HUMAN CLONING FACTS

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

Does the Weldon/Stupak bill only ban human cloning?

Yes.

HR1357, The Human Cloning Prohibition Act of 2005, 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 ban other forms of cloning?

No.

Sec. (d) of HR1357 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.

Does the Weldon/Stupak cloning bill ban embryonic stem cell research?

No.

The lead opponent to prior versions of HR1357, Rep. James Greenwood (R-PA), acknowledged 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."

The Human Cloning Prohibition Act of 2005 does not effect in any way "embryonic stem cell research" in which the embryos are created from sperm and egg in IVF clinics; these embryos are not created by cloning (somatic cell nuclear transfer), and so HR1357 bans the neither the creation or the use of these embryos.

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.

Although human research cloning does not involve fertilization by sperm, the product is still a human embryo and is indistinguishable from embryos created by fertilization.

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 the following definitions:

"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.

Does somatic cell nuclear transfer (SCNT) produce an "unfertilized egg" or an "activated oocyte" and not a cloned embryo as some 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 *Unanimously* 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, <u>On Terminology</u>, *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, but is no longer only an egg. If implanted, a normal or cloned embryo could grow into a 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. This approach has been extended to human patients, and has resulted in significant improvement in patients with spinal cord injury.

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 200 people. Dr. Denise Faustman, of Harvard University has completely reversed diabetes in mice using adult stem cells, and has gained FDA approval to test this therapy in human clinical trials.

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 58 peer-reviewed studies to treat humans. For example, adult stem cells have already been used to treat cartilage defects 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. In 2002, 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.

In April, 2004, the FDA approved the first human clinical trials to test bone marrow stem cells for treating severe heart failure and results so far have been promising.

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, stated: "[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 therapeutic 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 <u>Our Bodies</u>, <u>Ourselves for the New Century</u> 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?

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