RARE DISEASE PATIENTS’ PERSPECTIVE ON EMBRYONIC STEM CELL RESEARCH AND THERAPY

SEPTEMBER 2006

SUMMARY

The purpose of this paper is to give a balanced ethics overview of the patient perspective on the use of embryonic stem cells (ESCs) in research.

ESCs are found in the inner cell mass of the human blastocyst, an early stage of the developing embryo (4th to 7th day after fertilisation only). In normal embryonic development, ESCs have the most potential to lead to cures in regenerative medicine, because they have demonstrated long-term self-renewal and multipotency.

- Patients in general and rare disease patients in particular, are in dire need of treatments. They are placing high expectations on ESC research.
- Eurordis considers that individuals must have free choice of therapy, and that they should be free to refuse or demand treatments issued from ESC research.
- Eurordis is concerned that the current debate could deprive products derived from ESC research of an EU centralised procedure offering quality, effectiveness and safety guarantees.
- The EU principle of subsidiarity allows individual Member States to ban ESC research at national level. This could potentially lead to therapies being available in some States only, creating further inequities between EU citizens (by limiting patient access to potentially life saving treatments). This is contrary to the principle of free choice for individuals.
- ESC research is currently performed by a number of countries representing half the world population that have a permissive or flexible policy on ESC research. Products issued from such research will eventually be made available in the EU.
- Thousands of human blastocysts created by couples with fertility problems lie in the freezers of EU laboratories, only to be destroyed later. It seems illogical that ESC research is considered as murder by some, but not the destruction of such blastocysts.
- The latest Eurobarometer (June 2006) shows considerable support for ESC research, provided it is tightly regulated. The same goes with the US, where a September 2005 survey found wide support for ESC research.
Conclusion:

- EURORDIS believes that the “protection” of pre-implanted human blastocysts (which will be destroyed later anyway as supernumerary embryos) must be balanced against the potential cure of European citizens condemned to a slow and painful death.

- To potentially save the lives of millions of patients, affected by rare or common diseases, EURORDIS supports research on ESC, provided it is done within a tight regulatory framework.

- EURORDIS does not support a ban on the use of EU funding for ESC research, nor taking therapies issued from ESCs out of the scope of the future Regulation on Advanced Therapies.

- While supporting research on ESCs, EURORDIS also strongly supports research on methods which do not destroy the embryos and research on adult stem cells, stem cells from umbilical cord and from aborted foetuses.

About EURORDIS

The European Organisation for Rare Diseases (EURORDIS) represents more than 260 rare disease organisations in over 30 different countries, covering more than 1,000 rare diseases. It is therefore the voice of the 30 million patients affected by rare diseases throughout Europe.

EURORDIS is a non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases, dedicated to improving the quality of life of all people living with rare diseases in Europe. It is supported by its members and by the French Muscular Dystrophy Association (AFM), the European Commission, and corporate foundations and the health industry. EURORDIS was founded in 1997. Further details concerning EURORDIS and rare diseases are available at: http://www.eurordis.org
EURORDIS - the European Organisation for Rare Diseases - represents 264 rare disease organisations from 31 countries, 19 of which are EU member states, and thereby reflects the voice of an estimated 30 million patients affected by rare diseases in the European Union.

In response to the current debate on ethical issues linked to research on embryonic stem cells (ESCs), EURORDIS - as representative of patients who are currently lacking effective medicinal products and who have high expectations from Advanced Therapies - feels the need to present its observations on rare disease patients' perspective concerning ESC research.

In particular with regards to the Commission's proposal on Advanced Therapies, EURORDIS is concerned that advanced products issued from ESCs could be deprived of the EU centralised procedure that will benefit all the other advanced therapies, such as gene therapies and cell therapies based on non-embryonic stem cells.

Rare disease patients are perfectly aware that today there is no treatment issued from ESCs and that the reflection presented below is based on expectations linked to this promising area of research and to the current state of research on animal models. Although it is impossible to predict the precise outcomes and timetable of any type of research, including ESC research, scientists and the public will gain new knowledge in the biology of human development that is likely to hold remarkable potential for therapies and cures.

Furthermore, the current ethical debate is linked to the limits of the technology available at present: today, the embryo is destroyed after the extraction of ESCs. However, in the future, this problem may disappear with the development of new techniques preserving the embryo. Good reasons for hope in this area of research have recently come to light with the announcement, on 23 August 2006, of a ground-breaking technique for growing human stem cells from an early human embryo without destroying it.

1. Individual free choice and consequences of subsidiarity

EURORDIS considers that free choice must be left to individual patients and parents as to which therapeutic approach they decide to follow. EURORDIS therefore respects the fact that each individual is free to refuse a therapy that could in the future be issued from embryonic stem cells.

EURORDIS acknowledges that research on embryonic stem cells is not allowed in certain Member States. While respecting subsidiarity as the principle leading EU activities, we would like to stress that all European patients should be able to benefit from a robust evaluation for quality, safety and efficacy through an EU centralised procedure at EMEA.

In addition, there will be a range of consequences for EU patients:

- **First consequence at the patient level:** therapies issued from ESC research will only be available in some Member States. This means that inequity between European patients will be worsened: rich patients will be able to travel abroad and buy these therapies themselves, while poor patients will not have access to therapies forbidden in their countries;

- **Second consequence at the national level:** the day that therapies issued from ESC research will be placed on the market and will prove their effectiveness, what will restrictive EU Member States do? Will they take benefit from the “bad research” performed elsewhere? Will they prohibit their patients from benefiting from these therapies by refusing access to their market? Restrictive governments will have to face their public opinion, their patient organisations and be held accountable for their actions.

1 Advanced Cell Technology announces technique to generate human embryonic stem cells that maintains developmental potential for embryo – Approach published in Nature, 23 August 2006
decisions. Patient representatives, who are constantly fighting for equal access to medicinal products, will not allow further inequity to be installed and therefore may consider bringing the case of Advanced Therapies to the European Court of Justice.

- Third consequence at the international level: ESC research will in any case be performed outside the EU, in countries with less strict regulation and boundaries, possibly with different ethical standards than it would be done in the EU. Afterwards, therapies issued from a type of research which is controversial in Europe will be imported in the EU and bought by patients who can afford it. Do EU decision-makers really want to establish this system of “ethical dumping”?

2. Respect of patients’ needs versus respect of personal convictions – A Public Health perspective

While recognising that because of religious, cultural and historical reasons, some EU Member States have a restrictive approach on ESC research, EURORDIS is concerned about the possibility for the individual freedom of choice to be jeopardised and for potential treatments based on ESC research to be forbidden - thereby limiting the available therapeutic options for individual patients.

In fact, as repeatedly stated during the Conference “Patients and Stem Cells” (15-16 December 2005, in Brussels), patients are - here and now - in a state of crying need and cannot afford to neglect any promising area of research.

What was evident during the Conference is that as long as a person has been lucky enough to be preserved from injury and disease, it is possible to place religious and ethical principles at the top of his/her priorities. But when the same person – or his/her loved ones - is struck by a life-threatening disease, the scale of priorities can change dramatically.

When it occurs, this radical change derives from the perspective and the state of need, which is particularly acute for patients affected by rare diseases and their families for whom gene and cell therapies are often the last hope.

3. Co-existence of different logics

EURORDIS would like to draw the attention on the following reasoning, which doesn’t seem logic to everybody, and certainly not from the patients’ perspective:

Thousands of human early embryos, created by couples with fertility problems – using the most recent advances of research and medicines to serve their worthwhile purpose - but not implanted, are lying in the freezers of European laboratories and will be eventually destroyed once they are no longer the object of a parental project. It would not make sense and would be technically impossible to keep them for hundreds, thousands or millions years.

According to certain positions, these supernumerary embryos must not be used for stem cell research because that would be “murder.” But letting them expire or be destroyed (for reasons of medical institutions’ logistic or budget constraints) is not considered murder. This position leads to prohibition of research on future destroyed embryos that could bring cures for children and adults with life-threatening rare diseases who continue to suffer and die prematurely.

From the rare disease patients’ perspective, this is not acceptable and even unethical.
As reported in an article from the International Herald Tribune (“EU to finance stem cell research” by Dan Bilefsky, 25 July 2006), the British Science Minister David Sainsbury stated that “It is morally unacceptable to withhold these advances from patients, because it offers potentially tremendous advantages to EU citizens”.

In the same article, it was reported that Stephen Hawking considers banning the use of stem cells from human embryos as equivalent of opposing the use of donated organs from dead people. "The fact that the cells may come from embryos is not an objection because the embryos are going to die anyway," he told the newspaper The Independent in London. "It is morally equivalent to taking a heart transplant from a victim of a car accident."

4. Scientific definitions

4.1 Stem cell (SCs)

Generally, an undifferentiated cell capable to reproduce itself and to produce distinct differentiated tissues. Because SCs have the potential to mature into many different kinds of cells, they are expected to have great potential for regenerative cures. SCs can be derived from early-stage “embryos”, called blastocysts, from aborted foetuses, from umbilical cord blood or from some adult tissues.

4.2 Adult stem cell

Adult stem cells (ASCs) are undifferentiated cells within differentiated tissue. For example, in the bone marrow, hematopoietic stem cells continually create new blood cells. In the brain, very few stem cells seem to be able to generate some new nerve cells that make new connections when we learn or try to heal from injuries. Researchers have induced hematopoietic stem cells to give rise to liver cells, and it is the plasticity of hematopoietic stem cells that accounts for the success of bone marrow transplants.

Harvesting adult stem cells is more difficult than producing ESCs. Adult stem cells are rare and difficult to isolate in a pure form. Scientists have not been able to maintain adult stem cells in culture for indefinite time. Because they are somehow already engaged in a preliminary differentiation process, adult stem cells are not as plastic as embryonic stem cells, but they are already "poised to create a particular tissue" and can, in some cases, be able to migrate to injured areas, which may prove advantageous when the patient's injury or disease is localised. A potential advantage of using adult stem cells is that the patient's own cells could be in principle expanded in culture and then re-introduced into the patient, thus limiting the risks of rejection.

Unfortunately, this advantage would be useless in the case of genetic diseases where the patient's cells carry themselves the genetic defect.

4.3 Embryonic stem cell (ESCs)

ESCs are undifferentiated cells, found in the inner cell mass of the human blastocyst, an early stage of the developing embryo lasting from the 4th to 7th day after fertilisation. In normal embryonic development, ESCs disappear after the 7th day after fertilisation.

The human blastocyst has 30 to 150 cells. Contrary to the public perception, at this stage, the term "embryo" does refer to a tiny aggregate of undifferentiated cells, not a body with a head.

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2 American Association for the advancement of Science (non profit organisation)
3 Katherine Bourzac, Biology and Comparative Literature, University of Southern California, Journal of young investigators.
4 80% of rare diseases have a genetic origin
5 Katherine Bourzac, Biology and Comparative Literature, University of Southern California, Journal of young investigators
limbs or heart. It is a 0.14 millimetre sphere of cells with an inner cell mass. Each of the cells still has the potential to give rise to a complete embryo. It also has the potential to treat thousands of patients. As the embryo develops, its cells become more and more differentiated until each cell is completely specialised (e.g. into a liver, nerve or blood cell). They are not ESCs anymore.

ESCs have the most potential to lead to cures in regenerative medicine because, contrary to adult stem cells, they have demonstrated long-term self-renewal and pluripotency (each cell can differentiate into any tissue type in the body). Furthermore, adult stem cells are rare in mature tissues and efficient methods for expanding their numbers have not been found yet. Because of this intrinsic limitations, research on stem cells from adults and spontaneous abortions will proceed more slowly and be less likely to yield cures:

“Access to embryonic stem cells is likely to ultimately determine the rate at which scientists make progress in this field. In fact, the successful culture of postnatal and adult sources of stem cells for regenerative medicine is likely to advance more rapidly if the study of embryonic stem cells proceeds and cells from different sources can be compared” (National Academy of Science, 2001).

Research on embryonic stem cells is also necessary for rapid progress in research on embryonic germ and ASCs. Without optimal levels of ESC research, progress towards cures will be greatly retarded.

Current studies performed throughout the world in animal models already show that ESCs have the potential to treat neurodegenerative diseases, replace skin cells and other cell types. Research is still necessary to master culture and safety issues. The readily available, with an almost indefinite proliferative capacity, ESCs makes them a powerful biological base for the screening and development of new therapeutic drugs.

4.4 Cell nuclear replacement (CNR), known as therapeutic cloning

EURORDIS position paper is not about this technique which consists in removing and replacing the nucleus of an egg cell with the nucleus of another cell, usually from a somatic cell. EURORDIS does not support human cloning.

5. Co-existence of different ethical and religious viewpoints

In the debate on ESCs, EURORDIS believes it is important to have a broad picture of the different ethical and religious perspectives, without focusing on the ones which are the most present in the media.

For the debate on ESC research, it is also important to underline that, as shown below, the moment when human life starts, is the result of an arbitrary decision, based on religious/ethical convictions. Some religious communities believe the embryo is a full human from the moment of conception. Other religions take a developmental view, believing that the early embryo only gradually becomes a full human being and thus may not be entitled to the same moral protection as it will later. In this last view, “healing the sick”, curing a sick child or a sick adult, is a moral obligation.

EURORDIS represents patients and families with different religious/philosophical/ethical backgrounds and cannot consider any of these arbitrary decisions and viewpoints to be intrinsically better than the others.

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6 Katherine Bourzac, Biology and Comparative Literature, University of Southern California, Journal of young investigators
As it was done at the Conference on “Patients and Stem cells” (December 2005), where leaders from the major monotheistic religions were invited to present the official position of their religion, it is possible to summarise from a chronological perspective the main viewpoints as follows:

5.1 The Jewish Perspective

"Judaism has always encouraged scientific and medical advances. The practice of healing is not merely a profession - it is a mitzvah, a righteous obligation." Concerning ESC research, Jewish law considers the embryo as part of the mother's body until 40 days after fertilisation. Before 40 days, the embryo is not considered as a "human life". Furthermore, an embryo created in a Petri dish is not considered human because it is not implanted in the womb. Therefore, taking stem cells from a pre-implantation blastocyst is morally neutral. "From a Jewish perspective, we have a duty to proceed with that research."8

"Jewish law consists of biblical and rabbinic legislation. A good deal of rabbinic law consists of erecting fences to protect biblical law. (…) But a fence that prevents the cure of fatal diseases must not be erected, because the loss would be greater than the benefit. Mastery of nature for the benefit of those suffering from vital organ failure is a religious and moral obligation. Human embryonic stem cell research is considered as holding that promise, and therefore is encouraged by Jewish law."9. The moral imperative to pursue stem cell research is clear: it is an embodiment of the mitzvah of healing. Shulchan Aruch, Yorei De'ah 336:1: “Our tradition requires that we use all available knowledge to heal the ill, and when one delays in doing so, it is as if he has shed blood."10

5.2 The Christian Perspectives

5.2.1 Roman Catholicism

Within the Catholic tradition a case can be made both against and for ESC research, each dependent on the different interpretations of the moral status of the human embryos.

- A significant number of Catholics make the case against ESC research. In fact, the most widespread understanding of Catholicism absolutely condemns ESC research because "human life is a continuum from the one-cell stage to death." The argument is that human embryos must be protected on a par with human persons. An illustration of this viewpoint is represented by the recent remarks of Cardinal Alfonso López Trujillo, who heads the group that proposes family-related policy for the Church. He said in an interview with the Catholic weekly Famiglia Cristiana (29 June 2006) that stem cell researchers should be punished in the same way as women who have abortions and doctors who perform them. "Destroying an embryo is equivalent to abortion," said the cardinal. "Excommunication is valid for the women, the doctors and researchers who destroy embryos." The article affirms that, according to some experts, Cardinal Trujillo’s remarks raise the possibility that being involved in stem cell research might be added to the category of excommunication for acts deemed so serious that no verdict or judgement is required.

- According to Margaret A. Farley (Ph.D. Yale University), (…) “a case for ESC research is also made on the basis of positions developed within the Catholic tradition. A growing number of Catholic moral theologians do not consider the human embryo in its earliest stages to constitute an individualised human entity. In this view, the moral status of an embryo is not that of a person - and its use for certain kind of research can be justified. Those who would make this case argue for a return to the centuries-old Catholic position that a certain amount of development is necessary in

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7 Resolution on stem cell research, Union for reform Judaism
8 Rabbi Elliot N. Dorff, Ph.D. University of Judaism
9 Stem Cell Research in Jewish Law by Daniel Eisenberg, MD
10 Resolution on stem cell research, Union for reform Judaism
order for a conceptus to warrant personal status. Embryological studies show that fertilisation is itself a process (not a moment) and therefore provide support for the opinion that in its earliest stages (including the blastocyst stage) the embryo is not sufficiently individualised to bear the moral weight of personhood.  

5.2.2 Protestantism

Protestants' views are very varied and cover a wide range of opinions from the one calling to protect the embryo, "the weakest and least advantaged of our fellow human beings," to the other end of the spectrum where some opinion-makers in the Protestant Church are open to the use of cloning (somatic cell nuclear transfer) to create embryos for their stem cells.

It is therefore difficult to summarise this variety of positions, but from what we could gather Protestantism also rely on individual freedom of choice in this area.

5.3 The Muslim perspective

For Muslims, the debate that drives Catholic concerns is not pertinent because, according to Muslim Law, ensoulment (the moment at which a foetus receives a soul) does not occur until the fourth month of pregnancy. Therefore, modern Muslim opinions speak of a moment beyond the blastocyst stage when a foetus turns into a human being with moral status. Therefore, the embryo not being a person, ESC technology is morally neutral according to Muslim Law.

According to Abdulaziz Sachedina, Ph.D. (University of Virginia) - speaking for the Islamic tradition in general (embracing both Sunni and Shi'ite perspectives) - in Islam, research on stem cells made possible by biotechnical intervention in the early stages of life is regarded as an act of faith in the ultimate will of God, as long as such intervention is undertaken with the purpose of improving human health.

6. Public support for ESC research and Stem Cell Policies

6.1 Public opinion in the EU: the last Eurobarometer

In comparison to earlier surveys, the portrait of European citizens painted by the 2005 Eurobarometer "Europeans and biotechnology" shows EU citizens to be more optimistic about technology, more informed and more trusting of the biotechnology system. The European public is not risk-averse about technological innovations that are seen to promise tangible benefits. The Eurobarometer shows that most Europeans are in favour of medical applications of biotechnology when there are expected benefits for human health.

In particular, the Eurobarometer, which was published in June 2006, shows widespread support for medical biotechnologies, including considerable support to ESC research, provided that it is tightly regulated. In fact, a majority of EU citizens lean towards a utilitarian position on ESC research because there is an assumption of significant benefit. Only 9% "do not approve ESC research under any circumstances".

Among the countries in which approval for ESC research is highest are Belgium, Sweden, Denmark, Netherlands and Italy. In countries where approval is low -- Baltic States, Slovenia, Malta, Ireland and Portugal -- around 1 in 3 say they don't know. Another interesting feature is

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11 Roman Catholic views on research involving human ESCs, Testimony of Margaret A. Farley, Ph.D. Yale University (Ethical issues in Human Stem Cell Research, Volume III Religious Perspectives).
12 Federal Funding for Stem Cell Research? Imad-ad-Dean Ahmad, Ph.D.
13 Abdulaziz Sachedina, Ph.D.University of Virginia, Islamic Perspectives on Research with Human ESC
that, providing stem cell research is tightly regulated, an absolute majority approve ESC research in 15 countries, including Germany, Czech Republic and Spain.

6.2 Public opinion in the U.S.

A survey of 2,212 Americans conducted from the 9 to the 19 September 2005\textsuperscript{15}, reveals a public opinion landscape that bears little resemblance to the polarized, deep moral divide expressed on the floor of the Congress and in the op-ed pages of American newspapers.

The survey found wide support for ESC research that cut across political, religious and socio-economic lines, with two-thirds of respondents either approving or strongly approving of ESC research. Even Fundamentalist and Evangelical Christians - long considered to be the most hard-line opponents of ESC studies -- split evenly on approval for ESC research.

Respondents were given a choice of four ESC research policy options:

- Banning all ESC research;
- Retaining the current Bush administration policy;
- Relaxing restrictions along the lines of some Congressional proposals that would allow federal funding of research using ESC lines created using private funds;
- Allowing Federal support for ESC creation and research.

Twenty-two percent of respondents expressed support for the current Bush administration policy; fewer still (16 percent), would ban ESC research altogether. A majority favoured relaxing ESC restrictions, including 40 percent who would support federal funding for both the creation of new ESC lines and further research using them.

6.3 Stem Cell Policies world-wide

According to a study on “International Stem Cell Policies” made by the Genetics and Public Policy Center\textsuperscript{16}, countries representing about 3.5 billion people - more than half the world's population - have a permissive or flexible policy on human ESC research (see list of countries in Annex I). All these countries have banned human reproductive cloning.

7. Conclusions

7.1 The individual level

EURORDIS respects that people, at the individual level, may have strong (religion-driven or not) ethical concerns regarding the research on ESCs and may consequently decide to refuse a life-saving treatment because of it origins from ESCs.

7.2 The societal level

EURORDIS also strongly believes that, at the societal level, the temporary “protection” of pre-implanted human blastocysts must be balanced against the protection of human beings, both adults and children, who are currently in pain and are condemned to either a premature death or a lifetime of suffering, in the absence of effective therapies which may derive from ESC research.

\textsuperscript{15} Values in Conflict: Public Attitudes on Embryonic Stem Cell Research - Hudson KL, Scott J. and R Faden - Washington, DC: Genetics and Public Policy Center. The Center is supported at the Berman Bioethics Institute of Johns Hopkins University by The Pew Charitable Trusts.

\textsuperscript{16} Idem.
7.3 EU competitiveness

Concerning the efforts of our European researchers, EURORDIS fully agrees with Lord Rees, the President of the Royal Society, who appealed to EU Ministers attending the European Council on 24 July 2006 not to impose a blanket ban on the use of European funding for scientific and medical research on human ESCs. Lord Rees said: "Last week the United States decided to stay in the slow lane on SC research, hindering the global race to develop therapies that could benefit millions of people. It now appears that some countries wish to force the EU as well into the slow lane alongside the US. While a ban on the use of European Framework support would not prevent national funding for this research, it would still deliver another big blow to the hopes of patients worldwide. It may also encourage researchers to look outside the European Union to carry out important work on ESCs."17

7.4 Solidarity and equity

As a rare diseases patient organisation, EURORDIS considers that solidarity between humans must favour the ethical duty of “healing the sick” by also performing research on stem cells taken from human blastocysts - within the limits of tight regulation - in the whole of the European Union, bearing in mind the right to equal access to healthcare for all EU patients.

This Position Paper has been elaborated by the European Public Affairs Committee of EURORDIS.

It has been adopted by EURORDIS Board of Directors, on 6 September 2006, by:

- 11 votes in favour (Terkel Andersen, Danmarks Bløderforening – Denmark; Pierre Birambeau, Association Française contre les Myopathies – France; Suzana Díaz Rubiales, Asociación de Deficiencias de Crecimiento y Desarrollo – Spain; Jean Elie, Vaincre la Mucoviscidose – France; Torben Grønnebæk, Rare Disorders Denmark - Denmark; Marianna Lambrou, Tuberous Sclerosis Association of Greece - Greece; Flavio Minelli, Federazione Italiana Malattie Rare - Italy; Harald Niemann, Guillain-Barré-Syndrome Initiative e.V - Germany; Christel Nourissier, Alliance Maladies Rares - France; Anders Olausson, Agrenska - Sweden; Rosa Sanchez de Vega Asociación Española de Aniridia – Spain);

- 1 vote against (Andreas Reimann, Mukoviszidose - Germany);

- No abstention.

17 Royal Society, the UK’s National Academy of Science
Annex I - Countries with a “permissive” or “flexible” policy on human embryonic stem cell research 18

Population: M = million.

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<th>Country</th>
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<td>United Kingdom</td>
<td>59.2 M</td>
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“Permissive” = a permissive policy is intended as allowing various embryonic stem cell derivation techniques including somatic cell nuclear transfer (SCNT), also called research or therapeutic cloning. SCNT is the transfer of a cell nucleus from a somatic or body cell into an egg from which the nucleus has been removed.

These countries include United Kingdom, Belgium, Sweden, Iran, Israel, India, Singapore, China, Japan, South Korea, South Africa, and others. These countries represent a global population of more than 2.7 billion people.

"Flexible" = a flexible policy is intended as allowing derivations from fertility clinic donations only, excluding SCNT, and often under certain restrictions.

Countries in this category include Australia, Brazil, Canada, France, Spain, The Netherlands, Taiwan and others. These countries represent a global population of more than 700 million people.