

Statement for the Record
Of the
American Society of Nephrology
To The
House Committee on Ways and Means
Subcommittee on Health

Hearing on Safety Concerns Regarding the Dosing of Erythropoiesis Stimulating Agents

June 26, 2007

Chairman Stark, Ranking Member Camp, and distinguished members of the Ways and Means Subcommittee on Health, the American Society of Nephrology (ASN) appreciates the opportunity to submit a statement for the record to the Subcommittee and commends the committee for its commitment to the provision of high quality, cost-effective care in Medicare's End Stage Renal Disease (ESRD) program. The ASN is a not-for-profit organization of 10,000 physicians and scientists dedicated to the study of nephrology and committed to providing a forum for the promulgation of information regarding the latest research and clinical findings on kidney diseases.

Brief Background

The ASN recognizes that Congress, the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) recently raised questions on the provision of safe, quality dialysis services and care to ESRD patients. It is well documented that anemia management for patients with kidney disease and ESRD is complex and can vary among each individual patient. The Medicare Payment Advisory Commission (MedPAC) has also looked at this question and examined reimbursement policy in an effort to assure high quality care in an efficient and fiscally responsible manner.

In order to ensure continued improvement in patient access to safe, quality kidney care, Congress must take into consideration the patient – doctor relationship, physician prescribing autonomy and variability in patient hemoglobin levels. ASN looks forward to working with Congress and the Administration to ensure that the clinical effect of any policy change has no unintended and harmful consequences for patients and their relationship with their physicians.

Discussion

The ASN believes - as does the entire renal community – that anemia management in ESRD patients is a critical component of care and should be medically appropriate and designed to maximize benefits and minimize risks. The Committee should recognize that determining and maintaining optimal hemoglobin levels is not straightforward, but is complex and linked to patient variability. It is common for ESRD patients to experience variations in hemoglobin levels resulting from co-morbidities (diabetes, cardiovascular disease), physiology and

hospitalizations. Because of this high-degree of variability, optimal anemia management requires an individualized approach to treatment. Unfortunately, there is no single, predictive response to a given dose of EPO, a fact that accounts for the wide range in individual responses to treatment.

There are volumes of research studies that highlight the clinical and scientific complexity surrounding anemia management in ESRD patients. The ASN believes that Congress and the Administration should take all these studies into account before setting Medicare policy and payment reforms that will directly impact the physicians' pursuit of optimal care for ESRD patients.

It is the essence and foundation of clinical medicine that the physician should act as the patient's advocate and in the patient's best interest at all times. The nephrologist should be the final arbiter of the complex interaction between the corporate provider, statutory regulators, and the pharmaceutical companies as they all relate directly to patient care. A physician's ability to exercise clinical judgment in prescription of drugs such as EPO is important because specific patient needs may vary based on a wide range of factors.

We have attached a scholarly paper recently published in the *Journal of the American Society of Nephrology (JASN)* which highlights these and other important issues that impact cost, quality and value in the changing political climate of dialysis care. The paper shows that as medical, economic and policy trends converge to alter the way dialysis care is organized and financed, protecting the unique relationship between dialysis patients and the kidney specialists who direct their care becomes a top priority.

Conclusion

ASN is supportive of efforts to ensure that ESRD patients continue to have access to high quality dialysis care while maintaining the patient-doctor relationship and physician autonomy. We thank you for the opportunity to provide this statement and offer our assistance and resources to the Committee and staff as we work together to ensure that ESRD Medicare beneficiaries receive the best possible quality of life and achieve the best health outcomes.