



March 22, 2007

The Honorable Mike Leavitt  
Office of the Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Leavitt,

As America's largest dialysis patient organization, we are proud to represent over 20,000 pre-dialysis and dialysis patients and their families. On a wide variety of issues, we seek to ensure that the patients' point of view is heard and considered by policy makers so that continued progress may be made in the quality of care and life for patients with kidney disease.

First of all, DPC and the kidney care community are grateful for the time and consideration that CMS has put into reviewing and improving the EMP. We believe that the revised EMP addresses many of the concerns raised regarding the original April 2006 policy and puts patient clinical outcomes and quality of life first — a real win for patients. We hope that the review of this policy will find that the current EMP is the best solution for ensuring that ESRD patients receive appropriate anemia management.

A Black Box Warning issued on Friday, March 9<sup>th</sup> by the Food and Drug Administration (FDA) has potentially put dialysis patients back at risk, however. Issued for all erythropoiesis-stimulating agents (ESAs), we fear this warning could unintentionally result in negative clinical outcomes for dialysis patients.

The FDA warning states that "ESAs increased the risk for death and for serious cardiovascular events when dosed to achieve a target hemoglobin of greater than 12 g/dL." We have several concerns with this statement and how it could be interpreted, absent clarification:

- Research referenced in the FDA warning was conducted on Chronic Kidney Disease (CKD) patients in stages 1-4, not End Stage Renal Disease (ESRD) patients at stage 5 of this disease. In other words, the studies did not focus on patients who, like us, are on dialysis.
- The warning also does not account for the fact that clinical guidelines in broad use in the dialysis community target a hemoglobin range of 11 to 12 g/dL, not greater than 12 g/dL, and in fact call for titration (reduction) of ESA dosing as patients near 12 g/dL.
- Further, the warning does not acknowledge that some patients invariably – and temporarily – rise above 12 g/dL due to their individual reaction to ESAs. Whenever this occurs, ESA dosing is reduced as the patient is managed back into the optimal 11-12 g/dL range.

We believe it is essential that the FDA clarify its warning as it relates to dialysis patients. The FDA must give consideration to the fact that the studies leading to the increased warnings were not based upon studies of ESRD patients who are managed differently than non-dialysis

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patients. The differences between dialysis and non-dialysis patients in monitoring, dosing, and dose adjustment must be considered when setting policy.

If dialysis patients are unable to receive ESAs to treat their anemia when their hemoglobin temporarily rises above 12 g/dL, their anemia will worsen, their hemoglobin will crash, and hospitalization and even death could result. Ironically, this scenario would actually result in the use of greater ESA dosing than would otherwise be needed because physicians would have to scramble to keep their patients from falling into the life-threatening sub-11 g/dL range.

In short, Mr. Secretary, the FDA warning – if not clarified for dialysis – could have a direct impact upon us, including clinical confusion and coverage changes that would threaten patient care and outcomes.

As you may be aware, many kidney community members including the Renal Physicians Association (RPA) and American Association of Kidney Patients (AAKP) share our concern and urge that public policy not be changed in a manner that could harm patients. Policies, package inserts, and regulations are meant to protect and assist patients and physicians. However, when such policy is undertaken without a clear picture of clinical realities, the result could be very harmful.

We therefore respectfully request that communication within HHS be undertaken to ensure that no action is taken that could endanger dialysis patients.

If we can serve as a resource during this process, please do not hesitate to contact us for additional information or a meeting with your staff and our patients. On behalf of the more than 20,000 members of DPC, I thank you for your time and welcome the opportunity to discuss with your staff in person in the future.

Sincerely,

Patricia Orna  
President

cc: Dr. Andrew von Eschenbach, FDA Commissioner  
Leslie Norwalk, CMS Acting Administrator  
Dr. Barry Straube, CMS Director, Office of Clinical Standards and Quality and Chief Medical Officer