Statement of Paul Berg
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Mr. Chairman, Members of the Committee, thank you for inviting me to testify before you on this most important issue. I have followed the debate on the cloning questions we will address today and I welcome the opportunity to weigh in with my own views on the matter. It is also a distinct privilege to join Mr. Reeve, who has been such an articulate spokesman for support of research that could contribute therapies and cures for debilitating diseases, spinal cord injury being a most personal issue.

For the record, I am Paul Berg, Robert and Vivian Cahill Professor of Cancer Research and Biochemistry, Emeritus and Director of the Beckman Center for Molecular and Genetic Medicine, Emeritus at Stanford University Medical Center. I am also Chairman of the American Society of Cell Biology Public Policy Committee. For my work in developing recombinant DNA technology, I received the Nobel Prize in Chemistry in 1980.

The specter of cloning generated by films and novels has obscured the role and importance of the process in some of the most important recent advances in biomedical research. Cloning is a scientific term to describe the preparation of an "infinite" number of copies of, for example, a single molecule, cell, virus or bacterium. For example,

cloning DNA molecules was essential for solving the human genome sequence. Similarly, cloning DNA is critical to fight against bioterrorism and has already been used in the determination of the entire genome sequences of several organisms identified as bioweapons. Furthermore, cloning is integral to modern forensic procedures, medical diagnostics, vaccine development, and the discovery and production of many of the most promising drugs. Cloning is also used to make genetically identical plants and livestock enabling continued agricultural breakthroughs necessary to feed a rapidly growing and undernourished world population. I regret greatly that the frightening thoughts conjured up by the term alone have clouded the issues that confront us.

That said, very few, if any, reputable biomedical scientists condone attempts to produce a cloned human being. In the words of the distinguished National Academy of Sciences Panel that considered this issue, "it is dangerous and likely to fail"; in short, there are unacceptable risks to the mother and any fetus that would result from the procedure. Moreover, there is no compelling reason today or perhaps in the immediate future to attempt such a procedure. Therefore, I support the portion of Senator Brownback's bill (S-790) that mandates a legally enforceable ban on reproductive cloning. However, I am loath to permit the possibility that this mode of reproduction would remain for all time an anathema. I would advocate that the legislation establish a mechanism for reviewing the statute periodically, perhaps every ten years, to determine if the judgements made today remain valid in the light of new scientific information.

But Senator Brownback's proposed legislation goes far beyond a prohibition of reproductive cloning. His bill also includes two provisions that would deprive American patients access to potential therapies for some of the most debilitating diseases. The first of these would impose criminal penalties and heavy fines on scientists who attempt to transplant the nucleus from a normal body cell into a human egg cell whose own nucleus had been removed. The power of this procedure is that such an asexually produced product can be nurtured to divide a sufficient number of times to produce a ball of cells within which embryonic stem cells reside. These cells can be propagated in Petri dishes indefinitely all the while retaining their capacity to be coaxed into forming any of the body's many cell types. The particular value of nuclear transplantation technology is that the embryonic stem cells and the differentiated cells and tissues they yield have the same genetic makeup as the individual that donated the nucleus. Consequently, they can be used to repair or replace damaged or diseased tissues without invoking immune rejection that would occur with unmatched cells. In a sense, a person's own DNA is used to create compatible cells for the treatment of, for example, that individual's cancer, diabetes, spinal cord injury or Parkinson's disease.

A particularly promising opportunity that is also foreclosed by the Brownback bill is the preparation of stem cells using body cell nuclei from individuals with inherited mutations; particularly, ones that predispose such individuals to an increased probability for developing a variety of life-threatening and debilitating illnesses late in life: for example, breast, colon, prostate and other cancers, as well as heart, neurological and autoimmune diseases. Such currently unavailable stem cell lines would provide a new

way to explore how these life-threatening, late-onset diseases develop and possibly generate clues to their prevention or cure. Such studies might help illuminate the interrelations among inheritance, environment and chance that govern so much of the balance between health and disease.

Senator Brownback has been outspoken in his belief that experimentation with embryonic stem cells for therapeutic purposes is unnecessary. He believes that we already have the means to meet that challenge by using adult-derived stem cells, specialized cells that already exist in many of our tissues and are capable of repairing damaged or diseased tissue. Unfortunately, Senator Brownback has relied on claims that are largely anecdotal, most often unreplicated by others and, in some cases, experiments that are demonstrably flawed. While some adult-derived stem cells undoubtedly hold promise for certain therapies, e.g., bone marrow reconstitution, repair of damaged heart muscle, liver and neural tissues, their potential is limited by their rarity and the consequent difficulty of harvesting and propagating them in quantities sufficient to be useful. Furthermore, their developmental potential is limited compared to the multi-potentiality of embryonic stem cells. Every scientific review of the therapeutic opportunities afforded by adult-derived and embryonic stem cells has concluded that embryonic stem cells are far more versatile for medical therapies. Nevertheless, scientists working in these fields recommend strongly, as do I, that research should proceed vigorously with both adult and embryonic cells so as not to delay or forgo reaping their benefits for patients as soon as possible.

One of the concerns that has been cited as justification for the criminalization of the nuclear transplantation procedure is to guard against rogue attempts to implant the product into a woman's uterus for the purpose of creating a cloned child. But surely we have other means for preventing that very unlikely possibility. You may recall, Senator Kennedy, that 25 years ago, in response to widespread concerns about the possible dangers of recombinant DNA research, the U.S. Senate came close to imposing severe criminal penalties on such research and development in this country. Had that occurred, it would have cost us our nation its scientific eminence and the world's leading biotechnology industry. Fortunately, another means was adopted to ensure that the work could be done safely. That included regulation, which mandated oversight by an institutional review process and approval by a National Institutes of Health Recombinant DNA Advisory Committee before such research could be undertaken. Once approved, the Committee monitored the research's progress to ensure compliance with governing regulations. A process resembling the one I outlined or the one that was instituted to oversee gene therapy experimentation could be implemented to ensure that nuclear transplantation technology is done only to advance medical knowledge and develop medical therapies, and not for procreation. Appropriate penalties could certainly be levied on individuals or organizations for gross infractions or deliberate violations of the prescribed procedures.

The third provision in the Brownback bill, which has escaped close scrutiny in the public debate, is one I find particularly onerous. The bill mandates the same severe criminal penalties on those who import into the United States materials or medical

treatments that were developed using the nuclear transplantation technology. It seems unbelievable to me that the United States Senate would deny physicians or their patients from access to the most advanced therapies. It would appear, therefore, that millions of suffering Americans would be denied hope of cures for their disabilities because certain members of our Congress possess an aversion, admittedly deeply felt, to a procedure that was used in its development. Surely we must concede that all of us have a responsibility to those suffering from life-threatening diseases and severe handicaps to explore every opportunity and every means to alleviate their suffering.

We take considerable pride in being a pluralistic society. So, there must be ample room for differences concerning the moral and ethical interpretations of early and intermediate stages of human development, especially where acknowledging these alternate and equally legitimate views can mean the difference between life and death for many of our citizens.

Thank you for the opportunity to express my views. I am ready to respond to the committee's questions.