Scientist

Dear Scientist Stakeholder Group,

We are the National Committee on Embryonic Stem Cell Research. We have been given the responsibility of drafting legislation for our beloved country Adanac. Your group has been identified as having a particular interest in our country's ongoing embryonic stem cell debate, and we would very much like to hear from you.

We invite you to share your opinions on the following four issues:

- The use of embryonic stem cells from existing stem cell lines;
- The use of embryonic stem cells from discarded embryos from *in vitro* fertilization (IVF) clinics;
- The use of embryonic stem cells from embryos created by IVF solely for research; and
- The use of embryonic stem cells from embryos created by therapeutic cloning.

As you may or may not be aware, there are three legal possibilities for these activities. Under Adanac's constitution, an activity is either unrestricted, controlled (and must fulfill certain criteria in order to occur) or outright prohibited. For activities that you believe should be prohibited or controlled, please suggest an appropriate punishment. For controlled activities, describe the criteria the activity must meet before being granted permission. For example, a common view is that discarded embryos from IVF clinics should be available for embryonic stem cell research only if the donors of the embryos have given their consent. This activity would be classified as "controlled," and the criteria would be "donor consent required." Please provide a rationale for all of your classifications.

To help you create your presentation, we have compiled a package of documents that represents the views of similar groups in different countries. These documents include speeches, press releases and articles. The package also contains a worksheet to help you identify the authors' stance. But be warned: you may run into conflicting views within this package. If this is the case, choose the view that you prefer.

Please begin your presentation by introducing yourself. We encourage you to be as persuasive and creative as possible. Remember, your opinions are helping to create legislation we must all abide by.

We very much look forward to seeing you. By sharing your views, you are facilitating Adanac's legislative process and making a valuable contribution to the future of embryonic stem cell research in our country.

Sincerely,

National Committee on Embryonic Stem Cell Research

TIMELINE

DAY 2:
In your group, choose one article to read overnight.

BETWEEN DAY 2 AND 3:
Read this letter. Read your article and complete this part of the worksheet.

DAY 3:
In your group, complete the worksheet and prepare your presentation.

DAY 4:
Present your views to the Committee.

WORKSHEET

	Stem Cell Network Letter to MPs from Dr. Ronald Worton	**Washington Post.com** Nobel Laureates' Letter to President Bush	**Coalition for the Advancement of Medical Research (CAMR)**	**American Society for Cell Biology** Position Papers on Funding of Stem Cell Research/Cloning	**UNESCO** Universal Declaration on the Human Genome and Human Rights
Whose point of view is expressed in this document?					
What is their role in society?					
Position on use of embryonic stem cells from existing cell lines					
Position on use of embryonic stem cells from discarded embryos from IVF clinics					
Position on use of embryonic stem cells from embryos created by IVF for research					
Position on use of embryonic stem cells created by therapeutic cloning					

LETTER to MPs from DR. RONALD WORTON,

Scientific Director of the Stem Cell Network

May 22, 2002

Dear Member of Parliament

I am writing to you on behalf of the Stem Cell Network, one of Canada's 22 Networks of Centres of Excellence. The Network has the goal of making stem cell therapy a reality for the citizens of Canada, and to do so in a manner that reflects the ethical and moral values of Canadians. The Network involves more than 50 of Canada's leading scientists, engineers, clinical researchers and social scientists. Scientists in the Network include virtually all of Canada's top stem cell researchers from Vancouver to Halifax and our clinician-scientists are actively involved in innovative therapies for diseases amenable to stem cell therapy. The social, ethical and legal aspects of stem cell research is a major Network theme and our researchers include some of Canada's most respected lawyers and ethicists.

Legislation dealing with reproductive technologies was recently introduced in the House of Commons. One of the issues addressed in this legislative package is what research with stem cells derived from early-stage human embryos will be allowed in Canada and how it will be regulated. Since you will eventually be asked to vote for or against the proposed legislation, full knowledge of the relevant ethical, social and scientific issues is important to the development of an informed decision. The purpose of this communiqué is to provide some of the basic information about the nature and promise of research that uses human embryonic cells and to invite you to a Stem Cell network-sponsored workshop to discuss the relevant issues further with a group of Canadian experts. This workshop will be held on June 4th, from 7:30 A.M. to 9:00 A.M., in Room 308 of the West Block. For those who are unable to attend the workshop, we can arrange individual meetings with scientists in a mutually convenient location. (Call Drew Lyall, Executive Director of the Stem Cell Network, at (613) 562-5384 or send an email to dlyall@uottawa.ca).

Legislation and the challenge for Parliament

The ability of Canada to contribute to the development of stem cell therapy will depend on the support you give to the legislative package before you. As written, the legislation would allow research on embryonic stem cells derived from very early embryos that were produced for in vitro fertilization, but remain in the freezer after the couple's family is complete. If they were not to be used for research, they would be discarded.

For the most part, I and the members of the Stem Cell Network support this legislation. We consider it to be balanced, preventing such abuses as human reproductive cloning, while allowing the use of early stage embryos for research under appropriate regulatory authority. It provides a legal and regulated framework within which scientists can work, respecting the wishes of Government and the people of Canada.

Members of Parliament and others who oppose research with embryonic stem cells have argued that recent results with stem cells derived from adult tissues (adult stem cells) are sufficiently promising that we do not need to conduct research with embryonic stem cells This premise does not stand up to scientific scrutiny. The fact is that very little research has been done with either human embryonic stem cells or adult pluripotent stem cells and for most diseases we are very far from drawing any valid conclusions about the cell types that will provide the best opportunities for therapies.

Adult and embryonic stem cells – a brief history

In the early '60s stem cells with the capacity to make all cell types found in blood were identified in the bone marrow of adult mice. These blood-forming stem cells became the subject of intense worldwide research. The Canadian scientists who made this discovery led the international research effort for many years, and their students and research fellows (myself included) are now

located in universities and hospitals throughout Canada. Several of them are members of the Stem Cell Network. The clinical exploitation of this pioneering work to cure leukemia in many children and adults was the successful development of bone marrow transplantation, now a routine life-saving procedure.

More recently stem cells have been discovered in other tissues of adults. For example, neural stem cells are capable of specializing into different cell types found in the brain or spinal cord, and retinal stem cells are able to form the retina of the eye. Neural stem cells were discovered in Calgary, retinal stem cells in Toronto.

In the early '80s it was discovered that in very early mouse embryos, before any recognizable tissues are formed, the cells present can each give rise to all of the tissues that eventually make up a normal mouse (e.g. blood, brain, liver, kidney, bone, etc). We also know that when placed under certain conditions in culture, the same cells can stay unchanged and be propagated indefinitely. We do not yet know if the adult contains cells with equivalent properties.

New developments – exciting times in stem cell research

With two developments in 1998, stem cell research emerged from the scientific realm into the public domain. First it was reported that that human embryonic stem cells could also be grown in culture and, like mouse embryonic stem cells, they were capable of making a range of different cell types. This suggested that such cells might be used to repair or regenerate damaged tissues in patients with diseases such as osteoporosis, diabetes, hemophilia, muscular dystrophy, Parkinson's disease, stroke or spinal cord injury.

The same year researchers began to report that adult stem cells seemed to be able to specialize into cell types characteristic of other tissues – a phenomenon termed stem cell "plasticity". Thus, hematopoietic stem cells were reported to make muscle and brain tissue, while muscle and neural stem cells were reported to make blood.

The potential plasticity of certain adult stem cells could make them very attractive as therapeutic agents. Taking stem cells from a healthy tissue to repair and regenerate a diseased tissue in another part of the body avoids the rejection problem that characterizes transplants from one individual to another.

This is a powerful reason to encourage research on adult stem cells - but it is not, as some have suggested, a reason to ban research on embryonic stem cells.

The critical question – embryonic vs. adult stem cells

A critical question facing stem cell researchers concerns the relative merits of embryonic vs. adult stem cells for therapeutic purposes. Despite encouraging evidence that therapies based on adult stem cells might be developed (and we will be doing our best to develop such therapies), the fact is that we do not yet know how they will stack up compared to embryonic stem cells in this regard.

It is only in the last 2-3 years that scientists have begun to appreciate that tissues and organs might be amenable to repair and regeneration by stem cells, and little research has been done to date with embryonic or adult stem cells to exploit this potential. With regard to human embryonic stem cells, research is very limited since research guidelines and legislation are only now being developed around the world. With passage of the current legislation we will have the ability to conduct the necessary research to determine the true potential of embryonic stem cells.

Some have also argued that the newfound plasticity of human adult stem cells means that they have all the promise of embryonic stem cells and therefore we do not need to conduct research on the latter. It is worth examining this critical issue in greater detail.

Adult stem cell plasticity – how good is the evidence?

Results from the last 3-4 years have suggested a degree of plasticity for adult stem cells that went against 35 years of previous research. These findings were greeted with both excitement and scepticism. Initially the evidence for plasticity was weak and it has now been shown that some results were due to hematopoietic stem cells residing in muscle or brain. More recently, fusion of stem cells from one tissue with cells from another tissue has been shown to occur and this might also account for some claims of adult stem cell plasticity.

Despite the need for caution in the interpretation of plasticity experiments there is now very convincing recent evidence for the existence of adult stem cells with extensive tissue generating potential. Researchers hold out considerable hope for the therapeutic potential of

these cells but very little is yet known about what this actually might be.

One of the groups to first discover the existence of such cells is Dr. Freda Miller, a Network scientist at the Montreal Neurological Institute. Her group demonstrated such stem cells in the deep layers of the skin. These cells are able to grow in culture, and under appropriate conditions they can develop into a variety of specialized cell types including those characteristic of brain, muscle, and fat. Cells with similar characteristics have been found in bone marrow and muscle.

Whether such adult stem cells will be superior to embryonic stem cells in effecting tissue repair and regeneration remains to be seen. Indeed, a bigger question is whether either cell type can live up to the enormous promise that has been ascribed to them by the scientific community and the media. Is it all hype, or is there a real hope?

Hype or Hope – what is the reality?

Most scientists now believe that the potential is real, although we are likely still a number of years from a cure for most of the diseases that might be amenable to stem cell therapy. Scientists recognize that just because a stem cell population is able to make a few brain cells in culture, it does not follow that injecting such cells into the brain will cure Parkinson's disease.

For example, before Freda Miller's skin-derived stem cells can be used to treat Parkinson's disease, it must be shown that the stem cells injected into the brain will make only brain cells (not bone or muscle), that they will make enough brain cells to be effective, that they will make the right type of brain cells to replace the missing ones and that in the end they will function properly.

This will not happen just because we want it too. It will happen as a result of years of painstaking research, defining what happens to stem cells that are injected and determining the factors that control stem cell behaviour under defined conditions so that we can better regulate the process. Such regulation is essential to prevent bone from forming where we want brain cells, or brain cells where we want muscle, etc. Identifying the molecules that regulate specialization of stem cells is a major project of the Stem Cell Network, and we think important clues will come from embryonic stem cells since these have the greatest potential to form many different cell types.

Despite the need for much additional rigorous science to develop safe and effective therapies, there are signs that such approaches will deliver on the promise. Dr. Ivar Mendez, a Network researcher at Dalhousie University in Halifax, has clear evidence that two Parkinson's disease patients were vastly improved after receiving an injection of fetal-derived brain cells. Much further study will be required to determine whether embryonic or adult stem cells will give a similar result, and to determine if the improvement is long-lasting. However, even this early result provides real hope for the thousands of Parkinson's disease patients across Canada and the millions around the world.

Research of the Stem Cell Network

The Stem Cell Network has decided to focus initially on four diseases where we think we can make an early impact. Parkinson's disease is one. Another is hemophilia, a bleeding disorder due to deficiency of clotting factor 8.

The third is diabetes, a disease that despite the availability of insulin is still a leading cause of blindness, kidney failure and death. Transplantation of pancreatic "islets" that produce insulin was developed in Edmonton, and the "Edmonton Protocol" is heralded worldwide as a breakthrough in the treatment of type 1 insulin-dependent ("juvenile") diabetes. But "islets" are in short supply and a key objective of the Network is to generate insulin-producing islets from stem cells. Conditions have already been found for making insulin-secreting cells from embryonic stem cells and scientists are optimistic that these will lead to treatment of type 1 diabetes in the near future.

The fourth is muscular dystrophy. My own laboratory discovered the gene defect responsible for the most common form of muscular dystrophy, and showed that the gene makes a muscle protein called dystrophin that is absent from the muscle of affected children. My dream is to be able to take stem cells from bone marrow or skin, or an embryo if necessary, and use them to repair and regenerate the severely damaged muscle. I am convinced that stem cell therapy will give a better life to a child who is otherwise destined to live in a wheelchair, with progressive loss of the ability to walk, dress, eat, swallow and breathe.

To me it would be unethical to deny the opportunity for a decent life to that child, if taking stem cells from a five-day-old embryo holds the key to an effective therapy. The embryo at that stage consists of a sac of cells; it has no organs or tissues; it has no neurons and therefore no

sense of feeling and no awareness of life. Furthermore it will be discarded if it is not used for research.

This legislation will allow the critical research necessary to maximize the opportunities for these children who have virtually no other hope. Members of Parliament have a duty and responsibility to support research with embryonic stem cells. To do otherwise will deny this hope to the hundreds of Canadians with muscular dystrophy. The same could be said for all the other diseases that might be treatable with stem cells.

Some parting thoughts

Canadian scientists are becoming concerned by their portrayal in recent weeks by some opponents of embryonic stem cell research as self-serving, immoral and interested only in the profits to be made from stem cell research. I have even heard it said that Canadian stem cell researchers are "out-of-control" for being anxious to get going on life-saving research.

These claims are completely unfounded. Canadian scientists have been approaching stem cell research in a very responsible manner. There is not a single scientist as yet identified in Canada who has made, or is even set up to make, stem cell lines from human embryos. Certainly many recognize the need to do this, but all are waiting for the passage of legislation and implementation of the CIHR Guidelines.

On the issue of being self-serving, I want all Members of Parliament to know that I have absolutely no possibility of financial reward for my work, beyond my salary. I am not involved in any company as a stockholder or as an advisor. Everything that I have done over a 37-year research career has been for the thrill of discovery and for the good of others.

You should, however, be aware that some scientists in the Network have participated in the formation of spin-off companies to generate the additional investment required to translate their scientific discoveries into therapies. This step helps ensure that economic benefits related to discoveries by Canadian scientists remain in Canada. To my knowledge, however, all such initiatives in Canada focus on adult stem cells and not embryonic stem cells. I am not aware of any Network scientist who has a financial stake in the use of embryonic stem cells for research or therapy.

Finally the point needs to be made that Canadian scientists are not out of step with the Canadian people on the ethics of embryonic stem cell research. A March 2002 Environics poll showed that 76% of Canadians support research using stem cells derived from spare embryos. There was little variation in the results with religion, political preference, income, education, geographical region within Canada, or age. Other recent unpublished polls show similar numbers, and polls published in 2001 by Pollara and PricewaterhouseCoopers also show a majority of Canadians in favour of using spare embryos for the derivation of stem cells.

I can only conclude that Members of Parliament who oppose embryonic stem cell research do so for reasons other than expressing the will of the Canadian people.

Further Information

To provide you with further information, the Network has assembled a variety of materials on its web site – including a primer entitled Stem Cells 101. We also provide easy access to the views of internationally respected scientists, and to the views of the health charities. It also links to the three polls that surveyed views of Canadians on embryonic stem cell research. Given the importance of this legislation I urge all Members of Parliament to take a few minutes to check it out (www.stemcellnetwork.ca).

Also attached to this letter is a list of some of the key questions that are being asked today about stem cell research, with brief answers in point form.

In closing we thank you for reading this. We hope it helps in making your deliberations on the legislation more informed. We look forward to meeting you at the workshop on June 4.

Sincerely

Ronald Worton, CM, BSc, MSc, PhD, DSc, FRSC
CEO & Scientific Director, Ottawa Health Research Institute
Vice President, Research, The Ottawa Hospital
Professor, Department of Medicine, University of Ottawa
Scientific Director, Stem Cell Network

FEBRUARY 22, 2001 -

LETTER FROM 80 NOBEL LAUREATES TO PRESIDENT GEORGE W. BUSH

To the Honorable George W. Bush,
President of the United States

We the undersigned urge you to support Federal funding for research using human pluripotent stem cells. We join with other research institutions and patient groups in our belief that the current National Institutes of Health (NIH) guidelines, which enable scientists to conduct stem cell research within the rigorous constraints of federal oversight and standards, should be permitted to remain in effect. The discovery of human pluripotent stem cells is a significant milestone in medical research. Federal support for the enormous creativity of the US biomedical community is essential to translate this discovery into novel therapies for a range of serious and currently intractable diseases.

The therapeutic potential of pluripotent stem cells is remarkably broad. The cells have the unique potential to differentiate into any human cell type. Insulin-producing cells could be used to treat - or perhaps even cure - patients with diabetes, cardiomyocytes could be used to replace damaged heart tissue, chondrocytes could be used for arthritis, and neurons for Parkinson's, Alzheimer's, ALS and spinal cord injuries to name a few examples. There is also the possibility that these cells could be used to create more complex, vital organs, such as kidneys, livers, or even entire hearts.

Some have suggested that adult stem cells may be sufficient to pursue all treatments for human disease. It is premature to conclude that adult stem cells have the same potential as embryonic stem cells -- and that potential will almost certainly vary from disease to disease. Current evidence suggests that adult stem cells have markedly restricted differentiation potential. Therefore, for disorders that prove not to be treatable with adult stem cells, impeding human pluripotent stem cell research risks unnecessary delay for millions of patients who may die or endure needless suffering while the effectiveness of adult stem cells is evaluated.

The therapeutic promise of pluripotent stem cells is based on more than two decades of research in mice and other animal models. This research confirms that pluripotent stem cells are capable of generating all of the cell types of the body. Most importantly, the therapeutic potential of these cells has already been demonstrated. Cardiomyocytes generated in the laboratory from these cells have been transplanted into the hearts of dystrophic mice where they formed stable intracardiac grafts. Nerve cells have successfully reversed the progression of the equivalent of multiple sclerosis in mice and have restored function to the limbs of partially paralyzed rats; and insulin-secreting cells have normalized blood glucose in diabetic mice. These findings suggest that therapies using these cells may one day provide important new strategies for the treatment for a host of currently untreatable disorders.

While we recognize the legitimate ethical issues raised by this research, it is important to understand that the cells being used in this research were destined to be discarded in any case. Under these circumstances, it would be tragic to waste this opportunity to pursue the work that could potentially alleviate human suffering. For the past 35 years many of the common human virus vaccines -- such as measles, rubella, hepatitis A, rabies and poliovirus -- have been produced in cells derived from a human fetus to the benefit of tens of millions of Americans. Thus precedent has been established for the use of fetal tissue that would otherwise be discarded.

We urge you to allow research on pluripotent stem cells to continue with Federal support, so that the tremendous scientific and medical benefits of their use may one day become available to the millions of American patients who so desperately need them.

Yours respectfully,

Kenneth J. Arrow*, Stanford University
Julius Axelrod*, National Institute of Mental Health, Education & Welfare
Baruj Benacerraf*, Dana-Farber Cancer Institute
Paul Berg*, Stanford University
J. Michael Bishop*, University of California, San Francisco
Nicolaas Bloembergen*, Harvard University
Herbert C. Brown*, Purdue University
Jose Cibelli, Advanced Cell Technology
Stanley Cohen*, Vanderbilt University School of Medicine
Leon N. Cooper*, Brown University
E. J. Corey*, Harvard University

James W. Cronin*, University of Chicago
Robert Curl, Jr.*, Rice University
Peter Doherty*, St. Jude Children's Research Hospital
Johann Deisenhofer*, University of Texas Southwestern Medical Center
Reneto Dulbecco*, Salk Institute
Edmond H. Fischer*, University of Washington
Val L. Fitch*, Princeton University
Robert Fogel*, University of Chicago
Jerome I. Friedman*, Massachusetts Institute of Technology
Milton Friedman*, Hoover Institute
Robert F. Furchgott*, State University of New York Health Sciences Center
Murray Gell-Mann*, Santa Fe, NM
Walter Gilbert*, Harvard University
Alfred Gilman*, University of Texas, Southwestern Medical Center
Donald Glaser*, University of California, Berkeley
Sheldon Lee Glashow*, Boston University
Ronald M. Green, Dartmouth College
Paul Greengard*, The Rockefeller University
Roger Guillemin*, The Salk Institute
Leonard Hayflick, University of California, San Francisco
Herbert A. Hauptman*, Hauptman-Woodward Medical Research
James J. Heckman*, University of Chicago
Alan Heeger*, University of California, Santa Barbara
Dudley Herschbach*, Harvard Medical School
David H. Hubel*, Harvard Medical School
Russell Hulse*, Plasma Physics Laboratory
Eric Kandel*, Columbia University
Jerome Karle*, Washington, D.C.
Lawrence R. Klein*, University of Pennsylvania
Walter Kohn*, University of California, Santa Barbara
Arthur Kornberg*, Stanford University School of Medicine
Edwin G. Krebs*, University of Washington
Robert P. Lanza+, Advanced Cell Technology
Robert Laughlin*, Stanford University
Leon Lederman*, Illinois Institute of Technology
David M. Lee*, Cornell University
Edward Lewis*, California Institute of Technology
William Lipscomb, Jr.*, Harvard University
Rudolph A. Marcus*, California Institute of Technology
Daniel McFadden*, University of California, Berkeley
R. Bruce Merrifield*, The Rockefeller University
Robert Merton*, Harvard University Graduate School of Business Administration
Franco Modigliani*, Massachusetts Institute of Technology
Mario J. Molina*, Massachusetts Institute of Technology
Ferid Murad*, University of Texas Medical School
Marshall W. Nirenberg*, NIH National Heart, Lung & Blood Institute
Douglass C. North*, Washington University
George A. Olah*, University of Southern California
Douglas Osheroff*, Stanford University
George E. Palade*, University of California, San Diego
Martin Perl*, Stanford University
Norman F. Ramsey*, Harvard University
Burton Richter*, Stanford University
Richard J. Roberts*, New England Biolabs
Paul A. Samuelson*, Massachusetts Institute of Technology
Melvin Schwartz*, Columbia University
Phillip A. Sharp*, Massachusetts Institute of Technology
Richard E. Smalley*, Rice University
Hamilton O. Smith*, Celera Genomics
Robert M. Solow*, Massachusetts Institute of Technology
Horst Stormer*, Columbia University
Henry Taube*, Stanford University
Richard Taylor*, Stanford University
E. Donnall Thomas*, University of Washington
James Tobin*, Yale University
Susumu Tonegawa*, Massachusetts Institute of Technology
Charles Townes*, University of California, Berkeley
James D. Watson*, Cold Spring Harbor Laboratory
Steven Weinberg*, University of Texas
Thomas H. Weller*, Harvard School of Public Health
Michael D. West+, Advanced Cell Technology
Eric F. Wieschaus*, Princeton University
Torsten N. Wiesel*, The Rockefeller University
Robert W. Wilson*, Harvard-Smithsonian Center for Astrophysics

* Nobel Laureate
+ Corresponding Author

Source: Juvenile Diabetes Research Foundation International

WHO WE ARE

The Coalition for the Advancement of Medical Research (CAMR) is comprised of nationally-recognized patient organizations, universities, scientific societies, foundations, and individuals with life-threatening illnesses and disorders, advocating for the advancement of breakthrough research and technologies in regenerative medicine - including stem cell research and somatic cell nuclear transfer - in order to cure disease and alleviate suffering.

CURRENT ADVOCACY EFFORTS

CAMR has focused its advocacy in two related areas:

1. Ensuring that somatic cell nuclear transfer (SCNT), also known as therapeutic cloning, remains a legal and viable form of scientific research, and opposing any effort that would allow reproductive cloning

Why?

Nearly 100 million Americans suffer from cancer, Alzheimer's, diabetes, Parkinson's, spinal cord injuries, heart disease, ALS, and other devastating conditions for which treatments must still be found. SCNT could hold the key to ending these patients' suffering.

2. Protecting and preserving continued federal funding of human embryonic stem cell research

Why?

Embryonic stem cells show tremendous promise, federal funding of the research protects the public interest, and the majority of Americans support stem cell research

TALKING POINTS
EMBRYONIC STEM CELL RESEARCH

Embryonic Stem Cells Hold Tremendous Promise

- *The suffering of millions could end*
  - These cells could be the "missing link" needed to cure some of the world's most deadly diseases
  - Scientists already have shown they can direct the development of human embryonic cells into insulin-producing cells that might help cure type-1 diabetes
  - Up to 100 million Americans may benefit from this research

Clinics Now Destroy Excess Embryonic Stem Cells

- *A majority of couples want these cells used to help save lives*
  - Stem cells come from excess fertilized eggs stored in freezers at in vitro fertility clinics
  - There are 100,000 of these excess cells that will be thrown away, if they aren't used for this research or offered to other, infertile couples. Both are ethical options
  - Nearly half of these couples say they would like to see some good come from their excess eggs

Federal Funding of the Research Protects the Public Interest

- *Private funding means research without safeguards and the possibility that more eggs than necessary will be destroyed*
  - Without federal funding, the nation's top academic researchers at universities, medical schools an teach hospitals cannot join in the search for cures
  - That means much slower progress
  - Tax dollars keep the "public" in public interest. This research should not be confined to the for-profit, commercial sector
  - The government should be providing oversight of the work and seeing that ethical guidelines are complied with

Stem Cell Research is at an Early Stage

- *Embryonic stem cells offer more promise than adult stem cells*
  - We support research involving both adult and embryonic stem cells. Both have shown promise.
  - Many scientists believe that embryonic stem cells will be more effective in curing diseases because they can grow and differentiate into any of the body's cells and tissues and thus into different organs

Public Opinion Strongly Favors Embryonic Stem Cell Research

- *The majority of Americans (regardless of religious affiliation) support embryonic stem cell research*
  - The American people want embryonic stem cell research to move forward
  - Independent opinion surveys show that public support is overwhelming - 70 percent or more
  - There is surprisingly strong backing among fundamentalist Christians, Catholics and abortion opponents
  - More than 100 newspapers have editorialized in favor of the research
  - At least 61 members of the United States Senate and more than 200 House members are on record as supporting the research and have urged President Bush to support it.

Source:
http://www.stemcellfunding.org/fastaction/
http://www.stemcellfunding.org/fastaction/news.asp?id=167

POSITION PAPER ON BUSH DECISION ON FEDERAL FUNDING OF STEM CELL RESEARCH

The American Society for Cell Biology represents over 10,000 basic biology researchers across the United States and throughout the world.

In President Bush's speech to the Nation on August 9, 2001, he acknowledged that the potential medical value of stem cell research "offers great promise. " His agreement to permit the use of federal funds for limited research on human embryonic stem (hES) cells is thus an important step forward.

The scientific optimism about human embryonic stem (hES) cell research is based on twenty years of research on mouse embryonic stem (mES) cells and from recent work on hES cells. This body of research demonstrates that such cells can grow and divide to give rise to more cells for numerous cell generations. However, when subjected to specific biological signals, these cells can respond by changing or differentiating into more specialized adult cell types. Thus, during the development of humans and other animals, the cellular offspring of ES cells ultimately form all of the normal tissue types in the human body, including pancreatic cells that secrete insulin, blood cells that carry oxygen, and brain cells that allow movement, emotion and cognition.

Although many critical details about the President's plan are still unknown, it is possible to begin to sketch its impact on the basic and therapeutic research that is projected to begin in the coming year. While there is cause for optimism, there are worrisome limitations that must be explored before the constraints imposed by the President can be evaluated.

The President's decision to add public funding to ongoing private efforts assures more rapid progress in this quickly developing area of medical science than either would achieve alone. Private companies will continue to work with ES cells, but this research tends to be limited to research to develop products and procedures with the greatest potential for profit.

Publicly funded research, however, is likely to be broader and deeper in its impact, because it can explore the general properties of hES cells and characterize the molecular details of their extraordinary capacities to differentiate into a variety of specialized cells. In addition, most of the information generated from publicly funded research will be published openly in the scientific literature for all scientists to examine and use in their own research. This will enhance the overall progress towards effective applications of stem cells.

Public funding will likely also support research on diseases where stem cell therapies may turn out to be critical, but where the profit potential or competitive advantage is not sufficient for private sector involvement alone. Finally, the use of public funds will allow greater public scrutiny and debate about the appropriate limits and uses of this new technology.

In evaluating the President's stem cell plan, the limitations imposed must be weighed against the potential for medical and scientific progress. The limitations regarding the source of the embryos and the need for informed consent in the procedures for obtaining the stem cells are justifiable and will be viewed by most biomedical scientists as being critical to the ethical conduct of this research.

Perhaps the most consequential limitation is the President's decision to limit federal funding to research with hES cell lines that were derived prior to 9:00 pm EDT on August 9, 2001. The President and the Secretary of Health & Human Services have made assurances that 60 lines meeting this condition will ultimately be available. But the usefulness of these cells can only be ascertained by

testing and further research. The National Institutes of Health (NIH) is actively compiling a registry of approved cell lines that will indicate the source, characteristics and availability of these lines. But even if each of the independent derivations were to yield a cell line that could be grown indefinitely in the laboratory and be capable of generating all adult cell types when exposed to the proper biological signals and cues, the lines' limited genetic diversity may still inhibit therapeutic development. In addition, considerable work with mES cells has also demonstrated that individual lines are idiosyncratic and can easily lose their effectiveness if handled improperly; initial data with hES cells suggest they too are variable, with some already known to be much better than others.

Five critical criteria must be met by each of the lines if they are to support rapid and rigorous research: (1) They must truly be available to both public-funded research scientists located at the NIH and at universities, academic health centers and research institutes throughout the Nation. (2) They must be free of restrictions that would impede publicly funded investigators from seeking important disease treatments. (3) They must be capable of robust growth. (4) Sufficient information must be available about each line's derivation so that it can be grown and handled under reasonable conditions. (5) Each of the approved lines must retain the important capacity to generate the three early embryonic cell types: ectoderm, mesoderm and endoderm.

If each of the lines stated to be available by the President meets these essential criteria, rapid and important research progress is likely to occur over the next three to five years. However, we are concerned that in the long run: 1) There may not be sufficient diversity and longevity in the existing lines to support the critical research that must be done; and 2) hES cell lines with enhanced and valuable qualities may well be derived in the coming year or two in the private sector or abroad, and their use by federally-funded investigators will be prohibited. In either case, the American Society for Cell Biology will renew its insistence that the President and the Congress act to permit federally funded scientists to derive or use newly developed stem cell lines as appropriate.

The President's plan also proposes vigorous funding of research with “adult stem cells”, indeed characterizing it as high priority. Most adult stem cells remain relatively uncharacterized because they cannot easily be propagated in the laboratory. Moreover, understanding of their developmental capabilities is comparatively limited, claims of unrestricted developmental capacities are anecdotal, and most have not yet been replicated by others. Nonetheless there is a clear and urgent need to pursue research with adult stem cells and to determine their utility for the treatment of some diseases.

To make the President's plan work in the short term, the NIH and the Administration must act quickly to determine the viability and availability of the approved cell lines. We believe that stem cell research will proceed more rapidly if the NIH:(1) creates a repository where each of the approved hES cell lines would be maintained and characterized with updated information regarding the stored lines provided to the entire scientific community; (2) clarifies the intellectual property issues with the Wisconsin Alumni Research Foundation and its commercial licensees as they affect academic researchers; (3) negotiates material transfer and licensing agreements with each of the institutions possessing viable cell lines so that academic and research institutions can use them as templates for their own purposes.

POSITION PAPER ON CLONING

(12/3/01)

Somatic Cell Nuclear Transfer Technology is Justified and Essential for Producing Embryonic Stem Cells for Basic Research and Therapeutic Applications

Since 1997 The American Society for Cell Biology has stated and stood by its strong opposition to the reproductive cloning of human beings. Media claims notwithstanding, current scientific information suggests that the technology now available will not be able to lead to the creation of a cloned human being or to an embryo capable of being born as a cloned normal human. Equally important, no responsible scientist favors reproductive cloning.

It is unlikely that current biomedical technology can be used to clone adult human beings. But there is substantial justification to believe that somatic cell nuclear transfer (SCNT), or what many have referred to as therapeutic cloning, will energize scientific progress in the fight against the most debilitating illnesses known to man. New embryonic stem cell lines, potentially capable of avoiding the rejection complications of stem cell therapies for cancer, diabetes, spinal cord injury, kidney disease, and Parkinson's disease, may be produced by using the genetic material of the prospective transplant recipient to generate recipient-matched stem cells. These procedures could be vital in solving the persistent problem of a lack of genetically matched, qualified donors of organs and tissues that we face today. Stem cell research is an essential first step if we are ever to be able to achieve the promise of regenerative medicine, a wholly new approach for repairing cells and tissues in the treatment of currently intractable human diseases. Beside the therapeutic promise, the SCNT procedure permits entirely new approaches to the study of the earliest phases of human development, of how a single cell is transformed into the trillions of different cells and tissues with myriad fates and capabilities during embryonic development. By deriving embryonic stem cells with defined mutations scientists gain a new approach to understanding how such inherited predispositions lead to serious disease in adulthood.

Unfortunately, an onerous cloud has been cast on the term cloning because it has been used in the public discourse both to refer to attempts to create genetically identical adult humans and to describe other procedures that are less controversial. However, cloning is a scientific term that describes the preparation of an infinite number of copies of, for example a single molecule, cell, virus or bacterium. For example, cloning DNA molecules was essential for solving the human genome sequence. Similarly, cloning DNA is critical to fight against bioterrorism and has already been used in the determination of the entire genome sequences of several organisms identified as bioweapons. Furthermore, cloning is integral to modern forensic procedures, medical diagnostics, vaccine development, and the discovery and production of many of the most promising drugs. Cloning is also used to make genetically identical plants and livestock enabling continued agricultural breakthroughs necessary to feed a rapidly growing and undernourished world population.

Conflating the term cloning as it is used for the creation of genetically identical humans with the valuable and appropriate uses of cloning embryonic stem cell lines for basic research and therapeutic purposes is inappropriate. The two issues need to be considered separately; otherwise we run the serious risk of sacrificing certain great benefits to prevent a perceived undesirable practice.

Source: The American Society for Cell Biology
http://www.ascb.org/newsroom/positionpaper.html
http://www.ascb.org/publicpolicy/cloning.htm

United Nations Educational,
Scientific and Cultural Organization

UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS, 1997

INTRODUCTION

The Universal Declaration on the Human Genome and Human Rights, which was adopted unanimously and by acclamation by the General Conference of UNESCO at its 29th session on 11 November 1997, is the first universal instrument in the field of biology. The uncontested merit of this text resides in the balance it strikes between safeguarding respect for human rights and fundamental freedoms and the need to ensure freedom of research.

Together with the Declaration, UNESCO's General Conference adopted a resolution for its implementation, which commits States to taking appropriate measures to promote the principles set out in the Declaration and encourage their implementation.

The moral commitment entered into by States in adopting the Universal Declaration on the Human Genome and Human Rights is a starting point, the beginning of international awareness of the need for ethical issues to be addressed in science and technology. It is now up to States, through the measures they decide to adopt, to put the Declaration into practice and thus ensure its continued existence.

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THE GENERAL CONFERENCE,

Recalling that the Preamble of UNESCO's Constitution refers to "the democratic principles of the dignity, equality and mutual respect of men", rejects any "doctrine of the inequality of men and races", stipulates "that the wide diffusion of culture, and the education of humanity for justice and liberty and peace are indispensable to the dignity of men and constitute a sacred duty which all the nations must fulfil in a spirit of mutual assistance and concern", proclaims that "peace must be founded upon the intellectual and moral solidarity of mankind", and states that the Organization seeks to advance "through the educational and scientific and cultural relations of the peoples of the world, the objectives of international peace and of the common welfare of mankind for which the United Nations Organization was established and which its Charter proclaims",

Solemnly recalling its attachment to the universal principles of human rights, affirmed in particular in the Universal Declaration of Human Rights of 10 December 1948 and in the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of l6 December 1966, in the United Nations Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Declaration on the Rights of Mentally Retarded Persons of 20 December 1971, the United Nations Declaration on the Rights of Disabled Persons of 9 December 1975, the United Nations Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the United Nations Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power of 29 November 1985, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Standard Rules on the Equalization of Opportunities for Persons with Disabilities of 20 December 1993, the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction of 16 December 1971, the UNESCO

Convention against Discrimination in Education of 14 December 1960, the UNESCO Declaration of the Principles of International Cultural Co-operation of 4 November 1966, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958 and the ILO Convention (N° 169) concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989,

Bearing in mind, and without prejudice to, the international instruments which could have a bearing on the applications of genetics in the field of intellectual property, inter alia the Bern Convention for the Protection of Literary and Artistic Works of 9 September 1886 and the UNESCO Universal Copyright Convention of 6 September 1952, as last revised in Paris on 24 July 1971, the Paris Convention for the Protection of Industrial Property of 20 March 1883, as last revised at Stockholm on 14 July 1967, the Budapest Treaty of the WIPO on International Recognition of the Deposit of Micro-Organisms for the Purposes of Patent Procedures of 28 April 1977, and the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1st January 1995,

Bearing in mind also the United Nations Convention on Biological Diversity of 5 June 1992 and emphasizing in that connection that the recognition of the genetic diversity of humanity must not give rise to any interpretation of a social or political nature which could call into question "the inherent dignity and (...) the equal and inalienable rights of all members of the human family", in accordance with the Preamble to the Universal Declaration of Human Rights,

Recalling 22 C/Resolution 13.1, 23 C/Resolution 13.1, 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3, 27 C/Resolution 5.15 and 28 C/Resolutions 0.12, 2.1 and 2.2, urging UNESCO to promote and develop ethical studies, and the actions arising out of them, on the consequences of scientific and technological progress in the fields of biology and genetics, within the framework of respect for human rights and fundamental freedoms,

Recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasizing that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics,

Proclaims the principles that follow and adopts the present Declaration.

A HUMAN DIGNITY AND THE HUMAN GENOME

Article 1

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 3

The human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment including the individual's state of health, living conditions, nutrition and education.

Article 4

The human genome in its natural state shall not give rise to financial gains.

B RIGHTS OF THE PERSONS CONCERNED

Article 5

(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.

(b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.

(c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.

(d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.

(e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

Article 6

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

Article 7

Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.

Article 8

Every individual shall have the right, according to international and national law, to just reparation for any damage sustained as a direct and determining result of an intervention affecting his or her genome.

Article 9

In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.

C RESEARCH ON THE HUMAN GENOME

Article 10

No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

Article 12

(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.

(b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

D CONDITIONS FOR THE EXERCISE OF SCIENTIFIC ACTIVITY

Article 13

The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.

Article 14

States should take appropriate measures to foster the intellectual and material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration.

Article 15

States should take appropriate steps to provide the framework for the free exercise of research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes.

Article 16

States should recognize the value of promoting, at various levels, as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its application.

E SOLIDARITY AND INTERNATIONAL CO-OPERATION

Article 17

States should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character. They should foster, inter alia, research on the identification, prevention and treatment of genetically-based and genetically-influenced diseases, in particular rare as well as endemic diseases which affect large numbers of the world's population.

Article 18

States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

Article 19

(a) In the framework of international co-operation with developing countries, States should seek to encourage measures enabling:

(i) assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;

(ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, to be developed and strengthened;

(iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;

(iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

(b) Relevant international organizations should support and promote the initiatives taken by States for the above-mentioned purposes.

F PROMOTION OF THE PRINCIPLES SET OUT IN THE DECLARATION

Article 20

States should take appropriate measures to promote the principles set out in the Declaration, through education and relevant means, inter alia through the conduct of research and training in interdisciplinary fields and through the promotion of education in bioethics, at all levels, in particular for those responsible for science policies.

Article 21

States should take appropriate measures to encourage other forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine, and its applications. They should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions.

G IMPLEMENTATION OF THE DECLARATION

Article 22

States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.

Article 23

States should take appropriate measures to promote, through education, training and information dissemination, respect for the above-mentioned principles and to foster their recognition and effective application. States should also encourage exchanges and networks among independent ethics committees, as they are established, to foster full collaboration.

Article 24

The International Bioethics Committee of UNESCO should contribute to the dissemination of the principles set out in this Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question. It should organize appropriate consultations with parties concerned, such as vulnerable groups. It should make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions.

Article 25

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights and fundamental freedoms, including the principles set out in this Declaration.

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IMPLEMENTATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

THE GENERAL CONFERENCE,

Considering the Universal Declaration on the Human Genome and Human Rights, which was adopted on this eleventh day of November 1997,

Noting that the considerations formulated by the Member States at the time of the adoption of the Universal Declaration are relevant for the follow-up of the Declaration,

1. URGES MEMBER STATES:

(a) in the light of the provisions of the Universal Declaration on the Human Genome and Human Rights, to take appropriate steps, including where necessary the introduction of legislation or regulations, to promote the principles set forth in the Declaration, and to promote their implementation;

(b) to keep the Director-General regularly informed of all measures they have taken to implement the principles set forth in the Declaration;

2. INVITES THE DIRECTOR-GENERAL:

(a) to convene as soon as possible after the 29th session of the General Conference an ad hoc working group with balanced geographical representation, comprised of representatives of Member States, with a view to advising him on the constitution and the tasks of the International Bioethics Committee with respect to the Universal Declaration and on the conditions, including the breadth of consultations, under which it will ensure the follow-up to the said Declaration, and to report on this to the Executive Board at its 154th session;

(b) to take the necessary steps to enable the International Bioethics Committee to ensure the dissemination and follow-up of the Declaration, and promotion of the principles set forth therein;

(c) to prepare for the General Conference a global report on the situation world-wide in the fields relevant to the Declaration, on the basis of information supplied by the Member States and of other demonstrably trustworthy information gathered by whatever methods he may deem appropriate;

(d) to take due account, in the preparation of his global report, of the work of the organizations and agencies of the United Nations system, of other intergovernmental organizations, and of the competent international non-governmental organizations;

(e) to submit his global report to the General Conference, together with whatever general observations and recommendations may be deemed necessary in order to promote the implementation of the Declaration

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PRESENTATION GUIDE

This table contains all of the topics that must be included in your presentation to the Committee.

Use this table to record your proposals. When presenting your proposals to the committee be as creative as possible. In other words, do not simply present this table.

ACTIVITY	LEGAL STATUS (prohibited, controlled or unrestricted)	CRITERIA (only for controlled activities)	PUNISHMENT (only for prohibited or controlled activities)	REASON (for all)
Use of embryonic stem cells from existing cell lines				
Use of embryonic stem cells from discarded embryos from IVF clinics				
Use of embryonic stem cells from embryos created by IVF for research				
Use of embryonic stem cells from embryos created by therapeutic cloning				