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HJR 588: Medical, Ethical, and Scientific Issues Relating to Stem Cell Research Conducted in the Commonwealth

June 21, 2005

House Joint Resolution 588 (Marshall, R. G.), the enabling resolution for the study, created a 15-member subcommittee. There are eight members from the General Assembly, Delegates Robert G. Marshall (chairman), Kenneth C. Alexander, Kathy J. Byron, David A. Nutter, John M. O'Bannon and Senators Richard L. Saslaw (vice chairman), Harry B. Blevins,and Janet D. Howell; three representatives of Virginia's medical schools, Paul J. Hoehner, M.D., Thomas Farris Huff, PhD., and Jacob F. Mayer, Jr., PhD.; and four nonlegislative citizen members at large, Dennis G. Fisher, PhD., Kris Gulden, Eileen M. Hall, RN, and Kelly Hollowell, JD, PhD.

STUDY DIRECTIVE

The resolution notes the controversy surrounding research using human embryonic stem cells (hEMS) and comments on the often discussed "distinction between embryos created for research purposes and those created for reproductive purposes." The joint subcommittee's directive is broad and nonspecific, to "examine the medical, ethical, and scientific policy implications of stem cell research and the efficacy of research using both adult and embryonic stem cells."

JOINT SUBCOMMITTEE STUDYING MEDICAL, ETHICAL, AND SCIENTIFIC ISSUES RELATING TO STEM CELL RESEARCH IN THE COMMONWEALTH

HIGHLIGHTS

- **The study directive is broad and nonspecific, to "examine the medical, ethical, and scientific policy implications of stem cell research and the efficacy of research using both adult and embryonic stem cells."**
- **There are five references to stem cell research in the Code of Virginia.**

VA LAW THAT ADDRESSES STEM CELL RESEARCH

Including SB 1194, which became law on July 1, 2005, Virginia statutes currently contain five references to stem cell research:

1. *Section 2.2-2233.2* (SB 646, 2004) established the Biotechnology Commercialization Loan Fund under the auspices of the Center for Innovative Technology (CIT), the operating entity for the Innovative Technology Authority (ITA) created in 1984 by the General Assembly. The fund is "for the sole purpose of financing technology transfer and commercialization activities related to biotechnology inventions made, solely or in cooperation with other organizations, at qualifying institutions," which includes Virginia's colleges and universities or intellectual property foundations associated with them. The law includes the caveat that "[n]o loan shall be made to any entity which conducts human stem cell research from human embryos, or for any loan to conduct such research; however, research conducted using adult stem cells may be funded."

2. *Section 2.2-2818*, relating to state employees' health plan, was amended in 1995 by SB 830 (Holland, C.A.) to "[i]nclude coverage for treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer Institute. For persons previously covered under the plan, there shall be no denial of coverage due to existence of a preexisting condition."

3. *Section 38.2-3418.1:1*, relating to health insurance, was added in 1994 by HB 240 (Christian). This law requires health insurers to "offer and make available coverage" for "dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to protocols approved by the institutional review board of any United States medical teaching college including, but not limited to, National Cancer Institute protocols that have been favorably reviewed and utilized by hematologists or oncologists experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants."

4. *Section 58.1-3506*, relating to other classifications of tangible personal property for taxation, was amended by HB 574 (May, 2002) to add subdivision A 32. The relevant subdivision provides authority for localities to tax classes of property at a different rate (a lower rate than the local rate established for all other classes of tangible personal property) that are "equipment used primarily for research, development, production, or provision of biotechnology for the purpose of developing or providing products or processes for specific commercial or public purposes, including, but not limited to, medical, pharmaceutical, nutritional, and other health-related purposes; agricultural purposes; or environmental purposes ***but not for human cloning purposes as defined in § 32.1-162.21 or for products or purposes related to human embryo stem cells [emphasis added].*** For purposes of this section, biotechnology equipment means equipment directly used in activities associated with the science of living things." In other words, equipment used for research relating to human cloning purposes or relating to human embryonic stem cells would not qualify for the lower rate.

5. *Section 23-286.1*, effective July 1, 2005, the Christopher Reeve Stem Cell Research Fund was created by SB 1194 (Potts). The Fund will consist of appropriations (if provided), gifts, grants, and donations from public or private sources and will be administered by the existing Commonwealth Health Research Board. Although no state appropriations are currently allocated, the law establishes a special nonreverting, revolving, and permanent fund for the support of stem cell research in honor of Christopher Reeve. However, embryonic stem cell research cannot be funded.

OTHER RELATED VIRGINIA LAW

In 2001, Chapter 5.2 of Title 32.1, Human Cloning, was added to the Code of Virginia with passage of two identical bills, HB 2463 (McDonnell) and SB 1305 (Newman). The law prohibits

(i) human cloning, (ii) the transfer of the product of a somatic cell nuclear transfer (cloning technology) into a uterine environment to initiate a pregnancy, and (iii) the possession of the product of human cloning or the shipping or receiving of that product in commerce for the purpose of implanting the product into a uterine environment so as to initiate a pregnancy. Cloning research or practices on animals other than humans is not prohibited.

BACKGROUND

The study's organizational meeting included a short chronology of the controversy relating to stem cell research:

- Scientists had postulated the existence of adult stem cells for approximately forty years.
- Adult stem cells have been identified and isolated for approximately twenty years.
- Adult stem cells derived from blood (peripheral and cord) and bone marrow have been used in the treatment of various cancers, including certain leukemias, breast cancer and other diseases for at least ten years—first in clinical trials, but currently moving into the mainstream of medical treatment.

From 1996 through 2004, the "Dickey Amendment," named for its sponsor Representative Dickey, prohibited federal funding for the creation or destruction of human embryos for research purposes. The amendment was added to congressional bills, including funding for the National Institutes of Health.

On November 5, 1998, two independent research teams, Dr. James A. Thomson and colleagues at the University of Wisconsin and Dr. John D. Gearhart and his research group at Johns Hopkins University School of Medicine, reported on the same day in two different journals the discovery of human embryonic stem cells.

In 1999, the Dickey Amendment was analyzed as banning the funding of the derivation of stem cell lines from human embryos, but not banning federal funding of research on embryonic stem cells after the cell lines had been established. This interpretation was based on the Dickey amendment definition of embryo in terms of "an organism that, when implanted in the uterus, is capable of becoming a human being" and the inability of an embryonic stem cell to become a human being regardless of whether implanted in the uterus.

In 2001, President Bush announced that federal funds may be awarded for research using human embryonic stem cells that meet specific limiting criteria.

MEMBERS VIEW STEM CELL WEBSITES*

Members viewed six relevant Internet websites in order to gain background information on stem cell research. The National Institutes of Health's "Stem Cell Research Information" web page *(http://stemcells.nih.gov/policy/NIHFedPolicy.asp)* concisely outlines the federal limitations on human embryonic research:

> "On August 9th, 2001, President George W. Bush announced that federal funds may be awarded for research using human embryonic stem cells if the following criteria are met:
>
> The derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 P.M. EDT on August 9, 2001.
>
> The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed.
>
> Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements."

The members visited the Univer-

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HIGHLIGHTS

- **Law prohibiting human cloning was added to the Code of Virginia in 2001.**
- **Adult stem cells have been identified and isolated for about 20 years and have been used for the treatment of cancer and other diseases for at least 10 years.**
- **President Bush announced in 2001 that federal funds may be awarded for research using human embryonic stem cells that meet specific limiting criteria.**

HIGHLIGHTS

- **A review of relevant websites provided the members with background information on stem cells.**
- **An early blastocyst, a development stage at which point stem cells can be taken, has been described by scientists as smaller than the dot at the end of a sentence.**
- **In 2002, the AMA adopted guidelines for stem cell research, which included monitoring of new research developments and the use of somatic cell nuclear transfer technology.**

sity of California Medical Center's *The Visible Embryo* web page *(http://www.visembryo.com/),* which is an interactive site designed to educate medical students and other interested parties. The site depicts a spiral that tracks human reproduction from fertilization through the embryonic stages, including the twenty-three stages occurring during the first trimester of pregnancy, every two-weeks during the second and third trimesters, as well as development of the fetus to the point of birth. A third stage link allowed the members to zoom in on a slide depicting the early blastocyst, a stage of development occurring within three to five days after fertilization, but prior to implantation in the uterus at which point stem cells can be taken. A blastocyst has been described by scientists as smaller than the dot at the end of a sentence.

Members visited the website of the International Society for Stem Cell Research *(http://www.isscr.org/).* On the "public" area of the website, the ISSCR includes the article *Stem Cell Primer,* which notes the distinction between embryonic stem cells and adult stem cells. The undifferentiated embryonic stem cells can mature into any cell type depending on the surrounding environment, such as brain cells, heart cells, muscle cells, blood cells, blood vessel cells, skin cells, pancreatic islet cells that produce insulin, and bone cells. This characteristic is referred to by scientists as "pluripotency." Adult stem cells, on the other hand, appear to be "multipotent," able to differentiate into several cell types, but not all cell types. The site also provides illustrations and diagrams of various stem cell differentiation such as embryonic stem cells; hematopoietic stem cells, an easily obtained type of multipotent adult stem cell found in bone marrow; mesenchymal stem cells, also a multipotent adult stem cell obtained from bone marrow; and the asymmetric cell division of stem cells that reproduce exact replicas of themselves and a progeny cell which may differentiate into various kinds of stem cells.

Stem Cell Primer includes a concise description of somatic cell nuclear transfer—the technology used in reproductive or therapeutic cloning. The "profound technical and, more importantly, biological problems," of reproductive cloning are cited, such as obesity—including obesity at birth, infection, and early death. Dolly, the sheep, was the first animal cloned via this technology. The age of the donor DNA is recognized to be a problem; however, the exact nature of the defects are unknown.

Therapeutic cloning, involving the nuclear transfer of a patient's cell into an oocyte, a human egg, is believed to be a mechanism in which stem cells that are genetically compatible can be produced and transferred to the patient to initiate repair of tissue damaged through disease or injury. Recent studies conducted in Korea and other countries relating to therapeutic cloning have received media attention.

The American Medical Association's website *(http://www.ama-assn.org/ama/pub/category/13630.html)* was visited, specifically, *Report 5 of the Council on Scientific Affairs*, which sets out the AMA's stem cell recommendations. The guidelines adopted by the AMA House of Delegates as AMA policy at the 2002 AMA Annual Meeting are:

1. Supports biomedical research on multipotent stem cells, including adult and cord blood stem cells.
2. Supports the use of somatic cell nuclear transfer technology in biomedical research (therapeutic cloning).

3. Opposes the use of somatic cell nuclear transfer technology for the specific purpose of producing a human child (reproductive cloning).
4. Encourages strong public support of federal funding for research involving human pluripotent stem cells.
5. Will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology.

A visit to the Iacocca Foundation website *(http://www.iacoccafoundation.org/index.htm)* provided an example of a private entity that supports research, including stem cell research. Lee Iacocca established the Foundation in 1984 in memory of his wife, Mary, a diabetic who died in 1983 from complications of diabetes. The Foundation's mission "is to fund innovative and promising diabetes research programs and projects that will lead to a cure for the disease and alleviate complications caused by it." Mr. Iacocca is currently soliciting support for a study and clinical trials of a drug that may be a viable treatment for Type I diabetes. Mr. Iacocca has already contributed $1 million to this effort.

The final website visited was the National Academies, a consortium of professional science organizations, including the National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and the National Research Council *(http://www4.nationalacademies.org/news.nsf/isbn/0309096537?OpenDocument).* The membersreceived the prepublication copy of the April 2005 *Guidelines for Embryonic Stem Cell Research.* The guidelines provide standards for ethical conduct of human embryonic stem cell research. The guidelines include recommendations for a new level of oversight with higher standards than are presently required, including a separate review committee to evaluate research proposals and limitations on in vitro embryo development. The guidelines have been published in book form and may be purchased online from the National Academies.

STUDY PLAN

During the website review, members asked numerous questions and discussed some of the many possible issues, including the impact of federal funding limitations on embryonic stem cell research, the availability and quantity of excess/unneeded human embryos created for reproductive purposes, and the potential for using adult and embryonic stem cells for medical treatments.

FUTURE MEETINGS

The joint subcommittee has tentatively scheduled a meeting on August 17 in Northern Virginia. The locations for the September 21 and November 15 will be announced and appear on the study website.

Links to the websites reviewed during the meeting may be accessed on the study web page.

Joint Subcommittee Studying the Medical, Ethical, and Scientific Issues Relating to Stem Cell Research Conducted in the Commonwealth

The Hon. R. G. Marshall, *Chairman*

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http://dls.state.va.us/stemcell.htm

JOINT SUBCOMMITTEE STUDYING MEDICAL, ETHICAL, AND SCIENTIFIC ISSUES RELATING TO STEM CELL RESEARCH IN THE COMMONWEALTH

HIGHLIGHTS

- **The members received the National Academies prepublication copy of the April 2005 *Guidelines for Embryonic Stem Cell Research,* which provides for standards of ethical conduct in human embryonic stem cell research.**
- **A meeting of the joint subcommittee will be held in August in Northern VA and two in the fall in September and November at locations to be announced.**