

# Congress Bans Patents on Human Embryos

## *NRLC-backed Weldon Amendment survives BIO attacks*

**F**or the first time ever, Congress has enacted a prohibition on the patenting of human embryos. The new law, known as the Weldon Amendment, went into effect on January 23, 2004.

The National Right to Life Committee (NRLC) played a key role in lobbying in support of the legislation, which will make it more difficult for biotech firms to profit from their ongoing attempts to create human embryos by cloning.

The powerful Biotechnology Industry Organization (BIO) led an unsuccessful four-month lobbying and propaganda campaign against the proposal, but these attacks ultimately failed because of strong support for the Weldon Amendment from the House and Senate Republican leadership and from the Bush Administration.

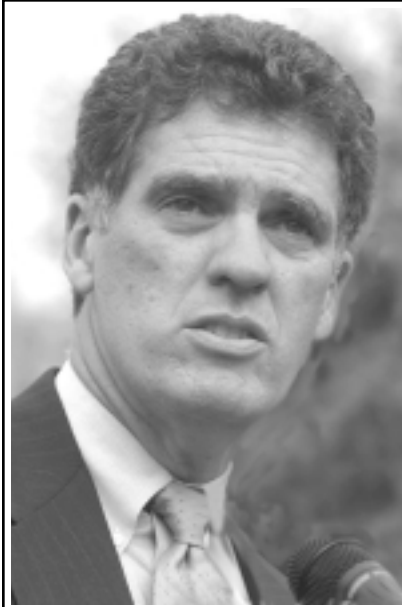
**“Enactment of the Weldon Amendment is not a cure-all, but it may serve as an important bulwark against some of the darker trends in contemporary biotechnology research,”** commented NRLC Legislative Director Douglas Johnson. **“The Weldon Amendment stands for the principle that human life is not a commodity and that a member of the human family can never be regarded as a mere invention.”**

The ban was sponsored by Congressman Dave Weldon (R-Fl.). Weldon is a physician who, along with Senator Sam Brownback (R-Ks.), has led efforts to ban human cloning in the United States.

The Weldon-Stupak bill to ban human cloning has passed the House of Representatives twice (in 2001 and 2003), but it does not yet have the level of support needed to pass the Senate.

Since the ban on human cloning has not been enacted, some biotech firms continue to work to overcome technical obstacles and create human embryos by cloning, for the purpose of using them in research that will kill them. Such “research cloning” is sometimes referred to by the misnomer “therapeutic cloning.”

Researchers plan to profit from human cloning in



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***—Rep. Dave Weldon (R-Fl.)***

several ways. Some researchers hope to create cloned human embryos with specific genetic traits, patent them, and then collect royalties each time researchers use a “copy” of the patented embryo.

A patent is a government-conferred property right that gives an inventor exclusive rights to manufacture or use his invention for a defined period, usually 20 years. The patent holder can license others to employ his patent for a fee, called a royalty.

“Unethical researchers and biotechnology companies are willing not only to create and destroy embryonic human beings for research purposes, but even to patent these fellow humans so they can license, market, buy, and sell them as mere commodities,” noted Richard Doerflinger, an expert on the issue of human cloning with the U.S. Conference of Catholic Bishops. “By prohibiting patents on human organisms, Congress has helped prevent such gross abuses and has taken some of the profit motive out of the drive for human cloning.”

Alta Charo, a professor at the University of Wisconsin who is a prominent supporter of research cloning, was unhappy about enactment of the Weldon Amendment. She told a reporter for the *Badger Herald* that lack of patentability would make investors less willing to put money into such research.

**“Investors hope for a return on their original investment with the basic research, but with no patent, there is no return,” Charo explained.**

#### **Patent Office Policy**

The U.S. Patent and Trademark Office (USPTO), the government agency that administers the patent system, has a long-standing policy against granting a patent on a “human being.” However, some experts believe that when somebody actually applies for a patent on a cloned or genetically modified human embryo, the courts would likely order the USPTO to grant the patent, unless Congress had acted to specifically prohibit it.

In order to head off this scenario, Senators Brownback and John Ensign (R-Nv.) offered an amendment on the Senate floor in 2002 to prohibit the USPTO from issuing patents on humans, but it was blocked procedurally by opponents, including Senators Arlen Specter (R-Pa.), Orrin Hatch (R-Utah), and Ted Kennedy (D-Mass.), who said it would discourage “stem cell research.” Some biotech researchers want to create human embryos by cloning in order to harvest their stem cells, a process that kills the embryo.

The issue resurfaced on July 22, 2003, when Dr. Weldon caught the pro-cloning forces off guard. As the House was considering an appropriations bill to fund certain federal agencies, including the USPTO, Weldon took the House floor and offered what is technically known as a “limitation amendment.”

Because of House rules governing “limitation amendments,” the amendment had to be very short and simple. **The Weldon Amendment read, “None of the funds appropriated or otherwise made available by this act may be used to issue patents on claims directed to or encompassing a human organism.”**

Dr. Weldon explained on the House floor that his amendment would ban only patents on human embryos, human fetuses, or other humans, and would not affect existing patents on stem cells. The House then passed the amendment on a voice vote.

#### **BIO Lobbying Campaign**

The Washington office of the well-funded BIO

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*NRLC Legislative Douglas Johnson*

quickly swung into action, launching a lobbying campaign to get the Senate to block inclusion of the Weldon Amendment in the final version of the appropriations bill.

However, BIO did not want the general public to see clearly that the biotechnology industry was fighting for the right to clone and own human embryos and fetuses. Therefore, BIO lawyers and lobbyists in Washington generated a smokescreen, in the form of

extravagant claims that the Weldon Amendment would ban patents on a host of biological products.

For example, in a memo issued to congressional offices on September 2, 2003, BIO claimed the amendment would block patents on genes, tissues, “all cell and tissue therapy products and methods including methods of making replacement tissue and organs,” “transgenic animals capable of making human proteins,” and other useful products.

“Investment and research into developing biotechnology products would halt if the amendment were enacted into law,” the memo asserted. “Treatments for tissue regeneration for burn victims, bone marrow regeneration after chemotherapy and growth hormone deficiency are some conditions for which life-saving biotechnology therapeutics would not be available.”

Buried in the same memo, however, BIO affirmed that it believed that “under current law,” patents should be granted on human organisms that are created through “human intervention,” and said explicitly that this would include a “genetically modified embryo.”

Likewise, in a September 11, 2003, letter to members of Congress, BIO President Carl B. Feldbaum complained that the Weldon Amendment “would preclude the U.S. Patent and Trademark Office (PTO) from granting patents on an organism of human species at any stage of development produced by any method, [or] a living organism made by human cloning....”

NRLC’s Douglas Johnson commented, **“The BIO memo and letter fully demonstrated the need for the Weldon Amendment. BIO’s theory of patent law would allow patents to protect what President Bush has called ‘human embryo farms.’ Beyond that, without a ban on patenting humans, we could**

also see ‘human fetus farms’ in the future—facilities in which cloned human fetuses would be grown to provide desired tissues or organs, using artificial or animal uteruses, with all of this protected by government-conferred patents.”

BIO continued to claim that the industry did not desire to patent a “human being.” But, as Johnson commented, “It required no very sophisticated analysis to discern that BIO understands the term ‘human being’ to apply only to *born* humans, and only to those who have been conceived and gestated by entirely *natural* means—not to those produced by laboratory techniques, such as human cloning.”

The *Washington Post* reported on November 17, 2003, that Michael J. Werner, BIO’s vice president for bioethics, “emphasized that the industry remains opposed to patents on humans, but he declined to define what he meant by ‘human.’”

In its attempt to defeat the Weldon Amendment, BIO enlisted in its lobbying campaign the Coalition for the Advancement of Medical Research (CAMR), an influential umbrella organization made up of patient advocacy groups and medical research organizations. In mailings to congressional offices and to its members, CAMR adopted BIO’s expansive claims about what the Weldon Amendment would do, and added even more imaginative interpretations of its own—claiming, for example, that the amendment would ban patents on “prosthetics.”

### Conference Battle

The full Senate never considered the bill to which the Weldon Amendment was attached. That bill was wrapped into a massive “omnibus appropriations bill,” the details of which were negotiated between members of the Senate Appropriations Committee and the House Appropriations Committee.

BIO’s sweeping assertions about the scope of the Weldon Amendment were based on its claim that the term “human organism” was not defined.

In negotiations, Senator Brownback, an Appropriations Committee member, called BIO’s bluff by proposing an expanded version of the amendment that spelled out in detail what it did and did not cover—explicitly covering human embryos

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U.S. Conference of Catholic Bishops*

and fetuses, and explicitly excluding all of the other products that BIO claimed to be concerned about, such as cells, tissues, genes, and hormones.

BIO, not wanting to have its smokescreen blown away, prevailed upon its Senate allies to reject the Brownback language.

Johnson explained that BIO’s rejection of Brownback’s clarifying language provided more evidence that BIO did not really believe its own claims that the

Weldon Amendment would ban patents on a host of biological products.

“If BIO had *really* believed that the Weldon Amendment would ban patents on cells, tissues, organs, hormones, and so forth, then by rejecting the Brownback Amendment, the BIO lobbyists were deliberately throwing into jeopardy the future patentability of countless products being developed by many BIO members—products that have nothing to do with patenting human embryos,” Johnson said. “BIO rejected the Brownback language because it knew there was really no such risk, because their claims that the Weldon Amendment would ban such patents was purely an invention, intended merely to deflect attention away from the embryo-patenting issue.”

### Patent Office Letter

In November, as the legislative battle moved into its final, critical phase, the Weldon Amendment received an important boost in the form of a letter from the head of the USPTO, strongly endorsing the Weldon Amendment and interpreting it consistently with Dr. Weldon’s statements.

In the letter, USPTO Director James Rogan, an appointee of President Bush, wrote, “The USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species *Homo sapiens* at any stage of development ... including a human embryo or human fetus.”

Rogan also said, “The USPTO’s policy of rejecting patent application claims that encompass human life-forms, which the Weldon Amendment elevates to an unequivocal congressional prohibition, applies regardless of the manner and mechanism used to

bring a human organism into existence (e.g., somatic cell nuclear transfer, in vitro fertilization, parthenogenesis)."

### **Leadership Intervenes**

Despite the USPTO letter, Senator Arlen Specter (R-Pa.), a senior member of the Senate Appropriations Committee who is closely allied with the biotechnology lobby (BIO President Carl Feldbaum was previously his chief of staff), made strenuous efforts to kill the Weldon Amendment.

At a conference committee on November 19, 2003, Specter won an 18–9 vote among Senate conferees in favor of an amendment that would have rendered the Weldon Amendment meaningless. But the House conferees, led by Congressman Frank Wolf (R-Va.), voted 15–6 to insist on the Weldon Amendment.

**When Specter and some other key senators continued to demand that the Weldon Amendment be dropped, House Speaker Dennis Hastert (R-Ill.), House Majority Leader Tom DeLay (R-Tx.), and Senate Majority Leader Bill Frist (R-Tn.) all made it clear that they would not allow the omnibus bill to come up for a vote unless the Weldon Amendment was retained.**

If the omnibus bill had died, it would have resulted in funding of many government agencies under a "continuing resolution" that would not have reflected the funding priorities or special projects important to members of the Appropriations committees. Faced with this prospect, Specter and his Senate allies finally gave up.

The House passed the omnibus bill on December 8, 2003, the Senate passed it on January 22, 2004, and the President signed it into law on January 23, 2004. There were no separate votes on any individual provisions of the massive funding bill.

### **BIO Covers Tracks**

Once it became clear that the Weldon Amendment would be part of the final bill, biotech staffers started telling journalists that conferees had adopted clarifying explanatory language that addressed their objections to the amendment.

"This was pure brazen duplicity," Johnson com-

mented. "The Weldon Amendment that was enacted was exactly the language that passed the House on July 22, 2003, and the only explanation issued by the conference committee was a repetition of Dr. Weldon's July 22 statement that it would not affect existing patents on stem cells. Yet, once BIO saw that the Weldon Amendment was going to become law, they backed quickly away from their extravagant misrepresentations of the amendment, and tried to cover their tracks."

Why would BIO suddenly abandon its sweeping claims about the amendment, and invent the fiction that the conferees had done something to change it?

Johnson explained, **"BIO never really believed its own claims that the Weldon Amendment would ban patents on anything other than embryos—and once they knew they had lost, they certainly didn't want investors reading that Congress had actually enacted the very same law that they had earlier claimed would ban patents on a vast range of biological products."**

"Limitation amendments" apply only to a single federal fiscal year. Therefore, it will be necessary to renew the Weldon Amendment on funding bills for future years. Once such an amendment initially becomes law, the legislative advantage generally shifts to those who wish to continue the policy, particularly if it is a policy supported by the White House, as is the case here.

Dr. Weldon expressed satisfaction about the outcome. "No one should be able to own a human being at any stage of development," he said. "Congress has never spoken to this issue, and I felt it was past time that we did." He said he thought less investor money would go into "this type of grisly research" on human embryos as long as the amendment remains in law.

*The letter issued by the U.S. Patent and Trademark Office on November 20, 2003, and some of the other documents referenced in this article are available on the NRLC Web site section on human cloning, at [www.nrlc.org/killing\\_embryos/index.html](http://www.nrlc.org/killing_embryos/index.html).*