

**Testimony of Carl B. Feldbaum**  
**Before the Senate Commerce Committee**  
**Subcommittee on Science, Technology and Space**  
**Wednesday, May 2, 2001**

Good afternoon. My name is Carl Feldbaum. I am the president of the Biotechnology Industry Organization, otherwise known as BIO. BIO represents more than 950 biotechnology companies, academic institutions and state biotechnology centers in all 50 U.S. states and 33 other nations. BIO's members are involved in the research and development of medical, agricultural, industrial and environmental biotechnology products. Most of the hard work in our industry is directed toward currently unmet medical needs: new therapies and cures for Alzheimer's and Parkinson's diseases, diabetes, various cancers, heart disease and hundreds of debilitating and many life-threatening genetic conditions.

Mr. Chairman, and members of the Subcommittee, thank you for the opportunity to testify today. Let me begin by making my position perfectly clear: BIO opposes human reproductive cloning. It is simply too unsafe technically and raises far too many unresolved ethical and social questions.

That's why I wrote to President Bush on February first of this year, urging him to extend the voluntary moratorium on human reproductive cloning, which was instituted in 1997. As I said in that letter, "Cloning humans challenges some of our most fundamental concepts about ourselves as social and spiritual beings. These concepts include what it means to be a parent, a brother, a sister and a family.

“While in our daily lives we may know identical twins, we have never experienced identical twins different in age or, indeed, different in generation. As parents, we watch with wonder and awe as our children develop into unique adults. Cloning humans could create different expectations. Children undoubtedly would be evaluated based on the life, health, character and accomplishments of the donor who provides the genetic materials to be duplicated. Indeed, these factors may be the very reasons for someone wanting to clone a human being.” I respectfully ask for the entire letter to be included in the hearing record.

Perhaps even more compelling, it is extremely unsafe to attempt human reproductive cloning. In most animals, reproductive cloning currently has no better than a 3 to 5 percent success rate. In fact, scientists have been attempting to clone numerous species for the past 15 years with no success at all. What that means, simply and graphically, is that very few of the cloned animal embryos implanted in a surrogate mother animal survive. The others either die in utero — sometimes at very late stages of pregnancy — or die soon after birth. Only in cattle have we begun to achieve some improvement. What I am saying is that we cannot extrapolate to humans the data from the handful of species in which reproductive cloning is now possible. This grim record emphasizes just how unsafe this procedure is, whether it’s applied to sheep, goats, dogs, cats, whatever.

I understand that it took over 270 attempts before Dolly was successfully cloned. Even if the odds of cloning a healthy child were brought down to one in three or one in two, it would be simply unacceptable. 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.

The Food and Drug Administration (FDA) has publicly stated that it has jurisdiction over human reproductive cloning experiments and that it will not approve them. BIO supports that view and hopes that the next FDA commissioner — whoever that might be — will assert FDA’s current statutory authority forcefully.

### **Beneficial Uses of Cloning Technology**

Allow me to shift gears now, and make a critical distinction. It is critical to distinguish the use of cloning technology to create a baby — reproductive cloning — from therapeutic cloning. Therapeutic cloning techniques are central to the production of breakthrough medicines, diagnostics and vaccines to treat

Alzheimer's, diabetes, Parkinson's, heart attacks, various cancers and hundreds of other genetic diseases. Therapeutic cloning could also produce replacement skin, cartilage and bone tissue for burn and accident victims and bring us ways to regenerate retinal and spinal cord tissue. Therapeutic cloning cannot produce a whole human being. This work should be allowed to move forward.

Allow me a minute or two to explain how therapeutic cloning can be used to develop products that will greatly improve the practice of medicine and, in turn, enormously improve the quality of life of individuals suffering from many of the most serious illnesses known to human kind.

### **Regenerative Medicine**

Many diseases disrupt cellular function or destroy tissue. Heart attacks, strokes and diabetes are examples of common conditions in which critical cells are lost to disease. Today's medicine cannot completely restore this function. Regenerative medicine holds the potential to cause an individual's malfunctioning cells to work properly again or even to replace dead or irreparably damaged cells with fresh, healthy ones, thereby restoring organ function. The goal is to provide cells that won't be rejected when they are transplanted into the body.

Again, as I wrote in my letter to President Bush in February, "To be perfectly clear, we support cloning of specific human cells, genes and other tissues that do not and cannot lead to a cloned human being." Therapeutic cloning technology can create pure populations of functional cells to replace damaged cells in the human body. Biomedical researchers are learning how to turn undifferentiated human stem cells into neurons, liver cells and heart muscle cells. Thus far, these human replacement cells appear to function normally in vitro, raising the possibility that they can be used in the treatment of devastating chronic diseases affecting these particular tissue types. This would, for instance, allow patients with heart disease to receive new heart muscle cells that would greatly improve cardiac function.

Studies published in last week's issue of *Science* magazine confirm the enormous potential of using cloning techniques in regenerative medicine. In those studies, which were done with mice, researchers were able to generate new neural cells and islets (insulin-producing cells). We hope to perfect these techniques to successfully transplant those cells. The potential benefit from this research to millions of people with diabetes, Parkinson's disease and spinal cord injuries is extraordinary.

Specific cellular cloning techniques, such as somatic cell nuclear transfer, are critical to these developments. They are necessary steps in producing sufficient quantities of vigorous replacement cells for the clinical treatment of patients, cells that could be transplanted without triggering an immune-response rejection.

### **Predictive Toxicology/Drug Discovery**

Companies also use therapeutic cloning techniques to develop research tools that help them determine if new drugs are safe for people. The use of normal, cloned human liver cells to test for certain toxic metabolites in drugs under development would reduce the danger of human clinical trials by eliminating such compounds before they are tested in humans. This process could both safeguard and streamline the drug development process, bringing drugs to patients sooner and more safely, and reduce the current reliance upon animal testing.

### **Legislative Action**

Mr. Chairman, Congress has debated reproductive cloning before. After the unveiling of Dolly the sheep, a physicist named Richard Seed announced that he would perform human cloning experiments. The congressional debate that followed is instructive. At that time, a few senators introduced legislation that would have not only banned human reproductive cloning, but also would have prohibited critical meaningful, biomedical research. When opponents of the underlying bill staged a filibuster, supporters received only 42 votes for cloture. A review of the debate shows that while all senators opposed human reproductive cloning, a majority would not support far-reaching legislation that would — perhaps inadvertently — shut down important biomedical research.

As the current Congress pursues legislative prohibitions on human reproductive cloning, we urge both caution and a distinction between reproductive and therapeutic cloning. We all agree that given the current safety and social factors, human reproductive cloning is repugnant. However, it is critical that in our enthusiasm to prevent reproductive cloning, we not ban vital research, turning wholly legitimate biomedical researchers into outlaws, and thus squelching the hope of relief for millions of suffering individuals.

Our nation is on the cusp of reaping the rewards from our significant investment in biomedical research. The U.S. biotech industry is the envy of much of the world, especially our ability to turn basic research at NIH and universities into applied research at biotech companies and in turn, into new therapies and cures for individual patients. Using somatic cell nuclear transfer and other cloning technologies, biotech researchers will continue to learn about cell differentiation,

oocyte “reprogramming” and other areas of micro and molecular biology. Armed with this information, they can eventually crack the codes of diseases and conditions that have plagued us for hundreds of years, indeed, for millennia.

### **Conclusion**

In conclusion, Mr. Chairman, human reproductive cloning remains unsafe, and the ethical issues it raises have not been reasonably resolved. The voluntary moratorium on human reproductive cloning should remain in place, and no federal funds should be used for human reproductive cloning. If the Congress in its wisdom decides that legislation to outlaw reproductive cloning is needed, that legislation must be carefully drawn to ensure that it will not stop vital research using therapeutic cloning.

Again, thank you for the opportunity to testify. I’ll be happy to answer any questions.