This paper focuses on three main topics: first, the paradoxical divergence in contemporary Europe between public opinions and legislations; second, the significant diversity in national regulation of stem cell research within the European Union; and third, some of the ethical arguments and complexities that have emerged in the European debate on this issue.

1. A paradoxical situation in Europe

«A recent survey shows that European citizens are interested in science and eager to learn, but also that they want, more than ever before, to participate in defining the research agenda» (Ph. Busquin, in: EC, 2002).

The debate on new biotechnologies is very active within the European Union. It has been encouraged by the European Commission (EC). A striking feature is that public perceptions of the values of new biotechnologies appear to be very homogeneous throughout the Union, while legislations are extremely heterogeneous from one member state to another.

1.1. From 1991 to 2003 a series of five Eurobarometer surveys of public perceptions of biotechnology and the life sciences was financed by the EC. The surveys were based on a representative sample of 16500 respondents (around 1000 in each of the - then 15 - member states). They were conducted and analyzed by a group of methodologists at the London School of Economics. The main findings are:

---

-- Europeans are not technophobic. When asked whether biotechnologies will improve our way of life or not, 44% answers are optimistic, 17% are pessimistic, 25% don't know. This is in agreement with the fact that, since the Enlightenment, European culture has tended to take a positive approach to scientific development, and has taken it for granted that knowledge derived from science and technology will benefit society. In the late twentieth Century, however, major crises such as the transmission of aids through blood transfusion, or the outbreak of the mad cow disease and the suspicion of meat being a threat to human health, have raised doubts and induced more differential approaches.

-- The people surveyed draw a sharp distinction between different types of applications, being globally in favor of biomedical uses of biotechnologies, and against agricultural and food applications. When asked for their judgments about six applications of biotechnology (is it useful? risky? morally acceptable?), here is the answer. Genetic testing of inherited diseases, and the cloning of human cells for therapeutic purposes, are supported by a clear majority in all the 15 member states, even though cloning is also seen as a risk. The use of transgenic animals for xenotransplantation (e.g. raising ‘humanized pigs’ for kidney transplantation), and the use of genetically modified enzymes for the production of environmentally friendly soaps, are moderately supported by a majority of respondents in all member states. On the other hand, genetically modified crops, and genetically modified foods, are almost unanimously rejected (the opposition to GMOs increased over the period 1996-1999 and stabilized afterwards).

-- Educated people, urban dwellers, citizens younger than 55, are on the whole more supportive than the uneducated, the peasants, or senior citizens.

-- The ‘confidence index’ points in the same direction. 70% of Europeans have confidence in physicians, university scientists, consumer organizations, patient's associations. Less than 50% have confidence in industry (including agro-industry), scientists working for an industrial firm, and ... their own government.

1.2. The European Commission has been aware of the need to lay down foundations for all actors in Europe to assess the social implications of new biotechnologies, and get public support, especially with respect to the use of human embryos in research, stem cell research, and other related issues. Two Action Plans were put forward in 2001 and 2002, one on ‘Science and Society’, the other on ‘Life
Sciences and Biotechnology: a Strategy for Europe’. Commissioner Philippe Busquin, head of European research policy (1999-2004), convened a group of advisers, the ‘European Group on Life Sciences’. The Group was at the origin of several ‘visible events’, such as a public forum on stem cell research and the acceptability of developing human cell therapies (Brussels, 2001\(^2\)), and more recently a widely publicised encounter on the theme ‘Modern biology and visions of humanity’, between ‘hard’ scientists and artists, writers, philosophers, anthropologists, etc. (Genoa, 2004\(^3\)).

The EC has also collected comprehensive information on opinions and national legislations, in member states and in other countries, on human embryonic stem cell research and use\(^4\). In France the public debate has been recurrent, in the press, in Parliament, and within a variety of patient's associations. The association of families of children suffering from muscular dystrophy had a panel of citizens discuss the acceptability of financing research on therapeutic cloning aimed at finding new experimental ways of treating the disease\(^5\): their recommendations were all positive in favor of using embryonic stem cells and in favor of therapeutic cloning.

1.3. The European Group on Ethics (EGE) in Science and new Technologies to the European Commission issued several “opinions”: on human tissue banking (July 1998), on human embryo research (Nov. 1998), on ethical aspects of patenting inventions involving human stem cells (May 2002). It has collected very useful information on national regulations in the various European countries\(^6\).

---


Several national ethics committees have also contributed solid studies and carefully argued recommendations. Interestingly the Belgian and the Nordic Committees each have published divergent opinions (majority and minority), rather than a consensual one.

1.4. To sum up: the situation in Europe is paradoxical because there is a contrast between the relative homogeneity of public perceptions of stem cell research (from pragmatic acceptance to positive lobbying in favor of potential medical applications of stem cell research, including research on embryonic stem cell lines, and human cloning), and the extreme heterogeneity of regulations (from very permissive in England and Sweden, to total ban in Ireland, for example) together with the irreconcilable character of ethical arguments on which such regulations are based.

2. Diversity of national regulations

For the time being, there is no global European regulation on the use of stem cells. 15 countries are surveyed in the EGE's report. I shall concentrate on three cases, with a view to evidence a north-south gradient between (roughly) a more permissive northern Europe and a more restrictive southern Europe.

2.1. United Kingdom

The situation in the United Kingdom is both centralized and very liberal (actually, one of the most liberal in the world). The British have had the merit to define an articulate research policy very early with respect to medically assisted procreation, including the storage and use of human gametes and embryos. They also have proved able to adjust it, following new advances in biological research, when new technologies became available, such as the derivation of cell lines from embryonic stem cells, and the technique of nuclear transfer with a view to develop autologous transplantation. In the UK nothing is forbidden in principle, except reproductive cloning, but everything is done under the oversight of an

---


independent authority. The English model is deemed the best of possible models by a recent American report, which deplores the inconsistencies of the situation in the US\textsuperscript{9}.

The Human Fertilisation and Embryology Act (1990), based on the Warnock Committee's Report on Human Fertilisation and Embryology (1984\textsuperscript{10}) regulates the practice of assisted reproduction and embryo research. The Act sets up a statutory body, the Human Fertilisation and Embryology Authority, which supervises a licensing process (for treatments, storage or research). The 1990 Act was completed by the Human Fertilisation and Embryology (research purposes) Regulations (2001), which were drafted following the recommendations made by an Expert group\textsuperscript{11}. Under those Regulations, research on human embryos is permissible up to the 14th day of development (when the primitive streak appears). Research on embryonic stem cells (ES cells), therapeutic cloning, and the creation of embryos by somatic cell nuclear transfer, can be authorized for the following purposes: increasing knowledge about the human development process, about serious diseases, or about treatments for serious diseases. The Human Reproductive Act (2001) prohibits reproductive cloning. A Parliament's report gives an overview of British policies \textsuperscript{12}.

Much public debate in the UK was generated by patients' groups, such as the Parkinson's Disease Society and the Alzheimer's Disease Society\textsuperscript{13}. Bioethics reflection groups, such as the Nuffield Council, also contributed public reports\textsuperscript{14}. The debate goes on: the House of Lords issued a report in 2002, the Government response to the House of Lords was published in July 2002\textsuperscript{15}.

Although the Swedish legislation is not as explicit as the British legislation, the practical situation in Sweden is similar to the situation in England. There is a consensus that existing legislation permits embryonic stem cell research. According to the Act on Measures for Purposes of Research and Treatment Involving Human Ova (1991), in vivo embryo research is legally permitted until the 14th day after conception (after which the embryo must be destroyed). The Swedish Research Council

\textsuperscript{13} see: <www.parkinsons.org.uk> and <www.alzheimers.org.uk>.
published ethical guidelines for stem cell research in December 2001. The Swedish National Council on Medical Ethics published an opinion in 2002, the conclusions of which are that «stem cell research should be pursued on a broad front, with adult, foetal and embryonic stem cells»\textsuperscript{16}. The Council declared that such research «did not justify the creation of embryos solely for research purposes», and left open the question of nuclear transfer. However, the Parliamentary Committee on Genetic Integrity proposed in 2003 «not to implement a general prohibition against producing fertilised eggs for research purposes», and declared that «the creation of embryos by transfer of somatic cell nuclei should be treated in the same way and thus in principle be allowed».

2.2. Italy

Italy is an example of the restrictive situation which exists in the traditionally roman catholic southern Europe. In Italy, Spain, Portugal, the creation of embryos for purposes other than reproduction is forbidden, human cloning is banned, and no distinction is made between reproductive and therapeutic cloning. So far, however, southern Europe is less restrictive than traditionally roman catholic Ireland.

The most restrictive country in Europe for assisted human reproduction and human embryonic stem cell research is Ireland (an exception \textit{wrt.} the north-south gradient of permissivity). The Irish Constitution (1937, amended 1983) grants the unborn a ‘right to life’ equal to that of the mother: «\textit{The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.}». It is not clear, however, how the term ‘unborn’ should be interpreted. Should the Constitutional provision apply from the moment of conception, whether \textit{in vitro} or \textit{in vivo}, then embryo research and embryonic stem cell research are unconstitutional, as well as embryo freezing and even some contraceptive methods. Should the Constitutional provision apply from the implantation of the embryo into the womb, some research might be compatible with the current constitutional framework. The Irish Commission on assisted human reproduction was expected to report on this issue in 2003.


\textsuperscript{16} Swedish National Council on Medical Ethics, \textit{Statement of opinion on embryonic stem cell research}, 2002 01 17 <\texttt{www.smer.gov.se}>.
In Italy, up to 2003, there was no specific legislation governing research on embryos and on human embryonic stem cells. An Italian doctor had publicly claimed to be able to produce cloned babies. However, orders issued by the Ministry of Health for definite periods (reiterated several times) banned: the importation or exportation of human gametes and embryos; the commercialisation of human gametes and embryos; and all forms of cloning. On the other hand, the research on adult stem cells was strongly encouraged. The Italian National Bioethics Committee (created 1988) has found ethically acceptable to derive stem cells, for therapeutic or research purposes, from aborted fetuses (1996), and even from supernumerary or spare embryos donated in the course of medically assisted procreation (2000). In the latter case a minority of the NBC was against using such cells for research. The NBC considered the creation of human embryos for the purpose of research, and therapeutic cloning, to be morally unacceptable, although a minority of members wanted to evaluate the acceptability of somatic nuclear replacement on a case to case basis (1997, 2000). The NBC opposes reproductive cloning.\footnote{17}

A law\footnote{18} approved by the Italian Senate in December 2003, due to be ratified by the the Italian Chamber of Deputies in 2004, puts a ban on all research on human embryos, including the extraction of stem cells for research, or for preimplantation diagnosis. Freezing or storing human embryos for use in medically assisted procreation is also forbidden. (Yet the Ministry of Health had issued a report on banks conserving embryos and gametes.) According to the magazine Nature, the law «prompted an uproar from researchers and clinicians», but there may be a loophole for researchers, to the extent that «the law does not explicitly prevent Italian scientists from importing and using stem-cell lines created from spare embryos in other countries»\footnote{19}. That is precisely the loophole which has been explicitly permitted in Germany and in France.

2.3. France

The so-called French «bioethics laws» of 1994\footnote{20} strictly prohibited the use of human embryos for research: «Any experimentation on embryos is forbidden» (Art. 152-8 of the Public Health Code).

\footnote{17} Italian National Bioethics Committee: <www.palazzochigi.it/bioetica>
\footnote{20} Loi n° 94-548 du 01 07 94 relative au traitement de données nominatives ayant pour fin la recherche dans le domaine de la santé et modifiant la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés, Journal Officiel de la République Française (JO), 2 juillet 1994, 9559-60. Loi n° 94-653 du 29 07 94 relative au respect du corps humain, JO, 30 juillet 94, 11056-59. Loi n° 94-654 du 29 07 94 relative au don et à l'utilisation des
However the law 94-654 authorised studies with a medical aim, which do no harm to the embryo. According to that same law, surplus embryos produced during in vitro fertilisation may be frozen and stored for a maximum of five years. After this period, they must be destroyed (and cannot be used for research). Creating embryos for the sole purpose of research is explicitly prohibited (Art. 152-8). Harvesting stem cells from human embryos is obviously not permitted.

However, removing (living) cells from (dead) aborted fetuses, for the purpose of research or therapy, was permitted (transplantation of tissues removed from dead bodies has always been encouraged in France)\(^{21}\).

The 1994 laws provided for their revision every five years. The revision was delayed. A first version of the revised legislation was discussed in 2001-2002\(^{22}\), it was adopted by the French National Assembly in 2002, in the wait to be examined by the Senate. Due to the political calendar (elections, reversal of majority), another version came under discussion in Parliament in the Spring of 2004\(^{23}\). It has just been voted as this paper is being written (July 2004).

The current version authorizes the use of spare embryos for research (for a period of five years) and prohibits the creation of embryos by nuclear transfer, either for the purpose of scientific research and medical therapy (misdemeanor, offence), or for the purpose of reproduction (crime).

The French National Consultative Ethics Committee, the Academies of sciences and medicine, have issued statements in favor of the research on nuclear transfer, and emphasised the distinction between reproductive and therapeutic cloning\(^{24}\).

The situation in the Netherlands is roughly similar to the French situation. Medically assisted procreation, including the practice of freezing gametes and spare embryos, is permitted. There is a large resource of surplus embryos potentially available for research. The use of existing surplus embryos for scientific research is considered more acceptable than the production of new embryos specifically for

---


\(^{24}\) See above: note 7.
research. In the Netherlands the *Embryos Act* in 2002 authorized the first and prohibited the second. In both countries also, there have been warnings not to put too strong a ban on the possibility of research on nuclear transplants, and the derivation of embryonic cell lines from those transplants. Here is, for example, a common statement of both Academies of sciences: «Both the Academie des Sciences de l’Institut de France and the Royal Netherlands Academy of Arts and Sciences acknowledge the potential benefit of stem cells in therapy. They realise that more knowledge on embryonic stem cells and adult stem cells is needed. Provided measures are taken to avoid reproductive cloning and to protect female oocyte donors, both academies support therapeutic cloning»25 (Amsterdam, Nov 2001).

Germany is a special case. The German legislation is extremely protective of the human embryo. The use of embryos for a purpose other than preserving their life is prohibited by the Embryo Protection Act (1990). Harvesting human stem cells from an embryo, either for diagnosis, or for research, is unlawful. In 2002 however, the German Bundestag decided to authorize the research on imported embryonic cell lines. Since then, at least one German academic laboratory has imported cell lines from Israel for the purpose of research. The choice to prohibit deriving cell lines from human embryos on German soil, and authorise the use in Germany of cell lines derived elsewhere, has been much criticized. Note that, while the revision of the French law was lagging behind, at least one French laboratory was authorized to import embryonic cell lines from abroad.

3. Ethical complexities

Contrary to what has been the case in the USA, the debate on human stem cell research in Europe has not strongly or explicitly been connected with the debate on abortion, even though termination of pregnancy remains illegal in a few old (such as Ireland) or recent (such as Poland) members of the European Union. Rather, while the theoretical debate centered on the status of human embryos (in what sense do they deserve ‘respect’?), the European Forum of 2001 in Brussels26 evidenced a capacity of European citizens to pragmatically take into account the complexities of cases: «As one of the participants pointed out, there are only two ethical positions that can be considered unassailable in terms of rationale: 1) embryos are human beings, with a right to life, and should not be

---

25 Royal Netherlands Academy of Arts and Sciences & Académie des Sciences de l’Institut de France. *Bioethics and Health in International Context*. Amsterdam: Royal Academy, 2002; Appendix 1, ‘Resolution on the use of embryonic and adult stem cells’, 87-88.
used for research and treatment, and 2) embryos are balls of cells which cannot be considered to be human beings so their use for research and treatment is therefore acceptable. However, many participants expressed an intermediate view that the embryo deserves special respect as it has the potential to become a human being, but that embryonic stem cell research and therapy should be allowed, with careful regulation» (Brussels Forum, EC 2002, p. 26).

During the European Forum a Nordic philosopher tried to clarify the discussions around the use of human embryos (or human embryonic cells) for research and therapy. His analysis went like this: «Three ethical controversies can be identified: 1) Is destructive research on embryos, or any other destruction of embryos, wrong in itself because embryos have significant moral status? 2) Is there a problem in producing embryos solely for the purpose of destructive research (or in the future derivation of stem cells leading to the destruction of the embryo)? 3) Is reproductive cloning acceptable and, if it is, is there a danger of a ‘slippery slope’?» (Sören Holm, ibid).

Starting at the point of minimal controversy, I am unaware of any objection, moral, political, or ideological, to doing research on adult stem cells, or using them for medical treatment. If you get leukemia, you may be transplanted with your own bone marrow, or with some one else’s bone marrow, and that involves no ethical difficulty (provided the other person has consented). The problem with adult stem cells, is that their virtues may have been overestimated for ideological reasons in countries, such as Italy, where the research on embryonic stem cells was considered unethical.

As we come to human embryonic stem cells: some people will say that they were created for the purpose of procreation and it is unethical to divert them from their natural destiny, others will argue that there is a waste of embryos in natural (and in medically assisted) procreation, so that using the surplus embryos for research or therapy, rather than destroying them, is a way of linking them to, and giving them meaning within, the human community, and that is morally justifiable. You also find people who draw a moral distinction between the very first cell at the beginning of the organism (the fertilized egg, the totipotent cell), and the subsequent embryonic cells (e.g. of the human embryo at the blastocyst stage, those are pluripotent): totipotent cells have the potentiality to develop into a complete human being, while pluripotent cells by themselves have the potentiality to differentiate into all (over 200) human cell types, but they have individually lost the potential to yield a complete

---

26 See above: note 2.
organism - it would therefore be permissible to derive cell lines from those embryonic cells, and store them in cell banks for the purpose of cellular therapy. Another way of justifying the use of early embryos for research or therapy, is to argue that until day 14 the human embryo may still become two or more human beings, or abort, and it makes no sense granting ‘human rights’ to a bunch of cells which is assuredly human stuff, but which is certainly not an individual human being yet. Indeed, the Catholic Church used to adhere to the doctrine (coming from Aristotle) that it takes about three months for the embryo to take a human shape - or in religious words, that God waits until the end of the third month of pregnancy to insufflate a human soul in the developing fetus; such a doctrine would agree, in practice, with the claim (of supporters of an Ethics of the Good, who equate Good with enjoyment, and Evil with suffering) that neither termination of pregnancy, nor research followed by the destruction of the embryo, are objectionable prior to the time when the human fetus has developed a central nervous system which allows it to feel and react to suffering. Finally, a pragmatic ‘common sense’ argument, in countries where medically assisted procreation includes the freezing of spare embryos, is that after the couples have fulfilled their procreative needs, thousands of frozen embryos remain there unused, and that instrumentalizing them for the benefit of medical research or therapeutics is less evil than letting them melt and go down the sink: «We are using embryos that would otherwise be destroyed - we're not generating new embryos here» (John Sinden, *ibid.*, p. 20).

Would it then be a sin to generate *new embryos* for the purpose of research or therapy? New ‘embryos’ can be obtained by the technique of nuclear transfer (cloning), that is, by the replacement of the nucleus of an oocyte by the nucleus of a mature body cell. That such a technique can work in the human species, and that human embryonic stem cell lines can be derived from the ‘cloned’ blastocyst, has been evidenced by a Corean group of researchers in 200427. That such a technique might yield immunocompatible transplants for cell therapy of diabetes, paraplegia, neurodegenerative diseases, and other severe diseases, is a great hope for many researchers, physicians and patients. But what is the status of the cloned cell? Some people argue that, since it could possibly develop into a human being, were it transferred into a woman's womb, then it has the same dignity, and deserves the same respect, as any human embryo. Other people argue, on the contrary, that the cloned cell has a moral status more or less equivalent to that of an adult stem cell: it is a mere technical construct, not intended for human

---

procreation, far less dignified or precious than a natural embryo, and it appears ethically more acceptable to treat a patient with cells the nucleus of which comes from his own body (thus, immunocompatible with his own), than treating him/her with cells resected from aborted fetuses (which is currently done, and deemed acceptable, for example in the case of Parkinson's disease, at the cost of having the patient take immunosuppressant drugs for the rest of his/her life). But what about the oocyte donors? Here again there are contrasting opinions; con: «The harvesting of ovules leads to the instrumentalisation of women» (Brussels Forum, EC 2002, European Youth Alliance, p. 23); pro: «I'm not allowed to donate eggs, but sperm donors can earn money - that's the sort of protection of women I can do without» (a female participant, ibid.). Finally comes the ‘slippery slope’ argument: should we make therapeutic cloning permissible, then reproductive cloning would irresistibly follow; the argument is poor, because a cloned cell could hardly be put into a woman's womb by accident or distraction; putting a ban on reproductive cloning, if one chooses to do so, is clearly possible without prohibiting therapeutic cloning.

It may be conjectured that the ethical complexities of the public debate in Europe reflect a process of assimilation into our culture of advances in biological research that have a deep impact on our ‘vision of humanity’28. Moral sensivity can evolve. It takes time. During the European Forum of 2001, a participant expressed his rejection of any therapy for himself implying the destruction of a human embryo: «I prefer to remain paraplegic rather than to kill a human being to be able to walk» (Guillermo Juez, ibid., p. 21). Another participant welcomed such therapies, on account of the suffering they could alleviate: «Diabetes can be cured by transplantation of pancreatic islets [resected from dead donors]. The so-called Edmonton protocol is 100% successful, yet it requires two or three donors per patient. In Spain, this means that realistically only about 200 patients could be treated per year. This figure is very small compared to the number of potential candidates for transplantation: all of the 100,000 people suffering from type I diabetes and most of the two million patients with type II diabetes. This is why we are turning to stem cells» (Bernat Soria Escoms, ibid., p. 31).

_______________________

28 See above: note 3.