

# Update on studies undertaken by the committee regarding gamete and embryo donation.

N° 18 - December 15, 1989

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## General Remarks

Since its creation in 1983, the National Consultative Ethics Committee for Health and Life Sciences, in response to questions from Ministers, has carried out in depth studies, drafted reports, given opinions on fundamental problems in bio-ethics, therapeutic drug trials, healthy volunteers, records, organ transplants, medically assisted procreation, diagnosis *in utero* , genetic prediction.

Frequently, there has been no follow-up to these opinions. The Committee found these delays and postponements regrettable and desired steps to be taken to reduce them.

On two successive occasions, at the request of Prime Minister Jacques Chirac in 1986, and of Prime Minister Michel Rocard in 1988, a mission was given to the *Conseil d'Etat* on this matter. The first mission was to examine problems arising when ethics become law, and the second was to draft a bill on life sciences and human rights.

Working groups were established, both of which were chaired by Guy Braibant, *Président de section* at the *Conseil d'Etat* . The report produced by the first group, called " From Ethics to Law" , was published early in 1988. The second group's report, that is the draft bill, has just been forwarded to the Government. Several members of the National Consultative Ethics Committee worked in the *Conseil d'Etat*' s groups.

Madame Labrusse, Madame Questiaux, Madame Sellier and Monsieur Michaud were in the first group. Madame Labrusse, Madame Questiaux, Monsieur Boué, Monsieur David, and Monsieur Michaud were in the second group. In both instances, Madame de Boisdeffre, Secretary General of the National Consultative Ethics Committee was general rapporteur.

The Chairman of the working groups of the *Conseil d'Etat* and the President of the National Consultative Ethics Committee conferred frequently in a spirit of mutual trust.

The National Consultative Ethics Committee is happy to observe that the passage from ethics to law which it particularly desired to see accomplished has now become a reality.

It notes with interest and gratitude that most of the recommendations of the *Conseil d'Etat* are inspired by the Committee's previous reports and opinions.

Please find hereunder replies to your questions.

1. Reminder of general principles which guide the Committee in this respect.
2. Specific replies to questions.

## Introduction

1. A couple's infertility is a misfortune and there have always been attempts to find a remedy. In spite of general progress, modern medicine has not succeeded in overcoming every kind of infertility, so that palliative methods have developed based on the donation of gametes.

In the last fifteen years, sperm donation has developed in France with the help of CECOS (*Centres d'étude et de conservation du sperme* - Centres for Sperm Conservation and Study). On the basis of these centres' activities which observe strict rules and seem to be socially acceptable, a logical extension of such techniques is now taking place : oocyte or even embryo donation (which in some quarters is considered acceptable) for excess embryos which exist through present IVF (in vitro fertilisation) techniques.

Gradually practices are developing which physicians, biologists, jurists, and legislators, are concerned about and which raise delicate problems.

2. There is a fundamental and obvious difference between tissue or organ donation, the principle of which is generally acceptable, and gamete or embryo donation. In the latter case, the result is the birth of a new human being and this gift has contributed to the genetic determination of a new-born's identity. Furthermore, new social and psychic dimensions of human reproduction are introduced and little is known of their possible effects.

In these difficult issues our major ethical preoccupation is to protect the present and future dignity of the human being which, through these methods, is exposed to numerous hazards. First and foremost, this is the case for those who are involved in this kind of procreation, and particularly so children born in this fashion. Since they are eagerly expected by an infertile couple they are likely to be particularly welcome. However, even supposing donor anonymity always possible - and if it was not, prohibitive difficulties of various kinds would ensue - such children cannot have any knowledge of their genetic background and may suffer in their quest for identity. Effects on the psyche are possible.

The plight of donors must also be considered. They are motivated by altruistic reasons no doubt, but they take on an ambiguous role which can be described as simply a " supplier of genetic material" and their freedom of decision may be impaired by pressures of various kinds. Recipients, whose aspirations are so humanly understandable, may be embarking on adventures of which all the dimensions are not fully clear and of which some of the ethical consequences may be worrying.

There are even more general aspects to these issues. Were an extension, and even more so, a legalisation of these practices to occur, all our rules of filiation would need revision as would connected notions such as family and person. Even if the numbers of couples and families were extremely limited, because of this dissociation between generation and parenthood there is a danger of a more or less partial replacement of the intimacy of procreation by a " biomedical production technique" which psychiatrists and psychologists warn against.

Extracted from the body and subjected to principles and methods which govern instrumental techniques, gametes and embryos - the source of life which conditions the lengthy and hesitant psychic construction of the individual - may well be represented as property, belongings, objects to be used for the satisfaction of sometimes ambiguous yearnings.

At the same time, it is inevitable that for these forms of procreation, intermediaries, either individual or institutions, will be needed and that there may be reason to fear that decisions are not always solely the result of free will and disinterested reflection. Commercial

objectives may come to play a greater role, in varying degrees. Furthermore, these impersonal forms of human reproduction could encourage unacceptable eugenic aspirations.

It is hardly possible to respond to all these questions by drawing a hard and fast frontier between what is acceptable and what must be prohibited. For instance, is it possible to refuse oocyte donation whilst accepting sperm donation? For some, the question even arises of whether it is possible to refuse embryo donation whilst accepting the dual donation of gametes.

The whole matter then is of the utmost complexity. On the one hand, there is the technical possibility that despite infertility, the natural aspirations of a couple to found a family can be satisfied. On the other hand, loom a host of obvious dangers and preoccupations.

3. The Committee has debated these issues at length. It considers that the extent of risk and the importance of principles involved justify the utmost caution. A plea is made for all necessary measures to be taken to ensure that, whatever solution is found to these issues, care be taken to prevent procreation techniques from becoming a lucrative activity for anyone, nor an occasion to apply eugenic convictions.

As to what option should be exercised, the set of conflicting preoccupations which are clearly seen by all to be of extreme gravity, may lead to two opposing attitudes.

The first of these is to consider that what is most important is that the possibility of forming contented families in spite of infertility should exist. This seems to be supported by evidence in the case of donor insemination (i.e. with donor sperm).

This view can be supported by the consideration that in the parental bond as in personal identity, essence is more than just biological filiation. The family history, the love which suffuses it, the identification which permeates it, are what really matter. There is the objection that in the present state of our knowledge, for all we know, these forms of human reproduction may well represent psychic dangers for offspring. But at least some of these risks are inherent and considered acceptable in the case of adoption. On the condition that gamete donation, or even embryo donation, can be implemented whilst protecting the welfare of the future child, respecting the principle of the human body never becoming an object of trade, and taking necessary precautions to exclude any risk of eugenic tendencies, one could consider that such a donation, giving as it does a chance to stable couples to take a fully responsible decision regarding their parental project, is an acceptable response to suffering brought about by infertility.

The contrasting attitude is to consider that dangers for individuals, families, society, the human race, are such that they must be opposed by ethical objections of principle. This case may be supported by the argument that in the individual as in the couple, corporeal and spiritual values cannot be disconnected and that the role played in begetting a child creates a bond which present practices of donor insemination tend to obscure but do not manage to efface. Why then do we distance the donor by establishing anonymity or even securing secrecy of conception, if our culture and our institutions did not attach fundamental importance to the genetic origins of a child? Law certainly creates purely social parental links through adoption, but this is to remedy an established factual situation for the well-being of existing children. Can the two situations be considered totally comparable? From this point of view, one should conclude that to legitimate gamete and embryo donation to respond to demand from infertile couples would lead us into unacceptable perils.

Since its creation, in accordance with the very principles that inspired its composition, the Committee is made up of individuals whose opinions, beliefs, sympathies, and experience are as diverse as they can be. It therefore naturally ensues that, although the debate that invariably takes place frequently leads to unanimity, or at least to acceptable compromise, on a subject such as this irreconcilable differences of ethical appreciation arise.

Some of these only touch upon the interpretation to be put on the following

recommendations : conditional authorisation, albeit vigilant and exploratory; or effort to set limits for existing practices which should be neither encouraged nor above all legalised. This is so for sperm and oocyte donation.

When we come to embryo donation, division of opinion is of a more fundamental nature within the Committee. For some members, the very principle is unacceptable and they wish it to be outlawed. For others, more numerous, it is allowable but with conditions which must be strictly defined by law.

4. The national Committee is nevertheless unanimous regarding conditions that must govern these practices and feels bound to emphasise the following points :

- procreation by gamete or embryo donation is only imaginable in any case by medical prescription for stable heterosexual couples. It must only be practised within *public* authorised centres, under medical supervision and strict rules, and in very small numbers;
- any donation must respect the principle of *anonymity* of the donor, which does not necessarily exclude communication of some non-identifying data;
- any legislation on the subject should include a clause whereby after a suitable lapse of time, it would be reviewed in the light of biomedical progress, appraisal and lessons to be drawn from existing practices, and a furtherance of ethical consideration of the subject;
- it is highly desirable that biomedical research and public health policies should make further efforts to reduce to a minimum cases concerned by these techniques, in particular by efforts to prevent STDs (sexually transmitted diseases) which frequently cause infertility.

5. Whatever the opinion on the ethics of sperm donation, donor insemination has become a social fact. To make it clandestine would very likely have worse effects than to regulate it. Thus, even those who are opposed to the very principle consider such regulation acceptable if it is not seen to be a legitimisation of a practice they do not wish to encourage.

6. Although there is no reason to take a different ethical view of male and female gametes, oocyte donation raises more difficult problems than sperm donation for various reasons :

- it necessitates medical treatment and an invasive technique which is not proven to be innocuous;
- it is possible to extract oocytes on the occasion of surgery or IVF attempts; donation may be requested in circumstances where freedom of consent can reasonably be questioned;
- an oocyte is unlike a male gamete in that it contains cytoplasm which is necessary for the development of the embryo. This cytoplasm can be used to produce other genetic material, which may open the way to various manipulations;
- oocyte donation anonymity would seem to be no less possible than sperm donation anonymity, but it is often felt that the female donor is more involved than is the case for a sperm donor. A strong feeling of indebtedness on the part of the recipient to the donor may lead to unforeseen psychic consequences for mother and child;
- oocyte donation implies a dissociation of genetic motherhood from " gestational" motherhood of which humanity has as yet practically no experience.

For all these reasons, oocyte donation provokes more reticence within the National Ethics Committee than does sperm donation.

7. The National Committee considers that embryo donation raises problems which in essence are more serious than those raised by gamete donation;

- gametes are the vectors of identity of a new human being; the embryo, to use an expression to be found in several of our Opinions, must be recognised as a potential human person. To reify it is a violation of the fundamental respect owed to human dignity. The very principle of deliberate action to induce fertilisation so as to be able to store embryos in "banks" and manage "stock" and possibly distribute them on demand to infertile couples, is in question;

- the dual donation of sperm and oocytes to a doubly sterile couple may lead to such practices which raise the same objections;

- the existence of "surplus" embryos because of present IVF procedures raises an immediate problem which the Committee could not ignore. Should such a donation be seen as reducing the embryo to the status of genetic material used in therapy for infertility, and should then their destruction be seen as the lesser of two evils? Some members of the Committee firmly support this view and consider that embryo donation cumulates and aggravates difficulties inherent in sperm donation and oocyte donation. To take the opposing view, should priority be given to respect for the life of these embryos and attempts be made to ensure their survival and development by giving them to infertile couples, in conditions which must be very carefully considered? Other more numerous members of the Committee respond positively to that view. These points are commented and amplified in the following Opinion.

In any event, the National Committee wishes to remind biologists and physicians that it is necessary to limit to an absolute minimum the number of fertilised oocytes. It considers highly desirable that a form of procreation which raises inextricable ethical problems should become avoidable in the near future.

## Replies to questions

1. In its first Opinion dated 22nd May 1984, the Committee stated that the embryo must be recognised as a potential human person and that this qualification is the foundation of respect owed to it.

2. Creating human embryos in vitro (1) and keeping them for any other aim than a parental project on the part of the two authors of the gametes, is prohibited. This therefore excludes the creation of human embryo "banks" for research or to donate to a third party with a parental project.

3. In the present state of scientific knowledge, in vitro fertilisation techniques lead to the conservation of embryos for achieving the parental project of an embryo's authors. Duration of this conservation must be compatible with the initial parental project to found a family, but must be limited. Maximum time allowable should be three years. The law must set conditions for exceptional extension of conservation and for destruction. A magistrate's involvement would be desirable.

4. With present methods for in vitro fertilisation, embryo fertilisation may, in a small number of cases, lead to the persistence of so called "surplus" embryos, in particular when the embryo's authors have achieved or ceased to pursue their parental project before conservation time has expired. It can be hoped that in vitro fertilisation techniques will progress to the extent that problems raised by the fate of surplus embryos remain temporary because they no longer need to be created. It should be underlined that they are in limited numbers. The very fact that human embryos remain as "surplus" raises serious problems to which the National Committee wished to draw attention in the above ethical considerations. None of the courses of action which could be envisaged such as donation of embryos to achieve the parental project of third parties, or donation for research, or destruction, are judged to be satisfactory by all members of the Committee. However, a

majority view emerged to accept the principle of embryo donation to achieve the parental project of a third party if the following conditions are observed.

Conservation of embryos conceived *in vitro* must, as a priority, respect the authors' original intention of founding a family.

Therefore, *only* surplus embryos raise the question of what should be done with them : destruction or donation to a " recipient" (2) .

## **Conditions for embryo donation to a recipient couple**

Embryo donation when it is the wish of its author-parents can only be contemplated if the procedure is subject to very strict rules to be established by law :

- embryo donation is a voluntary action for which the authors' written consent is required.

They must be informed of all the possible fates that may befall embryos of which they are authors : donation to an infertile couple, research, or destruction. Written consent must be renewed after a waiting time of three months. Consent can be withdrawn at all times. Conditions for obtaining consent shall be set by law. It would be best to provide for a magistrate's involvement;

- none of the steps required for achieving embryo donation can give rise to remuneration or profit. The principle of embryo donation being entirely free of any commercial aspect is inviolable;

- anonymity of the donors must be completely safeguarded as regards recipients, the child, and third parties. No filiation can be established between the child concerned and the donors of the embryo;

- amongst authorised centres for medically assisted procreation, only a small number of public institutions will be responsible for donating embryos (this restriction will make it possible to analyse needs, conditions and consequences of these practices);

- the Committee expresses the opinion that it is desirable that the embryo donors already have some experience of parenthood before they contribute to parenthood in another couple (to avoid possible psychological problems for a donor couple who remain childless);

- the indication of embryo donation can only be medical and in favour of a living heterosexual couple, infertile (bilateral and irremediable sterility), or exceptionally in the case of genetic diseases for which no prenatal diagnosis is possible;

- the age of a woman receiving an embryo donation must be compatible with customary procreation maturity.

A substantial minority in the Committee felt that embryo donation should be forbidden. One reason was that they feared that embryo banks might flourish and that it would be very difficult to keep them under control. They also rejected the notion of human procreation becoming an instrument by the existence of embryo donation. Destruction of surplus embryos seems the lesser of two evils.

The National Consultative Ethics Committee proposed recommendations regarding research on *in vitro* embryos in its Opinion dated 15th December 1986. (See Opinion n° 8).

Research entailing the use of human embryos can only be authorised in exceptional circumstances. The following rules must strictly apply.

## Conditions regarding in vitro human embryo research

Conservation of embryos conceived *in vitro* must give priority to respecting the authors of the embryos intention to found a family.

It is therefore *only* surplus embryos that are concerned by the problem of possible donation for research :

- embryo donation is a voluntary action for which the authors' written consent is required. They must be informed of all the possible fates that may befall embryos of which they are authors : donation to an infertile couple, research, or destruction. Written consent must be renewed after a waiting time of three months. Consent can be withdrawn at all times;

- embryo donation may not give rise to any form of remuneration. The principle of total exclusion of any mercantile element is inviolable;

- anonymity for the donor couple must be totally guaranteed as regards the research team.

After fertilisation, the crucial stages of embryonic development are :

1. on the third day, onset of protein synthesis coded by the embryonic genome;
2. on the seventh day, implantation in the endometrium ;
3. on the fourteenth day, appearance of embryonic structures (embryonic disk).

Present day biological science make it possible to differentiate a succession of stages. Nevertheless, embryonic development is a continuous process and in no way can they be granted any unanimously recognised ethical value as thresholds.

For the purpose of IVF-ET, embryo transfer must be performed before the seventh day, in practice the second or third day and this is the period during which the success rate is highest.

In any event, a continuation *in vitro* of embryo development beyond the seventh day means that it can no longer be used for a parental project but only for research. It must therefore be destroyed.

Any research project on the embryo *in vitro* , or any modification of an on-going project, must be submitted to the National Consultative Ethics Committee. The number of authorised laboratories must remain very restricted, about three or four.

No research project leading to any artificial modification of the human genome and eugenic practices can be authorised under any circumstances. Any re-implantation of an embryo which has been used for experimental research is prohibited. If the National Consultative Ethics Committee approves a project, research teams must, as a priority and before any publication or distribution takes places, report on the results of their investigations to the National Consultative Ethics Committee.

A significant minority of Committee members take a stricter view. They consider that any experimentation on the embryo must be forbidden. Respect for the potential person in the embryo, fear of the dangers of eugenics and consequent injury to the integrity of the human genetic heritage, are the prime motives of such prohibition.

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**Notes**

1. By human embryo in vitro, is meant an embryo produced by fertilisation taking place outside the maternal body.
2. Donation for research purposes is considered in the other reply.