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Legislative Bulletin……..…….……May 24, 2005

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Summary of the Bills Under Consideration Today:

Total Number of New Government Programs: 1

Total Cost of Discretionary Authorizations: $235 million over five years and unknown millions

Effect on Revenue: $0

Total Change in Mandatory Spending: $0

Total New State & Local Government Mandates: 0

Total New Private Sector Mandates: 0

Number of *Bills* Without Committee Reports: 2

Number of *Reported* Bills that Don't Cite Specific Clauses of Constitutional Authority: 0

H.R. 2520 — Stem Cell Therapeutic and Research Act (Smith of NJ)

Order of Business: The bill is scheduled for consideration on May 24, 2005, under a motion to suspend the rules and pass the bill.

Similar bills containing the cord blood provisions of H.R. 2520 were introduced earlier this Congress (H.R. 596) and last Congress (H.R. 2852). Both bills were referred to Committee, but no action was taken. A bill containing similar provisions pertaining to the bone marrow registry language in H.R. 2520 was introduced last Congress (H.R. 3034), but was not acted upon.

Summary: H.R. 2520 would amend the Public Health Service Act to authorize the creation of the new "C.W. Bill Young Cell Transplantation Program", which would direct the Secretary of Health and Human Services to enter into one-time contracts with "qualified cord blood stem cell banks" to assist "in the collection and maintenance of 150,000 units of high-quality human cord blood to be made available for transplantation."

The legislation would:

- operate a system for identifying, matching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients;
- create a database that would allow transplant physicians to electronically search for cord blood and bone marrow matches using a "single point of access," and require each recipient of a contract to submit data in a "standardized format" for inclusion in this database;
- create specific requirements to be met before the Secretary may enter into a contract with a cord blood stem cell bank (including length of contract, donor consent, and research provisions); and
- create a new advisory counsel to advise, assist, consult with, and make recommendations to the Secretary on matters related to the program;
- **expire on September 30, 2010**, unless the Secretary finds that 150,000 units of high-quality human cord blood have not yet been collected.

The legislation reauthorizes what was formerly known as the "National Bone Marrow Program," which would:

- operate a system for listing, searching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;
- carry out a program and support studies to recruit bone marrow donors, specifically to "ensure a genetically diverse donor pool;" and
- create and maintain a database of "patients who have been recipients of stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a biologically unrelated donor."

Additional Information: For additional information on recent medical studies and advances in adult stem cell research (cord blood stem cells and bone marrow stem cells are both classified as "adult" stem cells), the following links may be useful:

Cord Blood research studies:

1) http://www.nationalcordbloodprogram.org/patients/ncbp_diseases.htm
2) http://times.hankooki.com/lpage/tech/200504/kt2005041818233411800.htm
3) http://www.genengnews.com/news/bnitem.aspx?cat=Breaking%20News&name=519610XSL_NEWSML_TO_NEWSML_WEB.xml&searchtype=OneWordAtLeast&c=BioE
4) http://www.nationalcordbloodprogram.org/patients/patients_stories.html
5) http://biz.yahoo.com/prnews/050413/nyw030.html?.v=6

Bone Marrow research studies:

1) http://www.sciencedaily.com/releases/2005/03/050325225703.htm
2) http://www.stemcellnews.com/articles/stem-cells-knee-repair.htm

Adult Stem Cell Overall Success:

- "Patients could grow their own transplant organs or implants," *NetDoctor.co.uk*, Feb. 18, 2005, http://quis.qub.ac.uk/pugwash/Belfast%20Telegraph%20-%20Growing%20your%20own%20Transplant.doc
- "Potential seen in adult stem cells," *CNN.com: Science and Space,* March 21, 2005, http://edition.cnn.com/2005/TECH/science/03/21/australia.stemcell/

Alzheimer's:

- "Research may hold promise for treating Alzheimer's," *UCF News and Information*, Feb. 10, 2005, http://news.ucf.edu/UCFnews/index?page=article&id=00240041998c09010172bc803800783d

Diabetes:

- "Brain stem cells to cure diabetes," *BBC News,* April 25, 2005, http://news.bbc.co.uk/1/hi/health/4480875.stm
- "Progress seen in transplants for Diabetes," *The New York Times*, February 16, 2005, p. A18
- "Living donor diabetes transplant," *BBC News*, Feb. 4, 2005, http://news.bbc.co.uk/1/hi/health/4236873.stm

Heart:

- "Stem cells give heart patient new lease on life," *Reviewjournal.com*, Feb. 14, 2005, http://www.reviewjournal.com/lvrj_home/2005/Feb-14-Mon-2005/news/25855532.html
- "Adult stem cells repair damage caused by deadly parasites," *Corethics.org*, Feb. 17, 2005, http://www.corethics.org/document.asp?id=n170205.txt&se=4&st=6
- "Studies suggest adult stem cells heal hearts," *Philadelphia Inquirer,* Feb. 6, 2005

Kidney/Liver:

- "U.S. Patent Office grants multicell technologies new liver stem cell patent," *Genetic Engineering News*, http://www.genengnews.com/news/bnitem.aspx?cat=Breaking%20News&name=507120XSL_NEWSML_TO_NEWSML_WEB.xml&searchtype=OneWordAtLeast&c=liver%20stem%20cell%20patent

Parkinson's:

- "Israeli therapy uses adult stem cells to treat Parkinson's Disease," *Israel21c*, March 27, 2005, http://www.israel21c.org/bin/en.jsp?enDispWho=Articles^l952&enPage=BlankPage&enDisplay=view&enDispWhat=object&enVersion=0&enZone=Health

Outside Organizations: There are no known outside organizations opposing H.R. 2520. Because the bill does not involve the funding of research that destroys human embryos and promotes an ethical stem cell research alternative, many pro-life organizations are supportive of this bill.

Committee Action: H.R. 2520 was introduced on May 23, 2005, and referred to the Committee on Energy and Commerce s Subcommittee on Health. The bill was not acted upon.

Cost to Taxpayers: Though a CBO score of H.R. 2520 is unavailable, the bill includes two separate authorizations for a total of $235 million for FY06-FY10.

Specifically for the collection or maintenance of human cord blood, the bill authorizes $15 million per year for FY07-FY10 ($60 million total), and also applies this authorization bill to the unexpended, unauthorized earmarks inserted into the FY04 and FY05 appropriations bills. The unexpended earmarks are estimated to total approximately $19 million, according to the bill sponsor. Thus, while $60 million of the funds in H.R. 2520 are new authorizations, a total of $79 million will be available for the cord blood component of the bill over the next five fiscal years. The bill includes a provision to sunset this program at the end of fiscal year 2010, as long as certain conditions have been met.

Additionally, the bill authorizes $28 million for FY06 and $32 million per year for FY07-FY10, for a total of $156 million for FY06-FY10.

Does the Bill Expand the Size and Scope of the Federal Government?: Yes, as described above, the bill creates a new federal program to facilitate a national cord blood stem cell bank and reauthorizes a program that had expired in 2003 (though was still receiving unauthorized appropriations).

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: No.

Constitutional Authority: A committee report citing constitutional authority is unavailable.

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H.R. 810 — Stem Cell Research Enhancement Act of 2005 (Castle)

Order of Business: The bill is scheduled for consideration on Tuesday, May 24, 2005, either under a unanimous consent request to consider the bill. It is likely that UC will request the debate be divided in four time periods of 45 minutes each, Republicans opposing, Democrats opposing, Republicans Supporting, and Democrats Supporting.

Summary: H.R. 810 creates a new provision in the Public Health Service Act (42 U.S.C. 289 et seq.) requiring the Secretary of HHS to "conduct and support research that utilizes human embryonic stem cells…."

The bill defines as eligible for federal funding human embryonic stem cells that:

- "were derived from human embryos that have been donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment;"
- "it was determined … would never be implanted in a woman and would otherwise be discarded;" and
- were "donated … with written informed consent and without receiving any financial or other inducements to make the donation."

The bill requires final guidelines from NIH within 60 days of enactment and an annual report from the HHS Secretary describing the research conducted.

Additional Information: It is legal in the United States to destroy and conduct research on living and dead human embryos with non-federal funds. This bill will require the federal funding of research using human embryos, which is currently prohibited under federal law and the President's stem cell policy.

REVERSAL OF CONGRESSIONAL FUNDING BAN AND PRESIDENT BUSH'S POLICY

President's Policy:

H.R. 810 will reverse President George W. Bush's federal stem cell policy announced in an address to the nation on August 9, 2001. In that address, the President stated that **no federal funds** will be used for:

"the derivation or use of stem cell lines derived from newly destroyed embryos;
"the creation of any human embryos for research purposes; or
"the cloning of human embryos for any purpose."

The President's policy did allow federal funds to be used for stem cell lines that had come from embryos already destroyed prior to August 9, 2001. At the time, the President stated, "The embryos from which the existing stem cell lines were created have already been destroyed and no longer have the possibility of further development as human beings." The President stated his policy permits "federal funding of research using the more than 60 existing stem cell lines that have already been derived, but will not sanction or encourage the destruction of additional human embryos." He said in his address, "This allows us to explore the promise and potential of stem cell research" without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life."

Source: http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html

To see a list of those stem cell lines that are *currently* eligible for federal funding, go to: http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp

Congressional Funding Ban:

Since fiscal year 1996, Congress has included in the Labor, HHS and Education Appropriations bill a rider that has been signed into law, which states the following:

SEC. 509. (a) **None of the funds made available in this Act may be used for—**

(1) the creation of a human embryo or embryos for research purposes; or
(2) **research in which a human embryo or embryos are destroyed**, discarded, or **knowingly subjected to risk of injury or death** greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. (emphasis added)

Source: Section 509 of the FY05 Omnibus Appropriations Act (H.R. 4818)

[Explanation of cross-references: 45 CFR 46 is the part of the Code of Federal Regulations that contains protections for human subjects in federally funded research. 45 CFR 46.208(a)(2) requires that unless an experiment involving a human fetus is designed to benefit that particular child, **it cannot involve anything greater than a "minimal risk" of harm** (defined as a risk comparable to that involved in routine examinations or the activities of everyday life). These federal regulation protections cover all human embryos from implantation in the womb until birth; the appropriations rider on human embryo research (Sec. 510 above) covers all other human embryos (those not implanted in the womb).

The Public Health Service Act (42 USC 289g (b)) requires that in assessing allowable risk, a child intended for abortion must be protected as fully from harmful research as the child intended for live birth. The argument that an embryo or fetus is "unwanted" or "would be destroyed anyway" cannot be used to justify harmful experimentation at taxpayers' expense.]

THE HUMAN EMBRYOS AVAILABLE FOR RESEARCH UNDER H.R. 810:

H.R. 810 will allow federal funds for the destruction of and research on human embryos from in vitro fertilization (IVF) clinics.

The in vitro fertilization process involves combining an egg with sperm to create a human embryo. At this stage, clinics are able to determine whether or not the human embryos have the genetic makeup of a male or of a female. According to IVF clinics, a human embryo that is "graded" as a "quality" embryo is then implanted into a woman's womb (often more than one at a time) to try and achieve implantation and a full-term pregnancy. Those human embryos graded as "abnormal" are "discarded," according to various clinics. (See: http://www.advancedfertility.com/embryoquality.htm).

Those human embryos deemed "quality" human embryos that are not implanted into the womb usually then are frozen in a controlled-rate freezer and immersed and stored in

liquid nitrogen in a tank (at -196 degrees Centigrade), in a process called Cyroproservation (to see a photo of a human embryo storage freezer visit http://www.advancedfertility.com/cryotank.htm).

The frozen human embryos can be stored for many years and can be defrosted to be implanted into a woman's womb. Some parents place their unused frozen human embryos through an official adoption process with other couples (see: http://www.nightlight.org/snowflakes_description.asp and Congressional testimony: http://www.stemcellresearch.org/testimony/strege.htm). More commonly, parents allow the IVF clinic to offer their unused frozen human embryos to other infertile female patients through the clinic (see: http://embryodonation.org/downloads/pdf/DonationConsentGeneric.pdf).

The Number of Human Embryos Eligible for Destruction and Research Under H.R. 810:

Many of the human embryos do not survive the freezing and defrosting process. A group of RAND researchers estimated that only 65% of the human embryos survive the freeze-and-thaw process.

The most comprehensive study of the number of human embryos currently in existence at IVF clinics was done by the non-profit research organization RAND. In 2003, RAND released a study that found that as of April 11, 2002, nearly 400,000 human embryos have been "frozen and stored since the late 1970s."

Of the 400,000, 2.8% (11,000 total) have been made available by their parents for research, while the "vast majority of frozen [human] embryos are designated for future attempts at pregnancy."

The vast majority of stored human embryos, 88.2%, are being held "for family building;" 2.3% are awaiting donation to another patient (for implantation in her womb), and 4.5% are held in storage for other reasons, including lost contact with a patient, patient death, abandonment, and divorce.

The RAND researchers noted that based on current, non-federally funded research results, if all 11,000 embryos were used to create embryonic stem cell lines (the cell culture lines federal funds would be used for under H.R. 810), "about 275 embryonic stem cell lines could be created " and that "the actual number is likely to be much lower." The University of Wisconsin used 18 human embryos (that were grown for five days from the date of their conception before being destroyed) to create five embryonic stem cell *lines*. The Jones Institute used 40 embryos of the same age, to create only three stem cell *lines*.

Source: "How Many Frozen Human Embryos Are Available for Research?" RAND Law & Health Research Brief, May 2003, http://www.rand.org/publications/RB/RB9038/

NO TREATMENTS TO DATE FOR HUMANS OR ANIMALS FROM EMBRYO STEM CELL RESEARCH:

As of March 2005, no animals or human patients have been successfully treated with human embryonic stem cells (see: http://www.stemcellresearch.org/facts/treatments.htm)

Potential for tumor formation and tissue destruction:

Wakitani S *et al.*; "Embryonic stem cells injected into the mouse knee joint form teratomas and subsequently destroy the joint"; *Rheumatology* 42, 162-165; January 2003

Questions regarding functional differentiation:

Hansson M *et al.*, "Artifactual insulin release from differentiated embryonic stem cells", *Diabetes* 53, 2603-2609,October 2004

Sipione S *et al.*, "Insulin expressing cells from differentiated embryonic stem cells are not beta cells", *Diabetologia* 47, 499-508, 2004 (published online 14 Feb 2004)

Rajagopal J *et al.*; "Insulin staining of ES cell progeny from insulin uptake"; *Science* 299, 363; 17 Jan 2003

Zhang YM *et al.*; "Stem cell-derived cardiomyocytes demonstrate arrhythmic potential"; *Circulation* 106, 1294-1299; 3 September 2002

Problem of immune rejection • Genomic instability:

Cowan CA *et al.*, "Derivation of embryonic stem-cell lines from human blastocysts", *New England Journal of Medicine* 350, 13; published online 3 March 2004

Draper JS *et al.*, "Recurrent gain of chromosomes 17q and 12 in cultured human embryonic stem cells", *NatureBiotechnology* 22, 53-54; January 2004

Humpherys S *et al.*; "Epigenetic instability in ES cells and cloned mice"; *Science* 293, 95-97; 6 July 2001

Source: http://www.stemcellresearch.org/testimony/prentice_2005-01-03.pdf

H.R. 810 AND HUMAN CLONING:

Because the bill overrides current law, if a human embryo clone was created by an in vitro fertilization clinic for fertility purposes, H.R. 810 would allow federal funds for research on the human clone embryo. Opponents of H.R. 810 have noted that most of the organizations most actively promoting H.R. 810, such as the Biotechnology Industry Organization and the Coalition for the Advancement of Medical Research, are also strong supporters of a certain type of cloning they call "therapeutic cloning." At a May 11 press conference in support of H.R. 810, Senator Orrin Hatch, the sponsor of a pro-human cloning bill, referred to H.R. 810 as "a critical first step," an apparent reference to a pro-cloning bill being the next step.

Committee Action: The bill was introduced on February 15, 2005, and referred to the House Committee on Energy and Commerce, which did not consider the bill.

Cost to Taxpayers: A CBO cost estimate is unavailable. According to recent news reports, in FY04 NIH spent $24.6 million funding the research allowed on cell lines created from cells removed from human embryos prior to August 2001. H.R. 810

requires federal funding of human embryo research "regardless of the date on which the stem cells were derived from a human embryo" which would likely lead to millions of dollars in additional spending.

Constitutional Authority: An Energy and Commerce Committee report citing constitutional authority is unavailable.

Administration Position: On Friday, May 20, 2005, President Bush said, "I made my position very clear on embryonic stem cells. I'm a strong supporter of adult stem cell research, of course. But I made it very clear to the Congress that the use of federal money, taxpayers' money to promote science which destroys life in order to save life is — I'm against that. And therefore, if the bill does that, **I will veto it"** (emphasis added). A Statement of Administrative Policy (SAP) recommending a veto is expected out soon.

Outside Organizations: The following is a partial list of outside organizations opposing H.R. 810 (groups that have indicated they will "score" the vote are indicated with an asterisk):

*National Right to Life Committee
US Conference of Catholic Bishops
*Family Research Council
*Christian Coalition
*Concerned Women for America
Focus on the Family
Christian Medical Association
*Eagle Forum
Traditional Values Coalition
Southern Baptist Convention
Susan B. Anthony List
Republican National Committee for Life
Cornerstone Policy Research
Culture of Life Foundation
Religious Freedom Coalition
Coral Ridge Ministries
Center For Reclaiming America

Does the Bill Create New Federal Programs or Rules?: Yes. The bill would override current federal funding bans and the President's administrative policy to require the HHS Secretary to fund human embryonic research, including research on currently living human embryos stored in freezers at IVF clinics.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: No.

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