Testimony of

Mr. Andrew Kimbrell

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At the outset I want too thank you for the opportunity of testifying today on this crucial issue. Over the last many months I have worked with a coalition of progressive environmental, consumer and women's health groups to attempt to ban reproductive human cloning and obtain at least a moratorium on human cloning for research, often called "therapeutic cloning." While there appears to be little disagreement on the need to ban reproductive cloning, the issue of halting research human cloning has become quite controversial. In my testimony I would like to outline a number of reasons why many in the progressive community support a ban or moratorium on human cloning for research at this time. However, prior to discussing the current cloning controversy, I would like to put our discussion today in the context of similar issues we have faced in the last two decades. Sometimes there is a tendency to deal with issues like cloning in an historical vacuum -a kind of technological amnesia. George Santayana's truism "Those who cannot remember the past are condemned to repeat it," applies equally to technology issues a it does to political ones. Therefore I would like to begin by reviewing our past mistakes in assessing and regulating two "miracle" cures that preceded the current furor over stem cell research and human cloning. I fear that if we do not remember what happened with these prior technologies we will repeat the mistakes that have led to grossly inadequate regulation and real tragedy for many patients.

Hyperbole Versus Healing

Last December during a hearing before the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education on the controversy over stem cells and human cloning, Michael West of Advanced Cell Technology (ACT) predicted that within six months his biotechnology company would be ready to create "magic" cells that would save no less than 3,000 lives a day. West claimed that he would soon successfully clone human embryos, and then obtain stem cells from those clones which would cure everything from heart disease and Alzheimer's, to Parkinson's disease and spinal cord injuries. West sternly warned that even a half year halt on his embryo cloning research would cost over half a million lives. Horrified by what they called "these real numbers," some Senators pronounced themselves against any limit on human embryo cloning, and vowed to "push" the technology in any way they could.

Of course, West's promise of near term success in obtaining stem cells from clones, and the subsequent healing of thousands a day, was unadulterated hype. While there have been some preliminary indications that adult, fetal and embryo stem cells may some day result in helpful therapies, no such cells have ever been obtained from cloned human embryos. In fact, West and his Massachusetts company, ACT, had just published a paper that revealed that they had completely failed to garner stem cells from cloned embryos. Dr. Donald Kennedy, editor of the highly esteemed journal Science, summarized the ACT effort, stating, "Everything I have learned about the [ACT] study suggests that it is not an advance that would interest us. This scientific effort did not succeed by any measure." Even more telling was the resignation of Dr. John

Gearhart, of the Johns Hopkins Medical Institutions, from the editorial board of the magazine that published the ACT study. Dr. Gearhart, a pioneer in stem cell research, said that the experiment"should be considered a failure" and that the study should not even have been published.

Moreover, the same day West was predicting near term cloning success at the Senate hearing, his colleague at ACT, Tanja Dominko was explaining the company's failures to a medical conference. She noted that there was an unknown, unique characteristic about primates that makes them difficult to clone. "It might be that you just can't make humans this way," Dominko told the conference. Leading experts share this skepticism about cloning and any near term success of stem cell technology. Dr. Gail Martin, the co- discoverer of mouse embryonic stem cells, warns that there are still "a gazillion issues" to be resolved. Another stem cell expert, Dr. David Solter who directs the Max Planck Institute of Germany said he had "no idea" how someone expected injected stem cells to replace sick and dying brain neurons in Alzheimer's victims.

Most of us have experienced the tragedy of disease or disability either personally or through family and friends. Facing the crucible of disease, we search for some hope when bodies and minds are cruelly decimated by illness. Yet however much we want cures, it is essential to get the real facts, the full story, about medical advances. Unfortunately, in the past we have seen a continuous pattern of researchers and companies peddling hype instead of healing. These false promises about healing are not merely harmless self promotion by research companies eager for venture capital, or benign wishful thinking by naive legislators. Researchers' hype cruelly misleads those who are suffering into thinking that cures are imminent. Perhaps even more disturbing is that this hype is often successful in "blackmailing" legislators and regulators into taking a "hands off" approach to regulation of these new technologies, lest such regulation delay cures. The resulting public policy toward new medical technologies has been misguided, inadequate and even dangerous. It has resulted in the trampling of some our most important ethical norms, and in some cases to increased suffering and mortality among the very people we seek to cure.

Genetic "Wizardry"

A paradigm case of hyperbole over healing is gene therapy. In the late 1980s "gene therapy" was heralded as the new "miracle cure." Researchers were hailed as "gene wizards" and the media, policy makers and scientist/entrepreneurs predicted cures to cancer and virtually every other serious human ailment. Billions of public and private research dollars poured into biotechnology companies and human clinical trials. Despite public protest by some scientists, and law suits by health advocacy groups, human gene therapy trials were approved by the federal government with woefully inadequate oversight and virtually no enforcement. Unmonitored and virtually unregulated, the researchers themselves were relied on to report any adverse results in their test. Over the last decade there have been more than 400 gene therapy trials on patient groups. Despite all the hype, not a single person in any U.S. gene therapy trial has been cured of any disease. Abbey S. Meyers, a patients' group advocate noted, "We haven't even taken one baby step beyond the first clinical experiment. It's hardly gotten anywhere . . . I have been very disappointed."

For many, gene therapy has been far worse than a disappointment. Jesse Gelsinger was an active and altruistic 18 year old from Tucson, Arizona who suffered from a rare gene disorder. He volunteered to take part in a Philadelphia based gene therapy trial study on that genetic disorder. He hoped to participate in finding a cure. Instead, the gene therapy killed him. The media furor over Gelsinger's death resulted in revelations of serious misconduct by researchers in his case and in others' trials. Subsequently a half dozen other cases were found where patients' deaths were linked to gene therapy experiments. Eventually, it was revealed that there were over a thousand serious adverse effects potentially attributable to gene therapy trials, including numerous deaths. Left on their own, researchers had only reported 37 of these adverse events. As the hype about gene therapy held legislators and regulators at bay, researchers violated the most basic ethical tenets on the use of human subjects, which along with deficiencies in the technology, resulting in significant suffering and the death. Wide scale reporting of this scandal has led to an attempt to tighten regulation of gene therapy trials, but most agree that the new policies are far too little, and for the victims of the technology, far too late.

The Fetal Revolution

There is a similar and equally disturbing history with the hype over fetal tissue research. By the late 1980s fetal transplants were being heralded, as the "ultimate cure of the future." An editorial in the New York Times warned that "to interfere with these [fetal tissue] experiments is to interfere with progress that could save countless lives." Fueled by this hype, a moratorium on federally funding of fetal tissue transplants was lifted in 1992, and the proponents confidently predicted a cure for many of our most pernicious diseases and disabilities. Ethical concerns which had led to the moratorium were given only cursory attention. Now after 13 years of private and publicly funded trials some of the ethicists' worst fears have come to pass. There is a thriving market in the sale of various fetal parts from clinics to hospitals and researchers. There are also reports that clinics are changing the method and manner of abortions, potentially creating injury in women, in order to obtain more viable and valuable fetal tissue.

As for the hundreds of patients who have received fetal transplants, mainly for Parkinson's disease, there have yet to be proven benefits, but as with gene therapy we have seen very real and shocking health impacts. As reported last year, the most comprehensive study on the use of fetal tissue to treat Parkinson's showed no overall benefit, but researchers described side effects of the treatment as "absolutely devastating." The problem was that in a significant percentage of fetal tissue recipients the implanted cells created too much of the needed brain chemicals causing uncontrolled movements and spasm in the patients. "They chew constantly, their fingers go up and down, their wrists flex and distend," reports Dr. Paul E. Greene, a neurologist at the Columbia University College of Physicians and Surgeons and one of the researchers involved in the federally funded fetal tissue study. Greene also described patients as writhing and twisting, jerking their heads and flinging their arms about. The spasms were so severe in one patient that he could no longer eat and needed a feeding tube. For others the spasms made their speech unintelligible. Despite these effects, there is no way to remove the transplanted fetal cells or stop them from creating these impacts on the patients. "It was tragic, catastrophic," Dr Greene explained. "It's a real nightmare, and we can't selectively turn it off." As for the near future, Dr. Greene at least has seen the light: "No more fetal transplants. We are absolutely and adamantly convinced that there should be research only."

Stem Cells and Human Cloning

As the grim histories of gene therapy and fetal tissue use are left generally unexamined, stem cell research, including the cloning of human embryos, has succeeded them as the miracle cure du jour. As the testimony of West and other researchers indicates, we are once again being subjected to a full court press of hype, as companies and researchers vie for venture capital and federal research dollars. Unfortunately we also continue to witness a continued and unconscionable gullibility in many of our policy makers. Once again they appear to have become hostages to the hype about healing. This is particularly alarming because the stakes in this debate are very high.

As noted, West and many in the research community are pushing for an unregulated and unmonitored industry in cloned human embryos. West and his cohorts insist that only cells from cloned human embryos will be the panacea for all that ails us. This despite their failure to obtain stem cells from embryos, and the current availability of adult and placental stem cells for research.

Besides corporate profits West and some others in the research community have another very clear aim. They want to stop the Senate from following last year's House action in declaring a ban on human embryo cloning, and they may well be succeeding. In the next few months the Senate will be debating and voting on the human cloning issue. While there is general agreement over banning human embryo cloning to create children, there is confusion on halting the cloning of human embryos for research. Will our policymakers finally cut through the hype and ask the important questions about research cloning?

A number of those in the progressive community have several major concerns about human cloning for research. Environmentalists, consumer groups, women's and children's health advocates all want to see unprecedented regulatory and ethical questions resolved before and human embryo cloning for research is allowed. These issues include:

1) An unregulated industry and market in the production of cloned human embryos will inevitably lead to reproductive cloning. Imagine fighting the drug war by banning certain uses of drugs but allowing and even encouraging the mass production and dessemination of such drugs for 'legal' purposes. This is what those advocating a ban on human reproductive cloning but encourging human embryo cloning for research are advocating. It is irresponsible legislation. Clearly the time to regulate reproductive cloning is at the stage of the creation of the cloned embryo. Attempting to enforce a reproductive ban after a cloned embryo is implanted into a surrogate mother is a regulatory nightmare. Given the slippery slope from embryo cloning to reproductive cloning, the only scenario in which embryo cloning for research would be acceptable is if a strict regulatory procedure were in place which carefully montiored the chain of custody of each and every cloned embryo.

2) An unregulated industry in cloned human embryos will lead to unacceptable commodification of life. The U.S. Patent and Trademark office has already announced that cloned human embryos would be patentable. Additionally there is no bar on the sale of embryos or human ova necessary for this technology. Clearly if we sold the Congressional Medals of Honor we would degrade the meaning of this honor. If the Nobel Prize we up for sale it would cease to have meaning. If we buy and sell children we corrupt and demean the meaning of parenthood. Just so if we allow the patenting and sale of human embryos and human eggs we corrupt and demean what it means to be human.

3) As currently envisioned cloning of human embryos for research represents a serious threat to women's health. In recent testimony a researcher stated have stated that they could do up to 1.7 million therapies per year. this would require a minimum of 5-8 million eggs -- assuming a very high success rate of 1 out of 3-5 eggs -- to accomplish the therapeutic cloning required to support these therapies . Where will they get theses eggs? From women in this country or abroad. Egg donation can have significant health impacts on women including the effects of hormone therapies and other drugs administered to facilitate extraction and the extraction process itself. Most women who are lured into this process are economically disenfranchised and perform this operation for money. With research embryo cloning we could see a massive expansion in the use of women as paid egg "factories." This presents both a real threat to women and an expansion of the repugnant commodification of life discussed above.

4) Human embryo cloning for research could deprive us of our choice on when, how and where our genetic heritage will be replicated. Researchers may be able to clone "copies" of us by using cells from our hair, blood, or virtually any other tissue. There have already been several legal cases where patients have had their cells turned into valuable cell lines without their knowledge. Unless they are carefully monitored, how will any of us know if a researcher of company is replicating our genetic makeup in any number of human embryos at any time. This is a significant "choice" issue for all of us, especially for those whose religious or moral beliefs find human cloning in any form unacceptable.

5) Does the cloning of human embryos for research divert valuable health research dollars away form proven methods into highly speculative ones? There are only limited research and health dollars available. Diseases such as cancer are complex in origin. Genetic predisposition, environmental pollution, diet, stress and social habits (such as smoking) all can contribute to this disease. While it is tempting to believe that gene therapy, fetal tissue or stem cells form cloned embryos will be the 'magic bullet' that will cure cancer, this view is hopelessly naive. We have seen in the past that prevention is the best policy when dealing with major diseases or disabilities. This means significant contribution of resources to cleaning up the environment and work places, educating about diet and lifestyle, working to reduce poverty and and changing some of our unhealthy compulsive habits. While prevention may not be a good 'handle" to raise venture capital, it unlike speculative "miracle" cures has a proven record of success.

6) Cloning human embryos for research raises the key ethical issue of whether we should intentionally create any human life form solely for its exploitation and destruction. As a human community we have never done this before. Certainly there should be public hearings and wide ranging public participation on this key ethical issue before such cloning is allowed.

As we debate the human cloning issues, we must also demand responsibility and caution from those making claims about stem cell research. Many suffering from serious illnesses or disabilities have been misled by the false promises about gene therapy, fetal tissue and other medical "breakthroughs." The continued hype about stem cells is unconscionable. Moreover, Congress must establish stringent regulations that assure that no human trials using stem cells technology take place until research fully justifies such trials. Should there eventually be human trials, they must be carefully and independently regulated and monitored. Researchers cannot be left to regulate themselves. Our elected representatives owe nothing less to the families of those who have died, and the many now suffering, because of Congress' past failures to cut through the hype and appropriately regulate medical technology.

Thank you.

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