REPORT OF THE

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

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

# HOUSE DOCUMENT NO. 43

COMMONWEALTH OF VIRGINIA
RICHMOND
2006

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**IN THE COMMONWEALTH**
**TO**
**THE GOVERNOR AND THE GENERAL ASSEMBLY OF VIRGINIA**
**RICHMOND, VIRGINIA**
**2006**

To: The Honorable Timothy M. Kaine, Governor of Virginia
and
The General Assembly of Virginia

## I. Origin of the Study

### House Joint Resolution 588 of 2005

The enabling resolution for this study, HJR 588 (Marshall R.G.), created a 15-member subcommittee. The Joint Subcommittee was composed of eight legislative members: Delegates Kenneth C. Alexander, Kathy J. Byron, Robert G. Marshall, David A. Nutter, John M. O'Bannon, III, and Senators Harry B. Blevins, Janet D. Howell, and Richard L. Saslaw; three representatives of Virginia's medical schools: Paul J. Hoehner, M.D., of the University of Virginia School of Medicine, Thomas Farris Huff, Ph.D., of the Virginia Commonwealth University School of Medicine, and Jacob F. Mayer, Jr., Ph.D. of Eastern Virginia Medical School; and four nonlegislative citizen members at large: Dennis G. Fisher, Ph.D., Kris Gulden, Eileen M. Hall, R.N., and Kelly Hollowell, J.D., Ph.D.

The Joint Subcommittee was authorized to hold four meetings during the 2005 interim, with an approved budget for $15,600 direct costs (to cover per diems and expenses), which included $2,000 allocated for speakers, materials, and other resources.

### Study Directive

The resolution noted the controversy surrounding research using human embryonic stem cells and commented on the often discussed "distinction between embryos created for research purposes and those created for reproductive purposes."

The Joint Subcommittee's directive was broad and nonspecific, i.e., 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."

## II. Existing Virginia Law Related to Stem Cell Research

### Five Specific Code Citations

On July 1, 2005, Virginia statutes included five references to stem cell research, as follows:

- The Biotechnology Commercialization Loan Fund was established under the auspices of the Center for Innovative Technology's law in 2004 (see 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."

- 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]

- 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."

- 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

[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.

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.

- The Christopher Reeve Stem Cell Research Fund was created by SB 1194 (Potts), which became effective on July 1, 2005. The Fund consists of appropriations (if provided), gifts, grants, and donations from public or private sources and is administered by the Commonwealth Health Research Board. Although no state appropriations were allocated in 2005, 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, Human Cloning, was added to Title 32.1 of 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.

## III. A Short Chronology of the Stem Cell Controversy

Approximately forty years ago, scientists began postulating the existence of adult stem cells.[5] These theories began to be substantiated when adult stem cells were first identified and isolated approximately twenty years ago.[6] 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 to twelve years---first in clinical trials but rapidly moving into the mainstream of medical

[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 .

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

treatment.[7] However, the discovery of embryonic stem cells was more difficult, requiring new and controversial methodology. 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.[8]

The social controversy relating to human embryonic research preceded the 1998 announcements of the isolation of embryonic stem cells. Thus, the political debates had already begun at the federal level. 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.[9]

Following the 1998 publications of the isolation of embryonic stem cells, federal lawyers examined the limitations of the Dickey Amendment vis-a-vis the use of human embryonic stem cell lines. 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 after the cell lines had been established. The Dickey Amendment definition of embryo was stated in terms of "an organism that, when implanted in the uterus, is capable of becoming a human being"; thus, the inability of embryonic stem cells to become a human being regardless of whether implanted in the uterus fostered the 1999 interpretation.[10]

In 2001, President George W. Bush announced a policy restricting federal funding to certain embryonic stem cell lines that met specific limiting criteria.[11]

## IV. The Work of the Joint Subcommittee

### June 21 Meeting

The study's organizational meeting was focused on providing background information through a survey and discussion of six relevant Internet websites.[12] The website survey began with the National Institutes of Health's "Stem Cell Research

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

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

[9] 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 .

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

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

[12] Links to the websites reviewed during the June 21 meeting may be obtained from Appendix C or may be accessed on the study web page at http://dls.state.va.us/stemcell.htm.

Information" page, which concisely sets out the federal limitations on human embryonic research that were announced by President Bush, stating:

> "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 University of California Medical Center's *The Visible Embryo* was next visited.[13] *The Visible Embryo* is an interactive site designed to educate medical students and other interested parties. Upon entering the site, a spiral appears that tracks human reproduction from fertilization through embryonic stages, the twenty-three stages of the first trimester of pregnancy, the second and third trimesters, and development of the fetus to the point of birth. Clicking on the third stage will link the viewer to a slide depicting the early blastocyst, i.e., the early embryonic stage at which human embryonic stem cells can be taken. A blastocyst has been described by scientists and journalists as smaller than the dot at the end of a sentence.

From *The Visible Embryo*, the joint subcommittee was taken to the website of the International Society for Stem Cell Research.[14] On the "public" portion of its website, the ISSCR includes an article entitled ***Stem Cell Primer***.[15] This article 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, e.g., 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," i.e., able to differentiate into several cell types, but not all cell types.

The ISSCR site provides illustrations and diagrams of various stem cell differentiation, e.g., 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

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[13] The University of California Medical Center. *The Visible Embryo*. http://www.visembryo.com.
[14] The International Society for Stem Cell Research. http://www.isscr.org.
[15] Stem Cell Primer. The International Society for Stem Cell Research. http://www.isscr.org/public/index.htm.

division of stem cells (reproducing exact replicas of themselves and a progeny cell which can differentiate into various kinds of stem cells).

***Stem Cell Primer*** includes a concise description of somatic cell nuclear transfer---the technology that can be used for reproductive or therapeutic cloning. The "profound technical and, more importantly, biological problems," with reproductive cloning[16] are cited, such as obesity (including at birth), infection, early death, etc. 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 (human egg), is believed to be a mechanism in which stem cells that are genetically compatible with a patient can be produced and transferred to the patient to initiate repair of tissue damaged through disease or injury. Studies relating to therapeutic cloning being conducted in Korea and other countries have received much media attention.[17]

The American Medical Association's website was visited next, specifically, *Report 5 of the Council on Scientific Affairs*,[18] which sets out the AMA's stem cell recommendations , as follows:

*The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as AMA policy at the 2002 AMA Annual Meeting.*

*The AMA: (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; and (5) will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology.*[19]

The Iacocca Foundation website was next navigated to provide an example of a private entity formed for the purpose of supporting research, including stem cell research.[20] In 1984, Lee Iacocca established the Foundation in memory of his wife, Mary, a diabetic, who suffered complications from diabetes and died in 1983. The purpose of the Foundation "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." At the time of the June 2005 meeting, Mr. Iacocca was soliciting support

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[16] Dolly, the sheep, was the first animal produced through cloning.
[17] Please note that some of the most publicized therapeutic cloning research in 2005 has since been refuted.
[18] American Medical Association. *Report 5 of the Council on Scientific Affairs*. http://www.ama-assn.org/ama/pub/category/13630.html.
[19] Id.
[20] The Iacocca Foundation. http://www.iacoccafoundation.org/index.htm.

for clinical trials of a drug that a research study funded by his Foundation indicates may be a viable treatment for Type I diabetes; he had 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.[21] The Subcommittee was shown the prepublication copy of the April 2005 *Guidelines for Embryonic Stem Cell Research* and a copy of this document was provided in the subcommittee's packet. The guidelines are focused on providing standards for ethical conduct of human embryonic stem cell research. The guidelines include recommendations, for example, for a new level of oversight with higher standards than might be presently required, including a separate review committee to evaluate research proposals and limitations on *in vitro* embryo development. The guidelines were published soon after the Joint Subcommittee's June meeting in book form and may be purchased on-line from The National Academies.

During the website navigation, the Joint Subcommittee asked many questions, made numerous comments, and raised dozens of issues. For example, questions were posed about 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 development of treatments using adult or embryonic stem cells.

**August 17 Meeting[22]**

The Joint Subcommittee's second meeting was held at the Fairfax County Board of Supervisors Auditorium. The meeting, which convened at 5:00 p.m., featured an impressive panel of experts, who were seated and presented in alphabetical order.

**Dr. Gary S. Friedman**

Dr. Friedman is a physician with broad transplantation experience, having published extensively on clinical transplantation, transplant immunology, cellular pharmacology, and hematological issues in clinical transplantation, and directed a transplant program for ten years. He is also a founder of International Regenerative Medicine (a consortium focused on development of therapeutic applications of human stem cells), the Director of the Center for Regenerative Medicine in Morristown, New Jersey, and a trustee of the New Jersey Stem Cell Research & Education Foundation.

Dr. Friedman began by noting some historical landmarks in transplantation. For example, the first successful kidney transplant was performed in 1954 and the use of

[21] The National Academies. Guidelines for Human Embryonic Stem Cell Research. http://newton.nap.edu/catalog/11278.html.

[22] The materials distributed at the August meeting may be accessed on the study's website, including the audio-streaming of the four presentations. The Joint Subcommittee was the first Virginia legislative organization to use audio-streaming to document its work.

nonembryonic stem cells was expanded (from bone marrow derived cells) in the 1980s to include stem cells from umbilical cord blood. He also noted that the Organ Procurement and Transplantation Network (OPTN) was established by Congress under the National Organ Transplant Act (NOTA) of 1984. United Network for Organ Sharing (UNOS) was also founded in 1984 in Richmond and then became the federal contractor for the operation of OPTN. In addition, NOTA included language that led to the formation of the National Bone Marrow Donor Program, which was initiated through the Navy and later received some federal funding.

Dr. Friedman stated that these entities operate on a "two system model." The bone marrow program was established to provide a database of bone marrow tissue types in order to provide more access to therapies using stem cells for cancers and other disorders. UNOS, on the other hand, operates to provide solid organs on a need basis in an egalitarian manner. He also noted that transplants---whether solid organ or stem cell---are reimbursed as services, i.e., the physicians performing the transplants are reimbursed. He also noted that federal law prohibits the sale of human tissue. He stated that less than 20 percent of the people who are waiting for transplants actually get the transplant and that the wait list time for solid organs has increased from one to two years to five to eight years in many regions.

Dr. Friedman said that he became interested in stem cell therapy because of the long waiting times for organ transplants---he thought that, if it would be possible to increase the life expectancies of individuals waiting for organ transplants through the use of stem cells, the patients waiting for organ transplants could be kept alive with stem cell therapy and the organ supply and demand issues could be ameliorated.

He also noted that many uses have been found for umbilical cord blood, i.e., the stem cells that can be provided through umbilical cord blood. However, he noted that procurement programs for solid organs do not include the recovery of bone marrow on any regular basis, primarily, because bone marrow harvesting is not reimbursed at this time. He expressed concern that bone marrow was not being harvested and banked since human bone marrow contains stem cells that can differentiate into blood, heart muscle, and other tissues. Because the transplant community believes in building on what they already have, Dr. Friedman supports the reconfiguring to the present procedures to include the harvesting of bone marrow among the transplant procurement teams and the collection and banking of cord blood. Thus, stem cell therapy could be available, after the tissue had been analyzed and characterized, perhaps even on a 24-hour basis in order to respond to the growing needs for patient therapy for every American waiting for transplant of stem cells or solid organs.

Dr. Friedman stated that using embryonic stem cells would require massive culture of the cells and noted that there is risk of tumor incidence or even malignancies when using these cells. He also noted that stem cells can migrate to any part of the body and that the donor cells may reproduce in various parts. Thus, the patient receiving stem cell therapy may have donor cells migrating and reproducing in any part of the body. He said that the investigators have found this phenomenon when embryonic stem cells are

transplanted, but not with adult stem cells, and that care must be taken to avoid poor patient outcomes and litigation resulting from the formation of teratomas.

Dr. Friedman emphasized that he believes the existing structure for organ and bone marrow collection should be used for organized cord blood banking and the harvesting and banking of donor bone marrow in order to provide plentiful sources of stem cells for use in regenerative medicine.

**Dr. John D. Gearhart**

Dr. Gearhart is the C. Michael Armstrong Professor of Medicine, Institute of Cell Engineering, Johns Hopkins University. He is professor of gynecology and obstetrics and of physiology at the Johns Hopkins University School of Medicine, has been on the faculty since 1980, and holds a joint appointment in the Department of Biochemistry and Molecular Biology at the Bloomberg School of Public Health. Dr. Gearhart is one of the preeminent stem cell researchers in the United States. He led the Johns Hopkins University research team responsible for first deriving human pluripotent stem cells in 1998. In keeping with his stem cell research, much of his research career has been focused on how genes regulate the formation of tissues and embryos, particularly in examining the causes of mental retardation and other congenital birth defects.

Dr. Gearhart began by responding to Dr. Friedman's concerns about the formation of teratomas when embryonic stem cells are used in transplantation. He stated that he wanted to set the record straight, that "from the experimental side when you isolate derivatives, you don't put in a grafted embryonic stem cell. It will lead to a tumor...." He noted that the experiments must be performed correctly and that you must make sure your grafts do not contain embryonic stem cells, because the capacity of the stem cells to divide and differentiate is a major safety issue. The cells for therapy must be grown downstream from the stem cell.

Dr. Gearhart described the program he heads at Johns Hopkins as dealing with various sources of stem cells, including adult source, umbilical cord blood, embryonic stem cells, and bone marrow derived stem cells, and cutting across many departments and institutes. His research group seeks to address many stem cell biology issues; however, most of the research is preclinical and experimental; very little of the research has resulted in clinical trials. Dr. Gearhart believes that this is appropriate. He observed that one of the problems with stem cell research and the potential for therapies is that the public wants therapies right now, although the development of medical applications will take time.

Dr. Gearhart focused on the uniqueness of the stem cell---embryonic or adult, because it has the capacity to self-renew, i.e., it can produce another cell like itself and it can specialize into another cell type. Some stem cells can only divide one time and others can divide many times and produce many different cell types. This conundrum is the central focus of stem cell science---trying to figure out which stem cells have the capacity for generating what tissues. The only major clinical application of stem cells, at

present, uses bone marrow derived stem cells, which contain two kinds of stem cells, hematopoietic and mesenchymal. He noted that regardless of the stem cell source, certain criteria must be met: (i) self-renewal, (ii) stability, (iii) capacity to multiply and specialize, and (iv) reproducibility of the results for quality control.

In Dr. Gearhart's research group, they are comparing various stem cell sources. Dr. Gearhart noted that comparison is the only way to find out what works and what doesn't work. He explained that when you graft bone marrow, you are putting both types of stem cells (hematopoietic and mesenchymal) into the individual, and, as Dr. Friedman said, the cells can migrate to any organ in the body and may contribute to a variety of tissues. He described the issue as: Are the cells functional in the tissues to which they contribute or are the cells simply residing in the tissue? An example of these concerns is the neuron stem cell---which will not reproduce all the different types of brain cells, but will only produce the type of cell from the region from which they are taken.

In response to questions relating to new publications and various researchers' results relating to adult stem cells and reprogramming or dedifferentiation, Dr. Gearhart noted that potency is an issue and that experiments must be reproducible. Serving as an editor for *Science*, Dr. Gearhart noted that he reviews many papers and that even as a professional, it is difficult to discern interpretation and fact. He cautioned the Subcommittee to examine carefully the many headlines on stem cell research.

Dr. Gearhart stated that, internationally, there are probably over 250 validated embryonic stem cell lines of which 22 appear on the President's list. Harvard University's Stem Cell Institute has developed approximately 17 embryonic stem cell lines. The number of stem cells being used in the United States is unknown because private funds are being used for any stem cell lines that are not eligible for federal funding. He emphasized that in the studies of adult and embryonic stem cells, his research, thus far, shows that embryonic stem cells work better in his laboratory's model.

Speaking to somatic cell nuclear transfer, Dr. Gearhart stated that scientists agree that reproductive cloning of human beings should not be allowed. He noted that the term "therapeutic cloning" has been used since 1999 and that scientists now regret the coinage of this term. The actual process would be to match an embryonic stem cell line by doing somatic cell nuclear transfer from the patient to an oocyte and then generate a blastocyst. The resulting stem cell would be a precise match for the patient; thus eliminating host-graft rejection.

Dr. Gearhart concluded that studies of human embryonic stem cells will result in important drug developments and that only through studies demonstrating the capabilities of both adult and embryonic stem cells will the controversy relating to which stem cell source works better be resolved. He acknowledged that the United States has lost its lead in the area of stem cell research and therapy development. Now, however, the work being done in Australia, Singapore, Korea, Israel, and the United Kingdom is cutting-edge research. Many of this country's brightest graduate students are looking for

Postdoctoral positions in these countries because of the cutting edge research being conducted with funding from government and private entities.

**Dr. Jonathan D. Moreno**

Dr. Moreno is the Emily Davie and Joseph S. Kornfeld Professor of Biomedical Ethics and the Director of the Center for Biomedical Ethics at the University of Virginia. Dr. Moreno holds a bachelor's degree from Hofstra University and a doctorate in philosophy from Washington University (St. Louis). He is a member of the Board of Health Sciences Policy of the Institute of Medicine (of the National Academies), and the Council on Accreditation of the Association of Human Research Protection Programs. He is immediate past president of the American Society for Bioethics and Humanities and a bioethics advisor for the Howard Hughes Medical Institute. He has published more than 200 papers, reviews, and book chapters, as well as at least six books on subjects ranging from human experimentation to clinical studies and practice. Dr. Moreno was co chair with Dr. Richard O. Hynes of the Massachusetts Institute of Technology of the National Academy of Science Committee on Guidelines for Human Embryonic Stem Cell Research.

Dr. Moreno's presentation was focused on the National Academies recently issued human embryonic stem cell research guidelines (see study website), which have now been published as a book. He emphasized that the National Academies are not government agencies, although they are chartered by the federal government and approximately 90 percent of the budget of the National Academies comes from work requested by Congress or the executive branch. The embryonic stem cell guidelines project was, however, supported by two private foundations and some National Academies' funds. The National Academies embryonic stem cell guidelines have no legal standing, only intellectual persuasion.

The committee producing the guidelines consisted of individuals with scientific, legal, ethical, and other expertise. The Academies only addresses issues of national significance, i.e., mandated by Congress or the executive branch or for which there is a perceived very important public need expressed through the scientific communities.

Dr. Moreno cited the many reasons for developing the embryonic stem cell guidelines, such as: the significant public support for human embryonic stem cell research; the diverse funding for stem cell research (private, federal and state); the scientific concerns relating to the hodgepodge of federal regulations; the lack of regulation of privately supported human embryonic stem cell research; and public and scientific uncertainty about the appropriate procedures for conducting this research.

The charge to the committee was to develop the guidelines to encourage responsible practices in this area, including the use of stem cells derived from surplus blastocysts from *in vitro* fertilization clinics, stem cells derived from blastocysts derived from donated gametes, and stem cells derived from blastocysts produced using nuclear transfer. The guidelines were also required to take ethical and legal concerns into

account and to encompass policy issues relating to the use of human embryonic stem cells for research and therapy. Although the guidelines address human embryonic stem cell research and therapy, the recommendations could be used to address concerns about other human stem cell research, including adult stem cells, fetal stem cells, or embryonic germ cells.

Among the issues addressed were donor recruitment (informed consent, compensation, conflicts of interest, confidentiality, risks of oocyte retrieval, and use of genetic information); stem cell characterization and standardization; safety in handling and storage of blastocysts and stem cells; sharing of materials between laboratories; appropriateness of and limitation on human embryonic stem cell research and therapy; and safeguards against exploitation or misuse.

The National Academies had already recommended, in 2002, that "Human reproductive cloning should not now be practiced. It is dangerous and likely to fail." In other words, the National Academies' position continues to be that human reproductive cloning should not be conducted.

The recommendations included (i) review by an Institutional Review Board, (ii) informed consent of all donors, (iii) severing donation decisions from all clinical decisions, (iv) prohibition of compensation or reimbursement to donors except for direct expenses, (v) no commercialization (sale or purchase) of donated materials, and (vi) protection of donor privacy.

The establishment of institutional oversight committees and an independent national panel to evaluate and revise the adequacy of the guidelines, as necessary, was also recommended. The institutional oversight committees, referred to as Embryonic Stem Cell Research Oversight (ESCRO) committees, were recommended to include public and expert representation.

The guidelines recommended that certain research with embryonic stem cells should not be permitted at this time, including *in vitro* culture of any intact human embryo beyond 14 days (a standard that has been accepted by most scientists), any research in which human embryonic stem cells are introduced into nonhuman primate blastocysts or in which any embryonic stem cells are introduced into human blastocyts, and that animals into which human embryonic stem cells have been introduced at any developmental stage should not be allowed to breed.

Compliance with the guidelines is strictly voluntary through the adoption of policies/practices that are consistent with the recommendations and the imposition of appropriate institutional sanctions for noncompliance. The guidelines have been endorsed by the presiding or executive officers of many prestigious institutions and organizations, including, but not limited to, the University of California, UC Berkeley, Harvard University, MIT, the Federation of American Societies for Experimental Biology, American Association of Universities, Society for Developmental Biology, and the International Society for Stem Cell Research, and have been adopted by the

California Institute for Regenerative Medicine. It is hoped that other states or entities will also consider endorsing or adopting the guidelines.

**Reverend Tadeusz Pacholczyk**

Father Pacholczyk is an ethicist and the Director of Education at the National Catholic Bioethics Center in Philadelphia and is a Catholic priest for the diocese of Fall River, Massachusetts. Father Tad, as he is known, earned four undergraduate degrees in philosophy, biochemistry, molecular cell biology, and chemistry at the University of Arizona. He later earned his Ph.D. in Neuroscience from Yale University, focusing primarily on cloning genes for neurotransmitter transporters that are expressed in the brain. Father Pacholczyk further studied for five years in Rome conducting advanced work in theology and in bioethics, examining the question of delayed ensoulment of the human embryo. He has testified before members of the Massachusetts and Wisconsin State Legislatures on the subject of human cloning. He is frequently called upon to make presentations and participate in roundtables on stem cells, cloning, and other biotechnologies through the United States and Europe, including a Pontifical conference on stem cells and cloning.

Father Pacholczyk's presentation focused on the moral arguments and ethical considerations raised by stem cell research issues. He framed his presentation to ask questions about the proper direction for legislatures in the future with respect to these issues, and whether medical efficiency should trump and triumph over ethics.

He began with a short vignette about a mother teaching her young daughters a lesson after refusing to allow them to see a movie with just a little bit of immorality. She showed the girls how a little bit of bad can ruin a lot of good by baking cookies with just a little of their pet rabbit's droppings in them. Dr. Pacholczyk analogized this to embryonic stem cell research and warned that in the same way that a rabbit's pellets can ruin the cookies, society's attempts to cover up a little bad by adding some good is an effort to pretend that the "bad" does not really exist.

Father Pacholczyk posed the question: "what is wrong with a little bit of embryo destruction to help the greater good?" He asserted that everyone in the room came from an embryo and acknowledged that an embryo is a very small object. He insisted, however, that once everyone accepts the fact that they started out as an embryo, the focus is drawn to a discussion of whether all human beings are created equal, regardless of size. Thus, he opined, if all human beings are created equal, the size of the human embryo doesn't matter, and consequently, the destruction of human embryos to help other humans is wrong.

Father Pacholczyk disputed the argument made by those in favor of embryonic stem cell research that there are hundreds of thousands of embryos in a deep freeze at *in vitro* fertilization clinics that will be thrown away if not used. He stated that it is essential to realize that the argument relating to discarding versus using for research is being used largely as a lever arm to pry open the door to do what truly is the ultimate goal:

therapeutic cloning. Father Pacholcyzk reiterated that this discussion is very important and noted that *in vitro* fertilization had, in his opinion, "slipped under the radar screen." He commented, in response to various comments relating to society's taking of human life as a matter of law through war and the death penalty, that the human embryo was "innocent life."

Father Pacholczyk discussed alternatives to embryonic stem cell destruction, such as back-differentiating adult stem cells to become more primitive, simple and powerful (in the manner of embryonic stem cells). Dedifferentiation (or reprogramming) of adult stem cells was postulated as a solution to the human embryonic stem cell controversy because no human embryo would have to be destroyed to achieve the result, i.e., derivation of embryonic stem cells. The dedifferentiated adult stem cells could then be forward differentiated in a new direction and have the potential to become many different types of cells.

Father Pacholczyk concluded his presentation by arguing against being on the scientific forefront of stem cell research and the concerns about the United States falling behind in scientific development. He proposed that the United States should be a true leader in the ethical sense. He expressed fear that the raw power of science will be exploited. He declared that running after the herd is not the critical issue, rather taking the moral high ground is where the country should head.

**Dr. David A. Prentice**

Dr. Prentice is a Senior Fellow for Life Sciences at the Family Research Council in Washington, D.C., and an Affiliated Scholar for the Center for Clinical Bioethics at the Georgetown University Medical Center. Dr. Prentice received his Ph.D. in Biochemistry from the University of Kansas and has held positions at the Los Alamos National Laboratory and the University of Texas Medical School at Houston before joining Indiana State University, where he spent 20 years as Professor of Life Sciences and 11 years as Adjunct Professor of Medical and Molecular Genetics at Indiana University School of Medicine. Dr. Prentice is an internationally recognized expert on stem cell research and cloning and was selected by the President's Council of Bioethics to write the comprehensive review of adult stem cell research for the Council's 2004 publication "Monitoring Stem Cell Research."

Dr. Prentice began his presentation by discussing the current and potential problems with embryonic stem cells. He noted that these stem cell lines are difficult to establish, handle, and maintain and also carry the possibility for causing tumors and tissue destruction.

Turning to adult stem cells, Dr. Prentice presented the Subcommittee with evidence that some adult stem cells show pluripotent capacity. For example, scholarly articles have shown that adult stem cells from bone marrow can form new neurons in the human brain and that bone marrow stem cells can even go on to form all body tissues. Other studies have shown that the placental amniotic stem cell can potentially form any

tissue without producing tumors. Human cord blood stem cells--which are young stem cells---have been shown to be pluripotent.

Dr. Prentice continued by describing various studies from around the world in which adult stem cells have been demonstrated as being effective in tissue repair. For example, the first clinical trials are under way to demonstrate that adult stem cells from brain, bone marrow, and umbilical cord blood provide therapeutic benefit after a stroke. Clinical trials have been started in Australia and Portugal to determine whether adult stem cells are capable of re-growth and reconnection in the spinal cord.

In describing the current uses of adult stem cells, Dr. Prentice enumerated treatments for cancers, autoimmune diseases, anemias, immunodeficiencies, bone/cartilage deformities, corneal scarring, stroke, cardiac tissues repair after a heart attack, Parkinson's disease, growth of new blood vessels, gastrointestinal epithelia, wound healing, and spinal cord injury.

Dr. Prentice also addressed earlier discussions on back-differentiation and concluded that this process currently is not sufficiently developed to be effective.

Dr. Prentice concluded his remarks by highlighting the advantages of pursuing adult stem cell research: They are the most promising source for treatments; they can multiply almost indefinitely, providing numbers sufficient for clinical treatments; they have proven success in laboratory culture, in animal models of disease, and in current clinical treatments; they have the advantage to "home in" on damage; and they avoid problems with tumor formation, transplant rejection, and ethical quandary.

The August presentations were recorded and are available through audio-streaming on the study website.

**September 21 Meeting**[23]

The Joint Subcommittee's September meeting was focused on stem cell research activities in Virginia, particularly at the three medical schools.

**University of Virginia Health System**

Dr. Roy C. Ogle is Professor of Neurosurgery, Cell Biology and Plastic Surgery, and the Director of the Center for Human Stem Cell Translational Research at the University of Virginia's Medical School. Dr. Ogle's research interests include a variety of investigations of bone repair, including cranial bone repair with adipose-derived stem cells and regeneration of calvarial (dome of the cranium) defects with adipose-derived stem cells and multipotent stem cells from dura mater (the membrane covering the brain and spinal cord). Dr. Ogle's presentation covered stem cell research as well as the use of cell-based therapy at the University of Virginia.

[23] Pictures of the Joint Subcommittee deliberating during the September meeting may be accessed on the study website.

**Sources and Characteristics of Stem Cells**

Dr. Ogle began by emphasizing that stem cells can divide and differentiate into at least one other cell type. After clarifying the common terminology, i.e., embryonic stem cells, fetal stem cells, and adult stem cells, he stressed that better terminology would be pluripotent stem cells and multipotent stem cells. Stem cell research, he observed, holds promise for drug development and improved understanding of gene control.

Each type of stem cell, Dr. Ogle noted, has strengths and weaknesses and the embryonic and adult stem cell research is complementary. The strengths of embryonic stem cells are that they are pluripotent, i.e., capable of differentiating into any cell type, and have infinite replication capacity. The weaknesses of embryonic stem cells, particularly the human embryonic stem cell lines that are currently approved for federal funding, are that differentiation is difficult to control; they have the potential for tumor formation; only limited immunotypes are covered; and the approved lines are contaminated with bovine and murine proteins/pathogens.

The strengths of adult (multipotent) stem cells, Dr. Ogle remarked, are their abundance, more uniform differentiation, restricted differentiation potential, and their potential for use in autologous therapies (using the patients own tissue). However, the weaknesses of any adult stem cells are their limited replication potential (not immortal), and limited plasticity (ability to be build tissue). Adipose tissue is a great source of adult stem cells, because fat is plentiful and easy to collect and the proportion of resident stem cells in adipose tissue is greater as compared to bone marrow, which is difficult and painful to harvest.

Dr. Ogle mentioned that, among others, adult stem cell sources are blood, bone marrow, adipose tissues (fat), and dura mater. Blood and blood fractions that are prepared by apheresis (a separation technique) contain at least four types of stem cells. Further, multipotent stem cells are important in bone marrow transplants, migrating to the recipient's bone marrow and differentiating to produce all types of blood cells, and demonstrating great plasticity by developing into fat, cartilage, bone, muscle, adipose tissues, and neurons (nerve cells) and glia (supporting tissue of the brain and spinal cord).

Umbilical cord blood has advantages over bone marrow or other blood, for example, it is almost pure stem cells that are young and do not yet have cell markers, will reproduce into mature, functioning blood cells faster and more effectively than bone marrow stem cells taken from another individual, and, because the T-cells are not completely functional at this young life stage, the risk of severe graft-versus-host disease is less.

On the other hand, treatment through pancreatic islet cell transplantation to treat Type I diabetes requires lifelong treatment with immunosuppressant---but does offer a cure. Reconstructive surgery now often uses adipose, muscle, blood vessels and bone to mold new tissues, with the lasting results attributable to the stem cells in the transplanted tissue. Multilineage cells from human adipose tissue have been shown to differentiate *in*

*vitro* to become cells that may form fat, cartilage, muscle, and bone under the proper environmental conditions.

Cell-based therapies that depend primarily on stem cells include blood and blood product transfusions and infusions, including umbilical cord blood; bone marrow transplants; pancreatic islet transplantation; organ transplantation; reconstruction with autologous tissues; and fertility and contraception treatments. Bone marrow stem cells can be used to replace diseased bone marrow in leukemias, aplastic anemia, and sickle cell anemia and to rescue damaged bone marrow after radiation or chemotherapy in lymphomas, neuroblastomas, and breast cancers.

**University of Virginia Stem-Cell Related Activities**

At the University of Virginia (UVA), embryonic stem cell research using mice is centered on kidney development, smooth muscle differentiation, and bone regeneration. Human embryonic stem cell research at UVA involves only National Institutes of Health approved cell lines to study smooth muscle differentiation and bone regeneration. In 2004, 48 adult and one pediatric transplants were performed at the University. Over the past twelve months, eight pediatric bone marrow, cord blood, and peripheral blood transplants have been performed.

In addition, tissue engineering procedures involving knee joints, nerves, and the cranial bones have been developed and are being advanced. Dr. Ogle showed slides of the regeneration of the skull of a 7-year-old child who had received treatment with autologous bone, adipose stem cells, and fibrin glue, and reconstruction of facial atrophy of a 17-year-old German child, with the noticeable benefits being attributed to the presence of stem cells used in therapy. Pancreatic islet cell transplantation is also performed at UVA on individuals having Type I diabetes.

Adult or multipotent stem cells are used as model systems in research laboratories at the University of Virginia in studies of myeloid leukemia, diabetes, breast cancer, blood vessel formation, heart function, renal failure, and fracture healing.

**Benefits to Virginians from Stem Cell Research and Therapy**

Dr. Ogle concluded his presentation by explaining the potential benefits of stem cell research and therapy as: improved quality of health care; reduction in cost of health care and long-term care; increased productivity; and economic development through biotechnology.

He also listed the characteristics of a national immunotype library that would establish, characterize, and distribute embryonic stem cells that were derived from extra embryos produced for IVF; would not create embryos with the intention of destroying them; and could eliminate the use of somatic cell nuclear transfer to obtain a patient match. A national immunotype library would be created through the pending federal bill, HR 810.

**Virginia Commonwealth University School of Medicine**

Dr. Jerome F. Strauss is the Dean of the Virginia Commonwealth University (VCU) School of Medicine and Executive Vice President for Medical Affairs of the VCU Health System. He comes to VCU from the University of Pennsylvania Medical Center where he continues to serve as Director of the National Cooperative Center in Infertility Research, which is sponsored by the National Institute of Child Health and Human Development of the National Institutes of Health. Dr. Strauss's research interests include the regulation of steroid hormone biosynthesis; the genetics of polycystic ovary syndrome; trophoblast differentiation and placental endocrine function; the biology of fetal membranes; the molecular control of sperm motility; and embryonic stem cell differentiation. Dr. Strauss's presentation was focused on the role of and plans for the development of regenerative medicine at Virginia Commonwealth University.

Virginia Commonwealth University's blueprint for research calls for enabling research in genetics, bioinformatics, neurosciences, microbiology and immunology, cellular and molecular biology, and structural biology in order to fulfill its mission-based research relating to maternal and child health, behavioral medicine, pathogens and the environment, aging and metabolism, cancer, cardiopulmonary disease, and, especially, regenerative medicine. The rationale for emphasizing regenerative medicine is related to reduction of unmet needs, increasing accessibility of health care, and reduction of health care costs. Dr. Strauss explained that the demographics, e.g., the aging of Virginia's population and the concomitant increasing burden of chronic disease, expense of current more invasive therapies, the complex health issues created by trauma, war, natural disasters, and bioterrorism, and the need to train health care professionals in new technologies render regenerative medicine an attractive alternative.

Dr. Strauss elaborated on the appeal of embryonic stem cells, explaining that they are immortal, can be cloned, are undifferentiated, and have wide developmental potential. The challenges in the development of embryonic stem cell therapeutics are: the definitive proof of the embryonic stem cell capabilities has not yet been discovered; purity is a problem in the approved cell lines because of contamination with bovine and murine cells; limited available immunotypes; apparent genetic instability and risk of cancer; difficulties in production; and the ethical issues.

Further, the stem cell biology research challenges include the controversy concerning whether embryonic or adult stem cells are more efficient; the various alternative proposals for generating pluripotent cells; the appropriate development of preclinical models; and whether any intellectual property is in the public or private domain.

Dr. Strauss mentioned several alternatives to stem cell therapeutics, such as isolation of stem cells from extraembryonic fetal tissues (e.g., the placenta); activation of endogenous stem cells; chemical or genetic initiation of nuclear reprogramming of adult cells to be like the embryonic cell; and various biomaterials and devices.

**Regenerative Medicine at Virginia Commonwealth University**

Regenerative Medicine at VCU involves interaction between the VCU's transplant center, level I trauma center, burn center, and Virginia Commonwealth University Reanimation Engineering Shock Center (VCURES). The goal of the regenerative medicine initiative is to advance organ and cell transplantation, development of biomaterials and devices and drugs and biologicals, and advance the clinical application and research in stem cells. In addition, VCURES, a multidisciplinary collaboration among clinicians, basic scientists, and engineers, is working on microvascular response to hemorrhagic shock, acute decompression illness, and, particularly relevant to stem cell research, blood substitute development.

**Virginia Commonwealth University's Stem Cell Related Activities**

At this time, VCU's stem cell related activities are focused on adult stem cells, alternative strategies, the interface between engineering and biology, and activation of endogenous stem cells. Over 200 bone marrow transplants are performed per year; the bone marrow transplant program at VCU is a recognized National Marrow Donor Program transplant center that performs both pediatric and adult unrelated allogeneic transplants and bone marrow harvests. The organ transplant program includes liver, pancreas, kidney, pancreas-kidney transplants (for Type I diabetics with end stage renal disease), islet cell transplantation, heart, lung, and heart-lung transplants. The Virginia BioTechnology Research Park houses VCU programs, such as the Institute for Structural Biology and Drug Discovery and the Institute for Oral and Craniofacial Molecular Biology.

**Eastern Virginia Medical School**

Dr. William J. Wasilenko is the Associate Dean for Research and an Adjunct Associate Professor in the Department of Microbiology and Molecular Cell Biology at Eastern Virginia Medical School (EVMS).

In his role as Associate Dean for Research at EVMS, Dr. Wasilenko directs the EVMS Biomedical Sciences Ph.D. Program, a joint program with Old Dominion University, and is administrative director of the EVMS Biotechnology Workforce Training Program. Dr. Wasilenko's research interests include tumor and cell biology, signal transduction, and medical modeling and simulation.

Dr. Wasilenko began his presentation by noting that EVMS was only founded in 1973 and is a smaller institution than the University of Virginia and Virginia Commonwealth University.

However, EVMS is the cutting-edge institution in reproductive technology, with the Jones Institute being a highly regarded infertility program throughout the world.

**Previous Stem Cell Research**

In 2001, researchers at EVMS derived three embryonic stem cell lines from human blastocysts created through *in vitro* fertilization using donor gametes. Dr. Wasilenko clarified that, at this time, no human embryonic stem cell research is being conducted and the researchers who conducted the 2001 published study have left the institution.

**Current EVMS Stem Cell Related Activities**

At this time, EVMS has stem cell related activities in regenerative medicine, for example, in diabetes. The Strelitz Diabetes Institutes at EVMS include The Research Institute, which has conducted pioneering research relating to the pancreatic islet neogenesis associated protein, commonly referred to as INGAP. In 1997 the Strelitz Diabetes Institutes announced the discovery of the INGAP gene, as part of ongoing research relating to genes and protein products that may cause pancreatic islet cells to regenerate and produce insulin.

The INGAP gene was identified in a preclinical model, i.e., hamsters. Subsequent work has been focused on the purifying and engineering of the gene. Phase II Clinical Trials are in progress on the results of some of this work. Other stem cell related activities relate to treatment of various cancers, infectious diseases, and reproductive/infertility disorders. In addition, Eastern Virginia Medical School does collect cord blood, if the parents so wish.

**November 15 Meeting**

The Joint Subcommittee's final meeting completed its 2005 review of stem cell research activities in Virginia and included a public hearing, information on cord blood banking, and a work session.

**Revivicor, Inc.**

Dr. David L. Ayares is the Chief Executive Officer of Revivicor, Inc., based in Blacksburg, Virginia. Revivicor, a recent spin-off company of PPL Therapeutics, is a biopharmaceutical company that has produced products used in treatment, for example, alpha-1-antitrypsin (AAT), which was awarded "orphan drug" status by the federal Food and Drug Administration in 1999 and has been used in clinical trials for treatment of hereditary emphysema and cystic fibrosis. Revivicor is a world leader in animal cloning technology, being a subsidiary of the company in Scotland that produced Dolly, the Sheep, the first cloned animal. Revivicor concentrates on advancement of biomedical products and regenerative medicine, with a diverse product development pipeline focused on creating genetically modified pig organs and cells for xenotransplantation applications (between species, such as from pigs to humans), stem cell therapies for diabetes, and development of human polyclonal antibodies from genetically modified livestock for biological warfare countermeasures.

Dr. Ayares' research at Revivicor has primarily focused on pigs in order to develop a solution to the donor organ shortage for patients needing transplants. Revivicor is responsible for the first successful cloning of pigs as well as the first successfully cloned knockout pigs---pigs that are lacking the gene associated with hyper acute rejection of xenografts (use of tissue from one species to treat another species). The goal of this animal cloning technology is to produce pig tissue that can be used in humans without being rejected. The gene that was "knocked out" or removed from the pigs is responsible for production of a sugar on pig cell surfaces that is foreign to humans and will, therefore, trigger an immune response leading to hyper acute rejection by humans within minutes of the transplant.

Bearing in mind that even human to human transplants require the use of immunosuppressants (drugs that inhibit the body's immune system) to control graft versus host disease, the goal of this research is to produce organs and cells that are tolerized, i.e., modified so as to be histocompatible with the human recipient. In other words, Revivicor's mission is to produce pig tissue and cells that can be used to treat humans without requiring life-long treatment with immunosuppressants, e.g., pancreatic islet cells for the treatment of diabetes.

Revivicor has been awarded four grants from the Advanced Technology Program (ATP) of the National Institute of Standards and Technology within the United States Department of Commerce, a federal grant initiative to promote the technology development in private industry. Dr. Ayares explained that the federal ATP is very important to private research efforts as venture capital is difficult to obtain for the basic research that is necessary to develop preclinical biotechnology. Because basic research is time consuming and the outcomes are unpredictable, investors are difficult to attract.

In 2000, PPL Therapeutics (Revivicor's parent company) was awarded a $1.9 million ATP grant to fund research relating to the production and differentiation of pluripotent stem cells without using embryos. This research was exclusively conducted on nonhuman species, i.e., pigs, and involved changing or transdifferentiating pig skin fibroblast cells into pig embryonic-like stem cells. The concept was considered a viable option for deriving large numbers of pluripotent stem cell lines without the supply constraints acknowledged to exist with the embryonic-derived lines. Somatic cell nuclear transfer, an expertise of Revivicor, was used on the readily available skin cells to transdifferentiate the pig skin fibroblasts to stem cells. However, the development of the stem cells was limited and the cultures did not continue to divide indefinitely. Although the research goal was not reached before the grant expired, much was learned, and the goal of transdifferentiating skin cells into stem cells may still be successful as some recent research seems to indicate.

**Cord Blood Banking**

Dr. Curtis Thorpe, technical advisor to the Joint Subcommittee from the Virginia Department of Health, presented information on cord blood banking that had been researched by staff. The Joint Subcommittee had asked whether other states or countries

supported cord blood banking systems and the feasibility and cost of establishing a statewide umbilical cord blood banking system in Virginia.

**Other States' Cord Blood Banking Initiatives**

Three states, Florida, Massachusetts, and New Jersey have different models of public cord blood banks.

Florida's program is a consortium between the University of Florida, University of Southern Florida, the University of Miami, and the Mayo Clinic in Jacksonville. Providing for the collection, screening for infectious and genetic diseases, tissue typing, and cryopreservation of cord blood as a public resource, the Florida program offers the opportunity to donate to the pregnant woman at the time of hospital or birthing facility admission, requires written disclosure from providers who financially benefit from cord blood, and authorizes the consortium to charge reasonable fees to recipients.

Massachusetts' program is a partnership with the University of Massachusetts Medical School at Worchester, established as a public cord blood bank for umbilical cord blood and placental tissue donated by maternity patients at certain participating hospitals. Licensed hospitals must inform pregnant women of the opportunity to donate cord blood and education will be provided to maternity patients about cord blood banking. Research institutions may agree to pay the estimated expenses of the collection and storage of the donated umbilical cord blood and placental tissues. Massachusetts also established a 15-member Biomedical Research Advisory Council to make recommendations to the Governor about biomedical research relating to cord blood and placental tissue.

New Jersey's program provided for a $5 million loan to the Coriell Institute for Medical Research, an internationally known, not for profit biomedical research institution with a long history of cell banking, cryogenic storage, and retrieval of human cell cultures, to establish the New Jersey Cord Blood Bank. Strong relationships between the cord blood bank and the collecting hospital are established and written informed consent must be obtained from any woman choosing to donate cord blood. The Coriell Institute for Medical Research is required to repay the state loan as reimbursement is received for cord blood released for therapy.

In some states, for example, Maryland, cord blood banking is regulated by requiring hospitals to allow pregnant patients to donate umbilical cord blood to certified cord blood banks and prohibiting charges for the donation. Further, Maryland law notes that employees who have bona fide religious objects cannot be required to collect cord blood and hospitals are not required to make patients' arrangements for donations of cord blood.

**Other Countries' Cord Blood Banking Initiatives**

In a growing number of countries across the world, cord blood banking initiatives have been established. For example, Brazil has a public cord blood bank at one maternity

hospital in Rio de Janeiro. Colombia recently established a cord blood banking program through the University of Antioquia.

India also recently announced government cord blood banking initiatives in four locations through a contract with a private firm. In Korea, the Seoul Cord Blood Bank is not a government program and is run by the same private firm contracted to run India's initiative. Singapore has a government-supported cord blood bank, established in 2004, that will provide free cells to any child whose cord blood has been donated; others are charged for the units. Australia has a national network of cord blood banks in Melbourne, Sydney, and Brisbane and registers cord blood in the Australian Bone Marrow Registry.

The European Union forbids profit making from the sale of body material; however, operating expenses may be recovered. France prohibits private cord blood banking, considers cord blood a national resource, and has only three hospitals that collect it. In the United Kingdom, the National Health Service collects cord blood for the public good, with 80 or more units having been released for transplantation. Italy prohibits private cord blood banking and has a network of public cord blood banks maintained by its national health system.

**National Marrow Donor Program**

The United States' National Marrow Donor Program is part of a worldwide network of 500 medical facilities that searches for a donor or cord blood match when a patient needs a transplant and facilitates an average of 200 bone marrow or blood cell transplants each month. The National Marrow Donor Program has a registry of more than 45,000 cord blood units in cord blood banks across a number of states.

**Cord Blood Banking in Virginia**

In Virginia only approximately five percent of umbilical cord blood is currently being banked in the medical schools, primarily for the use by pediatric oncologists for the treatment of children with cancer. Most stored cord blood in Virginia is being deposited at parents' expense in private storage facilities.

**Process for a Virginia Cord Blood Banking Initiative**

The first step for developing a public cord blood banking initiative in Virginia would be to develop a database of existing cord blood supplies and perhaps legal authority to access any privately banked cord blood during an emergency. In order to store umbilical cord blood to meet a statewide emergency, a capacity of at least 40,000 doses would be needed, with the cells stored for up to five years to ensure recycling to maintain cell integrity.

Drawing from other states' programs as examples, a cord blood banking program could be integrated into an existing state cell storage infrastructure, started as a new cord

blood initiative under state supervision, or contracted for with a private sector provider. Integration into an existing system would probably be the least expensive option, involving coordination with existing facilities at Virginia Commonwealth University's School of Medicine, the University of Virginia's School of Medicine, and the Eastern Virginia Medical School and its contracting hospitals, as well as the private hospital systems in Western and Northern Virginia (for a total of five sites covering all regions of the Commonwealth).

Site requirements would be approximately 400 to 500 feet of space, at least two liquid nitrogen freezers, at least two vent hoods, and access to fluorescent cell sorting and tissue typing. Costs at each of the five sites are estimated as $200,000 for equipment, two laboratory technicians per site at approximately $50,000 each plus benefits; and supplemental salary for an existing supervisor to manage an additional program. The approximate start up costs for the initial year would be $1.5 to $2 million, with maintenance costs estimated at $1 million per year, with monitoring costs unestimated. If implemented, a collaborative arrangement of this kind would make cord blood accessible to all parts of the state.

Establishing a new system would be more expensive and may require a new building or a renovated structure specifically designed for the cord blood bank. The new system would also require equipping and would probably have to be a Good Manufacturing Practices (GMP)[24] facility with a level V laboratory that is strictly regulated. The costs of such a facility and system could be as high as $20 million to initiate.

A third operation would be to contract with a private stem cell storage company, which would require a bid process and could present issues relating to control of the cord blood and access in any statewide or regional emergency.

With any of these options, various issues relating to patient privacy, recycling of cells over five years old as new cells enter the system, and perhaps sale of exiting cells to research programs or others to offset costs would have to be addressed.

**Public Hearing**

Three speakers registered and spoke during the public hearing and two statements were submitted and read for the record. The submitted statements were from Dr. John T. Bruchalski, an obstetrician/gynecologist practicing in Fairfax, in support of cord blood banking and adult stem cell research, and Ms. Moira Hall, a 20 year old diagnosed with Hodgkin's Lymphoma, who was treated with high-dose chemotherapy with stem cell support, using cells donated by a twin sister, and when this treatment was not successful, a second transplant of cells donated by a younger brother, with successful remission.

[24] Federal Food and Drug Administration regulations on the manufacture of products for human consumption, referred to as GMP or cGMP.

Representing the Virginia Society for Human Life (VSHL), Dorothy Tims expressed strong opposition for human embryonic stem cell research and support for the use of adult stem cells. She stated that "[t]he weakest and most vulnerable member of the human family---the embryo---should not be the subject of scientific experimentation" and that "[i]t is never morally or ethically justified to destroy one human being in order to possibly save another."

Ms. Tims described the advances that have been and are being made in adult stem cell research, using alternatives to embryonic stem cells such as cord blood, bone marrow, and neural stem cells. She called for the use of research money and efforts to be directed to the adult stem cell therapies that are "free of the ethical dilemmas associated with destructive human embryo research." Ms. Tims closed by stating that the VSHL encourages continued efforts in the scientific community to develop treatment for life threatening and life limiting diseases in a manner free from ethical issues.

Mr. Richard M. Doerflinger, Deputy Director of the Secretariat for Pro-Life Activities, United States Conference of Catholic Bishops, presented a notebook of supplemental materials to the Joint Subcommittee. Mr. Doerflinger, while noting that the Catholic Church does not oppose stem cell research, stated that destruction of human life at any stage was opposed, thus, human embryonic stem cell research is opposed. He noted that adult stem cells and stem cells from cord blood provide viable alternatives and cited the many advances in the research and therapies using adult stem cells. He also mentioned the drawbacks to embryonic stem cells research, such as the development of teratomas.

Mr. Doerflinger said that even the embryonic stem cell researchers now have reduced expectations from their studies. He also reflected that excess embryos are not available in the numbers required to produce the number of cell lines desired, which would take the destruction of millions of embryos.

Dr. Doerflinger described the potential for exploitation of women in the creation of the embryos, including the current controversy involving the Korean researcher and reports that one laboratory technician donated oocytes for the creation of the embryos used for his research. Mr. Doerflinger described human reproductive cloning, which almost all groups oppose, as potential fetus farming.

Dr. Michael Valente, a physician practicing neurology in the Commonwealth, came as a taxpaying citizen who objects to the possibility of using state tax money to fund human embryonic stem cell research. He stated that embryonic stem cell research using mice has not produced any cure for diseased mice.

He also said that adult stem cells from bone marrow, pancreas tissues, and discarded placentas, even nasal epithelium, are being used to treat diabetes, heart disease, leukemia, and other diseases.

Dr. Valente stated that he sees value in taxes when used for necessary services, but he is opposed to using public money for unproven research, especially since, he said, citing his medical background as providing special insight in this regard, scientists are moving away from embryonic stem cell research to the use of adult and umbilical cord blood stem cells.

**Work Session**

In the last several years, the controversy surrounding stem cell research, particularly research using human embryonic stem cells, has become ubiquitous, with media attention and even hyperbole generated for virtually every new development.

*Stem Cell Characteristics*

Stem cells are unique in that they asymmetrically divide, producing another cell like themselves, and a progeny cell that has the potential of differentiating into one or more cell types/tissues.

Embryonic stem cells are said to be pluripotent, i.e., capable of maturing into any cell type depending on the surrounding environment and the signals being received.

Adult stem cells, on the other hand, appear to be "multipotent," able to differentiate into several cell types, but not all cell types.

Some stem cells may divide only once and others can divide many times, producing many different cell types. Thus, the most difficult problem in stem cell science may be to figure out how and which stem cells have the capacity for generating specific tissues.

*Stem Cell Therapies*

Adult stem cells have been identified and isolated for approximately twenty years. However, human embryonic stem cells (or, as they may be referred to, germ cells) are a new research development, having only been reported on November 5, 1998, by two independent research teams in two different journals.

At this time, only adult stem cells are being used for human therapies in the United States. Adult stem cells derived from blood (peripheral and cord) and bone marrow have been used in the treatment of various cancers, such as certain leukemias and breast cancer, and some other diseases, such as sickle cell anemias, for at least ten years.

There are more than 120 FDA-approved uses of adult stem cells for human therapeutics and FDA-monitored human clinical trials, using adult stem cells. Recently,

adult stem cells derived from adipose and other tissues have been used in regenerative treatments.

Embryonic stem cell research, however, is still in its early stages, with most of the research being preclinical and experimental. Thus, although the public wants therapies to be immediately available, the development of medical applications for embryonic stem cells will take time.

*Therapeutic Cloning: Somatic Cell Nuclear Transfer*

Clinical applications for embryonic stem cell research may involve "therapeutic cloning," a term regretted by many scientists. The actual process would be to match an embryonic stem cell line to the patient by performing somatic cell nuclear transfer from the patient into a female donor's oocyte and then to generate a blastocyst (an early stage embryo). The resulting stem cell line would be a precise match for the patient, thus eliminating host-graft rejection.

*Stem Cell Issues*

In the United States, the public discussion relating to stem cell research has been multidimensional, including religious, ethical, societal, commercial, scientific, and political views. For example:

- Some religions view the destruction of a human embryo as the taking of human life.

- Ethicists often discuss a distinction between embryos created for research purposes and those created for reproductive purposes.

- The vast potential for developing therapies has excited much of the public, particularly those individuals suffering from or having relatives suffering from degenerative diseases and other disorders with little hope of recovery.

- In many countries, the potential for commercialization of medical applications and the possibility of spinning ahead of American researchers has motivated government funding for human embryonic stem cell research.

- Among scientists, the race to be first to discover the answers to the many research questions and to identify the best source of stem cells for various applications is being funded more and more frequently with private money.

- Recently, the prestigious National Academies issued human embryonic stem cell research guidelines in response to concerns about the "hodgepodge of federal regulations," "the lack of regulation of privately supported human embryonic

stem cell research," and "public and scientific uncertainty about the appropriate procedures for conducting stem cell research."

In the political arena, many actions have taken place. For example:

- 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.

- In 1999, the Dickey Amendment was analyzed as banning 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.

- In 2001, President George W. Bush announced that federal funds may only be awarded for research using human embryonic stem cells that meet specific limiting criteria, i.e., derived prior to 9:00 P.M. EDT on August 9, 2001; derived from embryos created for reproductive purposes that were no longer needed; and donated after informed consent and without financial inducements.

- In states across the country, legislatures have taken actions to create state-funded stem cell initiatives, to promote cord blood banking as a source of "young" stem cells, to curtail stem cell research, and, more and more frequently, to study the many issues.

## V. Joint Subcommittee Recommendations

After receiving the presentations on stem cell research at Revivicor and cord blood banking and reviewing the issues and, on motion with a unanimous vote, the Joint Subcommittee conducted a short work session.

The Joint Subcommittee concluded its 2005 deliberations by determining to recommend the establishment of a Virginia cord blood banking initiative to the 2006 Session of the General Assembly. Included in the motion was that the Joint Subcommittee would seek continuation of its study for another year.

## VI. 2006 Approved Legislation[25]

### Virginia Cord Blood Bank Initiative

House Bill 413 (Marshall) and Senate Bill 370 (Saslaw), identical provisions, were introduced and approved during the 2006 Session. The bills establish the Virginia Cord Blood Bank Initiative as a public resource for Virginians for the treatment of patients with life-threatening illnesses or debilitating conditions, for use in advancing

[25] See Appendix B for 2006 Legislation, as passed.

basic and clinical research, and, in the event of a terrorist attack, to be used in the treatment of the injured citizens of the Commonwealth.

The Initiative will be established as a nonprofit legal entity to collect, screen for infectious and genetic diseases, perform tissue typing on, cryopreserve, and store umbilical cord blood, and will be a collaborative consortium covering all geographical regions of Virginia.

The State Health Commissioner will develop or arrange for or contract with a nonprofit entity for the development of the Initiative. Medical schools, hospitals, biotechnology companies, regional blood banks, laboratories, and others will be requested to participate and assist in the design and implementation of the Initiative. Participants will estimate the costs of implementation and the Commissioner will assist in the development of cost estimates, compare and evaluate the estimates, and negotiate with the participants.

The Commissioner will also coordinate the design of the Initiative, such as appropriate contact with pregnant women, obtaining informed consent for donations, storage periods, recycling of the samples and the sale or transfer of the samples being withdrawn from storage for use in basic or clinical research, and the development of reasonable rates and fees for cord blood products.

The Initiative will conduct outreach and research, particularly for ethnic and racial minorities. Information will be disseminated through health departments and Medicaid. Women will be offered the opportunity to donate umbilical cord blood; however, no woman will be required to make a cord blood donation.

Health care entities must disclose financial remuneration for the collection of the cord blood prior to harvesting it. No person who objects to transfusion or transplantation of blood on the basis of bona fide religious beliefs will be required to participate in the Initiative.

The Initiative will be implemented with such funds as may be appropriated or otherwise made available for its purpose. The Commissioner must, upon implementation of the Initiative, seek the development of a nonprofit entity to assume the operation and administration of it and may seek federal, state, and private grant funds for its continuation.

**Funding of the Virginia Cord Blood Bank Initiative**

HB 5002, as approved, includes an amendment to the Department of Health's appropriations providing $250,000 in the first year of the biennium and $200,000 in the second year of the biennium "to establish the Virginia Cord Blood Bank Initiative." The language in Item 291 requires:

that the funding for the Virginia Cord Blood Bank be used in the most cost efficient manner. To this end, the Department of Health should contract with a facility that already has a cell separator that can be used for this initiative. The Virginia Cord Blood Bank would serve as a public resource for Virginians for the treatment of patients with life-threatening or debilitating conditions, for use in advancing basic and clinical research, and, in the event of a terrorist attack, for use in the treatment of the injured citizens of the Commonwealth.

**Study Continuation**

House Joint Resolution 48 (Marshall) was also approved to continue the stem cell study for one year.

The 2006 enabling resolution describes the 2005 proceedings of the Joint Subcommittee as recorded on its website and notes its two unanimous recommendations to the 2006 Session: the establishment of an umbilical cord blood bank and continuation of its study for another year.

Thus, the Joint Subcommittee successfully concluded its 2005 study with both of its unanimous recommendations being approved by the General Assembly.

Respectfully submitted,

The Honorable Robert G. Marshall, Chairman

The Honorable Richard L. Saslaw, Vice Chairman

# APPENDIX A

# 2005 ENABLING RESOLUTION

# HOUSE JOINT RESOLUTION 588

**HOUSE JOINT RESOLUTION NO. 588**

*Establishing a joint subcommittee to study medical, ethical, and scientific issues relating to stem cell research conducted in the Commonwealth. Report.*

Agreed to by the House of Delegates, February 26, 2005

Agreed to by the Senate, February 26, 2005

WHEREAS, on August 25, 2000, the National Institutes of Health (NIH) published guidelines relating to stem cell research and the funding thereof, calling for the denial of funding for research involving stem cells derived from embryonic human beings created for research purposes and noting that the 42nd President of the United States, many members of Congress, the NIH Human Embryo Research Panel, and the National Bioethics Advisory Committee had all endorsed the "distinction between embryos created for research purposes and those created for reproductive purposes"; and

WHEREAS, the President announced on August 9, 2001, "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"; and

WHEREAS, according to NIH, "investigators from laboratories in the United States, Australia, India, Israel, and Sweden have derived stem cells from 71 individual, genetically diverse blastocysts which meet federal criteria for federally funded human embryonic stem cell research"; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That a joint subcommittee be established to study medical, ethical, and scientific issues relating to stem cell research conducted in the Commonwealth. The joint subcommittee shall have a total membership of 15 members that shall consist of eight legislative members and seven nonlegislative citizen members. Members shall be appointed as follows: five members of the House of Delegates to be appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; three members of the Senate to be appointed by the Senate Committee on Rules; one representative each of the University of Virginia School of Medicine and the Eastern Virginia Medical School, and two nonlegislative citizen members at-large to be appointed by the Speaker of the House of Delegates; and one representative of the Virginia Commonwealth University School of Medicine, and two nonlegislative citizen members at-large to be appointed by the Senate Committee on Rules. Nonlegislative citizen members of the joint subcommittee shall be citizens of the Commonwealth of Virginia. Unless otherwise approved in writing by the chairman of the joint subcommittee and the respective Clerk, nonlegislative citizen members shall only be reimbursed for travel originating and ending within the Commonwealth of Virginia for

the purpose of attending meetings. If a companion joint resolution of the other chamber is agreed to, written authorization of both Clerks shall be required. The joint subcommittee shall elect a chairman and vice chairman from among its membership, who shall be members of the General Assembly.

In conducting its study, the joint subcommittee shall examine the medical, ethical, and scientific policy implications of stem cell research, and the efficacy of research using both adult and embryonic stem cells.

Administrative staff support shall be provided by the Office of the Clerk of the House of Delegates. Legal, research, policy analysis, and other services as requested by the joint subcommittee shall be provided by the Division of Legislative Services. Technical assistance shall be provided by State Board of Health and the Board of Medicine. All agencies of the Commonwealth shall provide assistance to the joint subcommittee for this study, upon request.

The joint subcommittee shall be limited to four meetings for the 2005 interim, and the direct costs of this study shall not exceed $15,600 without approval as set out in this resolution. Of this amount an estimated $2,000 is allocated for speakers, materials, and other resources. Approval for unbudgeted nonmember-related expenses shall require the written authorization of the chairman of the joint subcommittee and the respective Clerk. If a companion joint resolution of the other chamber is agreed to, written authorization of both Clerks shall be required.

No recommendation of the joint subcommittee shall be adopted if a majority of the House members or a majority of the Senate members appointed to the joint subcommittee (i) vote against the recommendation and (ii) vote for the recommendation to fail notwithstanding the majority vote of the joint subcommittee.

The joint subcommittee shall complete its meetings by November 30, 2005, and the chairman shall submit to the Division of Legislative Automated Systems an executive summary of its findings and recommendations no later than the first day of the 2006 Regular Session of the General Assembly. The executive summary shall state whether the joint subcommittee intends to submit to the General Assembly and the Governor a report of its findings and recommendations for publication as a House or Senate document. The executive summary and the report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

Implementation of this resolution is subject to subsequent approval and certification by the Joint Rules Committee. The Committee may approve or disapprove expenditures for this study, extend or delay the period for the conduct of the study, or authorize additional meetings during the 2005 interim.

#

APPENDIX B

2006 LEGISLATION

VIRGINIA CORD BLOOD BANK INITIATIVE

CHAPTER 636
House Bill 413
(Marshall)

CHAPTER 735
Senate Bill 370
(Saslaw)

CONTINUING RESOLUTION

House Joint Resolution No. 40
(Marshall)

Budget Amendment
Item 291

**VIRGINIA ACTS OF ASSEMBLY---2006 SESSION**

**CHAPTER 636**

*An Act to amend the Code of Virginia by adding in Chapter 2 of Title 32.1 an article numbered 8.2, consisting of a section numbered 32.1-69.3, relating to establishment of the Virginia Cord Blood Bank Initiative.*

[H 413]

Approved April 5, 2006

Whereas, umbilical cord blood is a unique source of large numbers of young, undifferentiated stem cells; and

Whereas, umbilical cord blood is being used for the treatment of life-threatening illnesses and debilitating conditions and is being studied for its potential in the treatment of many disorders; and

Whereas, umbilical cord blood can provide hope for patients and advance the science of stem cell research, while posing no health risk to either a mother or her newborn infant; and

Whereas, umbilical cord blood can be easily collected and cost-effectively stored for medical and research use; now, therefore,

**Be it enacted by the General Assembly of Virginia:**

**1. That the Code of Virginia is amended by adding in Chapter 2 of Title 32.1 an article numbered 8.2, consisting of a section numbered 32.1-69.3 as follows:**

*Article 8.2.*
*Virginia Cord Blood Bank Initiative.*

*§ 32.1-69.3. Virginia Cord Blood Bank Initiative established.*

*A. There is hereby established the Virginia Cord Blood Bank Initiative (hereinafter referred to as the Initiative) as a public resource for Virginians for the treatment of patients with life-threatening diseases or debilitating conditions, for use in advancing basic and clinical research, and, in the event of a terrorist attack, to be used in the treatment of the injured citizens of the Commonwealth.*

*The Initiative shall be established as a nonprofit legal entity to collect, screen for infectious and genetic diseases, perform tissue typing on, cryopreserve, and store umbilical cord blood as a public resource and shall be formed as a collaborative consortium that covers all geographical regions of Virginia.*

*B. The State Health Commissioner shall develop or shall arrange for or contract with a nonprofit entity for the development of the collaborative consortium to be known as the Initiative, which may consist of any entity having the expertise or experience or willingness to develop the expertise or experience necessary to participate in the Initiative.*

*C. In developing the consortium, the Commissioner shall ensure that all geographical areas of the Commonwealth are included in the Initiative. To accomplish this goal, the Commissioner shall contact Eastern Virginia Medical School and its participating hospitals, Virginia Commonwealth University School of Medicine, Virginia Commonwealth University Health System, the University of Virginia School of Medicine, the University of Virginia Health System, and other entities located in Virginia, such as hospitals and hospital systems, biotechnology companies, regional blood banks, laboratories, or other health care providers or medical researchers, or local coalitions of health care providers that could provide coverage of the various geographical regions of Virginia, to request their participation in the Initiative consortium and assist in the design and implementation of the Initiative.*

*D. Any nonprofit entity having an arrangement or contract with the Commissioner for the development of the Initiative and any medical school, hospital, or other health care provider choosing to participate in the Initiative shall submit an estimate of the costs of implementing the Initiative for the region in which it is located. The Commissioner shall assist in the development of the cost estimates, compare and evaluate such estimates, and negotiate with the various entities to implement the Initiative.*

*Further, the Commissioner shall coordinate (i) appropriate contact with pregnant women to provide information about umbilical cord blood donations; (ii) the development of procedures for obtaining informed consent for cord blood donations; (iii) the design of the Initiative, including the period of years for storage of the cord blood to ensure the integrity of the cells; (iv) a system for recycling the blood at the end of the established storage period that provides for the sale or transfer of the cord blood samples being taken out of storage to be used in basic or clinical research development at reasonable rates and fees for cord blood products.*

*E. The entities joining the Initiative shall work collaboratively, each with the community resources in its local or regional area. The Initiative participants shall align their outreach programs and activities to all geographic areas and ethnic and racial groups of the Commonwealth, and shall conduct specific and culturally appropriate outreach and research to identify potential donors among all ethnic and racial groups.*

*F. The Commissioner shall disseminate information about the Initiative, focusing on hospitals, birthing facilities, physicians, midwives, and nurses, and providing information through local health departments.*

*Initiative consortium participants shall also be encouraged to disseminate information about the Initiative.*

*In addition, the Director of the Department of Medical Assistance Services shall include information about the Initiative in printed materials distributed by the Department to recipients of medical assistance services and persons enrolled in the Family Access to Medical Insurance Security Plan.*

*G. Any woman admitted to a hospital or birthing facility for obstetrical services may be offered the opportunity to donate umbilical cord blood to the Initiative. However, no woman shall be required to make a cord blood donation.*

*H. Any health care facility or health care provider receiving financial remuneration for the collection of umbilical cord blood shall, prior to harvesting the umbilical cord blood, disclose this information in writing to any woman postpartum or to the parent of a newborn from whom the umbilical cord blood is to be collected.*

*I. This section shall not be construed to require participation in the Initiative on the part of any health care facility or health care provider who objects to transfusion or transplantation of blood on the basis of bona fide religious beliefs.*

*J. The Initiative shall be implemented with such funds as may be appropriated or otherwise provided for its purpose. Upon implementation, the Commissioner shall initiate the development of a nonprofit entity to assume the operation and administration of the Initiative and may seek federal, state, and private grant funds for its continuation.*

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**VIRGINIA ACTS OF ASSEMBLY---2006 SESSION**

**CHAPTER 735**

*An Act to amend the Code of Virginia by adding in Chapter 2 of Title 32.1 an article numbered 8.2, consisting of a section numbered 32.1-69.3, relating to establishment of the Virginia Cord Blood Bank Initiative.*

[S 370]

Approved April 5, 2006

Whereas, umbilical cord blood is a unique source of large numbers of young, undifferentiated stem cells; and

Whereas, umbilical cord blood is being used for the treatment of life-threatening illnesses and debilitating conditions and is being studied for its potential in the treatment of many disorders; and

Whereas, umbilical cord blood can provide hope for patients and advance the science of stem cell research, while posing no health risk to either a mother or her newborn infant; and

Whereas, umbilical cord blood can be easily collected and cost-effectively stored for medical and research use; now, therefore,

**Be it enacted by the General Assembly of Virginia:**

**1. That the Code of Virginia is amended by adding in Chapter 2 of Title 32.1 an article numbered 8.2, consisting of a section numbered 32.1-69.3 as follows:**

*Article 8.2.*
*Virginia Cord Blood Bank Initiative.*

*§ 32.1-69.3. Virginia Cord Blood Bank Initiative established.*

*A. There is hereby established the Virginia Cord Blood Bank Initiative (hereinafter referred to as the Initiative) as a public resource for Virginians for the treatment of patients with life-threatening diseases or debilitating conditions, for use in advancing basic and clinical research, and, in the event of a terrorist attack, to be used in the treatment of the injured citizens of the Commonwealth.*

*The Initiative shall be established as a nonprofit legal entity to collect, screen for infectious and genetic diseases, perform tissue typing on, cryopreserve, and store umbilical cord blood as a public resource and shall be formed as a collaborative consortium that covers all geographical regions of Virginia.*

*B. The State Health Commissioner shall develop or shall arrange for or contract with a nonprofit entity for the development of the collaborative consortium to be known as the Initiative, which may consist of any entity having the expertise or experience or willingness to develop the expertise or experience necessary to participate in the Initiative.*

*C. In developing the consortium, the Commissioner shall ensure that all geographical areas of the Commonwealth are included in the Initiative. To accomplish this goal, the Commissioner shall contact Eastern Virginia Medical School and its participating hospitals, Virginia Commonwealth University School of Medicine, Virginia Commonwealth University Health System, the University of Virginia School of Medicine, the University of Virginia Health System, and other entities located in Virginia, such as hospitals and hospital systems, biotechnology companies, regional blood banks, laboratories, or other health care providers or medical researchers, or local coalitions of health care providers that could provide coverage of the various geographical regions of Virginia, to request their participation in the Initiative consortium and assist in the design and implementation of the Initiative.*

*D. Any nonprofit entity having an arrangement or contract with the Commissioner for the development of the Initiative and any medical school, hospital, or other health care provider choosing to participate in the Initiative shall submit an estimate of the costs of implementing the Initiative for the region in which it is located. The Commissioner shall assist in the development of the cost estimates, compare and evaluate such estimates, and negotiate with the various entities to implement the Initiative.*

*Further, the Commissioner shall coordinate (i) appropriate contact with pregnant women to provide information about umbilical cord blood donations; (ii) the development of procedures for obtaining informed consent for cord blood donations; (iii) the design of the Initiative, including the period of years for storage of the cord blood to ensure the integrity of the cells; (iv) a system for recycling the blood at the end of the established storage period that provides for the sale or transfer of the cord blood samples being taken out of storage to be used in basic or clinical research development at reasonable rates and fees for cord blood products.*

*E. The entities joining the Initiative shall work collaboratively, each with the community resources in its local or regional area. The Initiative participants shall align their outreach programs and activities to all geographic areas and ethnic and racial groups of the Commonwealth, and shall conduct specific and culturally appropriate outreach and research to identify potential donors among all ethnic and racial groups.*

*F. The Commissioner shall disseminate information about the Initiative, focusing on hospitals, birthing facilities, physicians, midwives, and nurses, and providing information through local health departments.*

*Initiative consortium participants shall also be encouraged to disseminate information about the Initiative.*

*In addition, the Director of the Department of Medical Assistance Services shall include information about the Initiative in printed materials distributed by the Department to recipients of medical assistance services and persons enrolled in the Family Access to Medical Insurance Security Plan.*

*G. Any woman admitted to a hospital or birthing facility for obstetrical services may be offered the opportunity to donate umbilical cord blood to the Initiative. However, no woman shall be required to make a cord blood donation.*

*H. Any health care facility or health care provider receiving financial remuneration for the collection of umbilical cord blood shall, prior to harvesting the umbilical cord blood, disclose this information in writing to any woman postpartum or to the parent of a newborn from whom the umbilical cord blood is to be collected.*

*I. This section shall not be construed to require participation in the Initiative on the part of any health care facility or health care provider who objects to transfusion or transplantation of blood on the basis of bona fide religious beliefs.*

*J. The Initiative shall be implemented with such funds as may be appropriated or otherwise provided for its purpose. Upon implementation, the Commissioner shall initiate the development of a nonprofit entity to assume the operation and administration of the Initiative and may seek federal, state, and private grant funds for its continuation.*

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# HOUSE JOINT RESOLUTION NO. 48

Continuing the Joint Subcommittee to Study Medical, Ethical, and Scientific Issues Relating to Stem Cell Research Conducted in the Commonwealth. Report.

Agreed to by the House of Delegates, February 10, 2006
Agreed to by the Senate, February 28, 2006

WHEREAS, House Joint Resolution No. 588 (2005) established the Joint Subcommittee to Study Medical, Ethical, and Scientific Issues Relating to Stem Cell Research Conducted in the Commonwealth; and

WHEREAS, the Joint Subcommittee has met four times during the 2005 interim and conducted a collegial and bipartisan study, hearing from scientists, ethicists, theologians, and the public; and

WHEREAS, the proceedings of the Joint Subcommittee's study can be viewed and heard on its website, including summaries of its meetings, the link to its survey of relevant websites, audio streaming of its Northern Virginia meeting, a diagram of stem cell asymmetric division, pictures depicting its work, and an issues paper; and

WHEREAS, the Joint Subcommittee agreed unanimously to make two recommendations to the 2006 Session: (i) the establishment of an umbilical cord blood bank initiative in Virginia that could serve as a resource for patients, research, and, in the event of a terrorist attack, treatment for injured citizens of the Commonwealth; and (ii) continuation of its study for another year; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Subcommittee to Study Medical, Ethical, and Scientific Issues Relating to Stem Cell Research Conducted in the Commonwealth be continued.

The joint subcommittee shall have a total membership of 15 members that shall consist of eight legislative members and seven nonlegislative citizen members. Members shall be appointed as follows: five members of the House of Delegates to be appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; three members of the Senate to be appointed by the Senate Committee on Rules; one representative each of the University of Virginia School of Medicine and the Eastern Virginia Medical School and two nonlegislative citizen members at-large to be appointed by the Speaker of the House of Delegates; and one representative of the Virginia Commonwealth University School of Medicine and two nonlegislative citizen members at-large to be appointed by the Senate Committee on Rules.

Nonlegislative citizen members of the joint subcommittee shall be citizens of the Commonwealth of Virginia. The current members appointed by the Speaker of the House of Delegates shall be subject to reappointment. The current members appointed by the

Senate Committee on Rules shall continue to serve until replaced. Vacancies shall be filled by the original appointing authority. Unless otherwise approved in writing by the chairman of the joint subcommittee and the respective Clerk, nonlegislative citizen members shall only be reimbursed for travel originating and ending within the Commonwealth of Virginia for the purpose of attending meetings. If a companion joint resolution of the other chamber is agreed to, written authorization of both Clerks shall be required. The joint subcommittee shall elect a chairman and vice-chairman from among its membership, who shall be members of the General Assembly.

In conducting its study, the joint subcommittee shall continue to review new developments in stem cell research and treatment and seek to fulfill its recommendation to establish an umbilical cord blood bank initiative in the Commonwealth.

Administrative staff support shall continue to be provided by the Office of the Clerk of the House of Delegates. Legal, research, policy analysis, and other services as requested by the joint subcommittee shall continue to be provided by the Division of Legislative Services. Technical assistance shall continue to be provided by State Board of Health and the Board of Medicine. All agencies of the Commonwealth shall provide assistance to the joint subcommittee for this study, upon request.

The joint subcommittee shall be limited to four meetings for the 2006 interim, and the direct costs of this study shall not exceed $12,800 without approval as set out in this resolution. Of this amount an estimated $2,000 is allocated for speakers, materials, and other resources. Approval for unbudgeted nonmember-related expenses shall require the written authorization of the chairman of the joint subcommittee and the respective Clerk. If a companion joint resolution of the other chamber is agreed to, written authorization of both Clerks shall be required.

No recommendation of the joint subcommittee shall be adopted if a majority of the House members or a majority of the Senate members appointed to the joint subcommittee (i) vote against the recommendation and (ii) vote for the recommendation to fail notwithstanding the majority vote of the joint subcommittee.

The joint subcommittee shall complete its meetings by November 30, 2006, and the chairman shall submit to the Division of Legislative Automated Systems an executive summary of its findings and recommendations no later than the first day of the 2007 Regular Session of the General Assembly. The executive summary shall state whether the joint subcommittee intends to submit to the General Assembly and the Governor a report of its findings and recommendations for publication as a House or Senate document. The executive summary and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

Implementation of this resolution is subject to subsequent approval and certification by the Joint Rules Committee. The Committee may approve or disapprove expenditures for this study, extend or delay the period for the conduct of the study, or authorize additional meetings during the 2006 interim.

**Item 291** #1h

| **Health And Human Resources** | **FY 06-07** | **FY 07-08** | |
|---|---|---|---|
| Department Of Health | $250,000 | $200,000 | GF |

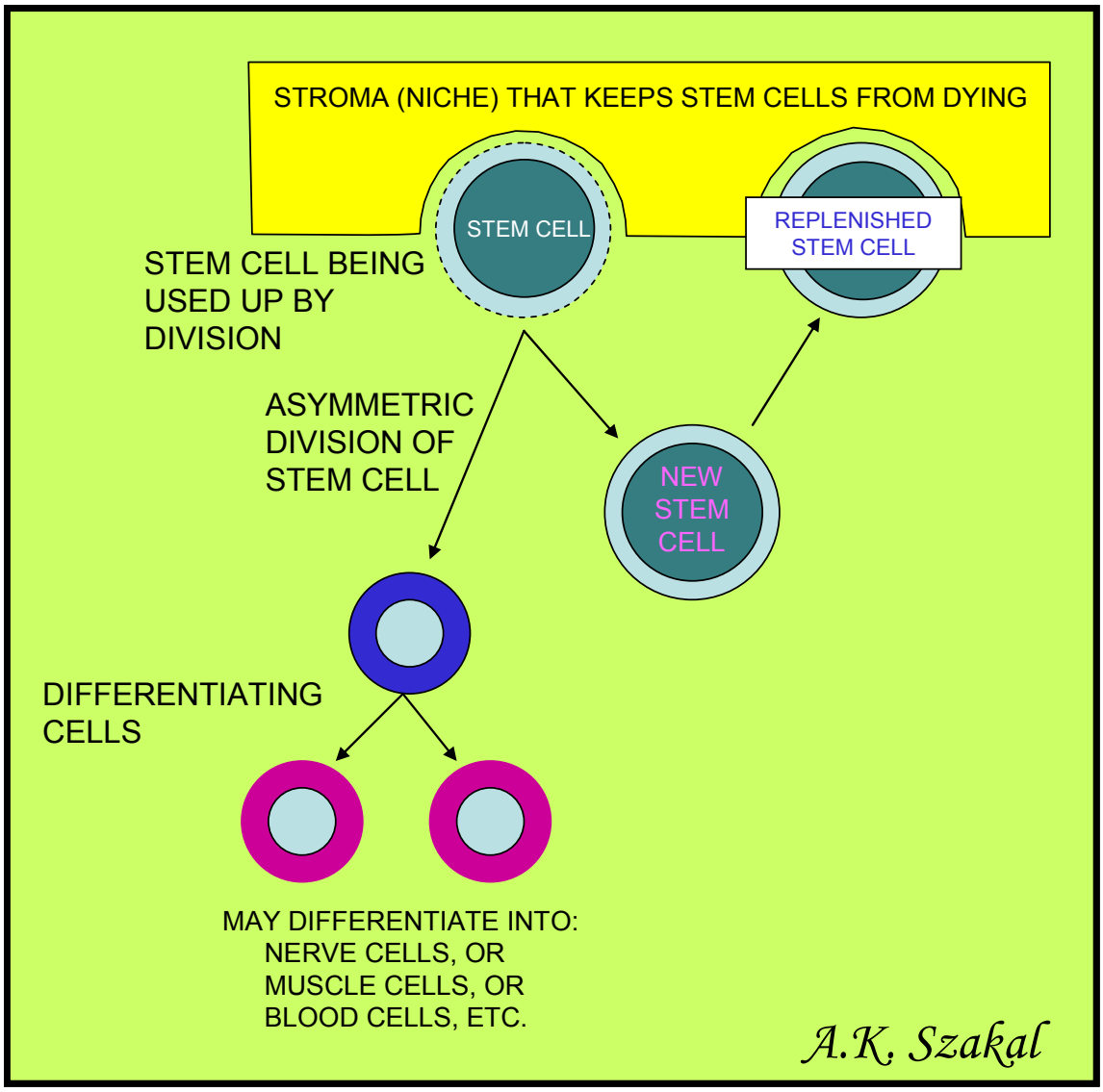
**Language:**
Page 248, line 35, strike "$98,678,581" and insert "$98,974,581".
Page 248, line 35, strike "$98,678,581" and insert "$98,888,581".

**Explanation:**
(This amendment provides funding to establish the Virginia Cord Blood Bank Initiative, pursuant to House Bill 413. It is the intent of the General Assembly that the funding for the Virginia Cord Blood Bank be used in the most cost efficient manner. To this end, the Department of Health should contract with a facility that already has a cell separator that can be used for this initiative. The Virginia Cord Blood Bank would serve as a public resource for Virginians for the treatment of patients with life-threatening or debilitating conditions, for use in advancing basic and clinical research, and in the event of a terrorist attack, for use in the treatment of the injured citizens of the Commonwealth.)

APPENDIX C

DIAGRAM

ASYMETRIC DIVISION OF STEM CELLS


STROMA (NICHE) THAT KEEPS STEM CELLS FROM DYING
STEM CELL
REPLENISHED STEM CELL
STEM CELL BEING USED UP BY DIVISION
ASYMMETRIC DIVISION OF STEM CELL
NEW STEM CELL
DIFFERENTIATING CELLS
MAY DIFFERENTIATE INTO:
NERVE CELLS, OR
MUSCLE CELLS, OR
BLOOD CELLS, ETC.
A.K. Szakal

# APPENDIX D

# VARIOUS LINKS

**VARIOUS LINKS**

**STUDY WEBSITE**

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

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

# 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 Human Embryonic Stem Cell Research**

http://newton.nap.edu/catalog/11278.html.