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Legislative Bulletin.....February 27, 2003

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H.R. 534— Human Cloning Prohibition Act of 2003

H.R. 534—HUMAN CLONING PROHIBITION ACT OF 2003 (WELDON (FL)/STUPAK)

Order of Business: The bill will be considered on Thursday, February 27, 2003 under a structured rule. To be considered are 1) a rule to bring up H.R. 534, 2) an amendment offered by Rep. Bobby Scott (D-VA) — which the bill sponsors plan to accept without objection, 3) a sense of Congress amendment by Rep. Cliff Stearns (R-FL), 4) an amendment in the nature of a substitute to be offered by Rep. Jim Greenwood (R-PA), 5) a motion to recommit with or without instructions to be offered by the Democrats, and 6) the underlying bill H.R. 534. The text of the rule and the amendments to be offered can be found on the House Rules Committee webpage http://www.house.gov/rules/108rule534.htm

Note: In the 107th Congress, a bill identical to H.R. 534 passed the House 265-162 on July 31, 2001. http://clerkweb.house.gov/cgi-bin/vote.exe?year=2001&rollnumber=304

The same day, Rep. Greenwood's amendment in the nature of a substitute was defeated 178-249. http://clerkweb.house.gov/cgi-bin/vote.exe?year=2001&rollnumber=302

A Democrat motion to recommit the bill was also defeated 175-251. http://clerkweb.house.gov/cgi-bin/vote.exe?year=2001&rollnumber=303

Summary: H.R. 534 amends the federal criminal code (Title 18) to make it illegal for any person or entity, public or private to "knowingly— (1) perform or attempt to perform human cloning; (2) to participate in an attempt to perform human cloning; or (3) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo."

Key definitions in the bill include:

- (1) HUMAN CLONING- The term 'human cloning' means human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism.
- (2) ASEXUAL REPRODUCTION- The term 'asexual reproduction' means reproduction not initiated by the union of oocyte and sperm.
- (3) SOMATIC CELL- The term 'somatic cell' means a diploid cell (having a complete set of chromosomes) obtained or derived from a living or deceased human body at any stage of development.

The bill specifically states that it <u>does not restrict</u> research not specifically prohibited in the bill, including research in the use of nuclear transfer or other techniques to clone "molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans."

Rep. Scott's Amendment: Rep. Bobby Scott (D-VA) will offer an amendment to require the General Accounting Office (GAO) to report a study to Congress within two years regarding developments in medical technology concerning cloning, the "prevailing ethical views" toward cloning, and "potential legal implications" of research on cloning research. Chairman Sensenbrenner and the bill sponsors have indicated that they do not object to the study and that they plan on accepting the amendment without objection.

Rep. Stearns Amendment: Rep. Cliff Stearns (R-FL) will offer a sense of Congress that says, "each foreign country should establish a prohibition substantially equivalent to the prohibition established by [the cloning ban]."

Rep. Greenwood's Substitute: The Greenwood substitute mirrors H.R. 801, a piece of legislation introduced by Rep. Greenwood on February 13, 2003. Unlike H.R. 534, the Weldon/Stupak bill, Rep. Greenwood's substitute does NOT prohibit all human cloning. The Greenwood substitute makes it illegal under the Food and Drug Act to implant a cloned human embryo into a woman's womb. Under this substitute it would still be legal to clone a human, just illegal to "grow" one in a woman's womb. This would be the first time the federal government explicitly would allow the creation of cloned human embryos but require their destruction.

"It shall be unlawful for any person— to use or attempt to use human somatic cell nuclear transfer technology, or the product of such technology, to initiate a pregnancy or with the intent to initiate a pregnancy" (emphasis added).

—Greenwood Substitute, Sec. 1001 (a)(1)(A)

Under the substitute, it would also be illegal to transport "the product" of somatic nuclear cell transfer, but only if "the product" is known to be intended for implantation in a woman's womb.

"It shall be unlawful for any person— ... to ship, mail, transport, or receive the product of such technology knowing that the product is <u>intended to be used to initiate a pregnancy</u>" (emphasis added).

—Greenwood Substitute, Sec. 1001 (a)(1)(B)

Under Rep. Greenwood's substitute, someone who puts a cloned human embryo in a womb will face a criminal sentence of not more than 10 years, and/or will be subject to civil fines of not more than \$10 million. The bill would appear to apply the prison sentence and civil penalties to a woman pregnant with a cloned child.

The Greenwood substitute sunsets in 10 years.

The substitute will require the federal government to register scientists involved in cloning human embryos, including scientists in for-profit human cloning laboratories, and will require government supervision on human embryos created through the cloning process (Greenwood Substitute, Sec. 1001 (a)(2)(c-d)).

The substitute would preempt all state laws that ban *all* human cloning, if the state passes the ban after the date of the enactment of Rep. Greenwood's substitute. In 2001, there were 45 states that had no human cloning bans on the books. A number of states currently are debating cloning bans but would be prohibited from enacting a ban on all human cloning if they didn't act before Rep. Greenwood's substitute became law.

Rep. Greenwood's substitute also calls on the Secretary of HHS to request the Institute of Medicine (or another public or nonprofit entity if IOM refuses) to do a study of "stem cells" and report no later than 3 years after this substitute's enactment. In a 2001 letter, HHS Secretary Tommy Thompson reminded Congress that the issue of human cloning is "unrelated" to the stem cell debate.

<u>Motion to Recommit:</u> At this time, it is unknown what the Democrat Motion to Recommit will be. In the 107th Congress, Rep. Lofgren (D-CA) offered the Democrats' motion to recommit which would have added the following new section to the underlying legislation:

"(e) EXEMPTION FOR MEDICAL TREATMENTS.--Nothing in this section shall prohibit the use of human somatic cell nuclear transfer in connection with the development or application of treatments designed to address Parkinson's disease, Alzheimer's disease, diabetes, cancer, heart disease, spinal cord injury, multiple sclerosis, severe burns, or other diseases, disorders, or conditions, provided that the product of such use is not utilized to initiate a pregnancy and is not intended to be utilized to initiate a pregnancy. Nothing in this subsection shall exempt any product from any applicable regulatory approval" (emphasis added).

Judiciary Chairman Sensenbrenner stated on the House floor at the time:

The Lofgren motion to recommit "allows for the production of cloned embryos for the development of treatments designed to address a number of diseases... [which] is a reworded Greenwood substitute amendment.

"The motion to recommit would allow the practice of creating human embryos solely for the purpose of destroying them for experimentation. This approach to prohibit human cloning would be ineffective and unenforceable.

"Once cloned embryos were produced and available in laboratories, it would be virtually impossible to control what is done with them. Stockpiles of cloned embryos would be produced, bought and sold without anyone knowing about it. Implantation of cloned embryos into a woman's uterus, a relatively easy procedure, would take place out of sight. At that point, governmental attempts to enforce a reproductive cloning ban would prove impossible to police or regulate.

"Creating cloned human children necessarily begins by producing cloned human embryos. If we want to prevent the latter, we should prevent the former."

—Congressional Record, House of Representatives, July 31, 2001

<u>Cost to Taxpayers:</u> Based on information from the Department of Justice, CBO estimates that not many cases would be prosecuted under the bill and that therefore enacting the Weldon/Stupak legislation would have a negligible budgetary effect. CBO estimates that a cloning ban would impose an unfunded mandate as defined in UMRA because it would prohibit public and private entities from performing human cloning. CBO noted the mandate did not exceed the UMRA thresholds and estimated minimal costs on state, local, or tribal governments, or the private sector.

<u>Constitutional Authority</u>: The Judiciary Committee report finds authority under Article I, section 8 of the Constitution (Powers of Congress), but fails to reference a specific clause.

<u>Does the Bill Create New Federal Programs or Rules:</u> Yes, the bill creates a new federal law against all forms of human cloning and creates a jail sentence of not more than 10 years and a civil penalty of at least a million dollars and possibly up to twice any financial gain attained for any violation of the new law.

Administration Position:

"The Administration strongly supports enactment of H.R. 534, which will ensure protection of human life as the frontiers of science expand. The Administration unequivocally is opposed to the cloning of human beings either for reproduction or for research. The moral and ethical issues posed by human cloning are profound and cannot be ignored in the quest for scientific discovery. Accordingly, the Administration strongly supports House passage of H.R. 534, a comprehensive ban against all human cloning.

"The Administration is strongly opposed to any legislation that would prohibit human cloning for reproductive purposes but permit the creation of cloned embryos or development of human embryo farms for research, which would require the destruction of nascent human life. Thus, the Administration would strongly oppose any substitute amendment that would permit human embryos to be created, developed, and destroyed solely for research purposes" (emphasis added).

—Excerpt from OMB Statement of Administration Policy on the Human Cloning Prohibition Act (H.R. 534), February 26, 2003

DOJ has testified that it could enforce the Weldon/Stupak cloning ban but that Greenwood-type legislation would pose serious difficulties for law enforcement.

"The task of **enforcing a general <u>ban on human cloning for any purpose</u> does not seem to pose insuperable challenges to law enforcement.** Such a ban would clearly define the exact activity to be banned, which is the use of the procedure known as somatic cell nuclear transfer to produce human embryos."

"Enforcing a modified cloning ban would be problematic and pose certain law enforcement challenges.... [T]here does not seem to be any reliable means for determining the difference between a fertilized embryo and a cloned embryo... there would simply be no way for a prosecutor to prove that the implanted embryos were the ones which arose from cloning [and] ...any government-directed attempt to terminate a cloned embryo in utero would create problems enormous and complex" (emphasis added).

— Excerpt from DOJ Testimony, May 15, 2002 See full testimony at http://www.house.gov/weldon/issues/doj.htm

<u>Additional Resources:</u> The following websites have large amounts of materials on cloning in general and specific information regarding legislation before the House:

http://www.house.gov/weldon/issues/cloning.htm (Office of Rep. Dave Weldon)

<u>http://www.cloninginformation.org/</u> (Americans to Ban Cloning)

http://www.nrlc.org/killing_embryos/index.html (National Right to Life)

http://www.usccb.org/prolife/issues/bioethic/factsheets.htm (U.S. Conference of Catholic Bishops)

<u>Votes Scored:</u> The following groups have stated that they intend to score the vote on the Greenwood Substitute and on Final Passage. Groups also note that they reserve the right to score procedural motions if they are used in an attempt to defeat H.R. 534.

- American Association of Christian Schools
- Christian Coalition
- Concerned Women for America
- Eagle Forum

- Family Research Council
- National Right to Life
- Traditional Values Coalition

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