



Biotechnology Industry Organization
1225 Eye Street, Suite 400, NW
Washington, D.C. 20005

February 25, 2003

The Honorable Jim Greenwood
2436 Rayburn House Office Building
Washington, DC 20515

The Honorable Peter Deutsch
2302 Rayburn House Office Building
Washington, DC 20515

Dear Sirs:

As President of the Biotechnology Industry Organization (BIO), I am writing to express our support for your bill HR 801, and our opposition to HR 534 sponsored by Representative Weldon and others. BIO represents over 1100 biotechnology companies, academic institutions and state biotechnology centers in all 50 states.

Let me be clear. BIO opposes human reproductive cloning. It is unsafe and unethical. As we have said in testimony before the House of Representatives, "rogue and grandstanding so-called scientists who claim they can — and will — clone humans for reproductive purposes insult the hundreds of thousands of responsible, reputable scientists who are working hard to find new therapies and cures for millions of individuals suffering from a wide range of genetic diseases and conditions."

However, it is critical to distinguish between repugnant reproductive cloning and potentially life-saving therapeutic cloning, sometimes called somatic cell nuclear transfer or "SCNT", which is research that does not and cannot lead to a human being.

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The National Academies of Science, NIH, and 40 Nobel Laureates, all attest to the value of this research. A February, 2002 report from the National Academies of Science concluded that while reproductive cloning is unsafe and should be banned, therapeutic cloning has scientific potential and should be allowed to continue. SCNT is supported by former Presidents Ford and Carter, former First Lady Nancy Reagan, and many groups representing patients.

Unfortunately, HR 534 would stop this research because although its stated purpose is to ban reproductive cloning, it goes too far and bans all cloning – including use of SCNT.

SCNT could lead to breakthrough medicines, diagnostics and vaccines to treat heart attacks, various cancers, Parkinson's Disease, diabetes, hepatitis and other diseases. It could also produce replacement skin, cartilage and bone tissue for burn and accident victims, and result in the regeneration of spinal cord and retinal tissue.

SCNT involves removing the nucleus of an egg cell and replacing it with the material from the nucleus of a "somatic cell" (such as a skin cell) from a patient. The egg is stimulated to begin dividing but is never fertilized by sperm. Once the cell begins dividing, stem cells can be extracted from it. These stem cells - or the specialized cells derived from them - will be a genetic match to the patient.

Scientists hope to use stem cells to treat many conditions by developing new, healthy cells that can be transplanted into patients to replace those cells damaged by disease. The promise of SCNT is that since these new cells would genetically match the patient, the patient's body would accept these cells after transplantation. Thus, millions of people could have access to life saving therapies developed from their own DNA.

An NIH report published in 2001 on stem cell research entitled "Stem Cells: Scientific Progress and Future Directions" makes the link between therapeutic cloning and stem cell research. It notes that immune rejection is a major obstacle in using embryonic stem cells for transplantation, and that somatic cell nuclear transfer is an appropriate tool to surmount that obstacle. Specifically, it says that "The potential immunological rejection of human ES-derived cells might be avoided ... by using nuclear transfer technology ..."

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SCNT could also help our nation's scientists better understand genetic causes of disease. By using SCNT, scientists could create cells that actually contain genetic diseases and study their development. By comparing this to the development of healthy cells, scientists could learn more about the progression of diseases. This could lead to new cures and treatments.

Thus, by stopping SCNT, HR 534 will deal a blow to vital research that could lead to cures and therapies for millions of Americans.

In addition shutting the door on important research, HR 534 will limit patient access to potentially life-saving products. At BIO, we believe Americans deserve the best science has to offer.

Regrettably, HR 534 denies Americans treatments and cures that would be available to citizens of other nations. In section 302(b) the bill prohibits the importation of "any product derived from [a cloned] embryo." That means that if a drug or treatment for a disease is developed overseas in a country that allows use of cloning for research purposes, it will not be available to patients in the United States – even if the FDA finds that it is safe and effective. Thus, Americans with diabetes, Parkinson's disease, or other ailments would be denied cures and treatments, while citizens of other nations receive the benefits of these products.

In contrast, your bill HR 808, will ban human reproductive cloning but allow critical research to advance. Thus, this bill strikes the appropriate balance between prohibiting acts that are unsafe and unethical while promoting vital medical research. Moreover, its provisions ensure that SCNT is performed within an ethical and regulatory framework with FDA oversight. It also will allow American patients to have access to the newest and most effective cures and treatments for diseases and disabilities.

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We can all agree that using cloning for reproductive purposes is repugnant. However, it is critical that in our enthusiasm to prevent reproductive cloning, we not ban vital research, and squelch the hope of relief for millions of patients and their families.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Carl B. Feldbaum". The signature is written in a cursive style with a long horizontal flourish at the end.

Carl B. Feldbaum
President
Biotechnology Industry Organization

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