

To the Chairman, Members of the Advisory Committee and Invited Guests:

Good Morning.

My name is Kathleen LeBeau and I have lived with kidney disease for the last 4 years, acquired as a result of primary hyperparathyroidism that produced a calcification of my kidneys. I have been on home hemodialysis since April of this year, and am on the kidney transplant waiting list.

I also work with the Renal Support Network, a patient-run, patient-driven organization dedicated to helping improve the lives of people with chronic kidney disease and providing hope to fellow patients. I am here today to share with you, from the patient's perspective, some reasons that the use of phosphate binders should be extended to those in earlier stages of chronic kidney disease, and the impact that could have in the lives of those patients, based on my experience and that of other individuals with kidney disease. I see everyday and understand all too well what it means to live with those things that result when treatment is delayed.

The Renal Support Network agrees with and supports the National Kidney Foundation's KDOQI guidelines on the use of phosphate binders in Stage 3 and 4 CKD patients: "... if phosphorus or intact PTH levels cannot be controlled within the target range despite dietary phosphorus restriction, then phosphate binders

effective in lowering serum phosphorus levels should be prescribed.”

As any renal nutritionist will tell you, dietary phosphorus is all too common in the everyday foods we eat and drink, such as dairy products, cheeses, dried beans and peas, colas and chocolate. But it is hard to control not only because of the food that it occurs naturally in, which can at least be easily identified and excluded from the diet. Rather, it is more because of the use of phosphates in preserving and processing foods, harder to discern as it does not appear by quantity on any food product at this time. Even reading food labels closely is not always foolproof, as you have to look carefully for phosphate in its many forms in the ingredients sections, finding the words that mean phosphorus, such as phosphoric acid, dicalcium phosphate, monocalcium phosphate, pyrophosphates, hexametaphosphate, polyphosphates, sodium phosphates and so on. Complicating the situation, these ingredients used as preservatives may be more easily absorbed than phosphorus from natural food sources. So it is often difficult to reduce phosphorus in the everyday diet, and dietary restrictions alone should not be the only treatment approach.

Further, the very nature of some CKD cohort and causal conditions can result in acceleration of the disease and the presence of abnormal levels of phosphorus in the body. With kidneys failing, their ability to regulate the delicate calcium-phosphorus balance is impaired early on in the disease process, long before any symptoms of this appear. Therefore, the damage begins long before any

treatment is considered or started.

Patients in earlier stages of CKD should be afforded the option of treatment for regulating phosphorus to prevent the advancement of symptoms prior to starting dialysis. Because kidney disease and its effects differ from patient to patient, the decision should be based on a total medical perspective of an individual patient's health and not on the arbitrary delineation of the start of dialysis. With the anticipated burgeoning of the CKD population doubling by 2010, these patients can benefit from the lessons learned from the existing end stage renal disease patients, who suffer with irreversible conditions for the very reason that treatment was not started prior to the initiation of dialysis. For example, my own calcium buildup as a result of the electrolyte imbalance due to the hyperparathyroidism resulted in not only the calcification of my kidneys and the start of the disease process, it also left me with painful kidney stones. A fellow patient, Bill Dant of Utah, suffers from even more marked difficulty as a result of "too little, too late" phosphate binder treatment. Not only is his vascular calcification so extensive that his blood vessels show up on an x-ray, but he lives with painful bone thinning and damage, as well as neuropathy in his extremities that has impaired his healing ability. Other friends who are patients have lived with an increased risk of fractures, extreme weakness and fatigue, debilitating aches and pains, soft tissue calcification in their eyes or other organs, and coronary artery calcification that leads to greater risk of a cardiovascular event. And has been pointed out this morning – all too often and too early -- we die.

The increasingly routine blood tests that screen for a wide range of CKD related conditions, including out of balance calcium, phosphorus and PTH levels, are alerting doctors to people who have forms of this disorder even though they may be symptom free and in the earlier stages of kidney disease. Along with the Renal Support Network, I urge the committee to embrace the current practice by many physicians and allow for the use of phosphate binders earlier in the disease progression to manage the problems and complications that result from high phosphorus levels, and therefore hopefully minimize life long and debilitating conditions for these fellow patients.

Thank you.

Respectfully submitted,

Kathleen D. LeBeau

6 Surrey Hill Drive

Latham NY 12110

518-785-5283

