

Oral Statement

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**Joint Meeting of the Cardiovascular and Renal Drugs
Advisory
Committee and the Drug Safety and Risk Management
Advisory Committee**

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Members of the Committee, thank you for inviting me before you today to testify. My name is Roberta Wager and I am the President of the American Association of Kidney Patients.

AAKP is the only national non-profit organization founded by kidney patients, for kidney patients. Our organization is dedicated

to serving the needs, interests, and welfare of all kidney patients and their families.

And this is the very reason I am here before you today. As a kidney transplant recipient myself and a practicing nephrology nurse, I am well aware of the human and financial cost of kidney care.

Our nation has the unique opportunity to provide better outcomes for kidney patients – and this can lead to substantial cost savings because better outcomes translate into less reliance on the drugs, dialysis, and hospitalization currently covered by Medicare. Let me begin by stressing how important it is to get the dosing of ESAs right for kidney patients. AAKP supports achieving a hemoglobin level of 11 to 12 grams per deciliter, as indicated by the FDA label for ESAs.

We view current CMS monitoring policy as somewhat out of sync with where the FDA is and where the mainstream medical community is. Although each case is different and there will always be outliers, from a patient perspective there is very little medical reason for a patient to remain at levels above 13 grams, especially in light of the current literature citing safety issues.

AAKP strongly adheres to the principle that *a physician and patient must be permitted to decide a care plan best suited for that patient*. Separate Medicare reimbursement for ESAs potentially distracts from the doctor/patient decision-making relationship, so we support bundling Medicare reimbursement for ESAs into the overall Medicare reimbursement rate. We believe that bundling the payment would not only result in cost savings, but also would

result in more appropriate dosing of ESAs and draw more attention to the comprehensive nature of kidney care.

Let me emphasize that underdosing of ESAs is a danger too. Let me stress again, that ESAs should be given to reach a hemoglobin level of between 11-12. We are concerned about any lower initiation point. Many kidney patients remember the difficult times before ESAs were available, suffering the debilitating fatigue associated with anemia. We don't want to scare patients away from being treated with these valuable life-enhancing medicines. Nor would we want to create a perverse disincentive that causes providers to "skimp on" doses of ESAs because they would no longer be receiving separate reimbursement.

What we need is a FDA and Medicare policy that strives for a “Goldilocks” solution on ESAs: not too much, not too little, but “just right.”

So, we believe Congress, CMA and FDA should: 1) establish guidelines regarding the proper dosage of ESAs, and 2) link reimbursement to meeting those guidelines.

Let me say just a few words about potential subcutaneous administration. We surveyed 3,600 patients about subq administration of EPO and we found that patients are willing to do subq. A majority of them told us they wouldn't mind getting EPO as a shot – and even giving themselves the shot. Most of these patients are already self-administering shots because of their diabetes.

We applaud the FDA leadership on this issue that is so important to us as kidney patients. We offer ourselves as a resource to you as your Committee works on these issues. Thank you and I look forward to responding to your questions.