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Opinion on the preliminary draft revision of the laws on bioethics (Referral by the Prime Minister)

Introduction

CCNE recognises that there are many points on which the preliminary draft submitted to it is an improvement and notes that most of the proposals contained in Opinion n° 60 on July 2nd, 1998 have been accepted by the Government. The extent of proposed modifications is such as to justify retrospectively the principle of periodic revision adopted in 1994. In this connection, CCNE points out that for the essential revision process in a field subject to constant change, to be efficient, it must respect deadlines. The proposed revision which was due to take place at the end of five years, cannot now be finally adopted before 2002, at best. Because of this delay, which will be further prolonged by the amount of time required to publish enabling legislation, certain obstructions and difficulties which the revision process was specifically designed to obviate, are inevitable. CCNE notes that the wording of the preliminary draft calls for clarification in order to avoid errors of interpretation. In view of society's great interest in the underlying debate, the Committee insists that the options chosen by the future law be entirely clarified. For those reasons, the present Opinion is in two parts :

- The first part concentrates on what CCNE views as the focus of the ethical debate raised by the preliminary draft, i.e. the definition of the field within which research on human embryos will now be considered legitimate. In this respect, the most controversial point is the elimination of existing legal prohibitions to therapeutic cloning, as it is generally called.
- The second part broaches the numerous other subjects which have been discussed and have led to proposals for the modification of the wording of the preliminary draft. Many of them do not actually fall within the specific competence of the Committee, which only offers them as modest contributions for the improvement of a draft the essential aims of which it generally approves. Amongst these subjects, the complex issue of samples taken from a deceased individual was the only one on which the members of the Committee were divided between the wish to reinstate autopsy in its unique role for medical progress and respect for the convictions of those who are opposed to any desecration of the defunct body.

Part I

Research on the human embryo

The issues of legitimacy and of ethical limits to research on the human embryo were addressed in the early days of CCNE, and the Committee has given much thought and published several reasoned Opinions on this subject. Its consideration is part of a

philosophical and ethical debate which has not ripened to a conclusion and may never do so. The substantive position defended by the Committee is to recognise that the embryo or foetus has the status of a potential human being who must command universal respect. Successive Opinions on the subject seek to attune this demand for respect to other intents which are also ethically acceptable. Such is the case today, since the question under discussion is the possible recognition by French law of new possibilities of research on the embryo, justified by new therapeutic prospects.

Prohibition of "reproductive" cloning

Firstly, CCNE approves the decision taken in the preliminary draft to prohibit explicitly "reproductive" cloning of human beings. This is obviously also true of any practice aiming to develop a human embryo for the purpose of creating a store of organs. Since there has been unanimous agreement on this point, the Committee will not repeat at this juncture the very potent arguments in favour of this position which it had already stated in its reply to the President of the French Republic (Report n° 54 of April 22, 1997).

Although it agrees that a sub-paragraph on this subject should be added to article 16-4 of the Code Civil, CCNE is in doubt regarding the wording of this sub-paragraph as set out in article L 1245-1 of the preliminary draft :

"Is prohibited any intervention with the purpose of giving birth to a child, or allowing the further development, after the phase of tissue differentiation has begun, of a human embryo not directly the issue of the gametes of a man or of a woman."

This unfortunate drafting, which is probably the result of a transcription error, gives the impression that reproductive cloning is not prohibited. This should of course read "...of a man and of a woman"...

In the same spirit of clarification set out above, the Committee further suggests that the Words " 'reproductive' cloning" be explicitly included in the wording of this sub-paragraph.

From medically assisted reproduction to research on the embryo

Mindful of the risk of ethical misuse which could result from the reification of the human embryo, i.e. considering it as a thing and no longer as a potential human being, CCNE has already made known its views regarding research on the embryo. On the substance, it agrees with choices made in the preliminary draft :

- on the one hand, re-stating the principle whereby producing human embryos by in vitro fertilisation for research purposes is prohibited;
- on the other hand, opening up regulated possibilities of research on spare embryos "which are no longer included in a parental project" (article L. 2141-12).

CCNE notes that if parents no longer wish to pursue their plans and do not donate the embryos, then inevitably these will not develop and will ultimately either die or be destroyed. In the circumstances, to allow them to be included in a therapeutic research project according to rules laid down by the law, may be viewed as an expression of virtual solidarity between parents, a life which is not to be, and those who could benefit from the research.

This potential solidarity is particularly clear as regards isolating embryonic stem cells from human embryo blastocysts. As CCNE's Opinion n° 53 dated March 11, 1997, noted at the time, using such cells for cell therapy offers very promising therapeutic prospects. Thus, the Committee is in favour of opening up limited and regulated research possibilities on spare embryos.

It therefore proposes that the wording of these two essential sub-paragraphs be modified as follows :

"The conception of human embryos by in vitro fertilisation for research purposes is prohibited. However, research for medical purposes may, as defined below, be undertaken on human embryos that are no longer required for a parental project, with the agreement of the procreating couple."

CCNE points out, however, that the number of spare embryos which could be available for research is likely to decrease in the future because of improved technical skills, and because

of smaller numbers needed on average for embryo transfer on each occasion. Care should therefore be taken to make sure that medically assisted reproduction is not used to voluntarily stock up on spare embryos so as to be able to use them later for research. CCNE approves inclusion in the text of the preliminary draft of an explicit statement to the effect that embryos which have been used for research cannot under any circumstances be subsequently transferred. The Committee considers that such a clause is essential to avoid any kind of misuse.

Evaluation of new medically assisted reproduction techniques

CCNE agrees with Article L.2141-5, which calls for a compulsory evaluation of new medically assisted reproduction (MAR) techniques before they are implemented. This sensible step, which aims to prevent a repetition of previous errors, raises the issue of what happens to embryos which will inevitably be produced by in vitro fertilisation during these validation procedures, which appears to be a reasoned exception to the general principle of not allowing the production of human embryos by in vitro fertilisation for research purposes. The course chosen, which is the destruction of embryos used in evaluation protocols, is clearly fitting.

However, the Committee points out that the text is not sufficiently explicit on two very important counts :

- the third sub-paragraph of Article L. 2141-5 refers exclusively to in vitro research, for which it logically provides that it must end in the destruction of those embryos which will have been "constituted" by IVF during the course and for the purpose of such research.

Yet, the evaluation protocols of the new MAR techniques necessarily include also in vivo observation phases, for instance to compare the effectiveness of two IVF techniques on the implantation and further development of the resulting embryos. Obviously, this in vivo research can only apply to embryos conceived for the pursuance of a parental project. Such protocols also deserve to be strictly controlled. In fact, the preliminary draft which focuses strongly on legislation to regulate research practices bearing on the biology of the pre-implantation embryo, is totally silent on legislation connected to pregnancy. The Committee finds this worrying and would recommend that this omission be corrected..

- No mention is made of the origins of the gametes to be used in the context of the implementation of this new legislation. The chapter in the preliminary draft which relates to the donation of gametes, and its article L. 1244-1 in particular, evidently do not provide for their use in order to proceed with evaluation protocols of new MAR techniques. CCNE is concerned by the legal vacuum that the preliminary draft allows in this respect (informed consent of women donors, approval of protocols, etc.) and by the negative consequences that might ensue. This very important point will be referred to again below.

Research on embryonic stem cells

This point represents the main ethical debate. As mentioned above, as early as 1997 the Committee pronounced itself in favour of the removal of legal obstacles which, up to the present day, prevented French researchers from constituting embryonic stem cell lines unless the embryos or foetuses were the result of spontaneous or induced abortions (Opinion n° 53 on the creation of human embryonic organ and tissue collections and their use for scientific purposes).

Rapidly developing scientific progress, opening up therapeutic possibilities, motivated this position. Since then, such hopes were amply met, at an even faster rate than was expected at the time. For this reason the Committee approves the fact that the preliminary draft authorises researchers to use spare embryos as a source of stem cells.

CCNE believes that two essential considerations must regulate this possibility. The first is that only embryos with no reproductive future can be viewed as available for this purpose. The second is that being subject to the constitution of stem cell lines cannot, for any reason and in whatever form, serve to give these embryos a new reproductive future. The

Committee finds that the wording of the preliminary draft explicitly takes these concerns into account.

According to this text, it appears that three categories of embryos may be used for the production of stem cell lines :

- The product of abortions. On this point, it is clear that new legislation should not in any circumstances result in restricting already existing possibilities, when these are perfectly acceptable. Such cell lines have been produced for decades and it is very important that they remain available for clinical research in particular as regards genetic disorders;
- embryos derived from in vitro fertilisation (IVF embryos) which are no longer required for a parental project and become available for "medical research" as defined by article L. 2141-12 (cf. supra) ;
- embryos created by inserting the nucleus from a somatic cell into an ovule with its nucleus removed, called cell nuclear replacement (CNR embryos).

The Committee has already dealt with ethical issues raised by the use of the first two categories of embryos. Use of the third kind, however, raises new ethical issues. Before going into the substance of the subject, the Committee wishes to draw attention to three related matters.

The nature of the embryo

CCNE stresses the fact - in its opinion a very positive one - that the preliminary draft law designates all three kinds of embryos by the expression "human embryo", which was not a foregone conclusion for two reasons.

Firstly, if one considers the procedure consisting in transferring a cell nucleus into an enucleated oocyte, the resulting product must needs be a human embryo by its very nature. To deny this would mean, were the prohibition disregarded, denying in advance human status to the child produced. Such a dividing line must not therefore be drawn between an IVF embryo and a CNR embryo, even though it is clear that their origins - sexual reproduction in one case, and asexual in the other - introduce an essential difference which is due in part to the nature of the project which originated them and which justifies the radical difference in treatment introduced by the law.

The second reason is related to the nature of the embryo in its pre-implantation phase. CCNE has always refused to attach normative definition to the embryo based on specifically defined biological stages. Similarly, legislation had so far refrained from distinguishing between phases in the development which follows the first division of the fertilised egg. In order to set a limit to in vitro development of embryos intended for the constitution of stem cell lines, the preliminary draft innovates in that it introduces a reference to a stage of development, that of tissue differentiation. CCNE understands the reasoning, but suggests the adoption of clearer references in biological terms.

In its view, tissue differentiation is in fact an abstract and ambiguous reference, since it relates to a continuing process, rather than to a specific stage of development. For instance, depending on whether one considers the moment when tissues that will become the placenta differentiate from those which will become the inner cell mass, or the moment when one or the other embryonic tissue differentiates, these events occur at very different times in the process of development. Conversely, implantation of the embryo into the uterus is a major single event. The Committee therefore recommends that instead of the proposed reference, a reference designating the end of the pre-implantation stage should be preferred, i.e. the moment when the embryo acquires the capacity to implant in the uterus. Introducing a reference of this nature should not however in CCNE's view, give any support to those who consider that the embryo can be reified in the early phases of its development. It would be just as excessive to consider the pre-implantation embryo as simply a bundle of cells of human origin, as to consider it sacred because it is a potential human person. The notion of "ongoing embryonic process" could perhaps represent the enigma which veils the exact nature of the embryo in the very first moments of life. Be that as it may, and

precisely because of this enigma, the Committee declares its attachment to the view that the human embryo must, as soon as it is formed, receive the respect owed to its status.

The origin of CNR embryos

Article L.1245-4 of the preliminary draft, in the third sub-paragraph, aims to regulate the conditions in which could be extracted "the cells" required for producing the CNR embryos to be used for extracting stem cells. In that respect, clearly the conditions in which oocytes are extracted need much closer attention than those pertaining to somatic cells. In fact, the legal vacuum referred to above is also present here. One might go so far as to wonder, as the text of the preliminary draft now stands, and the chapter on gamete donation in particular, whether the text actually opens the door to obtaining oocytes for research at all, and therefore to the constitution of CNR embryos..

In any event, CCNE considers that the question of oocyte extraction or ovarian tissue sampling for the purpose of producing oocytes by cultures, must be dealt with explicitly and with precision in the law, so as to provide safeguards to prevent in particular any risk of using women as instruments or as marketable items whose worth is reduced to the level of oocyte producers for research and therapeutic applications.

Creation of APEGH

CCNE approves the creation of the future Human Reproduction, Embryology, and Genetics Authority (Agence de la procréation, de l'embryologie et de la génétique humaines - APEGH) as set out in the preliminary draft. It sees as pertinent, in particular, that APEGH's tasks should not exclude the ethical dimension of issues it will be dealing with, since such a dimension appears to be so closely linked to their scientific, legal, social, and possibly economic, aspects.

However, with the aim of achieving the best possible conditions for its future relationship with APEGH, and avoiding any possibility of conflicting competence, CCNE suggests that present articles L. 1417-4 and L. 1417-5 be written in inverse order, and to modify as follows the latter text :

Present text : "(APEGH's) Council may refer to the National Consultative Ethics Committee for Health and Life Sciences any matter involving ethical issues. It may also be consulted by that Committee on any matters within its purview."

Suggested text : "The Council refers to the National Consultative Ethics Committee for Health and Life Sciences any matter involving ethical issues. It is also consulted by that Committee on any matter within its purview."

Following that would come present article L. 1417-4 which states that the Council's opinions "take into account the scientific pertinence of protocols, the importance of their objectives, and their ethical acceptability".

On whether 'therapeutic' cloning should be allowed

In its reply n° 54 to the request from the President of the French Republic dated April 22, 1997, CCNE made known its objections to 'reproductive' cloning, but did not broach the problem of 'therapeutic' cloning since the July 29 1994 Act which then applied, specified unambiguously that the creation of human embryos and their destruction for research purposes was prohibited.

CCNE considers that society has a duty to encourage therapeutic progress and to hasten improvements in the prevention and treatment of diseases which are presently incurable or difficult to treat. For this reason, it is very alert to the indisputable promises of cellular therapy using stem cells, be they derived from embryos or differentiated tissue.

Stem cells derived from CNR embryos seem particularly promising, in particular because of their immunological identity with the person who provides the somatic cells the nuclei of which are transferred into denuded ovula to constitute these embryos. It therefore seems probable that differentiated cell populations derived from such stem cells could make up transplants readily accepted by that person, which is the potential value of this technique for cellular therapy.

However, a vast quantity of difficult preliminary research is still required to develop and test such methods. Most of this could use embryonic stem cells derived from spare IVF embryos. Furthermore, research presently in hand on adult stem cells may give rise to therapeutic opportunities which obviate the need to use embryonic stem cells.

In this context, a difference of opinion arose within CCNE on the following question : do therapeutic benefits expected from the use of stem cells derived from CNR embryos justify transgression of the principle on which our legislation has been based so far, according to which the creation of human embryos for any other purpose than their own development, including research, is prohibited ?

Ethical positions expressed classify into the two following analyses of the situation.

1. Position unfavourable to legalising 'therapeutic' cloning

Even for those who accept the use of spare embryos obtained as a result of treatment for infertility, objections to the creation of cloned human embryos are strong.

On the one hand, this is in fact a creation of embryos for the purpose of research, or later on, a production of therapeutic material. This is a transgression of the rules discussed elsewhere regarding the respect owed the embryo because of its unique nature and is a step forward in the direction of a reification which so far had only been restricted by the fact that creating embryos was prohibited unless they were needed for infertility treatment.

On the other hand, the fact that a large number of human CNR embryos become available is an objective situation which could facilitate infringements of the strict prohibition of transfer in utero as prescribed by law, thereby opening the door wide to 'reproductive' cloning : in fact, the same embryos could theoretically be used both for reproductive and therapeutic purposes.

Finally, the need to have available large numbers of oocytes in order to perform therapeutic cloning could, for lack of strict regulation, put psychological pressure on women so that a market situation would be created.

According to scientific publications, research strategies using stem cells derived from differentiated tissue, could give rise to great hopes. A combination of this strategy and continuing research on the optimal conditions for the use of stem cells derived from IVF spare embryos, could suffice to ensure that this country does not lag behind, and would provide the best chances of success for a scenario in which the expected benefits of cellular therapy could be served without recourse to cloning.

For those who are of this opinion, the so far hypothetical nature of therapeutic benefit expected from stem cells derived from CNR embryos, are not convincing enough to warrant a lifting of objections.

If it turned out, however, once the results of research on spare IVF embryos are known, that 'therapeutic' cloning is truly irreplaceable, Parliament could then address the matter anew in the light of observation provided by the future Human Reproduction, Embryology, and Genetics Authority (APEGH), CCNE, and other competent bodies.

However, it would probably be impossible to repeal previous given authorisation to engage in human cloning, even if that method ultimately turned out not to be irreplaceable. In that case, a decision with considerable and irreversible ethical consequences would have been taken with undue haste.

Rules as set out in the preliminary draft, giving APEGH authority to decide in each case on its merits whether cloning protocols with therapeutic purposes are allowable do not satisfy CCNE, since this amounts to passing on to this future creation the burden of an unsolved ethical dilemma.

In the circumstances, it being clear that this position should not be interpreted as meaning final rejection of any therapeutic research bearing on stem cells extracted from embryos produced specifically for that purpose, it does not appear at present desirable to forsake the moral references which French society is attached to, by authorising the cloning of human embryos.

2. Position favourable to legalising therapeutic cloning

Those in favour of this position emphasise first of all that the prohibition of research on

embryos in the earlier text of the bioethics laws brought French research on embryonic stem cells to a complete standstill.

Therapeutic possibilities connected to 'therapeutic' cloning are such that it becomes eminently desirable to achieve the controlled opening proposed by the preliminary draft. Although early gene therapy successes called on stem cells from adults, it would seem possible - even though this has not yet been demonstrated - that 'therapeutic' cloning offers even more ambitious therapeutic possibilities. The major advantage is the immunological compatibility between donor cells and those of the recipient. A duty of solidarity with individuals suffering from disorders prohibits any attempt to hinder research and irremediably penalise sufferers. The risk of doing so is all the greater because the predictable future shortfall of spare IVF embryos will make it more difficult to base research strategy on their availability.

The facility provided by the preliminary draft appears desirable also because of the globalisation of research, keen international scientific competition, and the economic interests involved. Work on 'therapeutic' cloning of human embryos will inevitably progress in various countries. Should early results confirm expectations, French researchers will have no choice but to pursue such research themselves, in contradiction with inappropriate legislation and in circumstances which may not provide all the necessary safeguards. Rejecting that possibility would make France dependent on research abroad, and if this was successful, French society would of course use such therapies but without having had any say in the ethical rules which it wishes to follow, or could even find itself in contradiction with principles to which it is attached.

The fact that legislation is a cumbersome process also pleads in favour of authorising 'therapeutic' cloning immediately. If the ongoing revision of the legal system, which will only enter into force in 2003 at earliest, did not authorise research on stem cells derived from CNR embryos, the present prohibition would be immoderately extended and experienced as excessive constraints on research seeking to develop treatment for a certain number of presently incurable diseases.

The system in the preliminary draft provides both flexibility and necessary safeguards, with the creation of APEGH whose task it will be to examine each research protocol request submitted on its own merits. The extent of authority which the preliminary draft law gives to this future body, which will be an independent monitor, acting in close cooperation with CCNE, suffices to ensure adequate safeguards for the scientific quality of proposed research, the pertinence of its objectives, and conformity to ethical principles.

The controlled easing of the situation now proposed appears to those in favour of this position to be both a prudent and a pragmatic solution to the problem.

Conclusion

At the outset, CCNE recalls with emphasis that it is, as before, unanimously in favour of explicitly prohibiting 'reproductive' cloning

That being so, a broad consensus was arrived at within CCNE in favour of most of the features of the proposed reform as regards research on human embryos, providing the text of the preliminary draft can be clarified, for the very reason that this reform is of considerable importance..

Main points of agreement include :

- firm reminder of the principle that creation of human embryos for the purpose of research is prohibited;
- introduction of an exception to this principle in the context of evaluation of new medically assisted reproduction techniques;
- · controlled possibilities for the use of spare IVF embryos for research purposes, in particular research on embryonic stem cells;
- · creation of APEGH.

On the subject of therapeutic cloning, however, opinions differ. There is general agreement that this subject raises extremely difficult ethical issues, but members of CCNE are divided, depending on their vision of the world and of the future, between two positions which have been outlined above. There is a majority in favour of the second of these positions, i.e. the one which favours controlled authorisation to engage in 'therapeutic' cloning.

Finally, CCNE makes two recommendations :

- to fill the legal vacuum regarding the donation of oocytes or of ovarian tissue, so as to protect women from the risks of enactment of new oppressive legislation;
- to improve if possible the system for revision of the bioethical laws. On this score, it would appear to be highly desirable to arrive at practical, more flexible, and speedier means of limited reform in the interval between the cumbersome periodic revisions of the entire system. In this way, the debate on ethical issues and resulting conclusions would cease to be hindered by considerations relating to governmental and parliamentary deadlines. CCNE underlines the importance of giving continuing thought to this subject. Timetables for the evolution of ethic references, the construction of legal standards, and for progress in scientific knowledge, do not coincide. This is therefore an inherent difficulty in a strategy to have ethics and law monitor science. And yet, it is this strategy which complies with the wishes of our developed industrial societies.

Whatever decision is finally taken on this subject, it cannot dissipate the underlying ethical tension and will definitely not bring the discussion to an end. CCNE therefore suggests that in view of its importance, the debate should be extended beyond the strict parliamentary framework into society as a whole, in the form of very open discussion forums.

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Part II

Proposals for modifications to the preliminary draft revision of the laws on bioethics.

In ordinary lettering : original text of the preliminary draft

In Italics : CCNE's comments and proposals

Warning : consequences for the wording of the law of the possible adoption by legislators of the position refusing to allow 'therapeutic' cloning, has not been taken into account.

Code Civil, Book 1. Section 1, Chapter III

Article 16-4.

A new third sub-paragraph as worded below is added :

"Reproductive cloning is illicit. As a consequence, any intervention with the purpose of giving birth to a child, or allowing the development beyond the pre-implantation stage of a human embryo not directly the issue of the gametes of a man and of a woman, is prohibited".

Article 16-11, Caractéristiques et identification génétiques

Identification of a person using genetic prints is only permitted when the process is part of a judicial enquiry or of instructions implementing a judicial procedure, or for medical or scientific research.

The Committee suggests adding the following to article 16-11:

"Identification of a person using genetic prints is only permitted when the process is part of a judicial enquiry or of instructions implementing a judicial procedure, or of scientific research contained in a protocol approved by a CCPPRB". *ŠComité consultatif de protection des personnes qui se prêtent à la recherche médicale - French equivalent of an IRB - Institutional Review Board*

Article 16-11, paragraph 2

"In civil legal procedures, identification may only be sought in order to implement a judge's investigation in cases involving filiation claims or counterclaims, or obtaining or suppressing financial support. Prior and express consent must be secured from the person concerned. Opposition expressly stated by a living person to such investigation precludes any implementation after the death of the person concerned."

"In civil legal procedure, identification may only be sought in order to implement a judge's investigation. Prior and express consent must be secured from the person concerned. Opposition expressly stated by a living person to such investigation precludes any implementation after the death of the person concerned."

The principal modification is to eliminate the restriction introduced by the 1994 wording as regards civil procedures, since its scope goes far beyond cases involving filiation

Article 16-11, paragraph 3

When identification is for the purpose of medical or scientific research, prior consent must be secured from the person concerned.

"When identification is carried out in the framework of controlled scientific research, prior consent must be secured from the person concerned."

Code of Public Health, Part 1, Book 1, Section III, Chapter I.

Article L.1131-1

This article should stipulate that when identification is carried out in the framework of scientific research, both of two prior conditions must be satisfied : approval of the protocol by a CCPPRB and obtaining consent from the person concerned. Identification for medical purposes is regulated by a decree.

Article L.1131-3

"As regards identification by genetic prints for either medical or scientific research purposes, this must be carried out by personnel authorised to do so according to regulatory procedures."

"As regards identification by genetic prints for scientific research, this must be carried out by personnel authorised to do so according to regulatory procedures, acting in the framework of an approved protocol".

Book II, Section 1.

Article L.1211-8

"The Nation's gratitude is earned by those who donate elements or products of their bodies for therapeutic or scientific purposes."

This is rhetoric which is both out of date and little suited to the individual ethics of donation. CCNE points out that excessive value granted to donations has, in the recent past, been designated as one of the causes for malfunctioning of the French blood donation system. Furthermore, if this clause were to entail actual expressions of gratitude (diploma, decorations, medals..), it would be in contradiction with the fundamental principle of the law which is anonymity of donors.

Section II, Chapter 1

Article L.1221-5, sub-paragraph 2

"However, for minors, sampling may exceptionally take place when therapeutic emergency and tissue compatibility require it."

"However, for minors, sampling may exceptionally take place when therapeutic emergency and/or tissue compatibility require it."

Section III, Chapter 1

Article L.1231-3, sub-paragraph 4

" Decisions by the committee of experts to refuse authorisation are not explained. Decisions cannot be appealed."

"Decisions by the committee of experts to refuse authorisation must be explained. Decisions cannot be appealed."

On this point, CCNE refers to its view, as expressed in Opinion N° 60 on Re-examination of the laws on bioethics, dated March 27, 1998 : if authorisation is refused, the transplantation will necessarily be deferred. This could only be acceptable if the negative decision is properly explained.

Section III, Chapter II :

Samples from a deceased person

The issue of the kind of consent which must be secured before proceeding with an autopsy is a very sensitive matter in ethical terms which also has important repercussions on public health policies. .

There is in fact a conflict in values between the ethics of medical research which demand that everything scientifically possible be done to improve therapeutic practices, and the desire to take into account understandable reluctance and/or beliefs, in particular religious convictions, on the part of those who are opposed to action which they view as contrary to the respect owed to the body of a deceased person. In fact, autopsy should not be seen as a manifestation of disrespect; on the contrary, as it is now practised, it should be seen as the means whereby medical procedures can gain information and use it to help other patients. CCNE considers that efforts should be made to improve understanding of this point.

Articles of the 1994 law are contradictory, since article L. 1232.1 of the Code of Public Health (sampling for therapeutic or scientific purposes) refers to presumed consent given by the person concerned, whereas article L.1232.3 (sampling for scientific purposes other than those aiming to ascertain the cause of death) mentions mandatory and explicit consent from the deceased or his/her family. In practice, these articles have brought about the quasi disappearance in France of medical autopsy. They also created a very paradoxical situation of inequality as regards autopsy depending on where death occurred. In the name of public order, forensic medical autopsy with the sole aim of ascertaining the cause of death and no scientific objective whatsoever, is performed automatically when a person dies in a public place, even though that person may have expressly objected to the procedure when alive. On the contrary, autopsy on the person of someone who dies in a hospital can only be performed if the family is informed, which amounts to asking for prior consent in the few hours before death. Such consent is in fact so difficult to request and obtain in circumstances which are always distressing that most doctors have just about ceased to practice autopsy at all. It is difficult and painful for a family or loved ones to take into account the true - and generally unknown - wishes of the deceased. Furthermore, it is only natural to prefer that a loved one's body should rest in peace and not be subjected to what can resemble post-mortem desecration.

This situation leads to a number of consequences, because progress in medical imagery and biological analysis cannot completely replace autopsy, which uniquely is able to establish formally the causes of death, discover possible connected or occult pathologies, and finally correct or complement diagnosis in 20 to 25% of cases, according to available European and American statistics.

In particular, the precise diagnosis of neuro-degenerative cerebral disorders which are increasingly frequent in an ageing population, can only be made through autopsy. Therefore, if autopsies cannot be performed, there would necessarily be only limited possibilities for therapeutic progress in this field in France. Finally, the collection of epidemiological data regarding causes of morbidity and mortality is entirely based on insufficiently reliable clinical facts and forensic information which is inevitably biased. CCNE underlines that an absence of comparison with objective findings post-mortem limits the benefits one could expect from diagnostic and therapeutic breakthroughs. CCNE is therefore concerned as regards ensuing deterioration of the quality of healthcare.

In spite of the introduction, more than thirty years ago, of the system of presumed consent, which allows for the expression of refusal on a Registry kept by the French transplantation authority, only a very few individuals (0.06% of the population concerned) have availed themselves of this possibility. As a result, since the wishes of the deceased are not known, in practice and in law, consent from families and loved ones tend to replace them.

The system of explicit consent (living will) given before death, which is particularly dominant in Northern Europe, does not completely solve the problem however, since only about 15% of citizens avail themselves of this possibility.

In view of the above, the contradictions which are an integral part of the autopsy controversy must be dealt with. For example, the word "autopsy" should actually be incorporated into the text of the law, as should be clearly stated the various purposes of sampling and the consequently different conditions in which consent can be granted and

notification given to the French organ graft establishment (Etablissement français des greffes) to which samples are submitted.

- forensic autopsy, and autopsy by reason of a danger to public health, or the need to ensure epidemiological monitoring of diseases listed by ministerial circular, do not require consent from the deceased nor from next of kin, nor any notification to the French organ graft establishment;
- *medical autopsy which generally includes sampling, should not be contrasted to autopsy for scientific purposes which always pursues both retrospective and prospective purposes. This should be allowable on the basis of presumed consent, if objections have not been officially recorded, and it should not be necessary to notify the French organ graft establishment of the kind of samples, which should not of course lead to excluding the possibility of making a scientific examination of such samples if it serves medical research. The physician should respond to any request for information from family and loved ones, while respecting the principle of privileged information*

When there is from the outset a scientific purpose which is part of a research protocol previously submitted to the French organ graft establishment, the autopsy should, on the contrary, be subject to explicit consent from the deceased or, lacking that, from family or loved ones, and they must be clearly informed regarding the specific objectives of the above mentioned protocol and of its usefulness to the community;

- *Organ harvesting for therapeutic purposes is made on the basis of presumed consent. To the fullest extent possible, families must be previously informed and given specialised counselling in such traumatic circumstances. The French organ graft establishment is given prior notification;*

The preliminary draft law does not mention the case of individuals who have willed their bodies to scientific research. As it happens, such situations are theoretically governed by obsolete clauses in a law on funerals dating back to 1887, so that in consequence current practice is that bodies are sent to the Anatomical Institute which is of very little benefit to science. CCNE recommends that the legislator should pay due respect to the noble intent of such donations so that their real objective can be achieved and the bodies of those who have made their intentions known be in fact made available to researchers according to conditions which remain to be defined

The above considerations lead CCNE to propose a revision of Chapter II to include in particular the following modifications

Article L.1232-1, sub-paragraph 4

"When a physician has no direct knowledge of the deceased person's wishes, the family must be consulted if possible to provide testimony."

"When a physician has no direct knowledge of the deceased person's wishes, he/she must respond to any request for information from the family or loved ones concerning samples taken, while respecting the principle of privileged confidential information".

Article L.1232-1, sub-paragraph 5

"The French organ graft establishment is advised, prior to any action, of any sampling for therapeutic or scientific purposes, including those for the purpose of ascertaining direct or indirect causes of death. In all cases, families or loved ones are informed of samples taken."

"The French organ graft establishment is advised of any sampling for therapeutic or scientific purposes. Families or loved ones are informed of such sampling."

See also modifications proposed below for article L.1241-6.

Section IV, Chapter 1

Article L.1241-5, sub-paragraph 1

"Embryonic or foetal tissues or cells can only be sampled, stored, and used after induced abortion for solely therapeutic or scientific purposes. The person having undergone induced abortion must have received prior and appropriate information regarding the purposes of such sampling and not have expressed any objection to the procedure."

"Embryonic or foetal tissues or cells can only be sampled, stored, and used after induced abortion for solely therapeutic or scientific purposes. The person having undergone induced abortion must have received prior and appropriate information regarding the purposes of such sampling, and must have specifically consented to the procedure."

Article L.1241-6

"Sampling of tissues and cells and harvesting of products of the human body from a deceased person can only be performed for therapeutic and/or scientific purposes and according to conditions set out in Chapter II of Section III."

"Sampling of tissues and cells and harvesting of products of the human body from a deceased person can only be performed for medical, forensic, therapeutic and/or scientific purposes and according to conditions set out in Chapter II of Section III."

Chapitre IV

Title of the chapter : "Donation and use of gametes

"Donation and use of gametes in the context of medically assisted reproduction"

This chapter could include a definition of procedures governing the donation of gametes to be used for scientific purposes in the context of protocols for the evaluation in vitro of new techniques for medically assisted reproduction. Were "therapeutic" cloning to be authorised, the question of the origins of the necessary oocytes would need to be dealt with elsewhere in the text of the law.

Chapitre

V

Article L.1245-2

"As stated in the third sub-paragraph of article 16-4 of the "Code Civil" quoted below :

"Is prohibited any intervention with the purpose of giving birth to a child, or allowing the further development, after the phase of tissue differentiation has begun, of a human embryo not directly the issue of the gametes of a man or of a woman."

"As stated in the third sub-paragraph of article 16-4 of the "Code Civil" quoted below:

"Reproductive cloning is illicit. As a consequence, any intervention with the purpose of giving birth to a child, or allowing the development beyond the end of the pre-implantation stage of a human embryo not directly the issue of the gametes of a man and of a woman, is prohibited".

Article L.1245-2

"Allowing the development in vitro of a human embryo beyond the tissue differentiation phase, is prohibited."

"Allowing the development in vitro of a human embryo beyond the end of the pre-implantation stage, is prohibited."

Article L.1245-3, sub-paragraph 1

"Only embryos which have not reached the tissue differentiation stage can be used for the purpose of creating embryonic cell lines."

Only embryos which have not reached the end of the pre-implantation stage can be used for the purpose of creating embryonic cell lines in vitro."

Article L.1245-3, sub-paragraph 2

"It can only be undertaken for therapeutic purposes and if there is no alternative method of comparable effectiveness to achieve them."

"It can only be undertaken for therapeutic purposes.

The restrictive clause is pointless since it is ineffective by its very nature : a researcher cannot know beforehand whether there is an alternative method to the one he is using (cf. infra, comment under article 2141-12, sub-paragraph 2).

Article L.1245-3, sub-paragraph 3

"Embryos mentioned in sub-paragraph 1 of this article, and from which stem cell lines are constituted, are exclusively devoted to that purpose. They can neither be stored nor transferred."

"Embryos mentioned in sub-paragraph 1 of this article, and from which stem cell lines are constituted, cannot be used for any other purpose whatsoever. They can neither be stored nor transferred."

Article L.1245-3, sub-paragraph 4

"The creation of embryos from embryonic stem cells is prohibited."

"Using embryonic stem cells for the creation of a new embryo, in whatever form and by any method whatsoever, is prohibited."

Article L.1245-4, sub-paragraph 2

"The creation of embryonic stem cell lines from embryos in vitro which are no longer included in a parental project can only be undertaken, after a grace period for reflection, if prior and written authorisation of the members of the couple from which the embryos are issued is secured, or of the surviving member of the couple if the spouse or partner has deceased, and once information has been supplied to the individuals concerned regarding the possibility of the embryos being hosted by another couple, or of their being no longer stored."

"The creation of embryonic stem cell lines from embryos in vitro which are no longer included in a parental project, may be undertaken within the framework of rules defined by sub-paragraph 3 of article L.2141-12 of this code. It can only take place, after a grace period for reflection, with the prior written consent of the members of the couple from which the embryos are issued, or of the surviving member of the couple if the spouse or partner has deceased, and once information has been supplied to the individuals concerned regarding the possibility of the embryos being hosted by another couple, or of their being no longer stored."

Article L.1245-4, sub-paragraph 3

"Sampling of cells from individuals willing to undergo the protocol referred to in sub-paragraph 1, when it is necessary to do so, are subject to the rules set out in Section II of Book 1 of the first part of this code. In case of infringement of legislation or regulations or rules prescribed by authorisation, Ministers with responsibilities in the fields of health and research may, at any time and after consulting with the above mentioned authority, suspend or withdraw authorisation as provided by the first sub-paragraph of this article."

This wording, which deals with the constitution of embryos by transfer of a somatic cell nucleus into an egg, should be explicit on the subject. The law should also identify precisely the conditions governing the collection of oocytes and their use for this purpose. CCNE considers it essential that this issue which raises obvious ethical problems, should be dealt with explicitly in the text of the law.

It is further suggested that the reference to Section II of Book 1 should perhaps be complemented by a reference to Section IV of Book II, which is the first chapter of this code.

Book IV, Section 1, Chapter VII

Article L.1417-4 et L.1417-5

In order to clarify the respective missions of CCNE and of the Agency, and their relationship, CCNE proposes a reversal of the order of these two articles. CCNE also proposes a modification as follows of the wording of the existing article L.1417-5 :

Article L.1417-5

"The Council may refer to the National Consultative Ethics Committee for Health and Life Sciences any matter involving ethical issues. It may also be consulted by that Committee on any matter within its purview."

"The Council refers to the National Consultative Ethics Committee for Health and Life Sciences any matter involving ethical issues. It is also consulted by that Committee on any matter within its purview."

This modification requires a redrafting of Decree N° 97-555 of May 29, 1997, which provides for CCNE's composition and operating mode, in particular as regards referral rules.

Part II, Book I, Section III, Chapter 1.

Article L.2131-4, sub-paragraph 4

"The two members of the couple give written consent to the diagnosis procedure."

"The two members of the couple give written consent to the diagnosis procedure. However, should one of the two members of the couple not be able to do so, the diagnosis may be performed on the condition that the other member gives written consent."

Section IV, Chapter 1.

Article L.2141-2, , sub-paragraph 1^{er}

"Medically assisted reproduction aims to respond to the parental request of a couple."

"Medically assisted reproduction aims to respond to the request of a couple."

Article L.2141-2, , sub-paragraph 3

"The man and woman in the couple must have reached an age where they are capable of procreation, married or able to give proof of at least two years of cohabitation, and must give prior consent to embryo transfer or insemination. If the couple separates, this is an obstacle to insemination or embryo transfer. However, stored embryos may be transferred if the separation is the result of the man's decease and he has expressly consented during his lifetime to a continuation of the medically assisted reproduction procedure after his death. In this latter case, embryo transfer cannot be performed until at least three months have elapsed and no later than one year after his death. The woman must be provided with psychological counselling."

"The man and woman in the couple must have reached an age where they are capable of procreation, able to give proof of at least two years of cohabitation, and must give prior consent to embryo transfer or insemination. If the couple separates, this is an obstacle to insemination or embryo transfer. However, stored embryos may be transferred if the separation is the result of the man's decease and he has expressly consented during his lifetime to a continuation of the medically assisted reproduction procedure after his death. In this latter case, embryo transfer cannot be performed until at least three months have elapsed and no later than one year after his death. The woman must be provided with psychological counselling."

Since medically assisted reproduction is a costly procedure for society, and the best interests of the child are the prime consideration, CCNE suggests that the condition connected to the stability of the couple should be extended indiscriminately to all couples, married or not.

Article L.2141-3, sub-paragraph 4

"A couple in possession of stored embryos cannot engage in a new attempt at in vitro fertilisation before the stored embryos are transferred."

"A couple in possession of stored embryos cannot engage in a new attempt at in vitro fertilisation before the stored embryos are transferred, unless the thawed embryos are defective."

Article L.2141-5, , sub-paragraph 4

"Embryos created as a result of such an evaluation cannot be the subject of investigations as provided in the protocol mentioned in the second sub-paragraph. They can be neither stored, nor transferred, nor be the subject of a research project as described in article L.2141-12."

"Embryos resulting from in vitro fertilisation performed in the context of such an evaluation cannot be the subject of investigations as provided in the protocol mentioned in the second sub-paragraph. They can be neither stored, nor transferred, nor be the subject of a research project as described in article L.2141-12."

The purpose of this draft is to eliminate any ambiguity conveyed by the wording "embryos

created", which seems to refer to cloning

CCNE furthermore recommends that the text on evaluation protocols for new MAR techniques be clarified and complemented as regards rules applicable to entering the in vivo phase and later evaluation phases

Article L.2141-12, sub-paragraph 1

"In vitro conception of human embryos for research purposes is prohibited."

"Conceiving human embryos by in vitro fertilisation for research purposes is prohibited."

Article L.2141-12, alinéa 2

"Research on a human embryo is prohibited without a medical purpose or if this aim cannot be achieved by an alternative method of comparable effectiveness."

"However, research with a medical purpose may be undertaken on human embryos which are no longer included in a parental project, according to the following conditions."

The proposed drafting seeks to achieve greater clarity

Suppressing the final restriction is based on the following argument : the use of stem cells from a CNR embryo may have in fine the same therapeutic aims as other methods using pluripotent stem cells taken from differentiated organs (for instance, hematopoietic or mesenchymal stem cells from cord blood or bone marrow). However, at this point of technical progress, no one is able to give an opinion on the future therapeutic effectiveness of techniques using either embryonic stem cells from pre-implantation embryos in the blastocyte phase, be they IVF or CNR, or pluripotent stem cells of differentiated organs. Therefore, it does not seem reasonable to subordinate authorisation for research to supplying proof that alternative methods would not be effective. The chosen wording, which stipulates that research can only be undertaken if the therapeutic purpose " cannot be achieved by an alternative method of comparable effectiveness", cannot apply since it is only once research has been undertaken, once it has achieved its aim, that it becomes possible to compare its effectiveness with alternative methods.

Sub-paragraph 3

Consequently, remove the first sentence ("Research can only be undertaken with embryos which are no longer included in a parental project.")

january 18, 2001

NOTES

The Chief Rabbi Michel Gugenheim

(Director of The Jewish Seminary of France)

January 18, 2001

Section III, Chapter II : Samples from a deceased person

Article L. 1232-1, sub-paragraphs 4 and 5.

The Jewish religion attaches as much importance to respect owed to the lifeless body of a person as to the rights of ownership of a deceased person over his or her own body. For that reason, I particularly appreciate the wording of the article mentioned above since it expresses the highly ethical purpose of protecting the wishes of the deceased person, and therefore I do not wish to have it modified.

Henri Caillavet

January 22, 2001

This preliminary draft is a little diffident and at times lacks realism. However, both the spirit and the construction are acceptable. I therefore approve it for the sake of realism since I was a legislator for a number of years and because some of the amendments of the National Consultative Ethics Committee are undeniably an improvement on the government's text

Since my approval is conditional, I am asking that my reservations be appended to CCNE's Opinion.

Genetic characteristics and identification

Article L 16-11 sub-paragraphs 1 et 2

I reject the 2nd sub-paragraph of this article which would in future prevent the exhumation of Yves Montand, for instance.

Organ donation

Article L 12-11-8

This article is in contradiction with the individual ethics of donation. I reject it, as does CCNE.

Human blood (collection, preparation, storage)

Article L 12-21-5 sub-paragraph 2

I approve CCNE's amendment

Samples taken from a living person

Article L 12-31-1

Firstly, the scope of donation should be enlarged. Therefore, add to the list of donors, the quality of half-brother or half-sister.

Furthermore, should also be added, in order to avoid sterile argument, that by "donor in a stable relationship with the recipient" is meant in particular a partner in law (pacsé, French legal contractual partnership), a homosexual.

Article L 12-31-3 sub-paragraph 4

I approve CCNE's amendment.

Samples taken from a deceased person

Article L 12-32-1 sub-paragraph 4 et 5

I fully approve CCNE's two amendments.

Tissues, cells, and products of the body (sampling and harvesting)

Articles L 12-41 et L 12-41-4

In order to harmonise with article L 12-31-1, introduce the notion of half-brother and half-sister.

Articles L 12-41-5 et L 12-41-6

I accept CCNE's proposed amendments.

Donation and use of gametes

Article L 12-44-4

I would propose that the gametes of a single donor should not be used deliberately to produce more than 5 children.

Article L 12-44-7

I reject this article which prohibits the practice of exceptionally calling on surrogate mothers. This concept is completely acceptable according to legislation prevailing in the United Kingdom and United States. A sterile spouse may, in order to satisfy a need for fatherhood, benefit from the gift of sperm. We accept the notion of a surrogate father.

On the contrary, a woman whose womb cannot carry - an embryo has to be expelled at some point - who also experiences an intense desire to love a child, is not authorised to call on a surrogate mother. She cannot therefore have her egg which has become an embryo carried by a third party she has herself chosen. This is morally shocking and legally contradictory.

I regret this existing anomaly, in spite of the fact that I am not a libertarian. Furthermore, the gift of acceptance, in this particular case, cannot be mistaken with making the body into an instrument or goods for sale, nor can it morally infringe the principle of the anonymity of donation.

I consider that for exceptional reasons, a waiver could be granted in as much as consent could be given in the presence of a magistrate or a committee of experts to avoid possible psychological pressure.

Nevertheless, I am clear that with present day mores, morals, and law, it is possible to obtain authorisation to create embryos specially for research and so continue to make do with frozen non parented embryos, and therefore I am inclined to no longer support this proposal.

However, the discussion within CCNE on therapeutic cloning must be taken into account. I maintain that in a democracy therapeutic progress must be promoted in order to hasten improvement in the treatment of the sick. Thus I approve the admittedly imperfect preliminary draft - in particular article L 12-45-4, sub-paragraph 3. We must take care not to penalise either research or discovery.

Extensive monitoring by APEGH, as planned, is reassuring in this context.

Special arrangements regarding embryonic stem cells

Articles L 12-45-2 et L 12-45-3

For my part, I can accept the concept of therapeutic prospects related to therapeutic cloning generated through CNR embryonic stem cells. Commitment requires boldness. I therefore support my colleagues in CCNE who have expressed their agreement with this course of action as outlined in the preliminary draft. It would be preferable to revert to the wording which prohibits embryo development beyond the tissue differentiation stage of the embryo in vitro (14 days) since as we know the United Kingdom accepts a time span which is slightly longer than 14 days.

Medically Assisted Reproduction

Article L 21-41-2 sub-paragraph 3

As I have always supported the acceptability and moral justification of post-mortem embryo transfer, I approve CCNE's text.

Article L 21-41-12 sub-paragraph 1

For lack of better understanding on the part of CCNE, and probably also of public opinion, I repeat that I abandon the concept of human embryos for research purposes created by in vitro fertilisation, but that I deplore that prohibition.

Article L 21-41-12 sub-paragraph 2

I can agree to the wording proposed by CCNE.

Note de Olivier de Dinechin

January 25, 2001

Contribution à l'avis concernant le projet de révision de la loi de bioéthique

In recognising that the reality "human embryos" is identical regardless of how such beings are obtained, CCNE's opinion demonstrates objectivity. This means that these beings are similar to what each human being was at one time in its life. But the contradiction embedded in the draft law - and in this Opinion and previous ones concerned with this same point - appears when a distinction is made in the process of consideration of the value of these beings and the respect owed to them, and when this distinction depends on the fate which human decision reserves for them, be that decision made by procreators, physicians, scientists, or society.

Invoking therapeutic prospects and thereby principles of solidarity to oppose the respect owed to these human beings at the start of their lives, is equal to ignoring the intrinsic value of each human being. To quote a statement once used by the Committee, it amounts to not respecting them as "potential human persons". It signifies giving legitimacy to an end, admittedly a morally laudable end, by means which I cannot in conscience approve of as valid : the reification of human beings.

On reflection, respect for the human embryo rests particularly on two fundamentally intertwined solidarities : solidarity between generations, to the descent of which this being

belongs, and the solidarity of the sexes, to which this being owes existence. This fundamental solidarity has also a powerful symbolic value, i.e. that human generation which is a highly social reality acquires significance from it. This takes priority over a common striving for better health which is another social solidarity, unless one were to adopt a sacrificial logic which our society justly rejects in every other domain concerned with human life. In fact, the proposed law crosses the threshold beyond which a category of living human beings becomes a mine of serviceable material.

In practical terms, the draft law only erects in the path of reducing early embryos to the dimensions of an instrument, the obstacles represented by the present achievements of scientific research. Discussions on cloning, and this latest Opinion reflects them, have already shown that such obstacles are fragile and mobile in the face of continuing pressure which is borne nowadays as much by economic urgency as by the aspiration to know and to heal.

To know and to heal, no doubt. But is it possible to know humans without due respect for their beginnings, where the enigma of our origin is expressed ? And can one claim to heal if one reduces humankind to simple corporeal materiality ?

Note de Jacques MONTAGUT

January 30, 2001

At the last plenary session on the government's preliminary draft for the revision of the bioethics laws, it was decided to extend the criterion of stability to two years of cohabitation to married couples engaged in medically assisted reproduction (MAR).

As I was unable to attend by reason of ill health, I wish to contribute further information and thought to the consequences of such a proposal.

Imposing two years of cohabitation on infertile couples if the woman is over 37 years old, unfairly penalises both the couple and the future child.

For the couple, such criteria represent discrimination for infertile women aged over 37 and wishing to become mothers, compared to other women, be they infertile and younger or fertile and of the same age. It is a fact that the rate of embryonic implantation after the age of 37 drops very significantly as from oocyte age of 40, so that after 42 years of age, MAR success in terms of live and healthy births is very rare (<3% per IVF attempt - FIVNAT statistics from 1987 to 1996). This population represents almost a third of infertile couples undergoing MAR procedures in France (FIVNAT statistics from 1987 to 1996). The 1994 text left them the contractual possibility of marriage as a commitment to their future child. This is doubtless an imperfect solution, but it is at least more humane than being doomed to failure by this criterion - and a disputable one at that - only

As regards the future child, in agreement with the position adopted by the Committee, according to which the best interests of the child take precedence over any other consideration, I wonder whether the couple's stability is a criterion which really plays such a positive role since it would expose the child (for a third of sterile couples) to a considerably greater risk of anomaly - in particular chromosomal - as it imposes an extra two years on an already fairly advanced maternal age.

(with reference to Art. L. 2141-2 sub-paragraph 3, p. 20 and p. 21 of CCNE's text of January 22, 2001).

Note de CLAUDE HURIET

February 5, 2001

Preliminary considerations :

Once again, the authentically pluralist reflection of the Committee, the exactitude and precision of the drafting of the Opinion, must be emphasised. I have nevertheless decided not to take part in the vote, and this is for ..."ethical" reasons.

When the Sénat discusses the bill, I intend to take an active part in the discussion. I would not wish to appear to be the "spokesman" for our Committee, nor would I care to be obliged to disconnect myself from all, or more likely from some, of the positions adopted by the Committee.

Thus, the "proposals for modifications" (second part of the Report) to which I can subscribe for the most part, but not for all of them, could become "amendments" which I cannot today undertake to defend, and which I would be loath to object to if I were to co-sign this Opinion.

Fundamental observations regarding the human embryo :

On this essential point, the Opinion does not avoid the contradiction which stems from the impossibility of reconciling two opposite points of view and arriving at a consensus.

Reference is made to the Committee's concern regarding "the risk of ethical misuse which could result from the reification of the human embryo..."

In my view, one cannot refer to watchfulness in the face of the risk of reification of the human embryo and, at the same time, authorise the inclusion of spare embryos in a research project for therapeutic purposes, since this latter is clearly an instance of turning the embryo into an instrument. Furthermore, the concept of "virtual solidarity between parents, a life which is not to be, and those who could benefit from the research" is unacceptable because, as I see it, solidarity is based on generosity and therefore on free consent, which the embryo is incapable of granting.

Page 4 : Concerning the prohibition to produce human embryos for the purpose of research, the Committee justifiably emphasises the necessity of "an evaluation of new medically assisted reproduction techniques before they are implemented" which "appears to be a reasoned exception to the general principle of not allowing the production of human embryos by in vitro fertilisation for research purposes."

As regards the reification of the embryo, the "reasoned exception" weakens at the outset a previously stated fundamental principle.

When I was heard by the Conseil d'Etat two years ago, I mentioned the foreseeable reappraisal of the prohibition of producing human embryos for research, once research temporarily authorised on embryos had reached one of its objectives, i.e. the pointlessness of any longer producing spare embryos, insofar as it was improbable that research on embryos would stop at that point.

The Committee considers this possibility (page 3) and considers that "care should therefore be taken to make sure that medically assisted reproduction is not used to voluntarily stock up on spare embryos so as to be able to use them later for research".

I fear that this will be a "pious hope" (if I can venture to call it that) since other reasoned exceptions may well appear in future.

Page 10 : Finally, I would add that reference to the "keen international scientific competition", - the financial stakes of which deserve more detailed explanation - should include a mention of the fact that slippage on the timetable in France - the law cannot be implemented before 2003 - and the very recent announcement by the British Parliament to the effect that therapeutic cloning is now authorised, with expected therapeutic results in 5 or 7 years time, would lead to the conclusion that the competition has been lost before it started.

However, the time has come to mobilise energies and resources to develop research on the use of adult stem cells "derived from differentiated tissue" (page 8).

In the Report for the Parliamentary Office for Evaluation of Scientific and Technological Options which Alain CLAEYS and myself were asked to write, on the "implementation of law n° 94-654 of July 29, 1994, concerning the donation and use of components and products of the human body, medically assisted reproduction, and prenatal diagnosis", we pointed out that in these fearfully difficult matters, only two attitudes are possible.

The attitude adopted by those who insist on respecting life from its very onset, and the attitude adopted by those who defend deferred personification. The more I reflect on the subject, the more I am convinced that there is no "middle ground". The Committee's Opinion reinforces that conviction.