SCIENCE & ETHICS

OPINIONS ELABORATED BY THE BIOETHICS REFLEXION GROUP

Secretariat of the Commission of the Bishops' Conferences
of the European Community

Commission of the Bishops' Conferences
of the European Community
Rue Stévin, 42 – B-1000 Brussels – Belgium
Tel. +32 (0)2 235.05.10 – Fax +32 (0)2 230.33.34
comece@comece.org - www.comece.eu

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BIOETHICS DISCUSSION GROUP
OF THE SECRETARIAT OF COMECE

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INTRODUCTION

BIOETHICAL ISSUES AND THE EUROPEAN UNION - REFLECTIONS OVER A DECADE

It gives me great pleasure to hail the publication of the Opinions issued by the Bioethics Discussion Group of the Secretariat of the Commission of the Bishops' Conferences of the European Community (COMECE). Over a decade, this group elaborated 16 Opinions on a wide range of bioethical issues such as euthanasia, cloning, stem cell research, nanomedicine, patenting issues and organ donation. The members of the Group, from different EU member states, were chosen so as to provide for a multi- and inter-disciplinary exchange of views, combining theological, philosophical, ethical, legal, medical and other disciplines in the natural sciences. On a number of the subjects, specialists were invited to provide the Group with more specific knowledge.

The need for a thorough anthropological reflection on the implications of new technologies for humankind, on their impact on human identity, is evident. Indeed it has never been so urgent.

Many of these issues have been addressed with perspicacity and with wisdom by the Holy See. Its documents were consistently consulted and borne in mind by the Group members as they addressed issues arising from the EU agenda.

Institutions of public governance are ever more confronted with ethical issues arising in the biosciences as they seek to shape public policy. This is therefore true for Members of the European Parliament and of the European Commission, for European civil servants working in the EU institutions, and of course for those who advise them, and indeed, for those who represent related interests, be they research interests, pharmaceutical interests, financial interests. For these reasons, a Church forum at the EU level, where these emerging ethical issues could be examined with reference to the European Union and its institutions seemed necessary. Indeed, its

necessity was rendered more urgent by the rapid speed of scientific developments and also by virtue of the widespread prejudice suggesting that religion, and the Catholic Church in particular, were anti-research.

The major scientific advances in the biomedical sphere more than ever require sustained ethical reflection and discourse. The roots of conflicting ethical positions do not lie primarily in religious convictions, but in different anthropological worldviews. The fundamental questions at stake concern the future of humanity and such questions need adequate anthropological reflection. These issues have particular relevance for the concept of human dignity: an idea that, over the centuries, Christianity has developed in its complexity and which indeed has promoted the progress of science in Europe.

In the face of these developments, it is to be hoped that everyone - Christians, other believers, agnostics and atheists - would accept and engage in a serious dialogue. Such dialogue would not lead simply to decisions based on an over-simplified compromise between divergent interests, but they would consciously and transparently make justifiable choices for the benefit of mankind, seeking common ground for these fundamentally important technological advances.

It was in 1996, when the first meeting of the Bioethics Discussion Group took place at the Secretariat of COMECE, that the idea of a "working group" on bioethical issues took shape. The Group sought to provide for an exchange on emerging bioethical issues relevant to the European Union and its member states. On this basis, the Group presented over the past years the 16 Opinions brought together in this publication.

Mindful of the European Union's institutions and its officials, the Bishops of COMECE and the national Bishops' Conferences, these Opinions were elaborated in the context of the scientific data available at the time, and were duly made available.

I should like to thank the members of the Group for the expertise and the time they made available for the work of the Group, and for their readiness to undertake the preparation of these measured and judicious opinions. It was a joy and a pleasure to participate in the enlightening and lively debates upon which these opinions are based.

Together with the present members of the Group, I recall with affection the late Father Peter Jeffery and the late Father Edouard Boné who contributed enormously to our work, and who have crossed the threshold to eternal life. May they enjoy the full vision of God's glory. A particular word of thanks to two colleagues at the Secretariat for their exemplary work in coordinating the work of this group: Professor Silvio Marcus-Helmons and his successor Katharina Schauer.

I trust that the reader will find this collection of Opinions helpful and enlightening. May this work foster a climate of open dialogue and encourage science to pursue its course for the benefit of society and of mankind as a whole.

June 2008
Msgr. Noël Treanor
(Secretary General of COMECE)

ETHICAL ASPECTS OF ORGAN DONATION[1]

Meeting on 11 October 2007

The Bioethics Discussion Group of the Secretariat of the Commission of the Bishops' Conferences of the European Community (COMECE) read with great interest the Communication from the European Commission to the European Parliament and the Council entitled '***Organ donation and transplantation: Policy actions at European Union level***' dated 30 May 2007.[2] In it the European Commission explains a number of measures that it plans to take to guarantee the quality and safety of transplanted human organs, to fight organ trafficking and to "increase organ availability" (§ 1). Nobody would deny the importance of the first two objectives and the Bioethics Discussion Group fully acknowledges them. In addition, the Group highly commends the third objective of increasing organ availability, provided that it is pursued in a spirit of solidarity with persons who are suffering and with absolute respect for the persons concerned - both for those from whom it is planned to remove the organs and for their families. Provided that these conditions are met, the European Commission's recommendation to set up an effective organisation in each country that will be able to pinpoint potential 'donors', organise organ procurement, allocate organs equitably on the basis of patient needs, implement transplants and facilitate cooperation among the various countries, cannot fail to be fully endorsed.

The Bioethics Discussion Group stresses that organ donation must always be a donation made free of charge in a spirit of solidarity, that organ procurement must never be decided on financial grounds and that a human organ must never be considered or treated as a commodity. Moreover, the language used should avoid any

[1] This Opinion of the Bioethics Discussion Group refers solely to organ procurement for transplantation purposes. It is not concerned with organ procurement for research purposes (which should be the subject of a special study). The subject of tissue harvesting is touched upon only in passing.

[2] COM (2007) 275 of 30 May 2007: www.europarl.europa.eu/oeil/file.jsp?id=5531962.

commercial connotation; on the contrary, rather, it should reflect the spirit of solidarity.[3]

I. ORGAN PROCUREMENT FROM DECEASED PERSONS

"*We should rejoice that medicine, in its service of life, has found in organ transplantation a new way of serving the human family.*"[4] Pope John Paul II reiterated this strong approval on a number of occasions, while emphasising that, even after death, "*the human body is always a personal body, the body of a person.*"[5] This means that under no circumstances must a deceased person's body be considered as an object to be disposed of at will or simply as a source of organs and tissues to be ruthlessly exploited.[6]

Consent

It is common to use the term '*donor*' to refer to a person from whom organs are procured. This reflects the currently widespread conviction that no organ should be removed without there being a prior act of donation or at least not without the prior consent of the deceased person, the consent of those responsible for representing that person or in charge of the custody of his or her body after death.

In Europe, the required form of consent varies according to the differing *rationales* of national legislation. In some countries, this consent must be given explicitly by the person from whom it is proposed to procure organs; failing that, the family is approached. Obviously it is important for consent to be given freely and knowingly. In other countries, consent is 'presumed' if the person did not oppose organ procurement during his or her lifetime. Should this 'presumed consent' principle be rigidly applied, it could permit the supposition that doctors are totally at liberty to procure organs as

[3] The European Commission Communication makes several mentions of the term 'supply and demand' for organs, borrowed from business terminology. It would be better to use systematically the terms 'organ donation' and 'need for organs'.

[4] Pope John Paul II, Address to the Participants of the First International Congress of the *Society for Organ Sharing* on 20 June 1991, § 1.

[5] Ibidem, § 4.

[6] See the address of Pope Pius XII to the Delegates of the Italian Association of Cornea Donors and to Clinical Oculists and Legal Medical Practitioners on 13 May 1956, and the addresses of Pope John Paul II on 14 December 1989 to a working group of the Pontifical Academy of Sciences, on 20 June 1991 (op. cit.) and on 29 August 2000 to the 18th International Congress of the Transplantation Society.

long as they are not aware of the deceased person's prior refusal to be a donor.

Ambiguities of the 'presumed consent' system

The potential inflexibility of the presumed consent (or 'opting out') system is corrected or averted in a number of countries by a common practice among doctors of entering into dialogue with the family in cases where they are not aware of the deceased person's prior wishes. Furthermore, this contact with the family is provided for by some national laws, if only to inquire what views the deceased person may have expressed to his or her relatives. This means that doctors frequently have to accept a family's possible refusal. In this way they take account of the trauma that may be caused to relatives by interference with the integrity of a loved one's body and they show respect for the bond between the deceased person and his or her family, treasured by immemorial tradition. Moreover, this is what led the French Bishops' Conference to state firmly: "*It would be inhumane to procure organs in cases where the family is opposed or has expressed strong aversion, acute distress, or has no prior knowledge.*"[7] This applies especially where children, or more generally young people under the age of majority are involved. Clearly, the explicit consent of the parents is required in such cases.

Conversely, any '*opting out*' organ-procurement system which is applied so rigidly that it allows the medical profession to remove organs from deceased persons who have not previously made known their refusal - by such means as computerised national registers - would be profoundly questionable. For the notion of 'presumed consent' to be meaningful, the public must have been duly informed, as soon as persons reach the age of majority! However, in countries where surveys have been conducted, they have revealed that the public is either unaware or does not understand the rationale of '*silence gives consent*'.[8] It is therefore fundamentally deceitful to rely solely on alleged 'presumed consent'.

[7] Statement by the Permanent Council of the French Bishops' Conference, *Solidarité et Respect des Personnes dans les Greffes de Tissus et d'Organes*, 12 October 1993, *Documents-Episcopat*, no. 15, October 1993, unofficial English translation.

[8] In Hungary, for example, the 'opting-out' system has been in force since 1998. However, in 2003, only 42% of the general public knew about the legal regulation. Cf. Szántó Zs et al: LAM

Raising public awareness

However, respect for deceased persons from whom organs are procured and for their families is not incompatible with concern for those awaiting a transplant. In its Communication, the European Commission calls for increased public awareness. It rightly states: "*Organ donation and transplantation are medical treatments that require the full participation of society for their development*" (§ 3.2.2.). Indeed, it will only be possible to increase organ procurement and to guarantee a high level of availability if doctors feel that they are supported by widespread agreement in society as well as by the agreement of the people directly concerned.

The Catholic Church is ready to participate in this effort to raise awareness of the needs of persons waiting for a transplant and to invite the public to agree to the *post-mortem* removal of tissues and organs, from one's own or a relative's body, provided that this is carried out with absolute respect for human dignity and the rights of the persons concerned. Indeed, the Church has not waited to be approached by public authorities. As early as 1956, Pope Pius XII stated: "*The public needs to be educated, and people should be informed, in an intelligent and respectful manner, that explicit or tacit consent to an infringement of the integrity of a dead body, for the benefit of ill persons, does not offend the reverence due to the deceased person, provided that there are valid reasons for such interferences with the body. All the same, this consent may inflict suffering and involve sacrifice for the relatives, but this sacrifice is blessed by compassion for our suffering brothers.*"[9] Pope John Paul II placed more emphasis on the consent of the 'donors' themselves when he stated in 1991: "*But to offer in life a part of one's body, an offering which will become effective only after death, is already in many cases an act of great love, the love which gives life to others.*"[10]

To facilitate the support that we wish to have in European societies and from citizens, the public must be informed honestly about the facts of organ procurement, the precautions taken to respect the body

2004; 14(89):620-6 (article written in Hungarian, cited by Anikó Smudla MD; Katalin Hegedüs Ph.D., Semmelweis University, Institute of Behavioural Studies, Budapest).

[9] Pope Pius XII, address of 13 May 1956, op. cit. (unofficial English translation).

[10] Pope John Paul II, address of 20 June 1991, op. cit., § 3.

of the deceased and the importance of transplants for ill people. It is also important to invite people to discuss these issues. The European Commission's Communication states that "*continued education should form an essential element of any communication strategy. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives*" (§ 3.2.2.). Indeed, a European Eurobarometer survey revealed a strong correlation between the fact of having discussed organ donation within the family and the acceptance of organ removal by potential donors themselves and by their families.[11]

A number of Bishops' Conferences have already made appeals for reflection and for discussions within families, parishes, movements, schools, universities and youth chaplaincies. Such initiatives could be multiplied, inviting every individual, irrespective of age, to consider their own death and the service which they could render to sick people by organ donation. Depending on different national legislations, this could mean completing a 'donor card' or stating before witnesses that one does not object to having organs removed.

For the Catholic Church, only such personal consent, or at least the tacit and legitimate acceptance by the duly-informed relatives, - and for exceptionally important purposes - justifies the infringement of the integrity of the body after death. As much as it is legitimate to 'invite' people to agree to such infringements, it would therefore be questionable to make it a civil or moral duty.

Respect for the deceased person and for his or her family and offering the necessary support

In most cases, vital organs can only be procured for transplantation purposes when death has occurred under specific circumstances that are particularly shattering for the family. In such cases, the death has usually been nasty and unexpected. The grieving family must therefore be listened to and relatives must be allowed to raise any questions that are troubling them. The family, should they so request, must be given the necessary information about the reality of the death and the conditions under which organs would be procured. They must therefore be given time. It would be inhumane to

[11] Cf. *Europeans and Organ Donation*, Report commissioned by the European Commission, Special Eurobarometer 272, May 2007.

pressurise the family, force their consent and obtain the organs with inappropriate haste. Some countries fully understand this and have set up special services to coordinate organ procurement and family counselling. It is desirable to provide relatives with psychological, spiritual and religious support from trained personnel where necessary.

Obviously procurement procedures must respect the dignity of the human body, even after death. The body's visible appearance must be altered as little as possible and should be restored to its original state, as far as is possible. This also raises the issue of limiting the amount of tissues and organs procured from a single body. It is unacceptable to consider the human body as merely a source of tissues and organs to be exploited as required. Many countries facilitate organisational arrangements by procuring from a single body not only the vital organs but also tissues such as the skin and cornea. Families may well regard this as beyond the limits of what is bearable. The possibility of allowing donors or their families to limit the number of body parts to be removed should therefore be considered. In general, it would be wise to limit the number of organs taken from a single body. Except in cases where deceased people had announced their intention to donate most of their body parts while they were still alive, or in cases where the family gives its explicit agreement to such multiple procurement, it may be desirable to avoid removing tissues from bodies from which vital organs have already been taken.

Confirmation of death

Clearly it is essential for every country to take the necessary measures to ensure that organs are removed only when death has been duly confirmed in line with recognised criteria. Before organs are procured, it is normal for the declaration of death to be based, not on a cardio-respiratory criterion (the total and irreversible cessation of circulatory and respiratory functions) but on a neurological criterion (complete and irreversible cessation of all brain activity – referred to as 'brain-stem death' or "whole-brain death"[12]). After wide-ranging debate, the Catholic Church pronounced its explicit

[12] Although Great Britain recognises a different criterion, it doubtless arrives at the same conclusion of brain-stem death, or total and irreversible cessation of all activity in the brain stem.

opinion on this matter. On 14th December 1989, Pope John Paul II urged scientists, moralists, philosophers and theologians to continue their research.[13] On 29th August 2000, he affirmed that doctors could use the neurological criterion defined above to confirm that death had indeed occurred.[14] The German Bishops' Conference had already reached this conclusion in August 1990.[15]

There exists a range of indicators that prove that the neurological criterion has been met. Such signs may evolve in step with advances in knowledge and in research techniques. For instance, some countries have proposed replacing the recording of electrical impulses in the brain with an alternative examination. However, it is important for individual countries to determine and compel compliance with a coherent and adequate range of indicators that must be present before death can be confirmed, and for them to ensure strict compliance with such rules.

A deceased person's family may find it very difficult to believe that their close relative is really dead. Oftentimes their death occurred unexpectedly and, because they are on life support, they look as though they are still alive (their chest continues to rise and fall, their heart beats and their body heat is maintained etc). The family is therefore entitled to express their distress and to raise questions, to be listened to attentively, and to receive patient and appropriate replies.

II. LIVING ORGAN DONATIONS

It is also possible to procure organs or tissues from the living. Procurement is acceptable only where the risks to the donor are low and reasonably proportionate to the expected benefits for the recipient. It is also important to be able to guarantee the quality of the information which has been provided on organ procurement, its risks and its constraints, as well as the free consent of the donor. This rules out organ procurement from minors or from legally incompetent adults. However, the very fact that a close relative is suffering from a serious illness, or the attitude of family members, can also exert strong pressures on the person whose tissue is judged

[13] Cf. Pope John Paul II, address of 14 December 1989, op. cit.

[14] Cf. Pope John Paul II, address of 29 August 2000, op. cit.

[15] *Organ transplantations*, Joint Declaration by the German Bishops' Conference and the Council of the German Protestant Church, 31 August 1990.

to be the most compatible with the person awaiting a transplant. It may be desirable to have the intervention of a judge or of a specially-appointed expert committee in order to guarantee, as far as is possible, this freedom of consent.

Owing to the increase in medical conditions suitable for organ transplants and to the small number of deceased people from whom organ procurement can be considered, there is in a number of countries a trend towards the expansion of organ procurement from living people who generously donate a kidney, or even part of a unique organ, such as the liver.[16] This raises the issue of expanding the circle of people entitled to act as donors. Countries that accept only an ill person's parents or grandparents, descendants, brothers and sisters as living donors have come to accept more distant relatives. It has even been suggested that unrelated living donors, known as 'altruistic' organ donors, be accepted. Such generous donations are only to be welcomed, provided that they are offered freely in an informed and disinterested manner. It is essential to ensure that such generosity does not mask a system of organ trafficking based on exploiting the destitute.

In 1990, the German Bishops' Conference declared: "*From a Christian standpoint, there is no fundamental objection to voluntary organ donation. Any hesitation stems solely from the possibility of abuse (such as trade in organs). According to Christian belief, life, and hence the body, is a gift from God which individuals may not dispose of as they please but which, after having carefully examined their consciences, they may use out of love for their fellow human beings.*"[17] In 1991, Pope John Paul II considered it an act of great generosity if people decide "*freely and consciously (...) to give a part of themselves, a part of their own body, in order to save the life of another human being*".[18] However, the Pope qualified this by saying: "*A person can only donate that of which he can deprive himself*

[16] This is not concerned with the procurement of bone marrow or blood because such tissues are renewable and relatively easy to procure.

[17] *Organ transplantations*, Joint Declaration by the German Bishops' Conference and Council of the German Protestant Church (EKD), op. cit. (unofficial English translation).

[18] Pope John Paul II, address of 20 June 1991, op. cit., § 3.

without serious harm to his own life or personal identity, and for a just and proportionate reason."[19]

Such endorsements for living donations are accompanied by reservations. Living donations are valid only for 'donations', which are, by definition, free of charge, freely given and made in full knowledge of all the issues involved: thus, after full information of the benefits for the recipient and of the constraints and risks for the donor. However, such apparent generosity may conceal a very different picture: in particular a lucrative trade in human body parts and the exploitation of the poverty of people who cannot find other means of providing for their own, and their family's needs. To prevent such trade in body parts, most national legislations recognise as potential donors only people in the organ recipient's family circle (defined more or less narrowly from country to country).

Indeed, it is this concept of organ 'donation' that many countries have accepted and organised and the Church has approved. The notion of donation implies that it is free of charge. It would be contrary to human dignity to turn body parts into a commodity that can be bought and sold. However, this does not rule out donors from receiving compensation for actual expenses that they have incurred.

III. CONCLUSIONS

Seen from this standpoint, organ donation and transplantation[20] represent both a genuine medical success story and an eloquent form of the kind of solidarity so necessary in our societies in order to keep alive their sense of human kinship. There are many people awaiting transplants. Nevertheless, this does not give them the right to someone else's body. Even after death, the human body is not an object for ill people or society to use. However, society is fully entitled to organise organ procurement in a way that respects the spirit of 'donation' and raises public awareness of the needs of

[19] Ibidem, § 4.

[20] The present Opinion deals essentially with questions related to the procurement of organs for transplantation. Many patients, for whom transplantation represents a real hope of staying alive or gaining a better quality of life, wait anxiously for an organ transplant. But, in most cases there remains the risk of rejection of the transplant; this requires immunosuppressive drug treatment which is itself not without secondary effects. Hence, transplantation has little to do with genuine recovery. It is therefore essential to pursue research into getting better control over the phenomenon of rejection.

people with a failing body organ. It is legitimate for society to invite all individuals to demonstrate their generosity by consenting to an infringement of the bodily integrity of their relatives after death, or of their own body, either after death or perhaps during their lifetime.

The Catholic Church has on many occasions openly declared itself in favour of what can with honesty be termed organ 'donation'. It could doubtless make an even greater contribution by playing a more active role in raising public awareness within its numerous communities and institutions in the various European countries. It might be useful to study this issue within the Commission of the Bishops' Conferences itself.

English translation from the original (French) version

THE CREATION OF HUMAN-ANIMAL ORGANISMS (HYBRIDS AND CHIMERAS) – AN OPINION ON ANTROPOLOGICAL AND ETHICAL ISSUES

Meeting on 1 March 2007

Humanity has long been fascinated by the idea of crossing the border that separates man from animal. Antiquity imagined many fabulous monsters, sphinxes, minotaurs, centaurs…, a human head and an animal body or the reverse. These "chimera" were attributed with human and superhuman capacities. On a more realistic level, man has succeeded in breeding "hybrids" such as the hinny, a crossbreed of two animal species, the horse and the donkey. Today it is becoming technically feasible to create mixed human-animal organisms, which inevitably raise serious anthropological and ethical issues. The question has been very specifically raised in view of the creation of hybrid beings by transferring a human cell's nucleus (through "cloning") into a bovine egg cell.

I. PRELIMINARY SCIENTIFIC CONSIDERATIONS

1. Hybrids

In Great Britain, scientists are currently studying the possibility of creating human-animal organisms in order to advance research on embryonic stem cells and their embryonic development. This research path is probably motivated by the difficulty associated with obtaining a sufficient quantity of human egg cells and/or human embryos. It could also be linked to the ethical reservations of other European countries concerning the use of human embryos for the creation of human embryonic stem cells – or it may be based on scientific curiosity in general.

Such human-animal organisms have already been created in the form of bovine-human[21] and rabbit-human[22] hybrids. For these experiments, the

[21] Kyung H. Chang et al., *An optimised protocol of a human-to cattle interspecies somatic cell nuclear transfer*, in: Fertility and sterility 82 (4), October 2004, 960-962.

[22] Yiwu Chen et al., *Embryonic stem cells generated by nuclear transfer of human somatic nuclei into rabbit oocytes*, in: Cell Research (2003); 13 (4), 251-264, see p. 262.

cloning method by which Dolly the sheep was created, was used to implant a human cell nucleus into an animal egg cell which had previously been enucleated. These clones, also called "cybrids" (a fusion between the term "cytoplasm" and "hybrid"), were able to develop over several days. They were made up of 99.9% of human genes and 0.1% of the genetic material contained in the DNA of the mitochondria of the animal egg cell. Thus, every cell contains a mixed genome. (From a semantic viewpoint, there is reason to question whether or not the term "cybrid" conceals the fact that the organism in question could be considered as a human embryo, by reason of its human nucleic genome and its capacity to develop.)

In any case, these organisms can only be used for research purposes. Due to being part animal, their use for therapeutic purposes would not respect the directives on Good Clinical Practice. When it comes to the interest in such experiments from a scientific angle, the question arises: what knowledge will it be possible to gain from them?

One can also imagine the creation of a hybrid created, not by cloning, but by fusing human sperm with an animal egg cell, so as to "create" a truly new life form, like the hinny in relation to the horse and the donkey. Such an intermediate organism between man and animal - with the intention of letting it develop - has (probably) not yet been created. Indeed, until recently we still resorted to fusing human sperm with the egg cells of a hamster in order to test the capacity of the sperm to penetrate the egg. But the development of such entities has apparently not yet been researched and it would, without a doubt, be impossible.

2. Chimeras

In hybrids the genome of every cell is mixed as they come from different species, whereas chimeras are composed of cells, and even tissues and organs of different genotypes, without a mixture of genomes. Chimeras exist naturally, even in the human species, in the case of a spontaneous fusion of two embryos at the very beginning of their development. More frequently, they are the result of human inventiveness.

For example, cerebral cells of a quail were implanted into the cerebral structures of a developing chicken. Following this implantation, the chicken, during its growth, began to make sounds similar to those of

quails.[23] It became clear that parts of the quail's brain had effectively been integrated into the chicken brain. The more immature the immune system of a given organism is (in the foetal stage, and even more so in the embryonic stage), the more easily foreign cells are integrated.

In this way it is also possible to bring about certain forms of human-animal combinations.[24] For example hematopic human cells from embryonic stem cells have been implanted into embryos/foetuses of sheep (and perhaps other animals as well). In the end the sheep born as a result of this experiment contained a certain percentage of human cells.[25] One wonders what were the objectives of these experiments. One cannot exclude the possibility, for example, that in the course of the development of these sheep embryos, human organs such as livers or kidneys could be developed, along with the possibility of forming human sperm and human egg cells which would raise serious objections.

Organisms, in which foreign cells or organs have been implanted at the adult stage, are also chimeras as in the case of the transplantation of bone marrow or organs. Due to the maturity of the immune system, this transplantation between individuals of the same species can only succeed with the help of immune suppressive treatment. Thanks to the progress made in this area, transplantation of human organs such as the kidney, the liver, the heart, or of bone marrow, are regularly carried out on human beings and have become effective therapies. Even if the transplantation of animal organs to humans has not yet resulted in long-term success (in spite of quite elevated survival rates in the short term), the transplantation of animal "material" into the human organism (xenotransplantation) is in principle possible. The transplantation of pig

[23] See also for the year 1988: Evan Balaban, Marie-Aimée Teillet, Nicole le Dourin, *Application of the quail-chicken chimera system to the study of brain development and behavior*, Science, Vol 241, 9 September 1988, 1339-1342.

[24] Tara L. Seyfer, *An overview of chimeras and hybrids*, The National Bioethics Catholic Quarterly (Spring 2006), 37-49; Sr. Renée Mirkes, O.S.F., *Is it ethical to generate human-animal chimeras?*, ibid., 109-130; Nicanor Pier Giorgio Austriaco, O.P., *How to navigate species boundaries. A reply to the American Journal of Bioethics*, ibid., 61-71; Marilyn E Coors, *Considering chimeras. The confluence of genetic engineering and ethics*, ibid., 75-87; Thomas Berg, L.C., *Human brain cells in animal brains. Philosophical and moral considerations*, ibid., 89-107; Phillip Karpowicz/Cynthia B. Cohen, and Derek van der Kooy, *Developing human-nonhuman chimeras in human stem cell Research: Ethical issues and boundaries*, Kennedy Institute of Ethics Journal 15.2 (June 2005) 107-134; Karpowicz/Cohen/van der Kooy, *It is ethical to transplant human stem cells into nonhuman embryos*, Nature medicine Vol. 10, No 4, (April 2004) 331-335.

[25] AD Narayan, JL Chase, RL Lewis a.o., *Human embryonic stem cell-derived hematopoietic cells are capable of engrafting primary as well as secondary fetal sheep recipients*, Blood, 1 March 2006, 107 (5), 2180-2183.

valves is frequently carried out on human beings. Yet the tissue is not vascular. Transplantation from one species to another of vascular tissue and, even more so of organs, clashes with the phenomena of rejection which cannot as yet be controlled.

Other living organisms carry foreign "material" in them if a gene or a chromosome of a different species has been introduced into their cells. However, these organisms are more frequently classified as "transgenic" organisms. This is the classification used to describe those bacteria in which the genome is modified by the transfer of a human gene so that they will produce human insulin; or in the case of mice which for research reasons have had cancer genes, other genes or even full chromosomes, introduced.

II. ANTHROPOLOGICAL AND ETHICAL QUESTIONS

The great diversity of experiments and innovations outlined above require nuanced examination. The anthropological challenges and the ethical questions can be very different according to the diverse characteristics of these experiments. In particular, it is advisable to differentiate between the introduction of an animal element into a human being (we shall call them "human chimera"), and the introduction of a human element into an animal (we shall use the expression "animal chimera"), and, furthermore, the creation of a real human-animal hybrid.

It is, moreover, appropriate to distinguish between the circumstances surrounding the transplant: whether the transplant will be practised on an adult person or animal, or on an embryo or a foetus; what kinds of genes or cells are implanted (for example, cerebral cells or heart cells?); and in the case of the transplantation of human tissues or cells, into which animals will they be implanted? (transplanting cerebral human cells into the brain of a monkey cannot be treated in the same way as their being transplanted into mice, due to the closeness of monkeys to mankind and to their cognitive capacities); and whether a new kind of living organism will be created.

It is also necessary to examine the scientific and therapeutic interests of the different kinds of research, as well as the risks which they entail, and their acceptability from the point of view of human dignity. Certain experiments are presented as fundamental for the future of humanity and for the treatment of severe illnesses which are currently without a cure. Wisdom and prudence require verifying the relevance of these

assertions. This will lead in most cases to very nuanced answers which allow for the development of ethical deliberations in a more dispassionate climate. In this way one can question their usefulness for human therapy on the basis of research results for "cybrids", given the differences in genome and cytoplasm between cybrids and human cells.

1. Human Chimera

When it comes to the introduction of an animal element into a human being, one will have to examine first of all the expected benefits for the person on whom this experiment is carried out, but also the disadvantages and foreseeable risks, as well as the risks for mankind as a whole. The usual rules regarding information and for the appraisal of informed consent must equally be respected.

In March 1999, the Bioethics Discussion Group wrote with regard to the transplantation of animal tissues and organs on humans:[26]

"*Xenotransplantation also raises questions concerning the relationship between humans and animals that have not yet been adequately explored.*

Unforeseen reactions have already been observed concerning allografts between humans. Problems of identity or possible violation of the "spiritual personality" could arise as transplants expand to cover the organs with a greater sentimental or emotional charge. Experience acquired in this field does not allow us to underestimate the changes in behaviour and the new, specific and unexpected relationships that may form between the human donor and the human recipient. The human being has an intrinsic spiritual dimension and thus is susceptible to develop problems with his or her sense of identity.

We cannot predict how human beings will tolerate the substitution of vital organs from animals for their own organs. The reaction will probably be different in cases of organs, tissue, cells and biotechnological devices. Furthermore, one might well wonder how a person could preserve the sense of his own identity and unity.

More generally, it is noteworthy that the relationship between animals and humans plays a role in how humans understand themselves. The use of animals not only as food, but also as an integral part of the human body, therefore poses anthropological questions that are of the greatest importance to explore."

[26] Opinion of the Bioethics Discussion Group of the Secretariat of COMECE, *Xenotransplantation*, 4 March 1999.

The emphasis was placed on the repercussions that xenotransplantation could have on an individual's perception of his or her identity. The meaning of identity could be endangered by the introduction of certain elements of animal origin, especially in the brain and in the reproductive organs.

In the last 10 years there has been hardly any progress in the area of xenotransplantation. This Bioethics Discussion Group continues to uphold the Opinion it expressed in 1999. It reiterates its call to reflect and be prudent, without formulating a principled objection in regard to respect for the person. The declaration of the Pontifical Academy for Life dated 26 September 2001 contains the following conclusions: ««"*When the moment arrives, it will be ethically correct, respecting the rules of informed consent indicated above, to involve initially only a restricted group of patients, patients who cannot be chosen - in the given circumstances - for allotransplantation*[27] *(whether because of waiting lists or individual counter-indications), and for whom no better alternative treatment is available.*"[28]

The same declaration of the Pontifical Academy calls for a rigorous medical follow-up of persons who have benefited from xenotransplantation, in order to detect as soon as possible any sign of infection by means of an unknown pathogen agent. Indeed, in the case of xenotransplantation, scientists emphasise the great uncertainty which there is with regard to the eventual transmission of viruses of animal origin to human beings; and notably of retroviruses integrated in the animal genome. It is for this reason that public health authorities all across the world encourage prudence.

When it comes to the introduction of an animal element into a developing human being and in particular into a human embryo (in vitro), one can hardly see any benefits to be gained for that human being. Such an undertaking, carried out for a purely scientific aim, would transform the human embryo into pure research material, and

[27] The term allotransplantation describes the transplantation of a tissue or an organ of an individual of one species to another individual of the same species. In fact, it is about cases where transplantation between humans has become impossible for different reasons.

[28] Pontifical Academy for Life, *Prospects for Xenotransplantation. Scientific Aspects and Ethical Considerations*, 26 September 2001.

would therefore need to be banned completely, even if one suspects positive developments at a later date in the area of general knowledge.

2. Animal Chimera

The introduction of human elements into different biological species, which has been practised for some time, has in many cases had great benefits for humanity. Genetic engineering applies to the transfer of human genes to bacteria, to plants or to animals in order to produce human proteins and vaccines in industrial quantities. One can equally imagine the transplantation of human cells into an animal for research purposes, but such *praxis* poses more or less serious questions depending on the cells and tissues transferred and their effects on the animal.

Since the transplantation of certain cerebral cells has resulted in animals acquiring the functions of other animals, one has to question the legitimacy of the transfer of human neurons to animals, if this were to mean the transfer to animals of capacities specific to mankind. There exist reports which emphasise the aversion many people have expressed for such a perspective, given the problems which would result for the uniqueness of mankind in relation to other animals.[29]

Considerable prudence is also required when it comes to the transfer of human stem cells to animals which could produce a modification to their brains or their reproductive organs, possibly leading to the production of human gametes. Even greater prudence is necessary with regard to the introduction of human stem cells or genes into an animal embryo.

At all times in animal experiments there has to be concern for the animal and its well-being, as well as raising questions regarding the objectives being pursued. Animals should only be subjected to research for the benefit of mankind in situations where there are important benefits which must be evaluated by the relevant authorities.[30]

[29] Report of the Scottish Council on Bioethics: *Embryonic, Fetal and Post-natal Animal-Human Mixtures: An Ethical Discussion*, http://www.schb.org.uk/.

[30] See recital 45 of the European Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

3. Hybrids

When it comes to hybrids, we need first to distinguish between hybrids in the classical sense which constitute a living species different from the species created by two genitors (such as the hinny), and secondly, what some propose calling "cybrids", i.e. an entity obtained by the transfer of a somatic nucleus cell of one species into the enucleated egg cell of another species (like the transfer of a human nucleus into the egg cell of a cow or a rabbit).

Research into and creation of hybrid human-animal beings, if that were ever to be feasible, must be strongly disapproved. These beings would create a major dilemma, due to the doubt which would surround the nature of this intermediate between man and animal obtained in this manner, and concerning the degree of respect to be owed to it. It would without any doubt have human capacities, but would not be the son or daughter of two human beings. Yet the link between a human being and his or her biological parents is fundamental to his or her identity as a human person.[31] There are some who seem to support such a perspective in order to legitimise experiments which would be prohibited on human beings. Yet such hybrids would not only be close to man, but they would be more or less part of humanity. To use them as pure research objects would therefore be inadmissible, and would represent an assault against humanity.

What is more, the creation of such intermediate beings would severely challenge the singularity of man vis-à-vis other living beings, and the dignity which we affirm must be attributed to man.[32] Yet, we find ourselves in an epoch where Western cultures display a tendency to relativist notions of human specificity, where man's intrinsic nature is brought into question and where the border between man and animal is sometimes denied (for example it is argued that the great similarity which exists between the genomes invalidates the fundamental difference between man and animal).

[31] Scottish Council on Human Bioethics, cited Report, point 4.2.

[32] The creation of hybrid human-animal beings is considered contrary to human dignity in recital 38 of the European Directive 98/44/EC: "*Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to* ordre public *and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability.*"

When it comes to "cybrids" derived by means of the transfer of a human cell's nucleus into another species' egg cell, this would result in embryonic structures, the genome of which would be almost completely human. One can only be perplexed by the nature of such entities. "Cybrids" as currently envisaged would hardly be viable in themselves, so that the term embryo is perhaps inadequate. But what life form should one attribute to them? Are they human life or not? Here again, one has to adopt a questioning stance, and note that such an initiative would obscure the distinction between human and non-human.

The creation of "cybrids" as well as hybrids would obscure or transgress the borderline between the human and animal. Moreover, since such entities are more or less part of humanity, their use as pure objects of research would represent an offence to humanity. Therefore such steps are to be challenged strongly, in the name of respect for humanity and the importance of recognising human specificity in relation to other life forms.

The considerations formulated above do not pretend to contest in any way the freedom of scientific research; it should be understood that no research, however important it may be according to the judgement of its promoters, should prevail over the dignity of persons and of humanity.[33]

English translation from the original (French) version

[33] The Universal Declaration on the Human Genome and Human Rights moves in this direction by explicitly recognising freedom of research (art. 12), and by affirming at the same time that no research concerning the human genome must prevail over respect for the human dignity of individuals (art. 10), and that experiments contrary to human dignity must not be permitted (art. 11).

ETHICAL QUESTIONS RAISED BY NANOMEDICINE

Meeting on 17 October 2006

Among the areas that have recently experienced significant developments, a special place is reserved for nanosciences and nanotechnologies. By definition, they relate to objects whose size is of the order of a nanometre. A nanometre is equivalent to one billionth of a metre (an atom has a size of the order of one-tenth of a nanometre, the diameter of a human hair is around 20,000 nanometres). Nanomedicine can be defined as the application of nanotechnologies to the field of medicine. In other words, this is a matter of using properties of physical, chemical and biological materials which they have, or can have, at the nanometric level, for a therapeutic objective or even for the purpose of preventing the development of diseases by making a reliable diagnosis of them at a very early stage.

I. THE PARTICULAR CHALLENGES OF NANOMEDICINE

Nanoparticles with the approximate size of a nanometre exist in nature and have for a long time been used in various technical fields. It is now intended to use them in medicine, especially in the fields of diagnosis, targeted therapy, as well as regenerative medicine.[34]

By using nanobiotechnologies in *medical diagnosis*, it could be possible to attempt to identify diseases well before they can be detected by traditional means; and furthermore, to monitor the progression of such diseases. Two different fields can be distinguished: *in vitro* applications ("biosensors" containing a biological element such as an enzyme used to identify the presence and concentration of specific biological elements) and *in vivo* applications (medical nano-imaging intended to study phenomena at the molecular level on the one hand and implantable devices on the other). Such methods would make it possible to diagnose diseases at an early stage, whether or not treatment exists for these diseases or

[34] Cf. European Technology Platform on NanoMedicine, *Vision Paper and Basis for a Strategic Research Agenda for NanoMedicine* http://ec.europe.eu/research/industrial_technologies/pdf/nano_medicine_vision_paper_en.pdf

the means of preventing their development. Moreover, they could be used at all stages of human life: from the *in vitro* embryo to the *in utero* embryo or foetus and for a child or an adult throughout their lives.

Nanoparticles might also be used *to direct medicines* to the precise area of the human body to be treated. Such a targeted delivery of medicines aims at reducing the secondary effects as well as optimising the availability of medicines in the chosen area.

Finally, it is hoped that nanobiotechnologies will contribute to the development of *regenerative medicine*. Tissue engineering is already under development. This uses cells and their molecules in artificial structures in order to obtain new tissue and thus replace diseased tissue. A recent strategy envisages the use of adult stem cells as a source of regenerative cells.

Such applications give reason to expect major benefits. But they also give rise to several problems, mainly of a toxicological nature.

First of all, these particles behave in a completely different way compared with particles of the same composition and of greater size. Their surface is large compared with their volume. This relationship between volume and surface and the smallness of their size give them specific characteristics (above all a different chemical reactivity). Moreover they can - because of their very small size - jump the placental and haemo-encephalic barriers. This latter characteristic could be used for the treatment of brain tumours, but at the same time it holds the danger of an uncontrolled jumping of these barriers by nanoparticles at the risk of unforeseeable effects on the encephalon. They can also jump the membranes of cells and cellular nuclei.

The fact that these particles of such a tiny size are governed more by the laws of quantum mechanics, with effects and risks for which a reliable method of calculation does not yet exist, is another problem. It has not yet been clearly established whether, when jumping the membranes of cells and cellular nuclei, they will not interfere with genetic material and the regulation processes. This is potentially dangerous due to the complexity of the functioning of genes: these are activated, deactivated and regulated in a very complex way. It is possible that nanoparticles may influence these regulatory

mechanisms. This could be used for therapeutic purposes, but could also result in dysfunctions.

Consequently, in view of these uncertainties and for the sake of a sound application of the precautionary principle, nanomedicine should pay special attention to the study of the possible risks arising from use of these nanoparticles. Research carried out in the field of nanotechnologies should certainly make provision for studies relating, not only to the benefits to be expected from them, but also to the potential risks to people. This concerns, on the one hand, the various forms of toxicity of nanoparticles depending on their chemical composition and their surface characteristics and, on the other hand, despite the current absence of data in these fields, particulars of their behaviour due to the laws of quantum mechanics and their possible influence on gene regulation.

It is also necessary to tackle the question of the management of "nanowaste" (which to a large extent is probably non-degradable) produced over time. Research should assess the risk of these nanoparticles settling in the body cells or even in the nuclei of cells and with what effects. Finally, it is also necessary to assess, on the one hand, the effects of these nanoparticles on the health of people who would be especially exposed to them, in particular persons employed in handling these particles and, on the other hand, the consequences for the environment as a result of their accumulation in the air, water and soil.

II. ETHICAL QUESTIONS WHICH ARE SPECIFICALLY RELATED TO NANOMEDICINE OR ARE INTENSIFIED BY THE POSSIBILITIES OF NANOMEDICINE – APPLICATION OF THE "PRECAUTIONARY PRINCIPLE" BALANCED BY THE "PRINCIPLE OF INITIATIVE"

In addition to these uncertainties in the safeguarding of health, nanomedicine gives rise to other ethical questions. While some are not fundamentally new, vigilance is required with regard to these questions.

The first concern is with the integrity of the human body. Up to what point can its modification, as a result of the introduction of nanoparticles, be judged to be tolerable? How can we assess the

threshold which is not to be crossed if we are still to speak of a "natural" or "human" body? Answers to these ethical questions can doubtlessly be found on the basis of criteria which are recognised and applied; for example, in the field of genetic modifications or in the field relating to the use of psychotropic medicines.

The means of early diagnosis gives rise to questions at various levels: firstly, the right of the person concerned to know or not to know; especially when it is a question of conditions, anomalies or functional upsets for which there is no treatment or means of prevention. More particularly, as regards human life before birth (whether this is a question of an *in vitro* embryo or an *in utero* unborn child), it is to be hoped that such a diagnosis will, in some cases, permit preventive treatment to be given in order to avoid the development of a disease. It is, however, to be feared that in most cases the lack of available treatment would lead *de facto* to the elimination of the embryo or to the abortion of the unborn child. This meets with strong objections based on human dignity, which are independent of health conditions or the risk of developing a disease.

Nanomedicine also raises questions regarding the objectives of its use and its consequences. These concern, for example, enhancement of the human organism and its performance for purposes other than therapy. One can imagine implanting sensors intended to register data relating to the various body functions and transmitting them in a way which will permit exercising control over these functions, acting on them and thus modifying behaviour or facilitating adaptation to various environments. It is then necessary to ask what will be the consequences for the identity, freedom and responsibility of the subjects. Furthermore, how can the power of those who would implant these sensors and the power of those who would have control over them be supervised?

In the face of such complex questions, the ethical debate persistently calls for the application of the "precautionary principle". It is noteworthy that this principle is nowadays often understood in a negative way which may induce failure to act.[35] Left to itself the principle leads to paralysis. However, the original intention of this principle was, on the one hand, to draw attention to the possibility of

[35] The influence of the "hermeneutics of fear" as proposed by Hans Jonas may be detected here.

major risks which would be difficult to assess, and, on the other hand, in the context of scientific uncertainty, to guide us towards concerted and reasoned decisions progressively taking note - in the perspective of advancing knowledge - of the extent of the risks involved, the means of protection against them and the expected benefits. In other words, it would now be reasonable to counterbalance this "*precautionary principle*" by what could be called a "*principle of initiative*". This latter principle calls for knowing how to assume one's responsibilities, after essential reflection and consultations.

III. RECOMMENDATIONS

Because research in nanotechnologies and, more precisely in nanomedicine, is comparatively new and because of the possibly harmful consequences for people and the environment, it is essential to provide information, as widely as possible, on both the positive and negative results of this research. To calm legitimate public concern, public supervision is essential as regards both the financing of this research and as regards analysis of the experimental protocols. Because of the current scientific uncertainty regarding the possible risks in applying these technologies, this supervision should include a developed and continuous assessment programme. This should relate in particular to the health risks and should be in accordance with the recognised international rules relating to biomedical research. This supervision should remain completely independent of the interests of companies and researchers involved in this field of research.

Research must be carried out with the utmost rigour and the results obtained have to be disseminated with a concern for complete transparency while resisting any pressures from scientific or industrial circles as well as unfounded expectations in public opinion.

The objectives pursued in research on nanomedicine have to remain within the framework of a medical science oriented towards the care of persons suffering from diseases, to the exclusion of efforts which aim at enhancing human performance. In addition, because of the previously mentioned uncertainties and in order not to take the risk of creating serious deformities, it is of the greatest importance to

avoid any modifications relating to germ cells by means of nanotechnologies, even for therapeutic purposes.

The importance of the aforementioned issues points to the need for a wide democratic debate not only in each country and with the participation of various representatives of society but also at the international level. In particular it would be beneficial to debate at world level the questions raised, for example, "*as regards nomenclature and metrology, common approaches to risk assessment and the establishment of a dedicated database to share toxicological and ecotoxicological as well as epidemiological data*", as considered necessary by the European Commission.[36] Evidently, it is imperative for there to be transparency in the policy decisions taken in this field.

By way of conclusion to these various remarks and recommendations, we invite all concerned to ensure a creative respect for recognised ethical principles and particularly to guarantee respect for human dignity which is independent of genetic characteristics, of age or of sex.

English translation from the original (French) version

[36] Point 7.1b) of the Communication of the European Commission COM (2005) 243 of 7 June 2006: *Nanosciences and nanotechnologies: An action plan for Europe 2005-2009.*

PATENTABILITY OF HUMAN STEM CELLS

Meeting on 5 May 2006

I. GENERAL REMARKS

Our societies expect a great deal from the use of human stem cells and are increasing research in this field. Thus, the question of patents soon presents itself.

Indeed, particularly in the area of biotechnologies, research and development call for major investments. Legal protection of inventions[37] by means of patents is therefore of great importance. A factor in the promotion of research is to permit the authors of these inventions to benefit from them by guaranteeing to them intellectual property rights for a specified duration. It also contributes to the dissemination of scientific knowledge because, to be patented, any invention must be described sufficiently so as to be capable of being reproduced. Generally speaking, all of this contributes to a justification for the granting of patents, except where serious requirements of an ethical or social nature stand in the way. Thus major interests relating to the common good can, in certain circumstances, lead to limiting or even suspending such intellectual property rights.[38]

European Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions introduces the notion of "*biological material*". It defines it as "*any material containing genetic information and capable of reproducing itself or being reproduced in a biological system*".[39]

"Traditional" patents relate to inventions with an industrial application which are based on a knowledge of inert matter. New questions arise when patents relate to biological materials as defined

[37] Article 3 of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions of 6 July 1998 rightly specifies that the idea of an invention involves "*an inventive step … susceptible of industrial application*". This excludes from patentability the mere discovery of what pre-exists in the natural state, in particular elements of human origin and their possible variations.

[38] See the Report of the WHO Committee on Intellectual Property Rights, Innovation and Public Health entitled, *Public health, innovation and intellectual property rights*, Geneva, April 2006.

[39] Article 2 of Directive 98/44/EC, op. cit.

above. When this biological matter is capable of reproducing itself, one can speak of "living matter" with more or less problematic status.

Such entities give rise to many questions. The report of the European Commission[40] recognises two vital questions:

1. "the scope to be attributed to patents on partial sequences or sequences of genes which have been isolated from the human body;
2. "the patentability of human pluripotent embryonic stem cells and stem cell lines obtained from them."

Stem cells are characterised by their capacity for indefinite self-renewal, to proliferate in culture and to be able to differentiate themselves under certain conditions into various types of specialised cells. A distinction is currently drawn between, on the one hand, embryonic stem cells obtained from the internal mass of the blastocyst (in the human species this is the embryo cultivated up to the fifth-seventh day after fertilisation) and, on the other hand, the cells obtained at a later stage and called adult stem cells or organ stem cells.

In Western societies there are great expectations for human stem cells because it is hoped to be able to use them for the treatment of many degenerative diseases (e.g. neurological diseases such as Huntington's disease and Parkinson's disease) or for the repair of certain tissues such as muscular heart tissue after a coronary thrombosis.

One of the general problems raised by the patenting of these stem cells (adult and embryonic) is to be found in the definition of the nature of the patent. Does the latter relate solely to the process of isolation, extraction, culture and differentiation or is it envisaged that it also relates to the material itself? The latter assumption would not be acceptable! In that case, it would no longer be a question of intellectual property alone but of a claim to the ownership of the living material itself. However, Directive 98/44/EC provides for the patentability of biological material itself under certain conditions:

[40] Report of the European Commission COM (2005) 312 dated 14 July 2005: *Development and implications of patent law in the field of biotechnology and genetic engineering.*

"*inventions which are new ... shall be patentable ... even if they concern a product consisting of or containing biological material*" (Article 3, paragraph 1). In addition, according to Article 8, paragraph 2, "*the protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics*." This gives rise to strong objections! It is highly desirable that the question of the adaptation of the traditional principles of patent law to the specific features of living matter be tackled by the European Commission.

This question also deserves to be raised not only as regards cells from human beings but also as regards any living matter.

Another key question is the scope of patents, whether they relate to living matter or to sequences or partial sequences of genes. It appears that the European Patent Office leans towards a very broad interpretation. The result would be to bring within the scope of a patent a large number of functions of biological matter. Patents can then become real obstacles to the development of research. In such a case they lose their legitimacy and give rise to real problems of social justice. Moreover this could have very serious consequences for research in the less developed countries.

II. HUMAN EMBRYONIC STEM CELLS

The granting of patents for human embryonic stem cells also gives rise to other specific questions. Many reservations have already been expressed in this regard.

The major problem raised by human embryonic stem cell lines is that they are derived from human embryos which are then destroyed. These human embryos are thus employed solely as a means of obtaining stem cells and they are therefore reduced to the status of an object: a source of biological material for the purpose of research or therapeutic use. This comes up against strong ethical objections in the name of human dignity.

Even although a patent is intended to provide legal protection for an invention and does not in itself represent moral approval of the procedures used, this does not prevent a patent from conveying a symbolic dimension of social acceptance.

That is why Article 53 of the Convention on the Grant of European Patents (*European Patent Convention*)[41] affirms that patents are not granted to "*inventions, the publication or exploitation of which would be contrary to 'ordre public' or morality*" and why recital No. 16 of the European Directive 98/44/EC specifies that: "*patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.*"

Paragraph (c) of Rule 23 of the *Implementing Regulations to the Convention on the Grant of European Patents*[42] states that European patents shall not be granted for biotechnological inventions which have as their object "*the use of human embryos for industrial or commercial purposes*".

It is often argued that much research and many requests for patents relate directly, not to the obtaining of stem cells, but to the use of stem cell lines which have already been created. There would therefore no longer be any direct use of an embryo. In response to this, one may argue that, on the one hand, such stem cell lines have still been created from human embryos and that, on the other hand, any patent relates to an industrial application of the procedure. Social acceptance of the use of embryonic stem cells can only lead subsequently to the creation of new stem cell lines requiring, in their turn, the destruction of embryos.

III. THE SEARCH FOR ALTERNATIVE PATHS

In order to avoid the problems posed by the use of human embryos, researchers have, in recent years, proposed alternative paths. Such research is in itself completely legitimate but, as regards the proposals currently being made, there is still a need for prudence. Some people propose creating new forms of life, others suggest

[41] Convention on the Grant of European Patents (Euroepan Patent Convention), 5 October 1973, http://www.european-patent-office.org/legal/epc/f/ma1.html.

[42] Implementing Regulations to the Convention on the Grant of European Patents, 5 October 1973, http://www.european-patent-office.org/legal/epc/f/ma2.html.

using the still-living cells of human embryos which have been declared dead, still others envisage the creation of pseudo-embryos or even the use of ovocytes, embryos or animal embryonic cells to create hybrids of human beings and animals…

It is undoubtedly premature to deliver a general and definitive judgement on everything which will emerge from reflection and inventiveness in a fast-moving scientific field. It is necessary, however, to remain vigilant and to be aware that the aim of some innovations could be to mask reality or to introduce, as a consequence, great confusion which would contribute to calling into question human specificity. Other aims could even show total disrespect for human dignity.

We cannot exclude the possibility that some of these alternative paths will open up genuinely new prospects which will be beneficial to mankind and respect its dignity. It is, however, clear that, before being implemented, all these research projects must be subject to a careful examination, which, avoiding all forms of fundamentalism, must do justice to all the questions raised by such interventions which could even lead to the generation of different life forms.

What, in particular, is required is a detailed anthropological reflection. It will need to determine on the one hand what represents the beginning of a human life and cannot therefore be reduced to the status of an object, and on the other hand what would be rightly considered to be biological material which could be used as material for research or the treatment of diseases. It must also pay particular attention to the consequences triggered by the introduction of any constituent elements of human specificity into animal cells or embryos. It is to be hoped that all of this will be the subject of a wide public debate and that the competent authorities in these fields will show the necessary vigilance.

English translation from the original (French) version

LIVING WILLS
(END-OF-LIFE ARRANGEMENTS)

Meeting on 21 October 2005

In more and more countries people are asking that attention should be paid to the wishes of a person regarding the medical treatments to be administered or withheld in cases of accident or serious illness, even when the person has lost the ability to make free choices in sound mind and/or to communicate them. To this end, these countries have given officially a value, more or less binding, to wishes expressed by the person concerned in anticipation of just such a situation. Some associations with different standpoints are proposing forms that are intended to enable any person who so desires to put in writing their hopes and wishes regarding the end of their lives.

It should be recalled that the obligation of human beings to take reasonable care of their health does not, according to the Christian tradition, mean that they should want to stay alive at any price. Viewed in this way, it is justifiable to raise objections to recourse to therapeutic methods that could be deemed useless or disproportionate, or which would place an excessive burden on the person concerned or on another person. This is what Christian moral theologians have been stating since the 16th century, and teachings of a similar nature have been repeated again and again up to the present day. Its legitimacy has been confirmed by Pope Pius XII and Pope John-Paul II.[43]

The final phase may be an essential part of a person's existence, the occasion to take steps thought to be impossible until that moment, to welcome relatives, to ratify the choices which have guided his[44] existence, to ask for pardon and reconciliation, to bequeath property or valuable possessions, to entrust himself into the hands of God, or quite simply seen as a slice of life in close communion with others. It would be highly regrettable if the constraints imposed by having to

[43] Pope Pius XII, Address to doctors on the religious and moral problems of resuscitation, 24 November 1957; Pope John-Paul II, Encyclical *Evangelium Vitae*, 25 March 1995, n° 65.

[44] The masculine forms - he, his, himself - are used for simplicity of style in this text.

resort to inappropriate medical treatments were to prevent a person from achieving these things when entering the final phase of his life.

It is entirely legitimate that any person should be able to request, in the form of instructions prepared in advance, that at the end of his life, when he is no longer in a position to communicate his wishes regarding his health care, that medical intervention should, as far as possible, be subordinated to his requests. As far as medical issues are concerned, the instructions might consist in asking, according to variations in circumstances, for tests and treatments to be limited or even stopped; and for the administration of palliative treatments for pain and other sources of suffering, even if these might have the unwanted secondary effect of a slight shortening of one's life.

On the other hand, there exist some forms of advance instructions that contain clauses relating to the practice of euthanasia, in preparation for the moment when certain anticipated events become a reality. This has its roots in a desire to exercise a form of mastery over one's own life that can only be condemned by the Catholic Church.

Quite apart from the strictly medical aspects which lie at the heart of certain phrasings that have been suggested, it would obviously be highly desirable that each person should anticipate in straightforward terms the different questions that could be raised: he should express his wishes regarding the place where he would spend the last moments of his life, regarding the presence of his relatives and any spiritual or religious guidance that he would like to have. These forms of expression derive their importance from the desire that they could communicate the wish to live out this period of their lives to the full, to remain in good contact with other people and not to be reduced to a pure object of medical care.

In conveying such wishes, the most prevalently used method until now has been a document written in advance. But another method has been recognised in several countries: that of designating a person of trust, with or without the title of proxy.

Similar instructions may be drawn up by people suffering from illnesses whose future development is already known and where the treatment is already being administered. In this situation, the person will be communicating his wishes in full soundness of mind, and his

instructions may be stated in a clear-cut manner that is relatively easy to interpret.

Other situations have different features, because usually it is not easy to anticipate the real life circumstances in which an illness will be diagnosed and then develop, or what issues will arise from the application of therapies. In this case, the interpretation and the application of the patient's wishes may turn out to be a very delicate matter, even running the risk of contradicting his current wishes if he is no longer able to communicate his intentions regarding the treatment he wants to receive. There are some studies[45] containing examples of this problem, and they also highlight some of the disappointments experienced by those who had been the most fervent supporters of "living wills".

However, while the patient is still able to communicate, a document of this kind could become the basis for consultation between the author of the instructions, the person whom he may have designated to interpret his wishes, the relatives and the doctor he has chosen for his medical care. A document like this would no longer indicate a lack of trust of the medical profession – as is so often the case with the current form of the "living will" – but would rather be a sign of trust in the people he has chosen. Moreover, the fact that it has been drawn up – and modified – in discussion with others would normally make it more relevant, easier to interpret, more adaptable to developments in the illness, and finally more faithful to what the patient really wants.

In any case, it is highly desirable that this drafting should be done in conjunction with the designation of a proxy or person who would have the task of explaining it to those who would have to take the decisions. Advance instructions may also consist solely of the designation of a person as a proxy, who would then have to talk to the patient to form a good idea of his wishes.

It could be useful for the author of the arrangements and the proxy to engage in a regular dialogue, so that the latter might become aware

[45] A. Fagerlin, C. Schneider, *Enough: The Failure of the Living-Will*, Hastings Center Report, Vol. 34, n° 2, March-April 2004, p. 30-42; S. Sahm, R. Will: *Angehörige als natürliche Stellvertreter*, Ethik in der Medizin, 1-2005 p. 7-20; S. Sahm, R. Will and G. Hommel, *Attitudes towards and barriers to writing advance directives amongst cancer patients, healthy controls, and medical staff*, J Med Ethics 2005; 31: 437-440.

of possible changes in the wishes of the person whom the proxy has to represent. This would help the proxy, when the time comes, to interpret the wishes of the patient who by that time has become incapable of communication. In this way, by reformulating his own wishes little by little, the patient will transform the proxy into a genuine intermediary. Obviously, even if it is required by the law, simply renewing the instructions is not sufficient to make others aware of any changes in the wishes of the person who drafted them.

Ultimately, end-of-life arrangements do not necessarily represent the search for a complete mastery of one's self and one's life; they can, on the contrary, be a testament, on the part of the person who wrote them, to a healthy desire to concern himself with how to live what could be a very important moment of life.

English translation from the original (French) version

ETHICAL AND CULTURAL ASPECTS OF GENETIC TESTING

Meeting on 27 February 2004

In the last fifteen years, genetic sciences have made spectacular advances. The human genome, that is the totality of human genes and the molecular chain DNA on which they are carried, has been almost completely deciphered. In addition, numerous genes have been identified and localised on different chromosomes, while at the same time, the particular patterns that these genes assume in certain people are increasingly being understood. These genetic particularities can have a more or less direct relationship with illnesses. A growing number of tests allow us to detect these particularities and thus to predict, with a varying degree of certainty, the occurrence of severe illnesses, and, in some cases, to implement preventive measures.

All of this has rightly been celebrated in many countries as a great achievement of the human mind and has given rise to a great deal of hope. However, at the same time, it has created illusions that could potentially be exploited for commercial reasons. It has also created a questionable impression of the human person. Unfortunately, an image has been formed, an *image of man completely determined by his/her genes and imprisoned in his/her destiny*. It is necessary to reject this deceptive image. We welcome the views of philosophers, scientists or ethics institutes on these issues.

"*The myth of the genes, the basis of the programme of life, is such that it leads to the illusion that a perfect knowledge of the genome of an individual would be the key to revealing the reality and the destiny of that person. It is this image to which a metaphor like the "great book of life" refers to, where it would be sufficient to know the alphabet and the genetic syntax to reach the essence of being. Yet, such a concept is scientifically unacceptable and ethically dangerous.*"[46]

[46] French National Ethics Committee (Comité consultatif national d'éthique pour les sciences de la vie et de la santé), Opinion n° 46, *Génétique et médecine : de la prédiction à la prévention*, Paris, 30 October 1995 – unofficial English translation.

The European Group on Ethics in Science and New Technologies (EGE), advisory body to the European Commission, recently declared in relation to genetic testing in the workplace that, "*in many cases the link between a particular genetic status and susceptibility to a particular hazard has only a theoretical basis at present. In the general debate there have been exaggerated beliefs about the predictive value of genetic tests, perhaps based on the concept of genetic determinism, which have been proved to lack foundation.*"[47]

Today, therefore, it is of the utmost importance that all available genetic tests are highly scrutinised, and that their objectives and the circumstances in which they could be used are examined.

The use of genetic tests in the medical context

In the *medical domain*, genetic tests can have the aim of confirming, refining or excluding the diagnosis of an illness where the patient has already shown certain signs of this illness, or at least symptoms which could be confused with such signs. We could therefore speak of '*diagnostic testing*'. In most cases, these will scarcely pose additional ethical problems than for any other diagnostic methods used for the same illness. They could even help to avoid diagnostic means that are more testing or more demanding**.**

In most cases, the aim is to estimate the risk of developing an illness in the near or more distant future. Thus the test is expected to have a '*predictive value'*. Yet, the predictive value of a genetic test varies greatly according to the condition under consideration. Moreover, the repercussions for the person concerned and for his or her family, as well as the benefits that can be realistically expected, vary greatly according to the tests. Thus, respect for the person requires, not only that they receive trustworthy professional information before anything is done, and their free and informed consent. In addition, no tests should be put on the market that do not demonstrate sufficient benefits for the patients in comparison with the negative repercussions which they could have.

Certain tests can be qualified as '*presymptomatic'*. These enable the diagnosis of a severe illness, with a high degree of certainty, more or

[47] European Group on Ethics in Science and New Technologies (EGE), Opinion no. 18 on *Ethical aspects of genetic testing in the workplace*, 28 July 2003, § 1.5.2.

less in advance. The benefits are evident if this knowledge were to open the way for feasible methods of prevention. However, for a condition such as Huntington's, the test only confronts the person with the knowledge of a future serious affliction of both body and psyche that will almost certainly be incurable. Some people who already know about their risk of developing such an illness due to its transmission in their family, prefer to escape the uncertainty and have recourse to a test. Others wish to take the test in order to be able to take responsibility when it comes to certain choices in their lives, such as marriage and children. Major precautions have to be taken by health professionals in order to ensure that these decisions are taken *freely*, and in full conscience, with protection from pressure and constraints. The attachments formed as a result of being closely involved with such decisions furthermore imposes on these professionals the obligation to provide *appropriate support* for persons who will have to live with the burden of the test results.

Many other tests merely indicate *a certain degree of probability* of developing certain diseases. This degree of probability is sometimes quite high. One could therefore, in the strict sense of the term, speak of '*predisposition tests*' and apply to them, modified as appropriate, what has already been said about presymptomatic tests. However, many other tests only reveal *a small risk* of developing a very common illness, such as diabetes, high blood pressure etc. To make such tests available for general use could be of interest to biotechnology companies. Yet, their usefulness to the population is very limited because confronting a person with the potential risk of developing a particular illness can create great anxiety for that person and have detrimental effects, even when the risk is small. This imposes great *responsibility on the medical staff and the health authorities*. Respect for the person and concern for the common good can require resisting industrial and commercial interests.

One of the essential characteristics of genetic tests is that they focus on hereditary attributes, which can be inherited from generation to generation. In most cases the tests therefore reveal information concerning the family. Quite often they even require the active participation of members of different families related to the person being considered. This is sometimes experienced as an intrusion into intimate matters. Consequently, this *family dimension* requires health

professionals, as well as those who are to benefit from the test, to act with a great deal of tact and respect for the freedom of the other.

This same respect for the liberty of the other person also requires that minors are not submitted to such tests, except where there is a strong case in the interests of their own health.

Also, it requires that campaigns for general surveys should not be developed for a whole population without serious reason, nor without having previously taken care to prepare the population, to inform them regarding the giving of consent and regarding the protection of persons against all forms of indiscreet disclosures regarding the results of the test.

Few genetic tests open the way for therapeutic or preventive measures. Yet, with exceptions, Western societies accept putting into practise the *termination of pregnancy* in cases of severe and incurable defects of the unborn child. In cases where there is a risk of genetically transmitted diseases, genetics now allows prenatal diagnosis. If this reveals the existence of an alarming defect, in most cases the mother, instead of receiving the appropriate support and reactions of solidarity, is subjected to strong pressure to request an abortion. This societal attitude of *rejecting people suffering from severe congenital diseases* is a serious problem. It would be even less acceptable to arrange *generalised prenatal tests* for certain genetic anomalies. It would demonstrate, in the current context, the conscious decision of a society to promote a selection of people who are permitted to join in the life of this society.

Outside the medical context

Individuals or institutions may well consider that they have an interest in knowing the results of the genetic tests of a given person, so as to learn about that person's future, which it is believed, rightly or wrongly, is revealed by the test results; the aim would then be to avoid long term dealings with this person to the extent that the tests seem to predict an illness or deficiency which would develop in the course of the period under consideration.

The person is therefore being perceived primarily from the angle of this risk. The person is *reduced* to the genetic characteristics revealed by these tests. The term *stigmatisation* is rightly used in these

circumstances, indicating the situation of one person's vulnerability taken together with the issue of another person having knowledge about that person's future health.

The *vulnerability* of the person calls for real *solidarity*. And insofar as people see themselves as deprived of benefits to which they are entitled, or excluded from a social life due solely to these characteristics, one has therefore to speak of *discrimination* and an *attack on justice*. This is the case, for example, if someone is refused, on the basis of his or her genetic characteristics, a job that he or she is completely able to do.

These imperatives of *justice* and of *solidarity* reinforce each other. An earlier Opinion of the Bioethics Discussion Group stated: "*Yet, it is only this notion of solidarity vis-à-vis vulnerable people which allows us to arrive at equitable legal rules and to provide them with a foundation. It is the recognition of this fundamental value which renders as discriminatory any intention to deny people employment which they are capable of doing, on the basis of genetic characteristics which give rise to the fear that they might develop an illness at a later stage.*" [48]

It is therefore of the utmost importance that every society remains vigilant so that *individual genetic information* remains appropriately *protected* and that access to it is reserved to those who have the mission of bringing health care to those concerned. Every exception would have to be subject to thorough reflection and would have to be based on solid arguments, taking on board the need for justice and the exercise of true solidarity.

English translation from the original (French) version

[48] Opinion of the Bioethics Discussion Group of the Secretariat of COMECE, *Comments on Opinion no. 18 of the European Group on Ethics 'Ethical Aspects of Genetic Testing in the Work Place'*, 10 October 2003.

COMMENTS ON OPINION NO. 18 OF THE EUROPEAN GROUP ON ETHICS (EGE) CONCERNING *ETHICAL ASPECTS OF GENETIC TESTING IN THE WORKPLACE*

Meeting on 10 October 2003

One can only appreciate and salute the efforts undertaken in this Opinion of the European Group on Ethics in Science and New Technologies (EGE) to evaluate the current scientific findings in the field of genetic testing, on raising questions as to how relevant they are to the protection of human health and, in particular, the predictive value of these diverse genetic tests. This Opinion of the EGE deserves great praise for leading us to a certain demystification of too often widespread perceptions which sometimes take the form of sincere beliefs and which have no foundation in the actual value of genetic tests.

The general tone of the Opinion is particularly to be noted: it is balanced and nuanced, and one perceives the fruits of work carried out over several years and based on solid documentation. However, in the space of 20 pages, the Opinion can only formulate a certain number of conclusions, without clarifying all the foundations and assumptions.

Therefore it seems important to us to highlight a number of fundamental affirmations, to reflect on their anthropological foundations and to propose complementary considerations.

We have to draw attention to the brevity of that part of the Opinion which is devoted to actual ethical reflection. This is paradoxical on the part of a Group specifically constituted for this purpose, as indicated in the title of the said Opinion. This fact is all the more regrettable as several remarks formulated at the legal level, could have been developed at similar depth at the level of ethical reflection: This is the case, for example, regarding the notion of freedom of consent and thus the validity of recourse to the concept of autonomy in the very special context of the employer-employee relationship. In this arena there are numerous legal considerations

and it was this dimension which received the primary attention of this group of experts.

Similarly, there is a marked disproportion between, on the one hand, the recommendations (of which there are twenty), and the specifically *ethical* part of the Opinion. It follows, that the assumptions underlying the recommendations, are not made clear.

The rejection of any form of discrimination is clearly expressed. Yet explanations on how this is arrived at and in particular the ethical foundations are painfully missing. This applies also to the right to confidentiality. The arguments advanced on this issue reveal a concept of the human being and of life in society which is quite individualistic: the ethical reflection does not draw on the principle of solidarity. Yet, it is only this notion of solidarity vis-à-vis vulnerable people which allows us to arrive at equitable legal rules and to provide them with a foundation. It is the recognition of this fundamental value which renders as discriminatory any intent to deny people employment which they are capable of doing, on the basis of genetic characteristics which give rise to the suspicion that they might develop an illness at a later stage. The lack of "predictive value" in genetic tests is not sufficient to justify any prohibition of their use in the framework of employment. A number of current tests already have a strong predictive value. And one cannot exclude the possibility of major advances in this area of genetics.

By way of conclusion, the Opinion of the European Group on Ethics certainly comes to a whole set of balanced recommendations, trying to reconcile conflicting interests, such as those of employers and those of employees, of workers and of third parties. It insists on respect for the rights of workers and of applicants, whilst reminding us also of their responsibilities. The concern to avoid any discrimination is there; however, the foundations are not sufficiently explained. The preoccupation with respect for human rights is evident, but the principle of proportionality, which is one of the crucial aspects, is not defined.

This remark about definition could, by the way, be generalised insofar as a number of other terms in the text are not provided with a definition.

English translation of the original (French) version

BIOMEDICAL RESEARCH IN DEVELOPING COUNTRIES

Meeting on 13 December 2002

Biomedical research on human beings has to follow, with urgency and as a precondition, two moral precepts. On the one hand, it must be directed towards the improvement of the population's health thanks to the progress of scientific knowledge, and to a better understanding of disease. On the other hand, there has to be respect for dignity; and, in the field of health, the interests of the person who submits to the research have to be considered.

Numerous international declarations on the ethics of research in developing countries insist on respect for different cultural expressions and values in countries where the research is undertaken by institutions or enterprises from developed countries. We can only endorse such declarations, whilst also stating that the invitation to respect these very different values could lead to relativism.

When undertaking or financing research in a developing country, the responsible institutions must be obliged to respect and act also in accordance with the values and fundamental rights that are recognised in their own countries.

Respect for human dignity implies in particular:

that a person must not be reduced to the status of an object for research;

that no act on the human body may be carried out without having first obtained the informed consent of the person on whom the research is to be conducted. This does not exclude, according to the culture, different forms of consent (for example in front of witnesses or use of a video recording) nor dialogue with the authorised representatives of the person and of the community concerned;

that financial or other incentives, which represent a form of commercialisation of the body, are excluded;

that the requirements of justice should be scrupulously combined with the fundamental requirement not to exploit the vulnerability of certain developing countries and their populations; whether due to the socio-economic characteristics of the country, the absence of specific legislation on biomedical research or for other reasons. Indeed, all kinds of vulnerability can lead to major dependency on industrialised countries.

By simply conducting research, an obligation of responsibility is created between the promoters of the clinical research on the one hand, and the host countries and the persons submitting to the research on the other. Where the European Union provides financial support, it must also guarantee that the obligations and responsibility conferred by this funding are respected. In particular, it must ensure that the research corresponds to the specific needs of the country where it is carried out.

The promoters cannot disregard, directly or indirectly, the future of the person that they have recruited to be the subject of the research. This implies that they must engage in advance in order to ensure that if there is a positive trial result then they should benefit from this; and to take appropriate measures if the research has had negative consequences or creates risks for those who have undergone treatment in the trial. In any event, the promoters will have to enable members of the community concerned to participate actively in the research, so as to achieve a dissemination of knowledge and know-how.

It is indeed appropriate to make sure that the community, in which the experiment has been undertaken, benefits from it and that, as a general rule, the local population has access to any medical developments that may result from the trials.

This Opinion lays out some of the fundamental principles that it is imperative should govern the medical research undertaken in developing countries.

English translation from the original (French) version

SOME REMARKS ON THE COMMUNICATION OF THE EUROPEAN COMMISSION: *LIFE SCIENCES AND BIOTECHNOLOGY – A STRATEGY FOR EUROPE*

Meeting on 19 April 2002

In its Communication[49], "*Life Sciences and Biotechnology - a Strategy for Europe"*, dated 23rd January 2002, the European Commission rightly emphasised the important role that life sciences and biotechnology (or, more precisely: biotechnolog*ies*) play in our societies and economies. It is obvious that they raise "*important policy and social issues*".[50]

Of course, the European institutions have to take into account the future importance of these biotechnologies for the world's markets, the jobs that they will create in Europe and the answers that they may provide in response to important needs in our societies. Therefore, one can understand the emphasis given to the EU's need to "*maintain competitiveness vis-à-vis major industrialised countries*".[51]

These technologies are numerous and varied and have, or will have, applications in many different areas such as health, agriculture, agrifood, energy, environmental protection...

Important innovations indeed stem from biotechnologies; however, these will undoubtedly be accompanied by great upheavals too. Understandably, these bring about both hope and fear at the same time.

Specifically in the field of ***healthcare***, one of the major difficulties for reflection lies in the fact that the consequences of present and future knowledge remain somewhat unpredictable (some people seem to consider this as an invitation to reject any limits on research, in the name of expected benefits to human health). At the same time, within scientific and industrial circles, certain perspectives are

[49] *Life Sciences and Biotechnology – a Strategy for Europe*, Communication of the European Commission of 23 January 2002, COM (2002) 27 final.

[50] Ibidem, I, 1, 2° §.

[51] Ibidem, I, 5, 3° §.

proposed without the critical analysis which is needed when dealing with something with such innovative potential. For example, the European Commission's Communication puts forward: *"the paradigm shift in disease management towards both personalised and preventive medicine based on genetic predisposition"*.[52] Is this an improvement that one can reasonably hope for on the basis of the development of knowledge, or is it an illusion which critical analysis should have dispelled a long time ago? Furthermore, one can say with certainty that it is premature to assert that "*stem cell research and xenotransplantation offer the prospect of replacement tissues and organs"*.[53] With regard to stem cells, it would be unwise to see them as a universal cure for neurodegenerative diseases. Responsible institutions owe it to themselves not to subscribe to hype with regard to new disciplines and technologies. The disappointments generated until now by gene therapy provide us with a salutary warning that should be taken into consideration in every prospective evaluation.[54]

These reservations do not prevent us from recognising the major repercussions that a scientific and technological revolution with such great potential will certainly have on different countries of the world. They are accompanied by increased obligations to ensure a responsible and durable development of these procedures, and genuine respect for the human person. Therefore, the COMECE Secretariat approves of the emphasis that the Commission's Communication places on being "*consistent with European values and standards*"[55] and, in particular, welcomes the recognition of "*fundamental values recognised by the EU in the Charter of Fundamental Rights*"[56].

Several times throughout the document, the Commission recommends ***holding a public debate***. This is something that is indispensable when adopting a democratic approach with regard to a problematic issue. Nevertheless, one is left wondering what are the fundamental aims being expressed in the text. Obviously the aim of

[52] Ibidem, I, 2, 2° §.

[53] Ibidem.

[54] The Bioethics Discussion Group of the Secretariat of COMECE notably has the aim of engaging in such a critical analysis of the progress of the scientific knowledge and the different ways they are presented to responsible politicians and to the public opinion.

[55] *Life Sciences and Biotechnology – a Strategy for Europe*, op. cit., I, 1, 4° §.

[56] Ibidem, I, 1, 3° §.

the dialogue cannot be to avoid a contentious issue and gain "*societal acceptance*"[57] for decisions that have already been taken by the responsible institutions. "*Ethical and societal implications and concerns must be addressed*".[58] We can only subscribe to this. Yet the aim of the proposal cannot simply be limited to securing "*large public support*"[59], or indeed to avoid a situation in which the reluctance of public opinion would bring "*our capacity for innovation and technology development and uptake*"[60] to a grinding halt. The intentions should be made more explicit.

For us, holding a public debate is still much more important. We subscribe entirely to the affirmation that "*our democratic societies should offer the necessary safeguards to ensure that the development and application of life sciences and biotechnology take place respecting the fundamental values recognised by the EU in the Charter of Fundamental Rights, in particular by confirming the respect for life and human dignity.*"[61] Research projects must be examined with specific reference to these two fundamental values, and we insist that they must be seen as covering human life from conception to death.

We also want to express the importance we attach to Europe's responsibilities towards the developing world - something that is specifically stated in the European Commission's Communication.[62] Protection of biodiversity, the sharing of the benefits derived from the use of genetic resources from different countries, compensation for the holders of traditional knowledge, the transfer of technology and fair and balanced north-south partnerships are affirmations that should not simply remain declarations of intent. They should be substantiated by means of binding regulations, in a spirit of true concern for international justice.

Finally, how can we fail to express the concerns raised by reading the ***plan of action*** proposed in the second part of the European Commission's Communication? Much has been said concerning

[57] Ibidem, I, 1, 1° §.

[58] Ibidem, I, 2, 5° §.

[59] Ibidem, I, 2, 5 °§.

[60] Ibidem, I, 1° §.

[61] Ibidem, I, 4, 2° §.

[62] Ibidem, I, 5, 2° §.

developments in the area of the life sciences and about the support for further research. The ethical dimension is the principal consideration in the section entitled *"Governing Life Sciences and Biotechnology"*.[63] To proceed with a full scale programme of persuasion obviously can not be the way forward. Here, once more, the essential point is not to reach a general consensus on decisions already taken. Rather the aim must be to achieve an honest and objective debate concerning the sensitive questions so as to hold on to the genuine values on which the European Union is based.

The European Commission's Communication proposes to emphasise the role of the European Group on Ethics. The question remains: what will be the composition and working methods of this Group with extended functions? The European Commission also wishes to co-operate, not only with public institutions, but also with "*private partners*".[64] This is something that we strongly support. However, in this regard, it is equally important to make clear what objectives are to be pursued. It cannot be the aim to limit co-operation to "*areas where it is possible to establish consensus*"[65] in ethical matters. Other areas would have to be pursued as well.

In conclusion, we recognise that the European Commission's Communication reminds us of the fundamental values promoted by the European Union. However, the European Commission does not adequately state how they should be given their due place in the debate. It is also not made clear how the European Commission will avoid simply submitting to scientific, industrial or commercial imperatives when taking important decisions in the fields of life sciences and biotechnologies. The concertation with the domain of life sciences and biotechnologies must be accompanied by dialogue with different philosophical, spiritual and religious viewpoints.

English translation from the original (French) version

63 Ibidem, II, 2, Actions 13-16.

64 Ibidem, II, 2, Action 16.

65 Ibidem.

MEDICAL EXPERIMENTS

Meeting on 26 October 2001

It is a well-known fact that biomedical research that would not be acceptable in the developed countries is conducted in medically less advanced countries. In general, such research is carried out in countries where legislation provides less protection for people than in the more developed countries.

For the Secretariat of the Commission of the Bishops' Conference of the European Union (COMECE) this situation gives rise to real concern. This is also the case for many institutions that work for the protection and respect of persons who are the subjects of biomedical research.

The populations of medically less advanced countries are far more vulnerable to proposals for experiments than in countries where medicine has advanced over several decades and where there are numerous sources of information. The very concept of research is foreign to them. This represents a major obstacle to providing adequate information. Consent is sometimes obtained by promising material benefits (or by applying psychological pressure), or even only on account of the prestige of the foreign investigators who have asked for their collaboration.

All too often the laws and regulations in force in the more developed countries are seen as an obstacle to advances in scientific knowledge. There is therefore a strong temptation to conduct research in countries with lower levels of protection. We also need to be aware of the pressures imposed by the conditions for the financing of research and the rationale of research that is always impatient to make further advances.

We welcome the efforts made by such institutions as the World Medical Association (WMA)[66] to ensure greater respect for vulnerable populations.

66 See the Helsinki Declaration amended by the 32nd General Assembly in Edinburgh.

The Bioethics Discussion Group fully supports the central tenet of the Helsinki Declaration, which states that "*in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.*" and "*Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection.*

The particular needs of the economically and medically disadvantaged must be recognized.

Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care."

This subject needs to be debated in depth with qualified representatives from the vulnerable populations concerned. Such consultation should mainly deal with explaining the realities of the experiments to be conducted and in obtaining genuine consent, taking into account education and cultural characteristics.

In any event, it should not be allowed that research which is useful for developed countries but which is difficult to conduct in developed countries because of their rules and regulations be carried out within vulnerable populations.

The above recommendations are all the more important since the financial and commercial interests at stake are considerable.

English translation from the original (French) version

REFLECTIONS ON THE USE OF HUMAN STEM CELLS[67]

Meeting on 25 August 2000

The issues surrounding the use of human stem cells and therapeutic cloning are currently arousing strong interest in the scientific community; they raise a number of ethical concerns, especially for the Catholic Church.

As it is currently used, the scientific term "stem cell" refers in fact to cells of very different types: pluripotent or already differentiated cells, cells at various and successive stages of life, from the first days of embryonic development up to the child or adult stages.

The concept of the stem cell alone is therefore not in itself relevant to ethical discourse. The ethical questions raised will differ according to the stage of life at which the cells are taken, the circumstances of their removal and the type of use.

Embryonic stem cells are considered to be pluripotent, i.e. they can become very different types of cells (cardiac cells, blood cells, nerve cells, etc.); they might therefore be used in the treatment of many diseases, and this is why they are of such interest. It nevertheless seems that *adult stem cells* that are already differentiated could also be used for the same purpose and therefore merit adequate attention.

Embryonic stem cells

One of the main questions to be raised concerning embryonic stem cells is how they are obtained.

Their collection and subsequent use of tissue create a delicate problem: these cells can only be obtained by in-vitro embryos from which the said cells are removed. This process therefore excludes any transfer of the embryo for the purpose of procreation and obliges

[67] In this context, it may be helpful to refer to the following documents:
- *Evangelium vitae*, Encyclical of Pope John-Paul II, 25 March 1995
- *The legal and ethical aspects of the human genome project*, an address by Pope John-Paul II to a Working Group at the Pontifical Academy of Sciences, 20 November 1993
- Pontifical Academy for Life: *Declaration on the production and the scientific and therapeutic use of human embryonic stem cells*, 24 August 2000.

the disposal of the embryo in question. The embryo is therefore *instrumentalised* and treated purely as a laboratory material that is simply used and then rejected.

Such reduction of a human embryo to the status of pure instrument comes up against serious ethical objections. Although it is the source of several philosophical enigmas, the embryonic stage is no less than the beginning of human life. It is not up to mankind to establish the threshold, the demarcation line, of humanity… a thing on this side, human on the other side, or *vice versa* at the other end of life!

No doubt scientists will claim that it is possible to reduce the number of embryos used: the extended development of cell cultures would make it possible to create veritable cell banks, and so avoid resorting to new embryos. It is nevertheless true that the initial cells would have been obtained by *instrumentalisation* of a number of embryos.

Others claim that it would be possible to avoid the creation of embryos by using ovocytes to reprogram the somatic cells of children or adults. The term embryo is then only avoided by resorting to ambiguity in the terminology: such a practice would effectively involve creating real embryos by cloning. These questions are sometimes evaded by playing with words and calling it “cell cloning”.

Proponents also vigorously advance the argument that the collection of embryonic stem cells opens up truly revolutionary avenues of research and treatment. They see it as a means of developing different types of cell lines that could be used in cell therapy to treat particularly serious degenerative diseases, such as degenerative neurological diseases or cells that cause the degeneration of the cardiac tissue.

Such an end is clearly laudable. But the argument calls for two comments: firstly, scientific and medical use does not necessarily justify any behaviour if it strays from respect for humanity in its most vulnerable forms.

Secondly, simply invoking the service to humanity remains debatable: not only, as we have already emphasised, because the use of embryonic stem cells would allow very debatable actions. What is more, it would risk the scientific community becoming fixed on a

specific research path without looking at other avenues that would raise no objections of an ethical nature and could be beneficial to medicine.

It would be particularly regrettable not to try to advance our knowledge of the properties of adult stem cells and to recognise their potential uses for the purpose of cell therapy.

English translation from the original (French) version

XENOTRANSPLANTATION

Meeting on 4 March 1999

Xenotransplantation involves the use of body elements from certain animals to replace organs, tissue and cells in the human body to make good a defect in human functions or organs.

This practice has been attempted a number of times due to a lack of human organs and tissue over several decades and because of the current impossibility of providing completely artificial devices.

If medical science continues along this path and if the practice were to be generally accepted by society, it has been estimated that xenotransplantation could create a market worth 6 million Euro by 2010. We understand that several pharmaceutical companies, commercial trusts, breeding-laboratories, etc. are already financially committed to research in this field.

Nonetheless, it should be noted that in the case of xenotransplantation of the liver *in situ*, the experiments carried out to date have resulted in a maximum survival period of 70 days for patients who have undergone such a procedure.

We also note the concern of many scientists who point to the great uncertainty over the risks that xenotransplantation may involve for humanity as a whole. Those who have taken part in ethical discussions in this domain have been similarly perplexed.

The members of the Bioethics Discussion Group set before themselves two preliminary questions: The first concerns the degree of importance accorded to biological life, and the second addresses the attraction exercised by the "scientific".

> There is a remarkable trend of pushing back ever further the frontiers of life, trying at all costs to cross the thresholds of human existence. Does this reflect a determination to "live at any price"?
>
> Are not Western societies, especially in Europe, tempted to give priority to anything that involves a high degree of the "scientific" and has a hint of the spectacular about it? Such a priority is likely to be exercised to the detriment of satisfying the basic health needs of the population.

Although the *magisterium* has justified allografts in the name of charity and the solidarity of humankind, it has nevertheless not pronounced on the subject of xenotransplantation. The Bioethics Discussion Group has not come to any definitive conclusions; however, it believes that it is necessary to answer a few major questions.

Firstly, concerning the health risk: xenotransplantation could cause infection of humans by retroviruses, whether they are present in animal cells or whether they appear after recombination with human viruses. We quote from a report prepared on this subject and presented by Gian-Reto Plattner, on 15 October 1998, to the Parliamentary Assembly of the Council of Europe[68]: "*Animals carry viruses that are not found in humans and for which we have no defence system. Transferred animal cells, tissue or organs into humans can carry with them such viruses or prions. These may develop in humans and cause diseases, which in the worst case might be transmitted to other humans and could cause major pandemics. Cell to cell contacts might favour recombination with human viruses, a mechanism known to generate pandemic viruses. Infections with long incubation periods are particularly dangerous because they may not be detected until after they have been transmitted to other individuals.*"

No doubt some scientists believe that the probability of such infections is low if the necessary precautions are taken when breeding animals destined for xenotransplantation, but we cannot ignore the potentially pandemic scale of any infection, and this calls for the greatest prudence!

This is the reason why there are proposals in both the United States and Great Britain for a moratorium on all forms of xenotransplantation, and why their governments set up authorities for the strict evaluation of trials already under way.

[68] Paragraph 8 of the Explanatory Memorandumg to the Report of the Committee on Science and Technology of the Parliamentary Assembly of the Council of Europe, *Xenotransplantation*, Doc 8166 revised 15 October 1998; draftsperson: Mr. Gian-Reto Plattner: http://assembly.coe.int/main.asp?Link=/documents/workingdocs/doc99/edoc8166.htm.

Xenotransplantation also poses ***medical problems*** that have not been adequately resolved. It is necessary to have a better understanding of the phenomenon of rejection and the physiology of the animal. The day may be near when these medical questions will be resolved. In that case, doctors may be faced with serious conflicts of conscience if they judge that some of their patients in a desperate situation would certainly benefit from xenotransplantation. Compassion could prompt them to take such an initiative.

The question of the risks involved varies depending on whether it concerns the transplantation of organs, grafting tissue, grafting cells (whether or not inserted in capsules), or the use of extracorporal systems using elements of animal organs (such as an artificial liver containing elements of an animal liver).

Even in such cases, caution is still called for in the name of the common good of the population as a whole.

Xenotransplantation also raises questions concerning the **relationship between humans and animals** that have not yet been adequately explored.

Unforeseen reactions have already been observed concerning allografts between humans. Problems of identity or possible violation of the "spiritual personality" could arise as transplants expand to cover the organs with a greater sentimental or emotional charge. Experience acquired in this field does not allow us to underestimate the changes in behaviour and the new, specific and unexpected relationships that may form between the human donor and the human recipient. The human being has an intrinsic spiritual dimension and thus is susceptible to develop problems with his or her sense of identity.

We cannot predict how human beings will tolerate the substitution of vital organs from animals for their own organs. The reaction will probably be different in cases of organs, tissue, cells and biotechnological devices. Furthermore, one might well wonder how a person could preserve the sense of his own identity and unity.

More generally, it is noteworthy that the relationship between animals and humans plays a role in how humans understand themselves. The use of animals not only as food, but also as an integral part of the human body, therefore poses anthropological questions that are of the greatest importance to explore.

For the Bioethics Discussion Group xenotransplantation – especially of organs – raises a number of still unresolved questions.

English translation from the original (French) version

BIOMEDICAL RESEARCH ON HUMAN EMBRYOS IN VITRO[69]

Meeting on 22 September 1998

The members of the Bioethics Discussion Group focused their efforts on this subject because of the discussions taking place on this theme in several European countries, the fact that there is a growing debate within the European Union, and the recent adoption by the Council of Europe of a Convention on Human Rights and Biomedicine. This Convention includes article 18, which does not take a position on the admissibility of the principle of research on embryos in vitro, but contents itself in paragraph 2 with prohibiting the creation of human embryos for the purpose of conducting research on them.

The Catholic Church maintains that, as soon as the egg is fertilised, one is in the presence of an original life that is not that of the father, or of the mother, but a new human being that develops independently. Without becoming involved in philosophical definitions, the Church nevertheless calls for true respect for the human embryo, in the same way as for a person.

However, respect for the person does not imply renouncing biomedical research on him.[70] It is only necessary to ensure consideration of his dignity so as to avoid reducing him to the status of an object; and, in order to avoid this risk, attaching appropriate protection and guarantees so that he is recognised as such by the experimenter and by the procedures being used.

This implies, firstly, obtaining the person's consent, and secondly, taking into account his interests. It could never be acceptable for a person to be sacrificed in the general scientific or therapeutic

[69] In this context, it may be helpful to refer to the following documents:
- *Declaration on procured abortion* of the Congregation for the Doctrine of the Faith, 18 November 1974
- *Instruction on respect for human life in its origin and on the dignity of procreation (Donum vitae)* of the Congregation for the Doctrine of the Faith, 22 February 1987
- *Evangelium vitae*, Encyclical of Pope John-Paul II, 25 March 1995.

[70] The masculine forms - he, his, himself - are used for simplicity of style in this text.

interest, however grand it may be, or to be reduced to the status of a pure object of research.

These conditions cannot be satisfied when the person is unable to express his truly informed consent. The traditional ethical position nevertheless recognises the legitimacy of certain research on minors and incapacitated persons, provided that consent is obtained from persons who are legally authorised to speak in their name, and provided that their interests are seriously taken into consideration. In principle, therefore, only research that has a direct therapeutic interest for the person in question, would be admissible.

International ethical declarations even go as far as allowing for research without any direct therapeutic benefits - provided that the research is deemed important; that it is scientifically necessary to apply this research to persons in the same category of age and disease; that they can only be carried out on persons unable to give consent (young children, persons in a coma or with certain mental handicaps, etc.); and, above all, that they involve only minimal harm or risk.

The same reservations and requirements are valid in the case of human embryos. They do not imply the *a priori* abandonment of all research on them. Yet it is necessary to challenge any act that would compromise the integrity of the embryo or would result in its sacrifice. Under no circumstances would it be admissible to reduce it to the status of a pure object of experimentation.

The creation of human embryos for research purposes is therefore strictly unacceptable, as their very existence would be based only on the will to "instrumentalise" them and then to destroy them.

This prohibition is, moreover, quite rightly enshrined in the Council of Europe Convention on Human Rights and Biomedicine.

New prospects are opening up in the biomedical field, in particular the use of human embryos in vitro, not only as objects of research, but also for therapeutic purposes. Current scientific literature frequently refers to "embryonic stem cells" and their culture intended to obtain stem cells that can be grafted. In reality, these "stem cells" are obtained by dissecting embryos in vitro, which then become sources of therapeutic material.

Two remarks need to be made on this subject: firstly, the language of "stem cells" masks the use of human embryos and, secondly, the rules referred to above concerning research also apply to therapeutic uses (however important they may be). The human embryo may also not be reduced to the status of a pure object for therapeutic use.

English translation from the original (French) version

EUTHANASIA[71]

Meeting on 19 March 1998

1. What is euthanasia?

   Euthanasia is defined as any behaviour that is aimed at causing the death of a person where the motive is to bring an end to current or predictable suffering, either at the request of the person or in the absence of such a request.

2. It is legitimate to distinguish between active and passive euthanasia, depending on whether the objective (causing death) is achieved by an act of commission or an act of omission.

   The term passive euthanasia is often incorrectly used, especially where death follows failure to provide for the discontinuation of treatment, or the use of pain killers. Nowadays doctors have such a range of therapies at their disposal that prudence and respect for the patient require the doctor to ask whether such means are appropriate. In addition, it has become possible to relieve most forms of pain without unduly endangering the life of patients**.**

   Failure to provide inappropriate or disproportionate medical treatment should never be referred to as passive euthanasia! By inappropriate medical treatment we mean any means that provides no therapeutic benefit, and by disproportionate we mean that it provides little benefit in relation to the costs or privations that it would impose.

   For example, there is no reason to call halting chemotherapy treatment against cancer passive euthanasia where in the judgement of the doctor, the treatment has become largely ineffective and more a source of suffering for the patient. However, it would be quite another thing if halting treatment was

[71] In this context, it may be helpful to refer to the following documents:
- Declaration *Iura et bona* on euthanasia by the Congregation for the Doctrine of the Faith, 5 May 1980
- *Evangelium Vitae*, Encyclical of Pope Jean-Paul II, 25 March 1995, chapter III
- Various Episcopal declarations between 1975 and 1991.

used as a means of intentionally causing death, or if pain killers were used to deliberately accelerate death.

3. In almost all European Union countries there are associations calling for the legalisation or other forms of tolerance for euthanasia. They use as arguments the autonomy of the person (implying the right to dispose of one's own life) and the desire to control suffering.

   These reasons given are subject to reservations: without going into the principle of autonomy in general, it should be stressed that, in these cases, the autonomy referred to involves another person. Indeed, the request for euthanasia is addressed to a third party, in the majority of cases to the medical profession. This involves an illegitimate transfer to doctors of an autonomy that is essentially alien to them. Moreover, such a request fundamentally changes their mission: they would no longer only have to fight to save life, but also have to cause death.

   The relationship between the doctor and patient would be profoundly affected.

4. A request for euthanasia is generally made in situations of great distress where the person could be influenced to a varying degree by the attitude of his entourage. The patient sees himself/herself as he/she is seen by others. A request for death could therefore stem from a conviction that he/she has become a burden on others; it then becomes a clumsy way of wishing for relief.

   Such a request then takes on an ambiguous nature that could easily be misunderstood: once relieved of their pain and discomfort and in good care, many people do not repeat their previous request for euthanasia. This seems to indicate that patients no longer wished to live under the earlier conditions, but did not really want to die.

5. It should also be forcefully stressed that this theory of "the right to die with dignity" and legal tolerance of euthanasia confer onto doctors an excessive right. In the final analysis, it would be the medical profession that would decide the fate of who should live and who should die. Even where trust in the responsibility of the medical profession seems to be merited, one should not overlook

the fact that abuses remain possible, especially in a situation where therapy becomes increasingly expensive in a context of limits on health expenditure.

6. No human being has the right to judge that the life of another is no longer of value. Any form of tolerance of euthanasia is symbolic in nature: it affirms that the life of a member of our society has lost its value.

   The prohibition of homicide occupies an important place in any society. We note that there are currently schools of thought that call for making a few exceptions in apparently well-defined situations, backed by a number of guarantees. However, these guarantees could prove to be rather fragile, and what a given legislator intended to apply to exceptional circumstances might subsequently be easily extended.

   Legalisation of death in exceptional cases and any form of social tolerance in this field would indicate that, in the eyes of society, certain lives are no longer worth living. Such legalisation would put unacceptable pressure on vulnerable persons who themselves doubt the sense of life.

   Denying the sense of life is to deny the very foundation underpinning the recognition of the dignity of persons, whatever their situation or whatever alterations affect their mental capacity. It is therefore a sophism to employ the argument of human dignity to justify such legalisation of death.

   It is true to say that certain persons do not accept interventions on their bodies or any alteration in their physical or mental capacity. However, in the view of the Bioethics Discussion Group, the unconditional recognition of the dignity of every person is the very foundation of human rights and a fully humane society.

Original English version

CLONING

Meeting on 29 September 1997

1. We first need to clearly define cloning. There is confusion even in ethical circles between “cloning” and “twinning”. There are several methods that can be used for cloning (from an adult cell, from a cell at an early stage of development, etc.).

2. In the case of Dolly the sheep, it should be noted that there were 277 attempts, including 29 positive fusion results, which resulted in a single Dolly the sheep! Again, it should be stressed that the process uses a matured cell (where the DNA may be damaged): it will only be possible to assess the consequences after three or four generations. The risk factor is therefore significant.

3. Analysing cloning from an ethical standpoint, we note:

The debatable character of its objectives (at least in relation to humankind)

The fundamental change brought about for human relationships

The search for an asexual system of human reproduction.

On 24 June 1997, the Vatican reacted negatively to cloning, placing the emphasis on the profound social transformation that the process would create: a clone has no parents.

The right to diversity would disappear. Love is removed from human relationships. The child becomes an object of the law, whereas before it was the subject of the law!

The Roslin Institute that created Dolly is continuing its research under the very aptly named programme: “*Orphan industrial products*”.

4. Note also that, using this process, we are neglecting the role of sexuality and the link between sexuality and children. Moreover, we are no longer transmitting life in general, but our own life. It is an egotistical choice: we reproduce strictly ourselves. The opportunity to create something new is abandoned: we compromise evolution! By cloning, we make a gene more fragile and we risk making a

group more fragile. We degrade the quality of life and destroy diversity!

5. What arguments could be put forward by the supporters of cloning?

the possibility of reproducing organs for transplantation, organs that will not be rejected;

the possibility of reproducing oneself and therefore extending one’s life into the future;

the possibility of avoiding hereditary diseases (on the contrary, we believe that this could encourage such diseases);

the possibility of practising eugenics starting with particularly promising material.

6. Since we live in a pluralist world, the Bioethics Discussion Group believes that, putting aside any defensive argument, we need to reflect in order to identify the rational arguments that illustrate the need to prohibit cloning. If we abandon the field, nothing will stop science going forward.

7. Scientific research is commendable, but what are its limits? What price do we have to pay? What are the real aims and the means employed?

Human beings may not do just whatever they want.

We may not compromise either evolution or diversity.

We may not fundamentally change the family relationship and create orphans.

We must respect what is “human”, “the goodness of humanity”, “the humanity of man”. This “humanity” concerns the specificity of the human person as opposed to other living things.

When research is destructive towards human beings, it must be prohibited!

Even in the field of animal cloning, questions need to be asked. In these cases, we also compromise the environment (“alteration of nature”). This goes against the general interest and therefore against ethics.

8. When we examine a certain evolution in the positions taken by the French National Ethical Committee, we note how easy and how worrying these apparently slight changes are. In order to know at what point we place "humanity" in danger, we need to come to a clear agreement on what are the essential values which should be safeguarded. Even if the manner in which they are protected varies over time and as science progresses, these values themselves never change.

A purely technical and scientific vision must be refused. Acting in accordance with this viewpoint, the scientist will not be guilty of abdication of ethical responsibility; on the contrary – he/she will score a victory.

NB

On 6 November 1997, the Committee of Ministers of the Council of Europe adopted an Additional Protocol to the Convention on Human Rights and Biomedicine: it is a text on the prohibition of cloning of human beings. This text constitutes an improvement, but it does not answer all the delicate questions. This protocol was opened for signature by the member states on 12 January 1998 in Paris.

English translation from the original (French) version

CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE OF THE COUNCIL OF EUROPE[72]

Meeting on 1 October 1996

In October 1996, the members of the Bioethics Discussion Group engaged in a critical analysis of the new version of the draft Convention on Biomedicine.

They are aware of the preoccupations of the Holy See in this area and they, in line with the experts of the Holy See, point out the flaws still contained in the text.

The members of the Bioethics Discussion Group are, nevertheless, of the opinion that the very existence of such a Convention constitutes progress in comparison with the previous situation: characterised by an almost total regulatory gap and by the complete freedom of States to act in this area. They propose to the Bishops' Conferences of the member states of the Council of Europe to invite their respective governments to sign and ratify this Convention and, where necessary, to set out their reservations.

Furthermore, they express their wish that, as far as possible, the States would later on comply with the additional protocols; these protocols will complement the Convention on delicate questions where it has not been possible, until the present time, to reach unanimity between the authors of the Convention.

The members highlight the fact that there are a number of inconsistent nuances between the French and the English texts, both of which are legally binding language versions.

Article 1: Purpose and object of this Convention: in the French version this Article sometimes makes reference to the human being and sometimes to the person; this distinction is ambiguous. Therefore, in the second line of the French version, the notion "à toute personne" should be deleted. This would remove any distinction between "human being" and "person", by referring simply to the human being.

[72] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, Council of Europe, Oviedo, 4 April 1997.

Article 3: Equitable access to healthcare: “equitable access”, which is quite a fluid notion, should be replaced by “equal access”.

Article 6: Protection of persons not able to consent: this form of expression will help France to adapt its health legislation concerning custody.

Article 8: Emergency situation: English law will have to be amended to allow for an intervention *ex officio* in emergency situations.

Article 9: Previously expressed wishes: the expression “*shall be taken into account*” is less binding than “*will be respected*”; this allows a medical doctor to take a considered decision according to the circumstances at the time - this is a good solution.

English translation from the original (French) version

MEMBERS OF THE BIOETHICS DISCUSSION GROUP

PROF. EDOUARD BONÉ SJ (+)

Doctor of anthropological studies, Professor em. of the Faculty of Theology and Science, Catholic University of Louvain (Belgium)

Member of the Group from 1996-2002

PROF. SILVIO MARCUS-HELMONS

Professor em. of European and International Law, Catholic University of Louvain (Belgium)

Speciality: Human Rights

Member of the Pontifical Council for Justice and Peace

Member of the Group from 1996-2007

PROF. ANTONIO AUTIERO

Professor of Moral Theology, University of Münster (Germany)

Director of the *Centre for Religious Sciences*, Bruno Kessler Foundation in Trent (Italy)

Member of the Group since 1996

FATHER PETER JEFFERY CSSP (+)

Moral theology, Holy Ghost Father Missionary Institute, Middlesex University (Great Britain)

Member of the Group from 1996-2004

FATHER PATRICK VERSPIEREN SJ

Director of the Department of biomedical ethics at the Centre Sèvres, Jesuit Faculties, Paris (France)

Member of the Group since 1998

PROF. MICHEL DUPUIS

Professor of Philosophy, Catholic University of Louvain (Belgium),

Vice-President of the Consultative Bioethics Committee of Belgium

Member of the Group since 2003

PROF. MATTHIAS BECK

Professor of Moral Theology, University of Vienna (Austria)

Dr. med, Dr. theol, Mag. Pharm,

Main research area: Medical Ethics

Member of the Group since 2005

DR. MARIA PILAR NÚÑEZ-CUBERO, ODN

Medical Doctor, Surgeon and Gynaecologist, Master of Bioethics

Professor of Bioethics at the Philosophical Faculty of the University Ramon Llull of Barcelona, at the Pontifical University of Comillas-Madrid and at the University of Granada;

Member of the National Commission on human assisted reproduction (Spain)

Religious Order of the Compagnia de Notre Dame (ODN)

Member of the Group since 2007