Kidney Health Australia supports the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* tabled in the Senate by Hon. Kay Patterson on September 26, 2006.

Kidney Disease in Australia

Approximately 1 in 7 (almost 2 million) Australian adults have chronic kidney disease. Chronic kidney disease causes or contributes to approximately 11% of all deaths in Australia. The severest form of chronic kidney disease is end stage kidney disease. Patients with end stage kidney disease require dialysis or a kidney transplantation to stay alive.

While these figures are alarming, we know that the incidence of chronic kidney disease and end stage kidney disease is going to increase rapidly in the coming decades. This is primarily due to the rising rates of obesity, hypertension and diabetes in our society. The number of Australians being treated with dialysis or a kidney transplant has increased more than 400% since the 1980s. By 2010, the direct costs to the health sector of providing these services to current and future patients are likely to exceed $800 million.

Kidney Health Australia Supports Stem Cell Research

In 2003, Kidney Health Australia awarded a $1 million grant (the Bootle Bequest) to a multidisciplinary team of researchers based at Monash University and the University of Queensland. This team of researchers, known as the Renal Regeneration Consortium, was established in 2001 to investigate and develop new cell and factor-based therapies for patients with end stage kidney disease. Together with funding from the US National Institutes of Health (NIH), the Renal Regeneration Consortium conducts research on many aspects of embryonic and adult stem cell biology, with the long term aims of identifying, isolating, expanding and ultimately utilising stem cells or factors to repair diseased kidneys. With the aid of Kidney Health Australia funding, the Consortium is investigating the potential capabilities and therapeutic potentials of both embryonic stem cells and adult stem cells for patients. The Consortium currently consists of approximately 40 researchers at Monash University and the University of Queensland. The Renal Regeneration Consortium in Australia constitutes one of the largest and best known research groups in the world investigating new cell-based therapies for patients with kidney disease.

Embryonic Stem Cell Research and the Kidney

Human embryonic stem cells offer enormous therapeutic potential to patients with kidney disease. As detailed above, the rates of end stage kidney disease in Australia are increasing rapidly, and the current therapies simply cannot cope with the epidemic of kidney disease. New therapies are urgently required. Embryonic stem cells offer great hope to patients with kidney disease, because potentially they can be induced to form any cell type of the human body, including any type of kidney cell. So if a cell type in the kidney (of which there are approximately 30 different types) is being lost due to disease, or parts of the kidney have been damaged or destroyed by disease, embryonic stem cells offer the promise of replacing these lost cell populations and/or repairing regions of the kidney.

But the journey of discovery has only just begun. While scientists have been able to induce human embryonic stem cells to form nerve cells, fat cells, and cardiac muscle cells for example, no one to date has been able to produce kidney cells from human embryonic stem cells. Members of the Renal Regeneration Consortium firmly believe that it is only a matter of time before kidney cells are generated from embryonic stem

cells, and indeed themselves have made solid progress in recent years, and probably lead the world in this field of research. But access to additional embryonic stem cell lines, and to patient-specific stem cells will be required should this research ever translate into therapies for patients.

From a basic science perspective, the production of kidney cells from embryonic stem cells would allow examination of the earliest differentiation decisions made by cells destined to become part of the kidney, a timepoint in human kidney development previously inaccessible to research. Moreover, study of the development of human kidney cells *in vitro* may identify novel factors that could enhance regeneration of adult kidney tissue. Finally, human embryonic stem cells could also provide the basis for high throughput toxicological and pharmaceutical screening of factors potentially harmful or beneficial to human kidney development and/or function.

The proposed amendments to the *Prohibition of Human Cloning Act 2002* and the *Research involving Human Embryos Act 2002* will enable the generation of new human embryonic stem cell lines and enable research into the generation of patient-specific stem cells. In the latter instance, the nucleus of a somatic cell (eg. skin cell) from a patient with kidney disease would be obtained. This nucleus would be combined with an enucleated egg (donated oocyte), and then induced to undergo a series of cell divisions to form a blastocyst. Cells from the inner cell mass of the blastocyst would be used to form an embryonic stem cell line. These patient-specific stem cells would then be induced in the laboratory to form the kidney cells required to repair the kidneys of the specific patient. If research into the generation of patient–specific stem cells is successful then the cells administered to the patient will not be rejected by the patient's immune system. This technique is known as therapeutic cloning or somatic cell nuclear transfer.

Why Not Use Stem Cells in the Adult Kidney to Repair Damaged Kidneys?

As stated above, members of the Renal Regeneration Consortium are conducting research on both embryonic stem cells and adult stem cells in an effort to develop new cell-based therapies for patients with kidney disease and are actively sharing data to advance each stream of research. Research in both fields is at a very early stage. No group to date has been able to produce kidney cells from human embryonic stem cells. Moreover, very little is known about the location, characteristics or therapeutic potential of stem cells in the adult kidney. Kidney Health Australia and the Renal Regeneration Consortium believe that research on both embryonic and adult stem cells is required to develop new therapies for patients with end stage kidney disease.