



Human Cloning Packet

February 2003

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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 *does not restrict* 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 intended to be used to initiate a pregnancy” (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.

Motion to Recommit: 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

Cost to Taxpayers: 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.

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

Does the Bill Create New Federal Programs or Rules: 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 ban on human cloning for any purpose 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>

Additional Resources: 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)

<http://www.cloninginformation.org/> (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)

Votes Scored: 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

RSC Staff Contact: Sheila Moloney 202-226-9719; Sheila.Moloney@mail.house.gov

HUMAN CLONING FACTS

COURTESY OF THE OFFICE OF
CONGRESSMAN DAVE WELDON, M.D.

Is there a scientific difference between “therapeutic cloning” and “reproductive cloning?”

No.

The only difference is the stated *purpose* for which the cloned embryo is created. The National Academy of Sciences cloning panel press release January 2002 stated:

"The method used to initiate the reproductive cloning procedure is called either nuclear transplantation or somatic cell nuclear transfer."

"If the procedure is successful, the cell will divide several times to produce a pre-implantation embryo -- "blastocyst" -- that is composed of about 150 cells."

"If the blastocyst is placed in a uterus, it can implant and form a fetus, which then may develop further and result in a newborn."

"Unlike reproductive cloning, the creation of embryonic stem cells by nuclear transplantation does not involve implantation of a blastocyst in a uterus. Instead, cells are isolated from a blastocyst about five days after the nuclear transplantation procedure and used to make stem cell lines..."

Thus, the only difference in the procedure is whether the cloned embryo is implanted or destroyed. The cloned embryo, regardless of the purpose for which it was created, is fully capable of developing into a cloned baby.

Does human research cloning (“therapeutic cloning”) produce a human embryo?

Yes.

President Clinton’s National Bioethics Advisory Commission, in its 1997 report *Cloning Human Beings*, explicitly stated:

“The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term.”

The President’s Council on Bioethics offers defines:

“*Cloned human embryo*: (a) A human embryo resulting from the nuclear transfer process (as contrasted with a human embryo arising from the union of egg and sperm). (b) The immediate (and developing) product of the initial act of cloning, accomplished by successful SCNT, **whether used subsequently in attempts to produce children or in biomedical research.**” (emphasis added), *Human Cloning and Human Dignity: An Ethical Inquiry Executive Summary* 2002.

Is a cloned embryo simply an “unfertilized egg” or an “activated oocyte” as Senators Feinstein and Specter allege?

No.

The President’s Council on Bioethics:

“What shall we call the product of SCNT? The technical description of the cloning method (that is, SCNT) omits all reference not only to cloning but also to the immediate product of the activity. This obscurity enables some to argue that the *immediate product* of SCNT is not an "embryo" but rather "an egg" or "an unfertilized egg" or "an activated cell," and that the subsequent stages of development should not be called embryos but "clumps of cells" or "activated cells."”

The Council Concludes,

“The product of "SCNT" is not only an embryo; it is also a *clone*, genetically virtually identical to the individual that was the source of the transferred nucleus, hence an embryonic clone of the donor.” (italics original)

—Chapter Three, On Terminology, *Human Cloning and Human Dignity: An Ethical Inquiry*, 2002.

An “unfertilized egg” would simply be a woman’s egg (oocyte), which if implanted cannot produce a child, because it only has 23 chromosomes.

However, a woman’s egg can be turned into an embryo by normal fertilization with sperm, or by cloning (“somatic cell nuclear transfer”). A cloned embryo is not “fertilized” by sperm, thus calling a cloned embryo an “unfertilized egg” is redundant. If implanted, a normal or cloned embryo would grow into a full baby.

If cloning does not produce a cloned embryo, but only an “unfertilized egg” which cannot produce a child, why do Senators Feinstein and Specter ban its implantation into a woman’s uterus, a so-called reproductive cloning ban? Because, they know it is an embryo that could produce a cloned child.

Therapeutic Cloning is necessary because it alone offers unique cures.

False.

Therapeutic cloning has not produced a single cure in animal models for any disease, nor has it produced any cures in human clinical trials.

By contrast, researchers have shown adult stem cells capable of re-growth and reconnection in spinal cord injury, allowing functional recovery in rats. Researchers have reversed diabetes in mice using adult pancreatic stem cells in March 2000. In human trials, researchers in Canada have developed the Edmonton Protocol to treat juvenile diabetes, and have shown long-term reversal of diabetes in human patients by transplanting pancreatic islets from cadavers and providing special immunosuppressive drugs. The American Diabetes Association issued a report in June 2001 that fifteen patients with serious type I (juvenile) diabetes had become insulin-free after the transplants; and that 9 still did not need insulin injections many months later. The Edmonton Protocol has now been used to treat over 100 people.

Promising treatments do not stop with diabetes. Today's medical literature abounds with publications demonstrating successful new human clinical applications of adult stem cells. Adult stem cells can be harvested from many areas of the human body such as bone marrow, fat tissue, even the nose. There are no immune rejection issues with adult stem cells.

Adult stem cells have already been used successfully in over 45 clinical trials to treat humans. For example, adult stem cells have already been used to treat cartilage defect in children, restore vision to patients who were legally blind, relieve systemic lupus, multiple sclerosis, and rheumatoid arthritis and cure severe combined immunodeficiency disease, and to treat various types of cancer such as leukemias, solid tumors, neuroblastoma, non-Hodgkin's lymphoma, and renal cell carcinoma. Just last year, it was reported that researchers in California have reversed the symptoms of Parkinson's disease in a man with his *own* neural stem cells; clinical trials in this approach are being extended to other patients.

Will therapeutic cloning yield cures for millions of patients?

Not likely.

There is a growing skepticism about the clinical applications of research cloning:

James Thomson, who discovered embryo stem cells, quoted from his paper: "[T]he poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision this [therapeutic cloning] becoming a routine clinical procedure..."

—Odorico JS, Kaufman DS, Thomson JA, "Multilineage differentiation from human embryonic stem cell lines," *Stem Cells* 19, 193-204; 2001.

"...Ministers in Britain have too easily swallowed the line that cloning human embryos is essential to medical progress. It is not. ...Like stuck records, ministers and policy makers continue to enthuse about therapeutic cloning even though the majority of bench scientists no longer think it's possible or practicable to treat patients with cells derived from cloned embryos. They have already moved on to investigating the alternatives."

—Editorial, "Brave New Medicine", *New Scientist*, Dec 1, 2001

"So to the casual observer, it may come as a surprise that many experts do not now expect therapeutic cloning to have a large impact. Aside from problems with the supply of human egg cells, and ethical objections to any therapy that requires the destruction of human embryos, many researchers have come to doubt whether therapeutic cloning will ever be efficient enough to be commercially viable. 'It would be astronomically expensive,' says James Thomson of the University of Wisconsin in Madison."

—Peter Aldhous, "Can they rebuild us?", *Nature* 410, 622-625; April 5, 2001.

Will therapeutic cloning solve immune rejection problems?

No.

Though some proponents of cloning claim normal embryo stem cells will suffer immune rejection problems, embryo stem cell researchers disagree: "[John] Gearhart [of Johns Hopkins University] also

says that many scientists 'feel there are ways of getting around [the rejection problem] without the nuclear transfer paradigm.' "

—Constance Holden, "Would cloning ban affect stem cells?" *Science* 293, 1025; Aug 10, 2001.

Speaking to the President's Council on Bioethics Dr. Irving Weissman explained, "I should say that when you put the nucleus in from a somatic cell, the mitochondria still come from the host." [from the female egg] "And in mouse studies it is clear that those genetic differences can lead to a mild but certainly effective transplant rejection and so immunosuppression, mild though it is, will be required for that."

Would research cloning turn women's eggs into commodities?

Yes.

"Because embryo cloning will compromise women's health, turn their eggs and wombs into commodities, compromise their reproductive autonomy and, with virtual certainty, lead to the production of 'experimental' human beings, we are convinced that the line must be drawn here."

—Judy Norsigian Co-Author *Our Bodies, Ourselves for the New Century*

Boston Women's Health Book Collective

Scientists estimate it would require at least 50 eggs to create one viable cloned embryo. To create one cloned embryo for each of, say, 16 million Parkinson's patients, 800 million women's eggs would need to be obtained. Where will all the women's eggs come from? How many women would take superovulatory drugs to donate their eggs, if they aren't doing so to have a cloned baby? How many women would suffer serious adverse effects from the procedure?

Does the Weldon/Stupak cloning bill (H.R. 534) ban embryo stem cell research?

No.

The lead opponent to H.R. 534, Rep. James Greenwood (R-PA), stated during the House of Representatives debate on July 31, 2001, that "the gentleman from Florida (Mr. Weldon) did not bring a bill [H.R. 534] to the floor to ban embryonic stem cell research."

H.R. 534 and S. 245 does not effect in any way "embryo stem cell research" which is done in the private sector, for these embryos are created from sperm and egg in IVF clinics; they are not created by cloning (somatic cell nuclear transfer), so neither bill bans the creation or any use of these embryos.

Does the Weldon/Stupak bill (H.R. 534) *only* ban human cloning?

Yes.

H.R. 534 only bans human somatic cell nuclear transfer, i.e., human cloning for research or reproduction.

This bill would make it unlawful to perform human “somatic cell nuclear transfer” for any purpose. It would make it unlawful to ship, receive or import the cloned embryos or products derived from that embryo.

Does the Weldon/Stupak human cloning bill (H.R. 534) ban other forms of cloning?

No.

Sec. (d) of H.R. 534 ensures that no useful and appropriate scientific research is banned, including ongoing research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells (other than human embryos), tissues, organs, plants, or non-human animals.

Produced by the Office of Rep. Dave Weldon, M.D. (R-FL). If you'd like more information please call 202-225-3671.

—Sample Press Release—

For Immediate Release

February 27, 2003

Rep. ____ votes to ban human cloning

Washington, D.C.—Rep. ____ voted today to ban all human cloning. The Human Cloning Prohibition Act, H.R. 534, passed the House of Representatives by a vote of XXX to XX.

“Cloning human beings is wrong,” said Rep. _____. “And, the practice of cloning humans and then killing them is even worse. Once we begin cloning, there are no good options, which is why we have to prevent humans from being cloned in the first place.”

The Human Cloning Prohibition Act places a ban on human cloning by prohibiting the use of somatic cell nuclear transfer techniques to create human embryos. This is the same process that scientists in Scotland used to create Dolly the cloned sheep in 1996.

“In his State of the Union, the President said, ‘because no human life should be started or ended as the object of an experiment, I ask you to set a high standard for humanity, and pass a law against all human cloning.’ Today, I’m proud to have answered the President call and to have voted for a ban on all human cloning. I urge the Senate to pass this ban immediately and send it to the President’s desk.”

Additionally, Rep. ____ voted today against an amendment that would have allowed human cloning as long as the clones were killed before growing to maturity and that could have put mothers pregnant with clones in jail.

“We can’t stand by while scientists create human clones, and we definitely can’t be in the business of monitoring to ensure clones are euthanized,” Rep. ____ said. “The American people overwhelmingly oppose human cloning. Today, the House of Representatives listened to America and moved us one step closer to a ban on all human cloning.”

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Comparison Weldon and Greenwood Cloning Bills

Cloning Bills	H.R. 534 (Weldon/Stupak) – would ban the creation of human cloned embryos for research or reproductive purposes.	H.R. 801 (Greenwood/Deutsch) – would allow human cloning for research and allow human reproductive cloning in 10 years. The bill does not ban the implantation of a cloned embryo into an artificial womb.
Unlawful Acts:	H.R. 534 bans creating cloned human embryos by “somatic cell nuclear transfer” for any purpose. Would <i>only</i> ban the creation of cloned human embryos, the first step in conducting research or reproductive cloning.	Imposes 10-year moratorium on the use of “somatic cell nuclear transfer technology” to “initiate a pregnancy.” Would <i>allow</i> the use of “somatic cell nuclear transfer technology to : a) create human cloned embryos for research, b) create human cloned embryos intended to be implanted into artificial wombs, and c) create chimeras (human-animal hybrids) by transferring human nuclear material into animal eggs.
Importation/Export:	Prohibits shipping or receiving cloned embryos, or “products derived from” cloned embryos, i.e., stem cells. It does <u>not</u> ban importation of knowledge or therapies developed from such cloning technology.	Prohibits the shipping or receiving of cloned embryos only if the recipient “knows” that the product is “intended” to be used to initiate a pregnancy. This provision provides a huge loophole: it does not prohibit the “reckless” buying or selling of cloned embryos for reproductive cloning, rather it only requires that they “know” that the product is “intended” to produce a clonal pregnancy.
Registration/Regulations:	N/A – practice is banned	Applies human subject protections, requiring researchers to register with HHS and attest along with human cell donors that the research will not be used to create cloned babies. FDA has zero track record in regulating IVF; has no idea about number and fate of embryos produced in IVF clinics. These regulations would <i>not</i> cover the solicitation and cost of thousands of women’s eggs needed to produce cloned embryos for research and reproduction. These regulations would not prevent implantation into an artificial womb.
Preemption of State Law:	N/A – practice is banned	Prevents states from passing more stringent laws to ban human cloning, but exempts current state law.
Sunset:	N/A – practice is banned	Allows cloning babies without restriction after 10 years-would allow “fetus farming” at any time before that if an artificial womb is used to grow cloned human fetus.
Forfeiture:	N/A – practice is banned	Forfeits to Gov’t any “property” used to create cloned baby, including the implanted embryo.
Study	None	Calls for the Institute of Medicine to report on cloning and stem cell science in three years.
Research Not Banned	H.R. 534 does not ban animal cloning, molecular or cellular cloning, embryo stem cell research or any other research not involved in creating human cloned embryos.	Same.

ADDITIONAL RESOURCES:

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)

<http://www.cloninginformation.org/> (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)