



September 7, 2007

Ms. Mimi Phan  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: September 11, 2007 Meeting of the Cardiovascular and Renal Drugs Advisory Committee  
and the Drug Safety and Risk Management Advisory Committee

Dear Ms. Phan,

Kidney Care Partners (KCP) appreciates the opportunity to provide comments related to the upcoming meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC) and the Drug Safety and Risk Management Advisory Committee (DSRMAC) to discuss updated information on the benefits and risks of erythropoietin-stimulating agents (ESA) used for the treatment of anemia due to chronic renal failure. KCP is a coalition of members of the kidney care community, including renal patient advocates, dialysis care professionals, providers, and suppliers who collaborate to improve the quality of care for chronic kidney disease (CKD) patients with irreversible kidney failure, also known as end stage renal disease (ESRD). While we appreciate the Food and Drug Administration's (FDA) commitment to ensuring the efficacy and safety of ESA treatment of anemia for ESRD patients, we would like to stress the importance of including practicing nephrologists on the panel at the September 11, 2007 meeting, considering the revised Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines on anemia management and addressing the critical patient quality of life considerations associated with this issue.

First, KCP would like to emphasize the importance of including practicing nephrologists as invited members of the panel at the upcoming meeting to discuss ESA use for patients. As practitioners who handle ESA treatment for CKD patients on a regular basis, these physicians offer a unique and important perspective on patients' clinical needs as well as issues associated with ESA use, such as variability of patient response to medication. Given that the goal of the Advisory Committees' further discussion of the benefits and risks associated with ESA treatment for CKD patients is to come to the best possible assessment of the appropriate patient use of ESA products, it is critically important that the FDA include practicing physicians responsible for CKD patient care as a significant component of the Advisory Committees' discussion. Although these physicians may be allowed to present during the public comment period, the seven minute time allotment may not provide sufficient time to collect the critical input offered by these experts. Based upon the informal

information we have been able to gather, we are concerned that the CRDAC and DSRMAC may be disproportionately relying upon cardiologists and non-nephrologists academics as the experts for its discussion, and KCP encourages the Advisory Committees to ensure appropriate representation of a cross-section of practicing nephrologists in its discussion to ensure the best outcome for CKD patients.

We also urge the Advisory Committees to consider the consensus recommendation by the Kidney Disease Outcomes Quality Initiative guidelines issued this month on anemia management in kidney patients. These guidelines are scientifically based recommendations developed by the nephrology community, which has evaluated all published information, including the recent CHOIR and CREATE studies. Such guidelines have served kidney patients well since their inception, and we believe the current guidelines on anemia management, consistent with the nephrology community's consensus recommendation, are consistent with safe and effective anemia management.

KCP would also like to stress the need for consideration of patient quality of life issues as part of the discussion of risks and benefits of ESAs. While other factors, such as transfusion avoidance, are certainly valid and important considerations, we strongly believe that any discussion of this issue must place significant value on how the use of ESAs impacts CKD patients' quality of life and day-to-day functional status. The significance of patient quality of life to overall patient health has been recognized consistently by health experts. Most recently, the Institute of Medicine included the need for 'patient-centeredness' in its six attributes of health care necessary to optimize outcomes and defined this factor as "providing care that is respectful of and responsive to individual patient preferences, needs and values and ensuring patient values guide all clinical decisions."

Before the availability of ESA treatment for anemia, most dialysis patients experienced a severely impaired quality of life as a result of physical and mental fatigue. Since the arrival of ESAs, clinical data measuring their impact on patient quality of life has repeatedly demonstrated improvements in factors including physical functioning, mental health, social functioning and vitality. Any assessment of the benefits and risks of ESA use for CKD patients must include meaningful discussion of the impact of the treatment on patients' quality of life, and KCP strongly encourages the CRDAC and DSRMAC to include this issue as part of their meeting agenda.

Once again, we thank the Advisory Committees for the opportunity to comment prior to the September 11, 2007 meeting, and we look forward to an informative and thoughtful discussion of this important issue. If you have any questions or need additional information, please do not hesitate to contact Piper Nieters Su at 202-457-6159.

Sincerely,



Edward R. Jones, MD  
Chairman  
Kidney Care Partners

Abbott Laboratories  
AMAG Pharmaceuticals  
American Kidney Fund  
American Nephrology Nurses' Association  
American Regent, Inc.  
American Renal Associates, Inc.  
American Society of Nephrology  
American Society of Pediatric Nephrology  
Board of Nephrology Examiners Nursing and Technicians  
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