RSC
Republican Study Committee
www.house.gov/pence/rsc

Rep. Mike Pence (R-IN), Chairman
Sheila Cole, Executive Director
426 Cannon House Office Building
Washington, DC 20515
Ph (202) 226-9717 / fax (202) 226-1633

Legislative Bulletin…….……July 18, 2006

Contents:
S. 2754 — Alternative Pluripotent Stem Cell Enhancement Act
S. 3504 — Fetus Farming Prohibition Act of 2006
H.R. 810 — Stem Cell Research Enhancement Act of 2005

Summary of the Bills Under Consideration Today:

Total Number of New Government Programs: 1

Total Cost of Discretionary Authorizations: Authorizes "such sums" over three years

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: 3

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

S. 2754 — Alternative Pluripotent Stem Cell Enhancement Act (Sen. Santorum, R-PA)

Order of Business: The bill is scheduled for consideration on Tuesday, July 18, 2006, under a motion to suspend the rules and pass the bill.

The House companion bill (H.R. 5526) was introduced by Rep. Roscoe Bartlett (R-MD) on June 6, 2006, but was not acted upon in the House.

Summary: S. 2754 would direct the Secretary of Health and Human Services (HHS) to conduct research to develop techniques for the isolation, derivation, production, or testing of stem cells that are capable of producing all or almost all of the cell types of the developing body, but are **not** derived from a human embryo.

S. 2754 would require the HHS Secretary to:

1) issue final guidelines within 90 days of enactment, in consultation with the National Institutes of Health (NIH) Director (under HHS authority), that provide guidance on the next steps required for additional research, including determining which specific techniques may require additional animal testing;
2) prioritize research with the greatest potential for near-term clinical benefit;
3) take into account techniques outlined by the President's Council on Bioethics and any other appropriate techniques and research.

In other words, NIH would be required to conduct research to derive human pluripotent stem cell lines using techniques that do not harm human embryos, taking into consideration guidelines from the President's Council on Bioethics. Pluripotent means the ability to mature or develop into every cell type of the body. It has been reported on scientific websites that pluripotent stem cells are the same as human embryonic stem cells, or only a property of embryonic stem cells, but this is incorrect. A cell may be "pluripotent" without being derived from a human embryo, and recent studies have shown that adult stem cells can turn into every tissue type of the body. NIH currently has the authority, but not required, to conduct the type of research required in this bill.

To view an NIH fact sheet on human pluripotent stem cell research, please visit: http://stemcells.nih.gov/news/newsArchives/stemfactsheet.asp.

Additional Information: *Under current law, embryo stem cell research is legal and unrestricted. Private research entities can create and destroy as many human embryos as they wish.* Thus, the current debate surrounding stem cell research, and specifically embryo stem cell research, is whether or not it should be **federally funded**. Many conservatives object to federally funding embryonic stem cell research on two fronts: 1) it destroys a human life (on the assumption that life begins at conception and a human embryo is beyond that stage), and 2) embryo stem cell research (which has been active for over 25 years) has not shown to be as promising as other research methods that do not require the destruction of a human embryo. For example, to date, there have been **72** different diseases treated in published clinical applications in humans using human adult stem cells (including sickle cell anemia, leukemia, spinal cord injury, Krabbe disease and others), but there have been **zero (0)** diseases treated in human clinical applications using embryonic stem cells. For more information on successful human clinical trials using adult stems cells, or for additional information on adult vs. embryonic stem cell research, please visit: www.stemcellresearch.org.

Current Law: (Dickey/Wicker amendment language in H.R. 3010, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006).

> **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 46.204(b) 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.

Administration Policy: The Administration supports passage of S. 2754 and released a Statement of Administration Policy (SAP) on July 17, 2006: "The Administration strongly supports Senate passage of S. 2754, a bill to aid research into techniques of deriving pluripotent stem cells without harming or destroying human embryos. In this promising era of biotechnological advances, the Administration believes it is critical to establish key moral boundaries that will allow the nation to vigorously move forward with medical research, while also maintaining the highest ethical standards and respecting human dignity and life." To view the full SAP, please visit: http://www.whitehouse.gov/omb/legislative/sap/109-2/s2754sap-s.pdf.

Committee Action: S. 2754 was introduced in the Senate on May 5, 2006, and is expected to pass the Senate within the next few hours (July 18, 2006). No Committee action was taken in the House.

Cost to Taxpayers: A CBO score of S. 2754 is unavailable. However, S. 2754 authorizes "such sums" for FY07-FY09 to carry out the provisions of this legislation, subject to appropriations. While this legislation requires NIH to conduct research that is already permitted under current law, it does create a new funding stream, and therefore is viewed by many conservatives as creating a new federal program.

Does the Bill Expand the Size and Scope of the Federal Government?: No.

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. House Rule XIII, Section 3(d)(1), requires that all committee reports contain "a statement citing the *specific* powers granted to Congress in the Constitution to enact the law proposed by the bill or joint resolution." *[emphasis added]*

RSC Staff Contact: Derek V. Baker; derek.baker@mail.house.gov; 202-226-8585

S. 3504 — Fetus Farming Prohibition Act of 2006
(Sen. Santorum, R-PA)

Order of Business: The bill is scheduled for consideration on Tuesday, July 18, 2006, under a motion to suspend the rules and pass the bill.

The House companion bill (H.R. 5719) was introduced by Rep. Dave Weldon (R-FL) on June 29, 2006, but was not acted upon in the House.

Summary: S. 3504 would make it illegal for any person or entity to: 1) solicit or knowingly acquire, receive, or accept a donation of human fetal tissue *knowing* that a human pregnancy was *deliberately* initiated to provide such tissue, **or** 2) knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal. The bill would amend the Public Health Service Act (42 U.S.C. 289g–2), which regulates human fetal tissue research, by adding this prohibition against buying or selling tissue from fetuses gestated [to carry in the uterus during pregnancy] for research purposes – whether in a human or animal womb. Current law (§ 289g–2) provides that violators will be fined or imprisoned for up to 10 years, or both. The fine would be not less than twice the amount of money that was received by the person providing the tissue in the transaction.

Additional Information: Researchers have already published peer-reviewed studies in which cloned animals (cows and mice) were grown in utero so that their more developed fetal tissue could be harvested and used to treat animal models of disease. Though there is no known case of this research being performed on humans, the typical next step following successful animal models is to perform the same research in humans in order to develop potential cures for human diseases. Several researchers have indicated that cells or tissues from human fetuses are more desirable than embryonic stem cells because they do not form tumors, are genetically stable, and have already begun developing into various tissue types. New Jersey has already explicitly authorized research involving fetus farming, and other states are considering similar legislation (see: http://www.nationalreview.com/lopez/lopez200401051346.asp and other various media reports). For more information, please visit the following websites:

http://lifenews.com/bio1584.html.
www.stemcellresearch.org.

Administration Policy: The Administration supports passage of S. 3504 and released a Statement of Administration Policy (SAP) on July 17, 2006: "The Administration strongly supports Senate passage of S. 3504, a bill to prohibit the solicitation or acceptance of tissue from human fetuses gestated and aborted solely for research purposes. The destruction of nascent life for research not only violates the principle that no life should be taken for the benefit of another, but also opens up a path to further egregious abuses." To view the full SAP, please visit: http://www.whitehouse.gov/omb/legislative/sap/109-2/s3504sap-s.pdf.

Committee Action: S. 3504 was introduced in the Senate on May 5, 2006, and is expected to pass the Senate within the next few hours (July 18, 2006). No Committee action was taken in the House.

Cost to Taxpayers: A CBO score of S. 3504 is unavailable, but the bill does not authorize new expenditures.

Does the Bill Expand the Size and Scope of the Federal Government?: No.

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. House Rule XIII, Section 3(d)(1), requires that all committee reports contain "a statement citing the *specific* powers granted to Congress in the Constitution to enact the law proposed by the bill or joint resolution." *[emphasis added]*

RSC Staff Contact: Derek V. Baker; derek.baker@mail.house.gov; 202-226-8585

H.R. 810 — Stem Cell Research Enhancement Act of 2005 – (Castle, R-DE)

Order of Business: The bill is expected to be vetoed by President Bush and a "veto message" will be forwarded to the House with the vetoed bill for reconsideration.

This bill was originally passed in the House by a vote of 238-194 on May 24, 2005. It is expected to pass the Senate later today, July 18, 2006. President Bush is expected to veto the bill as early as today or tomorrow, and the bill will be forwarded to the House. The vote on H.R. 810 is to either sustain or override the President's veto – the first of his Administration. For additional information on the process in the House regarding vetoed bills, please see the "Brief Veto History" section below.

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 would 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, please visit: 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 are then usually 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, please 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 July 2006, no animals or human patients have been successfully treated with human embryonic stem cells (see: http://www.stemcellresearch.org/facts/treatments.htm).

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. 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.

Brief Veto History: Since President Bush took office in January of 2001, he has yet to issue a veto. The most recent instances of a vetoed bill were in 2000 by President Clinton, during the 106th Congress:

- H.R. 8, Estate Tax Elimination Act. The House sustained the veto (the bill failed) by a vote of 274-157 on September, 7, 2000. Roll Call No. 458.
- H.R. 4810, Marriage Tax Relief Reconciliation Act. The House sustained the veto by a vote of 270-158 on September 13, 2000. Roll Call No. 466.
- H.R. 4733, Energy and Water Development Appropriations Act. The House overrode the veto (and passed the bill into law) by a vote of 315-98 on October 11, 2000. Roll Call No. 523.

Process for a Vetoed Bill:

- The House and Senate pass an identical bill.
- The President vetoes the bill and sends a veto message to the House.
- The Speaker "lays a veto message before the House on the day it is received...When the message is laid before the House, the question on passage is considered as pending."
- Consideration of a vetoed bill (a privileged matter) generally takes precedence over other floor matters (it can interrupt other floor business), *except* in certain specific instances: a motion to adjourn, a question of privilege under the Constitution (such as a blue-slip resolution), and unfinished business with the previous question order (such as a bill with the previous question ordered to passage on the day before, but the House adjourned before voting on passage of the bill).
- If the House does *not* wish to proceed immediately to reconsider the bill, three motions are in order:
  1) motions to lay on the table (if passed, a motion to take it from the table is in order at any time);
  2) motions to postpone consideration to a day certain (it becomes unfinished business on that day); or
  3) motion to refer to committee (a motion to discharge is highly privileged and in order at any time).
- If none of the above three motions are offered, the House proceeds to debate the override question under the hour rule and then votes on the question of overriding the veto.
- If the veto is sustained, the bill is referred to committee. Since the bill has been rejected (when the veto was sustained), a motion to take the bill from committee is not privileged.

Note: It is not clear what the options are after the veto is sustained and referred to committee. Also, according to the Parliamentarian's office, neither the House nor Senate is *required* to act on a vetoed bill (there were instances during the 106th Congress when the House and Senate chose not to act upon a vetoed bill).

The Vote on H.R. 810 – Sustaining the Presidential Veto:
When a vote is requested on a vetoed bill, the question is: "Will the House, on reconsideration, pass the bill, the objections of the President to the contrary notwithstanding." Thus, it is as if the bill is up for normal consideration again, only the threshold for passage is now 2/3 of those voting. **If a member opposes the bill and voted NO when it was originally considered and passed, then he would vote NO again (still opposing the bill, thereby voting to sustain the President's veto).**

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 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 federal spending.

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

Administration Position: The Administration opposed original passage of H.R. 810 and released a Statement of Administration Policy (SAP) on May 24, 2005, which stated:

> "The Administration strongly opposes House passage of H.R. 810, which would require Federal taxpayer dollars to be used to encourage the ongoing destruction of nascent human life. The bill would compel all American taxpayers to pay for research that relies on the intentional destruction of human embryos for the derivation of stem cells, overturning the President's policy that supports research without promoting such ongoing destruction. If H.R. 810 were presented to the President, he would veto the bill."

To read the full SAP, please visit:
http://www.whitehouse.gov/omb/legislative/sap/109-1/hr810sap-h.pdf.

Outside Organizations:
The following is a partial list of outside organizations opposing H.R. 810 (note: groups that scored the original House vote and are likely to score it again are noted 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 current 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.

RSC Staff Contact: Derek V. Baker; derek.baker@mail.house.gov; 202-226-8585

###