Study of Medical, Ethical, and Scientific Issues Relating to Stem Cell Research Conducted in the Commonwealth

House Joint Resolution 588

Initial Staff Study Report

Origin of the Study

House Joint Resolution 588, patroned by Delegate Robert G. Marshall, is the enabling resolution for this study of Stem Cell Research. HJR 588 creates a 15-member subcommittee, composed of 8 members of the General Assembly (5 House and 3 Senate), 3 representatives of Virginia's medical schools (one each from Eastern Virginia Medical School, Virginia Commonwealth University School of Medicine, and the University of Virginia School of Medicine), and 4 nonlegislative citizen members at large.

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 resolution also notes the August 9, 2001 announcement by President Bush "that federal funds may be awarded for research using human embryonic stem cells under the following criteria: (i) the derivation process was initiated prior to 9:00 P.M. EDT on August 9, 2001; (ii) the stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed; and (iii) informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements." Further, the resolution states that 71 stem cell lines were, at that time, in compliance with the criteria for grant funding.

The joint subcommittee is authorized to hold four meetings during the 2005 interim; the approved budget for this study is $15,600 direct costs (to cover per diems and expenses), which includes $2,000 that is allocated for speakers, materials, and other resources. Other unbudgeted nonmember-related expenses require written authorization of the chairman and the Chief Clerk of the House of Delegates.

No recommendations of the joint subcommittee can be adopted if a majority of the House members or a majority of the Senate members vote against the recommendation and vote for the recommendation to fail, notwithstanding the majority vote of the joint subcommittee.

The meetings must be completed by November 30 and an executive summary of the findings and recommendations must be submitted by the first day of the 2006 Session, which must state the subcommittee's intention concerning a report of its findings and recommendations for publication as a House document.

The resolution provides a very broad charge to the joint subcommittee, directing it 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."

As required by the resolution, the Joint Rules Committee has approved implementation of this study.

Related Virginia Law

Virginia statutes currently include four references to stem cell research and will include a fifth reference when SB 1194 becomes law on July 1, as follows:

1. The Biotechnology Commercialization Loan Fund was established under the auspices of the Center for Innovative Technology's law in 2004 (see attached history for SB 646 of 2004 (Howell) and § 2.2-2233.2 of the Code of Virginia).[1] 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" (Virginia's colleges and universities or any intellectual property foundations associated with them). This law contains the following caveat: "No 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 the 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."[2]

3. Section 38.2-3418.1:1, relating to health insurance, was added to the Code of Virginia through the passage of HB 240 (Christian) of 1994.[3] 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."

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[1] See Chapter 942, 2004 Acts of Assembly. Please note the Biotechnology Commercialization Loan Fund is effective law; however, it is not, at this time, funded by the Commonwealth.

[2] See Chapter 353, 1995 Acts of Assembly.

[3] See Chapter 699 of the 1994 Acts of Assembly.

4. Section 58.1-3506, relating to other classifications of tangible personal property for taxation, was amended by HB 574 (May) of 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. As of July 1, 2005, the Christopher Reeve Stem Cell Research Fund will be 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 Commonwealth Health Research Board (an existing organization). 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 law

In 2001, Chapter 5.2, Human Cloning, was added to the Code of Virginia via two identical bills, i.e., HB 2463 (McDonnell) and SB 1305 (Newman).[4] The law prohibits human cloning, the transfer of the product of a somatic cell nuclear transfer into a uterine environment to initiate a pregnancy, the possession of the product of human cloning or the shipping or receiving of that product of a somatic cell nuclear transfer in commerce for the purpose of implanting the product of somatic cell nuclear transfer into a uterine environment so as to initiate a pregnancy. Cloning research or practices on animals other than humans is not prohibited.

Chronology of Stem Cell Controversy

- Adult stem cells were thought to exist for approximately forty years.[5]
- Adult stem cells have been identified and isolated for approximately twenty years.[6]

[4] See Chapters 868 and 870 of the 2001 Acts of Assembly.

[5] American Medical Association. Report 5 of the Council on Scientific Affairs (A-03). Cloning and Stem Cell Research. http://www.ama-assn.org/ama/pub/category/13630.html .

- Adult stem cells derived from blood (peripheral and cord) and bone marrow have been used in the treatment of various cancers (certain leukemias, breast cancer, etc.) and some other diseases for at least ten years---first in clinical trials but currently moving into the mainstream of medical treatment.[7]

- From 1996 through 2004, the "Dickey Amendment," which prohibited federal funding for the creation or destruction of human embryos for research purposes, was added to congressional bills including funding for the National Institutes of Health.[8]

- On November 5, 1998, two independent research teams reported on the same day the discovery of embryonic stem cells, i.e., by Dr. James A. Thomson and colleagues at the University of Wisconsin, and Dr. John D. Gearhart and his group at Johns Hopkins University School of Medicine.[9]

- 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 these embryonic stem cells. 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 embryonic stem cells to become a human being regardless of whether implanted in the uterus.[10]

- In 2001, President George W. Bush announced a policy restricting federal funding to certain embryonic stem cell lines that were already in existence (at this point, we will begin to navigate the Websites).[11]

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[6] American Medical Association. http://www.ama-assn.org/ama/pub/category/13630.html .

[7] Lymphoma Information Network - Bone Marrow and Stem Cell Transplants. http://www.lymphomainfo.net/therapy/transplants/bmt.html .

[8] National Institutes of Health. STEM CELL INFORMATION. The official National Institutes of Health resource for stem cell research. http://stemcells.nih.gov/policy/NIHFedPolicy.asp .

[9] Washington Post Company. Rick Weiss. *A Crucial Human Cell Isolated, Multiplied*. Friday, November 6, 1998.

[10] National Institutes of Health. http://stemcells.nih.gov/policy/NIHFedPolicy.asp.

[11] National Institutes of Health. http://stemcells.nih.gov/policy/NIHFedPolicy.asp.

Survey of Some Relevant Websites

National Institutes of Health
STEM CELL INFORMATION
The official **National Institutes of Health** resource for **stem cell research**

http://stemcells.nih.gov/policy/NIHFedPolicy.asp

The University of California Medical Center's *The Visible Embryo*

http://www.visembryo.com

International Society for Stem Cell Research

http://www.isscr.org
http://www.isscr.org/public/index.htm

The American Medical Association

http://www.ama-assn.org/ama/pub/category/13630.html

The Iacocca Foundation

http://www.iacoccafoundation.org/index.htm

The National Academies

Guidelines for Embryonic Stem Cell Research

http://www4.nationalacademies.org/news.nsf/isbn/0309096537?OpenDocument

Suggested Study Plan Options

Established Meeting Schedule

First Meeting:	Tuesday, June 21, 2005 - 2:00 P.M. - House Room C
Second Meeting:	Wednesday, August 17, 2005 - 10:00 a.m. - House Room C
Third Meeting:	Wednesday, September 21, 2005 - 10:00 a.m. - House Room C
Fourth Meeting:	Tuesday, November 15, 2005 - 2:00 p.m. - House Room C

Your charge is 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.

Therefore, it is suggested that you design at least two meetings to receive presentations and engage in dialogue with various experts in the medical, ethical, and scientific implications of both adult and embryonic stem cell research.

Some options for the examination of the medical and scientific issues are:

1. Contact the Director of the National Institutes of Health to request presentations and/or dialogue with NIH researchers/administrators on stem cell research from the national prospective and the Virginia perspective. The subcommittee may wish to hold one meeting in Northern Virginia in order to be in closer proximity to NIH.
2. Request presentations from the three medical schools relating to stem cell research being conducted in the Commonwealth.
3. Seek input from the pharmaceutical companies and biotech centers operating in the Commonwealth.
4. Arrange for telephone conference calls with researchers across the state or the nation relating to adult and embryonic stem cell research and the potential risks and benefits of such studies.
5. Seek input from the various treatment programs, whether clinical trials or otherwise, being implemented in the Commonwealth using stem cell technology/support, i.e., to determine the disease states being so treated, the source of the stem cells, and the efficacy of the outcomes.

Some options for the examination of the ethical issues are:

1. Request the preparation of a Website List dedicated to the ethical issues for the meeting focused on ethics (to be e-mailed to the subcommittee).
2. Contact a diverse group of the many ethicists practicing in Virginia to obtain input relating to the various issues surrounding adult and embryonic stem cell research (some of the ethicists in Virginia have participated in discussions of stem cell research at the national level).
3. Identify issues of concern/interest through a survey of the subcommittee members.
4. Bring together various ethicists and theologians from across the Commonwealth to discuss specific issues.
5. Conduct a discussion of the identified issues with various ethicists and theologians from across the Commonwealth.
6. Hold a public hearing to receive the comments of all interested parties, i.e., medical, scientific, and ethical experts and the public.

Finally, it is suggested that you reserve at least part of the last meeting as a work session to make decisions and to take votes on the subcommittee's report and any potential recommendations.

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