. The transplant team at her center is not confident that they **will ever find her a match!** There are thousands of other patients like her across the country who will find it extremely difficult to find a suitable kidney if their antibodies levels increase after receiving a blood transfusion.

I would like to emphasize that I am not downplaying the safety results of the trials that have been published. **All drugs carry risks**, and patients deal with these risks everyday in every facet of medicine. However, patients are also acutely aware that the **potential risks** associated with drug therapy need to be **weighed against the benefits**.

I would like to reiterate that anemia is one of the most devastating conditions that affect those of us who have chronic kidney disease. **Physicians should retain the ability to individualize EPO therapy** in response to an individual patient's needs. Patients visit doctors in response to **"how we feel."** We simply have no other way to communicate with our physician.

The hemoglobin level of 11 to 12 that is currently recommended by KDOQI™ gives patients and clinicians some latitude in the treatment of anemia so that if we experience an **infection**, need to be **hospitalized**, or lose additional blood during hemodialysis, which is

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not uncommon, we will not be as threatened by the risk of receiving a blood transfusion or a **reduced** quality of life.

In the past, many of us have had the misfortune of living with lower hemoglobin levels and the constant threat of blood transfusions. Those of us who remember the “**bad old days**” know how necessary higher hemoglobin levels are to living a productive life.

If these therapies are restricted, and the patient is forced into a lower quality of life, it begs the question of why that patient is being kept alive in the first place!

I respectfully ask the committee to please consider the patients’ perspective in your policy decisions. **Quality of life - is measurable. Patients measure it everyday.**