Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Technology, Energy & Communications Committee

HB 1732

Brief Description: Developing guidelines for plant, animal, and human therapy research conducted in the state.

Sponsors: Representatives Morris, B. Sullivan and Chase.

Brief Summary of Bill

- Specifies the state's research policy involving human stem cells.
- Creates the Human Stem Cell Research Advisory Committee.
- Requires the Department of Agriculture to adopt rules for the appropriate management practices for coexistence of plant-based life sciences, including genetically engineered organisms.
- Prohibits cities or towns from regulating the use of genetically engineered organisms.

Hearing Date: 2/7/07

Staff: Scott Richards (786-7156).

Background:

The Biology of Stem Cells

Stem cells can be distinguished from other types of cells in three ways. First, they are capable of dividing and replicating (renewing) themselves indefinitely. Second, stem cells are unspecialized. This means that they do not perform any specific function, as do heart muscle cells, red blood cells, or nerve cells. Lastly, stem cells can create specialized cells. While stem cells do not perform a particular function, they can give rise to specialized cells while remaining unspecialized themselves.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Stem cells can be classified as embryonic stem cells, embryonic germ cells, and adult stem cells according to the stage of development of the organism. The key difference between embryonic stem cells and adult stem cells is that an embryonic stem cell can become any type of cell in the body, while adult stem cells can only vary between the different types of cells within the organ in which they are found. Some research, however, has suggested that adult bone marrow stem cells may have similar characteristics. Another significant difference is that embryonic stem cell replication can generate large numbers of new cells, while adult stem cells do not replicate as easily under current technology.

Scientists obtain human embryonic stem cells from the blastocyst stage of embryos that are not used after in vitro fertilization treatment. The blastocyst is the stage of embryonic development that occurs approximately four to five days after fertilization of the oocyte and prior to implantation in the uterine wall. In 1998 scientists first isolated and cultured human embryonic stem cells, a process that destroys the embryo. Current research using stem cells pertains to diabetes, Parkinson's disease, heart disease, strokes, cancer, arthritis, burns, congenital birth defects, and spinal cord injuries.

Federal and State Policy on Stem Cells

In 1995, Congress passed legislation prohibiting the use of federal funds for research that may harm a human embryo. The most recent executive order to interpret this law was issued in August 2001 when the President announced that federal funding of embryonic stem cell research would be permitted only for research on the embryonic stem cell lines in existence at that time; funding would not be available for any subsequently created embryonic stem cell lines. The limitation does not apply to privately funded research. At the same time, the President announced the creation of the President's Council on Bioethics to study the ethical and moral implications of developments in biomedical and behavioral science and technology.

In the past few years some states have passed legislation regulating stem cell research. Bills were enacted in South Dakota and Kansas to restrict the use of human embryonic stem cells for research, while California and New Jersey have declared that it is their policy to permit research regarding human embryonic stem cells, human embryonic germ cells, and human adult stem cells. Several states have created institutes to coordinate stem cell research, including California which recently passed Proposition 71 to provide $3 billion to fund stem cell research.

Somatic Cell Nuclear Transfer (SCNT)

Somatic Cell Nuclear Transfer is the scientific term for cloning. Somatic cells are any body cell other than gametes (egg or sperm). The process of SCNT can be used for therapeutic or reproductive purposes.

Therapeutic Cloning

The goal of therapeutic SCNT is to create cells that exactly match a patient. By combining a patient's somatic cell nucleus and an enucleated egg (nucleus removed), a scientist may harvest embryonic stem cells from the resulting embryo that can be used to generate tissues that match a patient's body. This means the tissues created are unlikely to be rejected by the patient's immune system.

Reproductive Cloning

The goal of reproductive SCNT is to create an animal being identical to the animal that donated the somatic cell nucleus. The embryo is implanted in a uterus and develops into a live being. The

first animal to be created by reproductive cloning was Dolly the sheep, born at the Roslin Institute in Scotland in 1996.

While SCNT can be used for therapeutic or reproductive purposes, the initial stage that combines an enucleated egg and a somatic cell nucleus is the same.

Life Sciences Discovery Fund

In 2005, the Legislature created the Life Sciences Discovery Fund Authority (Authority) with the purpose to promote life sciences research to foster a preventive and predictive vision of the next generation of health-related innovations, to enhance the competitive position of Washington in this vital sector of the economy, and to improve the quality and delivery of health care for the people of Washington. It is expected that this purpose will be achieved by making grants to research institutions in the state.

The Authority is governed by an 11 member board, with seven members appointed by the Governor and four members appointed by the Legislature.

Beginning in 2008, Washington's receipts from the tobacco settlement will increase by $35 million per year. The legislation establishing the Authority funnels these monies into a trust account and authorizes the Authority's trustees to expend it. The intent is to use the money to help Washington research institutions advance both their competitiveness for external grant support and their ability to move discoveries toward commercialization.

Genetically Engineered Organism

A genetically engineered organism (GEO) means an organism altered or produced through genetic modification from a donor, vector, or recipient organism using recombinant DNA techniques. Deoxyribonucleic acid (DNA) is a chemical found primarily in the nucleus of cells which carries the information for making all the structures and materials the body needs to function.

Federal Regulation of GEOs

The federal regulatory system governing agricultural biotechnology consists of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). The APHIS is responsible for regulating all genetically engineered (GE) plants, the EPA is responsible for GE microbes and plant-incorporated protectants, and the FDA is responsible for ensuring the safety of food from GE crops and for pharmaceutical chemicals produced in GE crops. States may develop laws and regulations related to GEOs, but the federal agencies have primacy over state regulators if conflicts arise.

Washington State Department of Agriculture (WSDA)

The WSDA regulates the introduction into or release within the state of a plant pest, noxious weed, bee pest, or any other organism that may directly or indirectly affect the plant life of the state as an injurious pest, parasite, predator, or other organism. The WSDA may issue a special permit for the introduction and release of a plant pest, noxious weed, bee pest, or any other organism. A special permit is not required for the introduction or release within the state of a GE plant if the introduction or release has been approved under provisions of federal law and the WSDA has been notified of the planned introduction or release.

Summary of Bill:

State Stem Cell Policy

It is the policy of Washington that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, is permitted after full consideration of the ethical and medical implications of this research by the Human Stem Cell Research Advisory Committee (Committee).

Human Stem Cell Research Advisory Committee

The Committee is created to develop and submit to the Life Sciences Discovery Fund Authority scientific, ethical, and legal guidelines for research involving the derivation or use of human adult stem cells, human embryonic germ cells, and human embryonic stem cells in Washington. The guidelines are due by July 1, 2008. The guidelines must inform potential researchers of specific scientific, ethical, and legal considerations that must be examined prior to a research project being approved by the Committee.

The Committee is responsible for reviewing all stem cell research proposals prior to commencement of such research in the state. After full consideration of the ethical and medical implications of the research, the Committee determines, by a majority vote, whether the research project may go forward.

The Committee shall consists of the following members:

- the Governor or the Governor's designee;
- a representative from the University of Washington;
- a representative from Washington State University;
- the Attorney General or an Assistant Attorney General with relevant expertise; and
- a representative from the Washington State Medical Quality Assurance Commission.

Genetically Engineered Organisms

The Washington State Department of Agriculture (Department) is required to adopt rules that establish appropriate management practices for coexistence of plant-based life sciences in this state.

In adopting these rules, the Department must consider the following issues:

- the possible spread of genetically engineered organisms by pollen drift;
- the need for isolation distances to prevent pollen drift where possible; and
- the possible financial liability for farmers, patent holders, and manufacturers of genetically engineered organism products.

In adopting these rules, the Department shall consider best available science.

State Preemption of Local Ordinances

The imposition of controls on genetically engineered (GE) organisms is of statewide significance and is preempted by the state. No city or town may enact, maintain, or enforce ordinances or other provisions that regulate the registration, labeling, sale, storage, transportation, distribution, notification of use, or use of GE organisms.

Appropriation: None.

Fiscal Note: Preliminary fiscal note available.

Effective Date: The bill takes effect 90 days after adjournment of session in which bill is passed.