



Cloning humans?

Although claims to date reporting the growth of cloned human embryos into fetal stages or beyond have not been substantiated, many predict that the birth of a human clone is inevitable. The attempted production of cloned human persons raises many ethical, moral, legal, social and cultural concerns



Is Human Reproductive Cloning Inevitable? – Future Options for United Nations Governance

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WAAS General Assembly - 18 October 2008 - Hyderabad

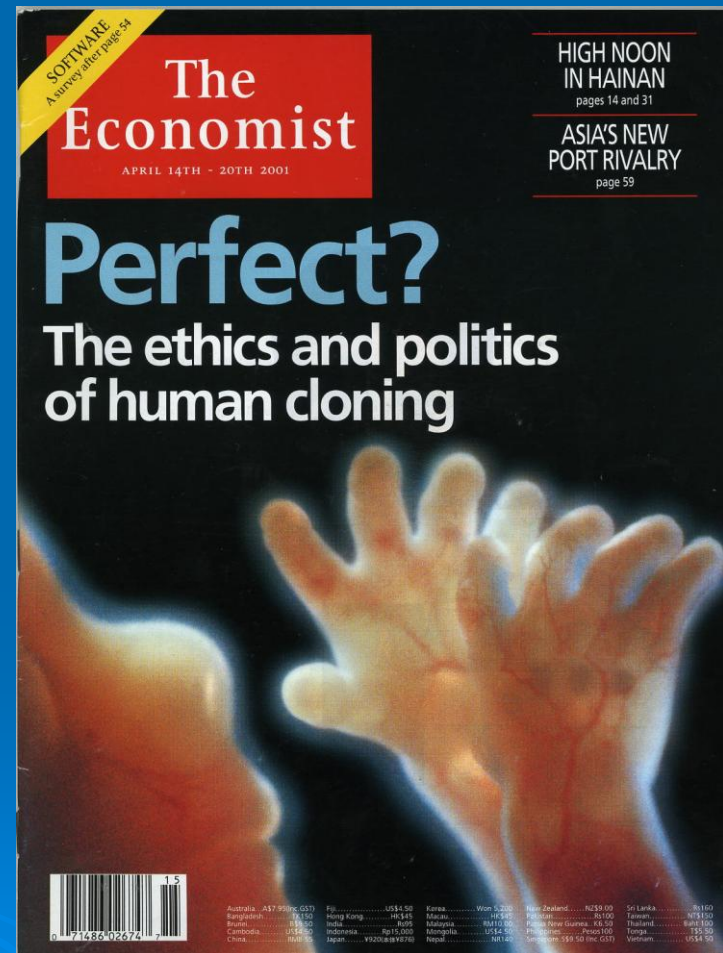
Cloning, an emotive and divisive issue among UN negotiators

- Apparent unanimity on the need to ban reproductive cloning
- But efforts to develop an international convention/treaty stalled due to severe divisions over the issue of research/therapeutic cloning
- Issue rests on whether researchers should be allowed to use cloning techniques to produce embryos to serve as a source of stem cells for potential therapeutic purposes



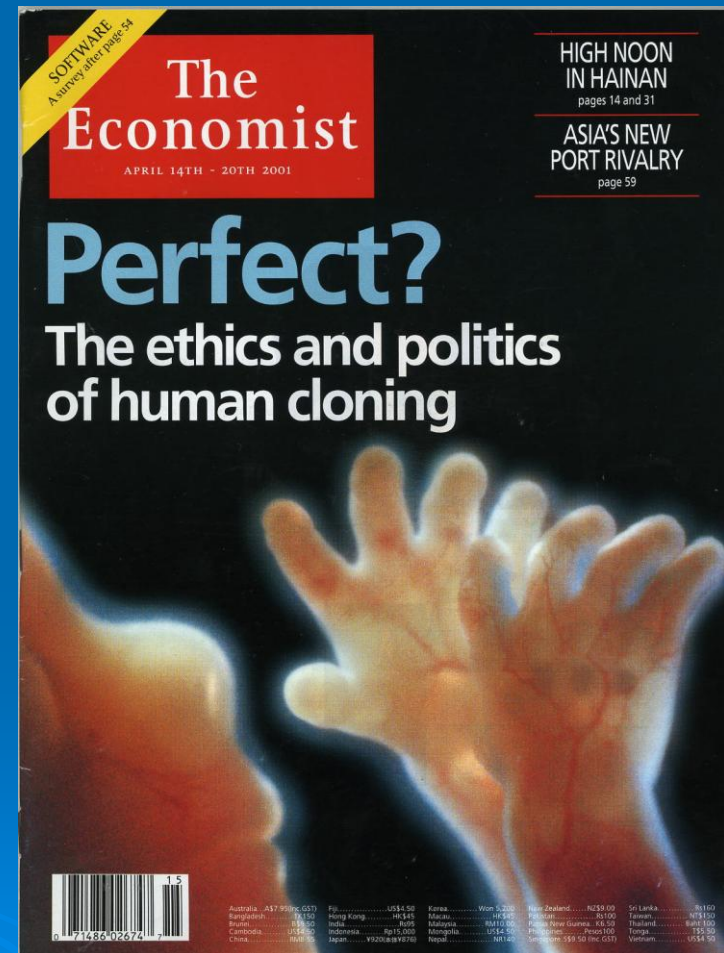
Ethical arguments for cloning

- There is an obligation to advance science
- People right to dignity entitles them to relief from degrading diseases
- Childless couples have a right to be parents
- Arguments against reproductive cloning are discriminatory
- There is no basis in bioethics for a full ban in particular when technology advances



Ethical objections to cloning

- Science is not sufficiently advanced
- Should not usurp God's role in reproduction
- Slippery slope to eugenics
- Start of the human body shop – body parts for the rich
- Unjustified use of resources for the few when the world needs to address poverty issues.



PRESENT SITUATION OF THE INTERNATIONAL GOVERNANCE OF HUMAN CLONING

- At the international level, two United Nations declarations and a World Health Organization resolution are the present instruments of governance of human cloning.
- The Universal Declaration on the Human Genome and Human Rights, adopted on 11 November 1997 by the General Conference of UNESCO and endorsed by the General Assembly of the United Nations by its resolution 53/152 of 9 December 1998, is the first international instrument which prohibits human reproductive cloning.
- Indeed, Article 11 of the Declaration states that:
“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.



PRESENT SITUATION OF THE INTERNATIONAL GOVERNANCE OF HUMAN CLONING



- The United Nations Declaration on Cloning of 8 March 2005 states in its paragraph b): Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and protection of human life.
- The World Health Organization found in its Resolution WHA51.10 of 16 May 1998 that “cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity”. Therefore it “urges Member States to foster continued and informed debate on these issues and to take appropriate steps, including legal and juridical measures, to prohibit cloning for the purpose of replicating human individuals”.
- This resolution confirms another WHO resolution adopted at the 50th session in 1997 (WHA50.37)

UNESCO says UN should re-open cloning debate (Press dateline October 17, 2008)

Later this month, the United Nations Educational, Scientific and Cultural Organization (UNESCO) will meet to discuss reopening the international cloning debate. The International Bioethics Committee (IBC) will gather in Paris to “explore whether the scientific, ethical, social, political and legal developments on human cloning in recent years justify a new initiative at international level, rather than to initiate an ethical and scientific analysis of the issue of human cloning.”

UNESCO says UN should re-open cloning debate (Press dateline October 17, 2008)

A UNESCO working group on cloning that first met in July 2008 concluded that “in view of the scientific, social and political developments, the existing non-binding texts on human cloning are not sufficient to prevent human reproductive cloning

Defining human cloning

The question of how to define human cloning remains at the center of the debate.


Some argue that there are two types of human cloning: “therapeutic cloning,” where the cloned embryo is experimented upon and killed, and “reproductive cloning,” where the cloned embryo would be allowed to fully grow.

Both “reproductive” and “therapeutic” cloning involve the creation of a human embryo.

While almost everyone wants to ban so-called “reproductive cloning,” the crux of the debate centers on whether or not to allow “therapeutic” or experimental cloning, which some call “clone and kill.”

Cloning debate at the U.N.

Many assumed that the UN General Assembly settled the issue in 2005 when it passed a non-binding political declaration that banned human cloning for any purpose, both “therapeutic” and “reproductive.” This occurred after three years of intense negotiations and resulted in a declaration which took into account countries’ deeply-entrenched and divergent views on the issue.



Cloning debate at the U.N.

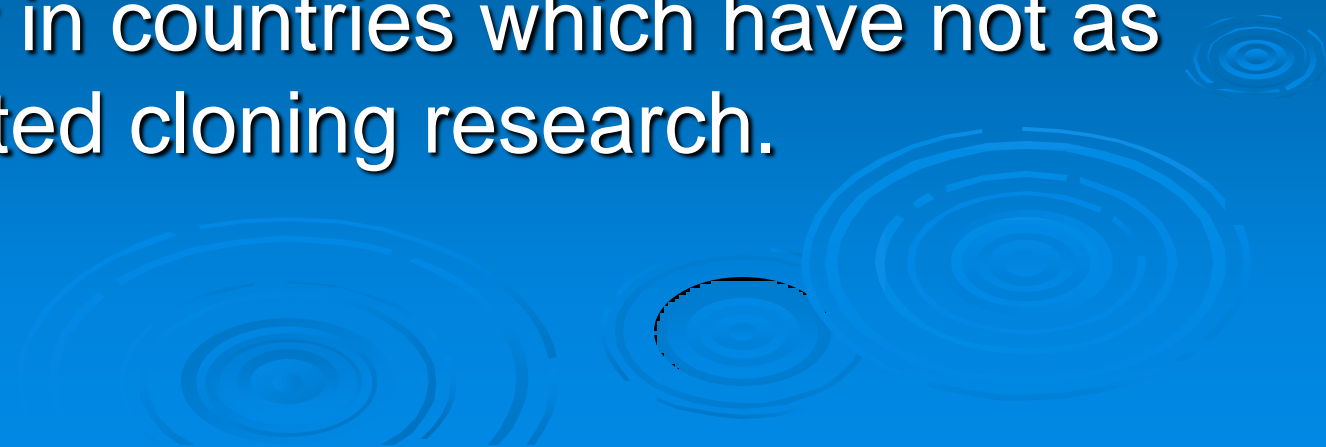
Despite widespread consensus amongst nations regarding the desirability of banning reproductive cloning, efforts to negotiate an international convention ground to a halt due to fundamental divisions regarding so-called research or therapeutic cloning

Cloning debate at the U.N.

Research cloning, viewed by some as a possible source of new therapeutic remedies for degenerative diseases, is seen by others as unethical where it involves the production of embryos as a source of stem cells upon which such therapies are based. Firm positions on both sides of the debate led to a compromise position in the form of a non-binding UN Declaration on Cloning, (A/RES/59/280).

Cloning debate at the U.N.

As a result of the failure to adopt an internationally binding legal instrument to regulate reproductive cloning activity, scientists committed to carrying out research in this area can do so in many countries where domestic regulations allow it, or in countries which have not as yet regulated cloning research.



Cloning debate at the U.N.

- Whereas reproductive cloning is meant to duplicate a person or animal, research cloning is meant to produce tissues that genetically match those of the person or animal whose cells are cloned.
- Proponents of research cloning for regenerative medicine say it offers great hope of producing replacement tissue without the fear of immunological rejection, that it offers a potential cure for millions of people suffering common diseases of the industrialized world – diabetes, stroke, spinal injury, and neurodegenerative diseases such as Alzheimer's or Parkinson's.
- Opponents view research cloning as the unethical production and destruction of living embryos to produce stem cells upon which such therapies are based.
- The clash of positions led to a compromise non-binding UN Declaration on Cloning



UNESCO working group

At the July 2008 meeting of the UNESCO working group, members attributed the confusion within the ethical debate between therapeutic and reproductive cloning to “differences in the status attributed to the human embryo in different cultures and societies.” But it added that “the number of countries which have ethically accepted therapeutic cloning seems to have grown” since the 2005 General Assembly declaration and that “considerable advancement made in the field of governance constitutes an important ethical and political change.”

Human Cloning

- The issues of human cloning and its practical applications and regulations have been discussed by the international community for some time.
- The UNESCO Universal Declaration on the Human Genome and Human Rights (1997) – a legally non-binding document for Member States - prohibits reproductive cloning (Article 11)

Human Cloning


- Recent technological developments and new prospects for the use of stem cells in the therapy of human diseases have once again raised the issue of adequacy of international regulations governing this research.
- In August 2001 in the United Nations General Assembly, the Permanent Missions of France and Germany requested the Secretary-General to include a supplementary item in the agenda of the 56th session entitled *International Convention against the Reproductive Cloning of Human Beings*.
- An international convention would be legally binding to Member States.

Human Cloning

- After almost 4 years of discussion the United Nations Declaration on Human Cloning was adopted on 8 March 2005 (A/RES/59/280).
- The Declaration was voted and passed with 84 countries supporting it, 34 countries voting against and 37 abstaining.
- The wording of the document left room for very different interpretations of the text, which reflected, in part, the lines of division between different Member States on this issue.
- The main point of contention was the question of linking the issues of reproductive and non-reproductive cloning, which was not agreeable to many States, who abstained and voted against the Declaration

Human Cloning

- In November 2007, the United Nations University Institute of Advanced Studies (UNU-IAS) produced a Report entitled *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*, which summarized up-to-date technical information on cloning, ethical issues accompanying it and the state of the art of international governance of these issues, specifically analyzing the discussions during the 4 years of United Nations General Assembly debate leading to the voting on the United Nations Declaration of Human Cloning.
- The Report expressed the view that further development of international governance would be needed and envisaged several options along this line



Is Human Reproductive Cloning Inevitable: Future Options for UN Governance



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- The study concludes that regulators missed an opportunity to develop clear and unequivocal measures banning cloning intended for the purposes of bringing about the birth of human life.
- Although it can be argued that there is overwhelming international opposition to reproductive cloning, coupled with numerous national legislation which make it a criminal offence, it is still difficult to establish that there exists a clear custom that prohibits reproductive cloning.
- However, there are strong grounds to believe that if such a case were to come before the International Court of Justice, the emerging custom against reproductive cloning will be a strong argument for the prosecution. The United Nations Declaration on Human Cloning is an important milestone on the road to customary international law on cloning.”

Cloning controversy

- There have been no substantiated claims of cloned human embryos grown into fetal stages and beyond but such an historic event is not far off, most experts agree.
- Clones have been achieved with mice, sheep, pigs, cows and dogs and U.S. researchers last year accomplished the first cloning of a primate – a rhesus monkey embryo cloned from adult cells and then grown to generate stem cells.
- National efforts to outlaw reproductive cloning of humans are easily skirted if researchers can simply move to other jurisdictions. Disgraced South Korean medical researcher Woo Sook Hwang, whose human clone claims were unsubstantiated, reportedly continues his work in Thailand.

Cloning controversy

- The UNU-IAS Report explores in depth the difficult ethical considerations behind the issue.
- It is frequently argued, for instance, that reproduction should occur by chance and through natural selection. This argument may be based upon religious lines, which defer to a supernatural or higher power for choice, or to natural selection and the importance of ensuring continued human diversity.
- More convincing for some are arguments against the commoditization of life. Fears exist that allowing reproductive cloning will lead to a spare parts market for harvesting human organs from cloned “brain-less bodies” for the rich as they seek to extend their lifespan, a result which many see as a contravention of individual and collective human dignity.
- These are not issues which can be lightly dismissed; however, it is clear that any debate on human dignity needs to separate the various elements of the debate in order to consider whether opposition to cloning stems from concern for human dignity or respect for divine dignity. As well as to determine whether it is designed to protect the individual that may be cloned or the society whose sense of personal and collective identity might be challenged by the concept of sharing the world with cloned individuals.

Future options for international governance of cloning

The main governance options:

- a. the International Bioethics Committee of UNESCO (IBC) takes up the issue of reproductive and research cloning, in the context of resolution A/RES/59/280 and also in the context of the Universal Declaration on Bioethics and Human Rights, adopted by the General Conference of UNESCO on 19 October 2005;
- b. the sixth committee of the General Assembly takes up the issue of customary international law on cloning;
- c. dissemination, discussion and debate on cloning issues at the international level, so that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology.

Future options for international governance of cloning

Options available for regulation of cloning:

- a) total ban on all cloning research,
- b) ban on reproductive cloning,
- c) ban on reproductive cloning and allow research cloning,
- d) ban reproductive cloning, allow research cloning for 10 years,
- e) place a moratorium on all cloning research.

UNU-IAS Report

“The world community quickly needs to reach a compromise that outlaws reproductive cloning or prepare to protect the rights of cloned individuals from potential abuse, prejudice and discrimination”

UNU-IAS Report

“A legally-binding global ban on work to create a human clone, coupled with freedom for nations to permit strictly controlled therapeutic research, has the greatest political viability of options available to the international community”

WHY ARE NEW ACTIVITIES OF INTERNATIONAL GOVERNANCE NEEDED?

- 1. There are new scientific developments, which make the need for international governance more urgent. On one hand, the construction of induced pluripotent stem (iPS) cells and their possible uses has created more technical possibilities for reproductive manipulation of human embryos and hence brings new problems into the debate. Since it has been demonstrated that functional germ cells may be created from embryonic stem cells, this raises the possibility of creating germ cells from somatic cells (via iPS cells) which further blurs the borders between different stages of human development and reproduction. On the other hand, it is clear to scientists that “cloning” in the sense of producing identical human beings is impossible because of differences in developmental and environmental conditions, epigenetic modifications of the DNA involved, etc. In addition, it is scientifically clear that in the current state of technology, reproductive cloning is associated with serious health risks for both women and foetuses.

WHY ARE NEW ACTIVITIES OF INTERNATIONAL GOVERNANCE NEEDED?

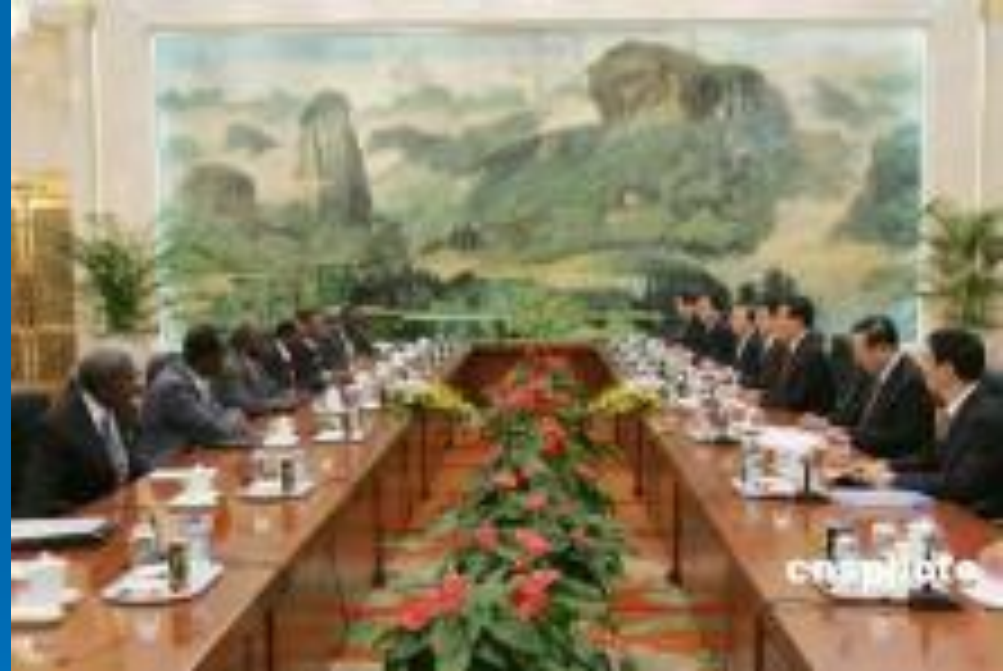
- 2. During the last three years since the adoption of the United Nations Declaration on Human Cloning the public sensitivity and awareness of the issues has increased, whereas the information and dissemination of the issues could be improved.
- 3. Several Member States have recently updated their national regulations of governance of human cloning and embryo research in general and therefore there is more awareness and information among politicians in these countries.
- 4. The financing of human embryo research has considerably increased over recent years, whereas more and more multinational commercial private interest is being involved. This is accompanied by international traffic (both legal and illegal) of embryos, eggs and stem cells.

WHY ARE NEW ACTIVITIES OF INTERNATIONAL GOVERNANCE NEEDED?

- 5. If the argument remains at the level of the moral status of the embryo, there is no room for achieving consensus. Also, as detailed in item #1 of this section, reproductive cloning may become possible without using embryos. So there is a clear need to move to ethics of international governance of cloning, where different countries can find agreement, e.g. a ban on reproductive cloning.
- Based on these findings, the UNESCO Working Group is of the position that the issues surrounding human reproductive cloning cannot be ignored and therefore a focused international dialogue considering a binding instrument against reproductive cloning is needed

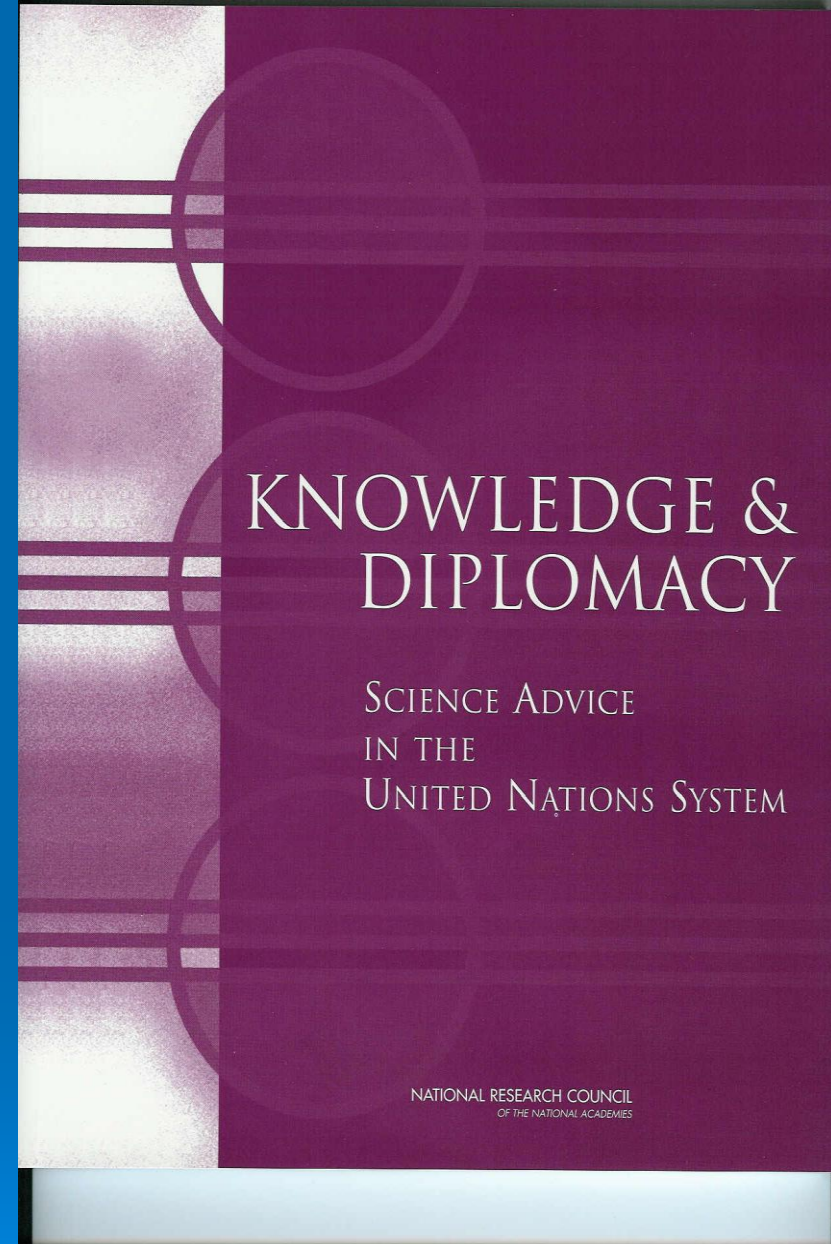
Bio-Issues on the Global Diplomacy Agenda

Increasingly, “bio-” issues are being brought onto the main table of discussion among political leaders, policy-makers and diplomats e.g. cloning, biosafety, biodiversity, ecosystems destruction



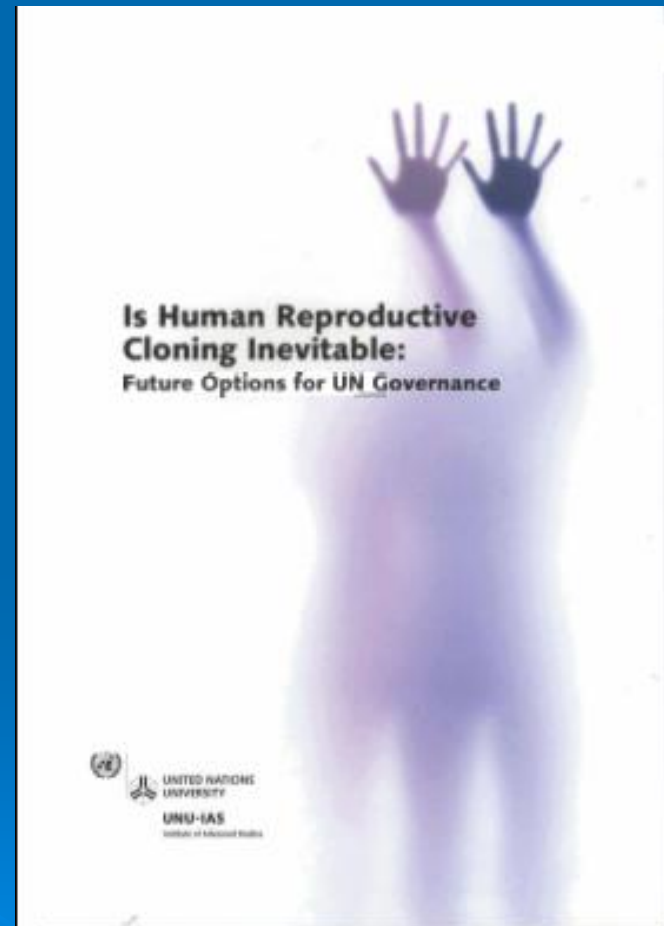
Knowledge and policy- making/diplomacy

- Greater need for making informed, equitable, sustainable, and representative decisions, based on scientific understanding
- Good examples: IPCC, soon IPBES?
- Roles of the World Academy of Art and Science (WAAS)?



Linking knowledge and diplomacy

- The UNU report argued that the current challenge for the international community is “to find a compromise position” with an “increased respect for ethical diversity”
- The Director-General of the UNESCO has expressed his wish that the examination of the UNU report be added as an agenda item for discussion by IBC at its sessions).



Skin cells coaxed to work like stem cells

Research could end the embryo debate

International Herald Tribune, P.1 and P.4, June 8 2007

Skin cells coaxed to work like stem cells

Research could end the embryo debate

By Nicholas Wade

In a surprising advance that could sidestep the ethical debates surrounding stem cell biology, researchers in Japan have come much closer to a major goal of regenerative medicine: the conversion of a patient's cells into specialized tissues that might replace those lost to disease.

The advance is an easy-to-use technique for reprogramming a skin cell of a mouse back to the embryonic state. Embryonic cells can be induced in the laboratory to develop into many of the body's major tissues.

If the technique can be adapted to human cells, researchers could use a patient's skin cell to generate new heart, liver or kidney cells that might be transplanted and would not be rejected by the patient's immune system. But scientists say they cannot predict when they can overcome the considerable problems in adapting the method to human cells.

Previously, the only way to convert adult cells to embryonic form has been by nuclear transfer, the insertion of an adult cell's nucleus into an egg whose own nucleus has been removed. The egg somehow reprograms the nucleus back to an embryonic state. That procedure is known as therapeutic cloning when applied to people, but no one has yet succeeded in doing it.

The new technique, developed by Shinya Yamanaka of Kyoto University, depends on inserting just four genes into a skin cell. These accomplish the same reprogramming task that the egg does, or at least one that seems very similar.

"From the point of view of moving biomedicine and regenerative medicine faster, this is about as big a deal as you could imagine," said Irving Weissman, a leading stem cell biologist at Stanford University who was not involved in the new research.

The technique, if adaptable to human cells, is much easier to apply than nuclear transfer, would not involve the expensive and controversial use of human eggs, and should avoid all or almost all of the ethical criticism directed at the use of embryonic stem cells.

Ronald Green, an ethicist at Dartmouth College, said it would be "very hard for people to say that what is created here is a nascent form of human life that should be protected." The new technique, if adaptable to human cells, "will be one way this debate could end," Green said.

Biologists learned how to generate human embryonic stem cells in 1998 from the few-day-old embryos discarded by fertility clinics, a procedure the embryos did not survive.

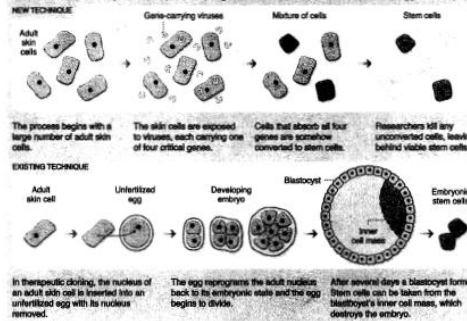
In the United States, this source proved controversial, and biologists supported by federal financing were unable to explore the new opportunity until August 2001, when President George W. Bush, in a political compromise, decreed that federally financed research on human embryonic stem cells could begin, but only with cell lines already in existence by that date. The restrictions have caused considerable frustration among U.S. biologists as research has progressed in other countries.

CELL, Continued on Page 4

INTERNATIONAL 147 June 8, 2007

From skin cells to stem cells

Researchers have developed a technique for creating stem cells without the controversial use of eggs or embryos.



Research could end ethical concerns

CELL, From Page 1

Years of patient research have identified many of the genes that are active in the embryonic cell and maintain its ability to morph into many different tissues. Such pluripotency had been the goal of Yamanaka and a colleague, Kazutoshi Takahashi, both at Kyoto University, when they generated 21 genes responsible in mouse embryonic stem cells, a breakthrough they described in a remarkable report last year.

When they inserted all 24 genes into mouse skin cells, some of the cells showed signs of pluripotency. The Kyoto team then narrowed genes one by one until they had a set of four genes that were essential. The genes are inserted into viruses that infect the cell and become active as the virus replicates. The skin cell's own copies of these

genes are repressed, since they would interfere with its function. "We were very surprised" that just four genes are sufficient to reprogram the skin cells, Yamanaka said.

An immediate issue is whether the technique can be reprogrammed for human cells. One problem is that the mice have to be infected with the gene-carrying virus, which is not ideal for cells to be used in therapy. A third issue is that two of the genes in the recipe can cause cancer. Indeed, 20 percent of Yamanaka's mice died of cancer.

Nonetheless, several biologists expressed confidence that all these difficulties will be sidestepped, somehow, and Yamanaka's report has revived the attention of other biologists.

Two teams set out to repeat and extend his findings, one led by Rudolf Jaen-

sch of the Whitehead Institute, in Massachusetts, and the other by Kathrin Fink of the University of California, Los Angeles, and Harald Hochholdinger of Massachusetts General Hospital, Yamanaka, too, set about refining his work.

In articles published Thursday in *Nature* and a new journal, *Cell Stem Cell*, the three teams show that injection of the four genes identified by Yamanaka can make mouse cells revert to cells indistinguishable from embryonic stem cells. Yamanaka's report of last year showed that only some portions of embryonic stem cells were attained.

This clear confirmation of Yamanaka's recipe is exciting to researchers because it throws open to study the key process of multicellular organisms, that of committing cells to a variety of different roles, even though all carry the same genetic information.

Stem cell debate steps up in Australia

By Tim Johnston

SYDNEY: Australia is no stranger to robust political debate, but even by Australian standards, the recent controversy over modifying restrictions on stem cell research has been particularly heating.

The lower house of the New South Wales Parliament passed a bill Thursday, 26, allowing limited therapeutic cloning but not before the Roman Catholic archbishop of Sydney, Cardinal George Pell, warned Catholic legislators that they could face unspecified consequences if they voted for the bill.

The Roman Catholic Church is strongly opposed to embryonic stem cell research, which it says involves the destruction of human life.

Pell's comments sparked an angry reaction among legislators, particularly those who are Catholic. The state premier, Michael Bennett, as well as at least a quarter of his cabinet, is Catholic.

In a speech to the lower house, Norman Rees, the state minister for water utilities and a Catholic, likened the car-

dinal to a "serial boogymen" and accused the church of hypocrisy, saying it would resist government attempts to influence Catholic teachings.

The bill, which now goes to the upper house, approves the use of somatic cell nuclear transfer, which creates stem cells with identical DNA sequences to patients and was the most far-reaching therapeutic cloning. A donor nucleus is inserted into a human egg cell, which then starts to reproduce itself, which is the first step toward creating an embryo.

Advocates of stem cell research, which has already been approved on federal lands in Australia, say it could ultimately help develop treatments for conditions as varied as Parkinson's disease, cancer and spinal injuries.

The archbishop of Perth, in Western Australia, where a similar bill is to be debated shortly, supported Pell's opposition to the bill. Archbishop Barry Hickey said he respected the conscientious decisions of legislators, but he could not understand how they could vote in favor of stem cell research and

still take Communion.

The role of religion in politics has become increasingly controversial in Australia, as it has in the United States.

Frank Brennan, a Jesuit priest and lawyer, called the debate an unedifying spectacle.

"I don't have a problem with church leaders expressing a view, as long as they don't pretend they are speaking for all of their church and country," said Brennan, who recently wrote a book, "Acting on Conscience" on the roles of politics and religion.

Brennan said Thursday of Pell, "The only thing I can think he was speaking when he threatened 'consequences' was some kind of move toward accommodation, but that is a legal process and in any case not appropriate in this case or denial of communion in the public square."

"I don't think it is correct for church leaders to say, 'These people don't respect human life,'" he added. "They might have a different view on what constitutes human life."

“Peacemaking and peace building should never be the exclusive preserve of diplomats and politicians...”

Kofi Annan, March 12, 2003

