Testimony of Mr. James Kelly

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Two years ago, while closely researching my own condition, I blindly accepted media reports claiming embryonic stem cells were our best hope to cure other conditions. When I realized the push for cloning was supported by companies that claimed they had no interest in pursuing the field (1), I wondered why. When I read media reports that sharply contrasted with information I had gathered from medical journals (2), I became concerned. When I read of my own condition being used to justify cloning (3), I began studying the issue in earnest. This is what I found: ?³In embryonic stem cells derived from cloning, chromosomes transferred in the cloning process retain physical changes that accrue with age. These age-related changes are known to contribute to age-related disease (4,5).

It is generally accepted that this physical change in chromosomes, called telomere deterioration, is a reliable indication of life span; the more rapid and serious the telomere deterioration, the shorter the expected life span. The creator of Dolly the sheep, Dr. Ian Wilmut, reported a marked shortening of telomeres in Dolly=s chromosomes compared to those from non-cloned animals, and even suggested Athe most likely explanation@ for the physical deterioration observed in these animals Areflects that of the transferred nucleus. Full restoration of telomere length did not occur because these animals were produced without germline involvement (6).@

Studies have shown that telomere restoration does occur in late-term fetal cows and newborn calves, but not in calf embryonic stem cells. The Proceedings of the National Academy of Sciences reports (7):

AThese results demonstrate that cloned embryos inherit genomic modifications acquired during the donor nuclei's in vivo and in vitro period but are subsequently reversed during development of the cloned animal.@

It is not known if Dolly=s telomere defects were due to the type of somatic cell she was cloned from, or the difference in species between cows and sheep (8). Nor has research indicated how human telomere length will react to cloning. However, this issue provides one explanation why biotech companies and researchers are pushing to legalize cloning to produce late-term fetuses and newborn babies in more than one state.

Since Dolly the sheep was cloned from the mammary gland cell of a six-year-old sheep, in essence her chromosome ends were already six years old, and therefore deteriorated more rapidly than those of non-cloned animals. In Dolly's case she died of a progressive lung infection normally seen in animals twice her age. (She was cloned from a six-year-old ewe and died when she was six.) An autopsy revealed she also suffered from cancer and arthritis (9).

?³Investors are unwilling to invest in cloning (10), since its potential for leading to clinical treatments, if any, is considered decades away or, as a recent New York Times article concluded (11), Ain the distant future.@

Scientist Janet Rowley is a pro-cloning member of the President=s Council on Bioethics. In speaking of the therapeutic potential of cloned embryonic stem cells she recently cautioned, AI think it's not fair to say that the promise will not be realized, but I think that it is fair to say that the promise may take a very long time. And I just want to point out that we began the war on

cancer in 1970 with the notion that it was all going to be over in 10 or 20 years and we're far from it (12).@

?³Biotechnology corporate leaders believe its chances of success are "vanishingly small (1)." ?³The public is being told that therapeutic cloning does not require the creation and killing of human embryos, when in fact that's exactly what it does.

^{?3}We've been led to believe that cloning's widespread and variable genetic defects pose no therapeutic risks. The truth is that researchers don't know how many genes are affected by cloning, or cloning's potential for mutation or aberrant imprinting during adult cell mitotic division, or the long term consequences of introducing such cells into adult organs.

Dr Robert Marcus, Director of the East Anglia Bone Marrow Transplant Unit, explains the risks (13):

"Any time you transfer genes within the cloning process, or change the genetic material within a cell, there may be defects introduced into a natural organ or species development. I think I would be quite cautious there."

Unraveling the genetic riddle will be difficult, warns stem-cell researcher Joanna Maldonado-Saldivia of Cambridge University. "This work shows that lots of genes go wrong after cloning," she says. But so many are unidentified that it could take years to discover their functions (14).

Davor Solter of the Max-Planck Institute agrees (15):

"Misreprogrammed genes are like cockroaches. Where you see one there are likely to be many more under the surface."

?³Embryonic stem cells derived from cloning are not expected to perfectly match the donor -- they may face rejection and require immune suppression.

Dr. John Gearhart told the President's Council on Bioethics there is Ano question@ in his mind that embryonic stem cells derived from cloning Acould be rejected (16). Absolutely.@ Dr. Irving Weissman explains (17):

AI should say that when you put the nucleus in from a somatic cell, the mitochondria still come from the host (the egg)... And in mouse studies it is clear that those genetic differences can lead to a mild but certainly effective transplant rejection and so immune suppression, mild though it is, will be required for that.@

At MIT researchers tried to fix a genetic defect in a mouse with embryonic stem cells derived from cloning (18). Unexpectedly, the mouse refused to accept its own cloned cells. The researchers were so surprised they tried the test twice with the same result. To fix the problem they resorted to using reproductive cloning to create a baby mouse with the defect fixed. They then used its adult stem cells to fix the defect in the original mouse. In reporting this finding the researchers say:

AOur results raise the provocative possibility that even genetically matched cells derived by therapeutic cloning may still face barriers to effective transplantation for some disorders.@

Another study implanted a cloned embryo in a cow's womb. The fetus was later aborted and its fetal stem cells removed. These fetal cells were then implanted in the donor without apparent rejection (19). This test is being promoted as showing cloning might avoid rejection. However, neither study reports cloned embryonic stem cell acceptance by donors.

If further proof were needed, the above perspective certainly provides another reason why pro-

Biotech legislation has been proposed in more than one state to permit the derivation and use of stem cells from cloned late-term fetuses and even newborn babies.

?³If custom treatments from cloning could someday exist, they're expected by leading scientists to be too Aastronomically@ expensive (20).

?³Australia=s leading embryonic stem cell expert, Professor Alan Trounson, says the pace of stem-cell technology has been so rapid that therapeutic cloning is now unnecessary (21). "My view,@ he said, Ais there are at least three or four other alternatives that are more attractive already."

?³In citing clinical results using adult stem cells to repair human hearts, the Director of a prestigious German medical journal presents a truth that Americans are not being told (22):

"The promises of unscrupulous embryo researchers, that clone without clear clinical goals and experiments, are insupportable. This remarkable proof has now given us a clear sign the Americans with their prohibitions are exactly right. The biotechnological revolution can take place without embryonic stem cells if the alternatives are developed."

Adult stem cells and cord blood have been used to cure 69 patients in France with sickle cell anemia (23). They've reversed multiple sclerosis in patients in Canada and China (24,25). In Germany, France, and the U.S. they've repaired the human heart (26,27,28). For my own condition, spinal cord injury, adult regenerative tissues are being clinically used in Portugal (29), Italy, Australia (30), and China. They=ve already been used to reverse paralysis in Portugal (31). In fact, with media attention focused on the threat of a "brain drain" if researchers are banned from cloning humans, we've totally overlooked the threat of a "patient drain," since foreign doctors are successfully treating patients with adult regenerative treatments.

Besides the above cited applications, adult stem cells have also been used to safely and successfully induce remission in several cancers and improve patient conditions with Stroke (32), Parkinson=s Disease (33), and Rheumatoid Arthritis (34). In mice, after drugs were used to remove the cause of type 1 Diabetes, the body=s adult stem cells regenerated its missing islets (35). Others have used adult pancreatic stem cells to directly replace beta islets in diabetic mice, which then respond to glucose challenge, induce vascularization, and completely reverse insulin-dependence (36,37).

Recently, bone marrow stem cells were found to mature into insulin-secreting beta-islets in a conclusive test (38,39,40). Moreover, researchers have reported a flaw in previous embryonic stem cell studies for Diabetes. It appears that ES cells reported as producing insulin may in fact have absorbed and re-released the insulin from surrounding tissues (41).

A Medline search for every condition that stem cells are hoped to address finds that adult regenerative results far outstrip embryonic and fetal results with far fewer reports of adverse effects. The reason for this is simple. Adult stem cells are designed to regenerate organs in the adult body, whereas embryonic stem cells are made for the embryo.

In an admirably honest admission that speaks volumes, Dr Michael Good, Director of the Queensland Institute of Medical Research, has declared as a doctor and scientist that using embryonic stem cells poses more problems than adult stem cells and is unnecessary (42).

"The difficulty with using embryonic stem cells,@ Dr Good said, Ais the tissue will be regarded as foreign and will be rejected by the body if the cells are not exactly matched to the patient. There are reports that prove that patients can donate their own adult stem cells, thereby dealing with the problem of the body rejecting the tissue." He said research has also shown that the use of embryonic stems cells caused cancer growth in animals.

Dr. Good explained that supporting ES research would drain money away from effective research into adult stem cells. He also said a lot of money going into embryonic stem cell research came from drug companies which wanted to test the side effects of drugs on pure human tissue from embryos. (This may help explain the Pharmaceutical push in NJ for access to late term fetal and newborn clones.)

^{?3}Embryonic stem cells from any source are not considered by most scientists to be the optimal transplantation cell of choice (43). This is another truth America is not being told, which further explains why in New Jersey Science and Biotech are pushing for access to cloned late-term fetuses and newborn babies (44).

Says the Director of Rutgers Neuroscience Center, Dr. Wise Young (45):

ADr. Carvey is expressing a growing consensus in the field that the most desirable cells for transplantation are cells that are far enough along the way to differentiating into desirable cells, such as neurons, insulin-secreting cells, radial glial or olfactory ensheathing glial cells, that they have a high likelihood of producing such cells. I recently heard a lecture by John Gearhart expressing the same goal, the differentiation of fetal stem cells to the point where they will produce a particular cell type predictably.@

To summarize, embryonic stem cells derived from cloning:

?3do not perfectly match the patient

?³contain known and unknown genetic defects, as well as defective imprinting

?3are expected to require immune suppression for immune-sensitive conditions

?³retain the genetic age of the donor

?³are not considered desirable for transplantation

?³may be too expensive for patients to afford.

Regarding the likelihood that science will overcome just one of these issues (defective imprinting), Dolly=s creator predicted in Nature (46):

"It should keep a lot of us in business for a long time."

Moreover, these flaws are in addition to critical defects already inherent in embryonic stem cells from any source. Regarding this point, The Institute for Science in Society, an international organization of 462 scientists from 57 countries, issued the statement (47):

AThe risks of cancer, uncontrollable growth, genome instability and other hurdles make ES cells a bad investment in terms of finance as well as public health benefits.@

The Institute adds that adult stem cells Aare more likely to generate affordable therapies that can benefit everyone.@

In other words, even if cloning's very real practical concerns could be overcome, including its need for female eggs and its expected exorbitant costs, and even if its rejection issues and genetic

flaws could be addressed, it still would do nothing more than provide cells known to be genetically unstable, grow uncontrollably, and cause cancer (48).

Why then are millions of dollars, which could have been used to develop cures, instead being spent on a national campaign to convince Americans that therapeutic cloning offers their brightest hope for cures?

The ISIS offers one explanation:

ACommercial imperatives are the major impetus for ES cell research, much more so than for adult stem cells. There are more opportunities for patenting cells and cell lines as well as isolation procedures.@

The Institute concludes:

AScientists should stop manipulating public opinion to promote research that=s both morally and scientifically indefensible. At the same time, governments need to invest our tax money in scientific research that can genuinely benefit the health of the nation, and not be misled by false promises of the next economic boom.@

The exaggerated Apromise@ of therapeutic cloning is not a path to cures in our lifetimes, but a dangerous diversion away from cures. It is in the interest of cures that I urge you to support S. 245, the Brownback-Landrieu ban on all human cloning.

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