Presidency of the Council of Ministers

PROTECTION OF THE HUMAN EMBRYO AND FOETUS THE ITALIAN NATIONAL BIOETHICS COMMITTEE STATEMENT CONCERNING THE PRELIMINARY DRAFT PROTOCOL OF THE BIOETHICS COMMITTEE OF THE COUNCIL OF EUROPE

31 March 2000

I. The Italian National Bioethics Committee (in Italian CNB), having been charged to make observations concerning the preliminary draft Protocol on the Protection of the Human Embryo and Foetus, examined the draft text being prepared by the Council of Europe, carefully analysing the successive preliminary drafts presented at the periodic meetings and preceded by the despatch of material to be studied to all the participants. In detail, the restricted documents submitted to the attention of the Committee are as follows:

1. CDBI.CO.GT3/Rap.1 Groupe de travail sur la protection de l'embryon et du foetus humains. Rapport de la septième réunion (9-11 février 1998);
2. CDBI.CO.GT3/Rap. 9 Id. Rapport de la neuvième réunion (25-27 janvier 1999);
3. CDBI (99)12. Division between CDBI.CO.GT2 and CDBI.CO.GT3 of issues relating to the research on pregnant women, embryo in vivo, foetus, and also concerning the research on embryonic and foetal cells and tissues; advantages and disadvantages of the different possibilities. Document prepared by the Secretariat at the request of the CDBI Bureau for the use of CDBI in providing guidance to CDBI.CO.GT2 and CDBI.CO.GT3.
4. Avant Projet de principes retenus par le Groupe de Travail relatifs à la constitution et au sort des embryons in vitro (document updated to 19-21 May 1999). Annexe IV;
5. CDBI.CO.GT3/Rap. 10. Avant Projet de Protocole sur la protection de l'embryon et du foetus humains. Réunion conjointe avec CDBI.CO.GT2 (28 septembre 1999). Annexe III;
6. CDBI/Rap. 17. Id. Rapport de la 17ème réunion (6-9 décembre 1999). Annexe V.

In this way it was possible to pay constant attention to any changes of approach liable to exert a significant effect on the content of the Avant Projet, as set out in document sub 6, to the provisions of which are explicitly referred to.
The considerations made by individual members and discussed by the Committee have been translated into observations either concerning the identification of the agreed principles or else issues that, although apparently marginal or terminological, actually had substantial implications concerning the interpretation and application of the Avant Project.
The method of analysis adopted was aimed at satisfying the type of evaluation requested from the Committee concerning both the basic philosophy of the document and, from a more analytical point of view, the examination of the provisions set out in it and all possible interpretative solutions. Nevertheless, analysis of the Avant Projet was limited to a consideration of the principles and provisions stated in the documents examined. However, even with these limitations, it was performed very thoroughly; moreover, equal rigour was applied to making proposals, in the awareness that, once approved, the Protocol will probably be considered definitive with regard to issues involving the formation and use of human embryos.

II. The first observations regard the definitions part of the Avant Projet, in particular art. 2 describing the biological concepts of "embryo" and "foetus" also as regards their juridical implications.
Art. 2 states that: "The term "embryo" applies to the zygote and all subsequent stages of its development until the completion of implantation. The term "embryo" does not apply to [non-totipotent] embryonic cells. The term "foetus" applies to each further development stage of the embryo from the completion of implantation until birth".
The definition of embryo is acceptable; however it would be preferable to specify: that, on the basis of such a definition, in order to consider the individual cell an embryo, it would be necessary for the two chromosome sets, both maternal and paternal, already "drawn", be

combined into a single nucleus (syngamic phase), as it is not sufficient for them to be situated in the same cytoplasm and confined in the two nuclei (presyngamic phase); and, with reference to isolated embryonic cells, it is necessary to ensure that no damage is suffered by the embryo from which they are taken and the need to ensure the use made thereof respects existing legislation.
With regard to the definition of foetus it is acknowledged that the definition adopted is a broad one, which involves an anticipation of the transition from the embryonic phase to the foetal phase in the narrow sense. This is interpreted as an intention to extend protection, which is generally greater for the foetus, to cover an earlier stage of development.

III. The provision regulating consent (art. 4), which merely refers to the "person(s) concerned" is deemed generic and evasive. Art. 4 runs as follows: "An intervention on the human embryo or foetus may only be carried out after the person(s) concerned, as indicated by law, has (have) given free, informed and documented consent". It would thus be preferable to make a clearer distinction between the phase preceding implantation of the embryo in the woman's uterus - for which the provision is adequate as it stands - and the subsequent phase, which marks the beginning of pregnancy. In the latter phase it would be preferable to specify that the pregnant woman's consent is essential and must be obtained also in the case of medical, surgical or diagnostic intervention on the foetus throughout the period of pregnancy. It was, however, also pointed out by some that the father's role cannot be considered secondary, above all with reference to decisions having no bearing on the mother's health but which are important for the protection of the unborn child's health (for example, prenatal therapy).

IV. Art. 6, in prohibiting the maintenance of an embryo in culture beyond 14 days after its formation, seems to refer implicitly to the distinction between embryo and pre-embryo, a distinction that however would seem to have been superseded by the above-mentioned extended definition of foetus. Art. 6 actually states that: "It is prohibited to maintain an embryo in culture for research purposes beyond 14 days or until the appearance of the primitive streak".
It is debatable whether it is suitable to use time as a criterion to determine the degree of protection of the embryo. On this point there was disagreement among the members of the Committee.

V. The final version of art. 7 does not allow it to be decided whether the expressions in parentheses - "in vitro fertilisation procedure" and "intervention on embryo in vitro" are to be given a disjunctive or a conjunctive interpretation. Art. 7 actually states that "a. The parties shall ensure that any [in vitro fertilisation procedure][intervention on embryo in vitro] shall only be carried out in conditions of technical competence and health safety. b The parties shall ensure that any [in vitro fertilisation procedure][intervention on embryo in vitro] shall only be carried out in the framework of duly approved centres by competent body". The Committee proposes that a unifying formulation should be adopted and suggests combining also the conditions laid down in paragraphs a and b, prohibiting any action "unless under rigorous conditions of technical competence and health safety, in the framework of centres duly approved by the competent body".

VI. The provisions governing the right to be informed (arts. 11 and 12) should be expressed more analytically, for example, after the style of the Directive 95/46/EC on the treatment of personal data (art. 11), in which a distinction is made between essential information (defined ad hoc) and supplementary information (indicated by way of example). Art. 11 of the European protocol actually states that: "Persons who donate their

gametes must be appropriately informed, prior to the donation, of the possible different uses of their gametes according to the law. Their explicit and documented consent thereto is required. As long as the gametes have not been used, the gamete donor can withdraw his/her consent". On the other hand, art. 12 states that: "Prior to any IVF procedure, the persons concerned shall be informed of the whole procedure and its implications. In particular, they shall be informed of all possibilities according to the national law relating to the number of embryos to be formed, to be transferred, of the possible destination of embryos which may not be transferred immediately and of storage conditions and termination of embryos."
It is also necessary to emphasize the need for the information to be comprehensible; and the need for the information to be given in a suitable fashion (according to the conditions of the beneficiary) stated in art. 11 (information of gamete donors) should be repeated in art. 12 (information for persons involved in an IVF procedure). For those subject to the latter norm it should be considered necessary to provide information relating to the medical, in particular genetic, aspects, to the psychological, bioethical and juridical aspects of the chosen fertilisation technique, to the chances of success, to the risk of damage to the physical and mental health of the persons involved and for the unborn child, also with reference to the possible conditions of the latter.
The decision-making freedom accorded to the couple in deciding the embryos' fate (art. 13) was discussed. Art. 13 actually states that: "The destination of embryos shall be decided in accordance with the decisions freely expressed by the persons concerned prior to the IVF procedure, within the framework of the national law and in accordance with the professional standards. When the persons undergoing IVF procedures have decided to store their supernumerary embryos with the view to using them in the future, they should specify in writing their decision concerning the destination of the embryos at the end of the storage period and in the case of their death before the end of the storage. If the couple subsequently disagrees, the law may provide for the termination of storage".
The solution proposed does not seem to prohibit the commercial exploitation of embryos explicitly enough. It is therefore recommended that the prohibition be made more explicitly: both those who view the present proposal as liable to encourage a commodifying conception of the embryo and those who, conversely, do not consider that the text of art. 13 gives rise to a similar interpretation agree on this point.
Reservations have been expressed also concerning the indication of the destruction of supernumerary embryos (in the case of the couple disagreeing) as the only solution that can be provided for by the national legislation. Also the use of the embryo by other couples could be proposed. In this connection, in more general terms, others suggest introducing some general indications that can be used to define the timing, the modality and the purposes, the couple's choices concerning the fate of the embryo. Others again consider it would be advisable to make the same amendment to art. 13 as that already made to art. 4, replacing "the persons concerned" with the expression "the person(s) concerned", as in some cases the national legislation does not exclude single persons from accessing assisted fertilisation.
In particular, with reference to the fate of the embryos at the end of the storage period, especially when this period is long, the couple should be helped to evaluate alternative solutions to the destruction of the embryo, suggesting those that offer greater protection of the embryo.

VII. An inconsistency has been observed between paragraphs one and two in art. 14: while paragraph one, although setting limitations, allows the number of embryos produced to be increased as a function of "good chances of success", paragraph two sets a true limit, namely, that of reducing the risk of multiple pregnancy. It has been suggested that to

this limit should be added also the need to protect the woman's health and that of avoiding the use of multifetal pregnancy reduction. The existence of these risks should however be explicitly mentioned at the time consent is obtained. Art. 14 actually states: "The number of embryos formed in vitro shall not be higher than that which, in accordance with professional standards, allows a good chance of the treatment succeeding being ensured. The number of embryos transferred shall be determined, in each case, in such a way as to limit the risk of multiple pregnancy".

VIII. As regards safety of medically assisted fertilisation techniques it has been pointed out that the provision is vaguely expressed; and in this regard it has been pointed out that it is not specified whether the techniques referred to in art. 15 are therapeutic or not. Art. 15 actually states that: "Any clinical application concerning a new technique for medically assisted human reproduction shall be based on the results of prior relevant research".
In response to the doubts raised by this provision it is postulated that it should be interpreted as a safeguarding rule in order to avoid the techniques being applied directly without any prior evaluation.
It is also reported that the norm is ambiguous when it hypothesizes that all clinical applications of a new technique of medically assisted procreation must be based on the results of prior research.
In actual fact, if it were meant merely to indicate the conditions of legitimacy of the, largely experimental, clinical applications of the new techniques of medically assisted fertilisation, in the first instance endeavouring to guarantee the safety of the woman undergoing the treatment, although without sidestepping the problem of protecting the embryo, it would be advisable to specify that research involving the use of embryos should be subjected to the same conditions as for research on embryos in vitro. Otherwise it might be claimed that this preliminary environment of experimentation is not subject to any limitation.
Should the meaning of the provisions be precisely the latter, namely not to take into consideration measures to protect the embryo during the phase leading up to the application of medically assisted fertilisation techniques, the criticism would be directed at its actual content as it would seem fitting that some form of protection should be guaranteed even when the embryo does not represent the immediate object of the experimental investigation, as in the case of research on embryos, but is only its operative instrument or its product.

IX. Lastly, the Committee unanimously expresses the hope that every effort will be made to achieve appreciable results of harmonization, without prejudice the right of each State to express reservations concerning individual provisions that would not be compatible with its existing legislation.