

Presidenza del Consiglio dei Ministri



**IDENTITY AND STATUS OF THE
HUMAN EMBRYO**

22nd June 1996

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INTRODUCTION

The ability to create human embryos in vitro, freezing them, subjecting them to manipulations (for scientific, therapeutic or eugenic purposes), implanting them in a female uterus for procreation, is one of the most controversial chapters of the bioethical debate. The NBC, since its institution, has believed it essential to reflect rigorously on these issues in order to give the institutions and public opinion criteria of ethical judgement and evaluation, also for the purpose (which now seems urgent) of elaborating a wise legislation on this issue, respectful both of the needs of scientific research, and the dignity of all those involved. Moreover, although aware of the urgency of the issue, the Committee has not moved hastily: it has formally established a Working Group on this matter only after the reflection on the bioethical issues concerning assisted fertilization was essentially completed. The Group was initially directed by Giovanni Berlinguer; later, in January 1995, it was entrusted to Evandro Agazzi; original members of it were Prof. Benciolini, Prof. Cappelletti, Prof. Chieffi, Prof. Coghlan, Prof. Danesin, Prof. De Carli, Prof. De Cecco, Prof. Fiori, Prof. Gaddini, Prof. Isidori, Prof. Leocata, Prof. Palumbo, Prof. Piazza, Prof. Romanini, Prof. Sgreccia, Prof. Stamatii. Subsequent members of the Working Group were Prof. Bompiani, Prof. Cattorini, Prof. Donati, Prof. Loreti Beghè, Prof. Nordio, Prof. Mathieu, Prof. Rossi Sciumè. Within the Working Group the conviction grew immediately that any bioethical discussion involving the embryo had to start from a preliminary adequate answer to the question of the embryo's nature. An ontological question, therefore, to use a difficult but unavoidable term, having as its object the search for the definition of an essence; a radical question, to answer which the contribution of biology has become indispensable, but which could not be just a biological question, because it did not query what biology perceives and defines – as embryo - with its methodological criteria, but what that 'object' that biology studies and defines as embryo, actually is. In short, never as during the debate on the embryo, it became obvious to the Committee members that bioethics presupposes (at least in this case, but it could be said more precisely in all cases) a bio-ontology.

The working group started in February 1995 and by the end of November of that year it considered its investigative work concluded.

From the group emerged an important point, which the CNB, in its plenary composition, has agreed upon (although there have been in some members justifiable doubts): it decided to give the document being drawn up a dense and especially synthetic character, focusing it exclusively on the ontological problem and referring to other documents, which will be printed soon, a more in depth study both of the domestic legal issues to protect the embryo, and the many ethical issues case by case.

After several plenary meetings (from the 14th of December 1995 to the 22nd of June 1996), in which Agazzi's continued presence and watchful sensitivity allowed the Committee to overcome many situations of dialectic standstill, the document was unanimously approved on the 22nd of June 1996.

The careful reader will notice that this consensus was won by paying a price: registering in the document differences of opinion on some particular and thorny points which arose within the NBC, resolving which proved to be not only impossible, but most of all inappropriate. This does not mean, however, despite appearances, that the unanimity reached by the CNB was not authentic or that

it has been somewhat flawed by supplementary statements accompanying the document, in which the differences of assessment recorded in the main document are clearly explained, with dutiful brevity. The unanimity of the NBC is real with regards to the essential aspects of the matter: the unanimous vote that ends the paper demonstrates that every line was read, pondered, discussed by all NBC members and that the dissenting views were also passed through the common filter of bioethical reflection. But it was real also from a different point of view, because the differences of opinion present in the document are conditional to a common basis of thought, of which we can never stress the importance enough. The embryo is one of us: this sentence, so easy to say that it is irritating for some, well expresses the fundamental bioethical attitude that emerges from our text: the sense of the limitation to our possible technological work. It's true: the NBC expressed different views on how to deal with embryos before their cells lose their totipotentiality. But even those NBC members who acceded to the more "possibilist" prospects, in any case share the idea that embryos are not mere biological material, mere collections of cells: they are the sign of a human presence, who deserves respect and protection. On this point, which is the one that is ultimately bioethically essential, the NBC was unanimous; and this is why no divergence of opinion among NBC members can make less important their bioethical agreement in principle.

Rome, 22nd of June 1996

The President
Francesco D'Agostino

IDENTITY AND STATUS OF THE HUMAN EMBRYO

1. Motivation and meaning of the matter

What is commonly referred to as the issue of the "ontological status of the human embryo" essentially comes from the fact that certain biomedical *practices* (especially in the field of assisted procreation and certain experimental research projects), even when intended for lawful *purposes*, can involve, in terms of *methods* or *consequences*, the harm or suppression of human embryos. Precisely this circumstance led to wonder whether such practices are *morally legitimate*.

As this is a moral question, it makes sense in the context of the principles and moral norms accepted or discussed today. These include, as a universally shared ethical principle (even though founded and stated in a variety of ways), the *duty* not to harm human beings and, even more so, not to suppress them. Now, the question of the legality of the abovementioned practices concerns (at least most of all) the appropriateness of *applying* this principle, precisely, to the case of embryos. In essence, the question of legality (prescriptive plan) gives rise to a question of knowledge (or descriptive), at the outset: "is the human embryo a *human being*"?

1.1 The answer requires first a definition that allows simply to *factually* identify the embryo and that, on the other hand, is not likely to contain in itself, surreptitiously, an implicit answer to this question for the sheer play in the *meanings* of words. A definition of this type, which recurs frequently in specific literature, is the following: "the embryo is the product of conception in its early stages". It does not say anything about the *nature* of the embryo, and even when it is enriched by a detailed biological *description* of these early stages, it still does not give the required answer. Even when clarifying that he/she is a *human* embryo: in fact, not one of those who raise the issue of the ontological status of the human embryo disputes that he/she is, precisely, human, at least in a very general sense. We must therefore conclude that the precise meaning of the issue can be rather expressed by a question like this: "is the human embryo a full human being"?

1.2 This wording may give the impression of accepting a *discrimination* among human beings (some are fully human, others are not), which contrasts with the "civil religion" that modern moral conscience declares to follow, which claims among its own highest principles that of non-discrimination and equal dignity among human beings. For this reason, the term "full human being" is not used in discussions on the status of the embryo, and in its place the term that is often used is *person*. The reason for this choice is that, for many contemporary ethical theories as well, the person has a very high, or even absolute, moral value, so that, for example, many of those who claim the moral duty of an unconditional protection of the embryo since fertilization, base their argument on the assertion that the human embryo is a person right from fertilization, while those who deny this unconditional duty to protect, often do so by arguing that the human embryo is not a person since fertilization, but only acquires that status at a later time. It must also be mentioned that authors who don't have a

specifically philosophical outlook, prefer to address the bioethical issues related to the embryo without explicitly recurring to the concept of person, believed to be on the one hand too technical from a *philosophical* point of view and, on the other, too controversial in philosophy itself. In addition, there is also the fact that the concept of person has a specific technical meaning in the *law*, meaning that it only partially coincides with the philosophical one, so that, when we must proceed with legal guidelines, we must differentiate carefully.

While aware of these circumstances - and in particular the fact that the allocation to the embryo of the ontological status of person is a prerequisite to address and resolve the bioethical issues mentioned above - the Committee gave deep consideration to this philosophical problem for two main reasons: because it is difficult to deny that the *force* of the moral obligation to respect and protect the embryo varies significantly depending on whether the characteristic of being a person is recognized or not, and because *in effect* the debate about the rights to protection accorded to the human embryo often focuses, in the literature on the subject, on the question of being a person or not.

2. Man and person

2.1 The concept of person has been understood and developed in a variety of ways in the history of philosophical thought. Also (as we have recalled) it has particular technical meaning in the law. Although aware of the relationship between the two levels of consideration, the Committee did not feel (at this stage in the study of the issue) that it falls within its duty to investigate the legal issues relating to the protection of the embryo, taking for granted that the conclusions reached (expressly *ethical* in nature) should receive an additional specific elaboration to be translated into concrete indications of *legal* regulations.

2.2 For the purposes of our problem, the different notions of person now present can be grouped into two basic types. The first represents a development of the "classical" concept, according to which the person is "a rational individual substance" (1), namely, a *concrete individual* with a certain *ontological* nature, which *manifests* itself in a series of abilities, activities and functions (which can without a doubt be regarded as characteristic of rationality), but cannot be reduced to them. Therefore, a certain individual can have a rational nature (and thereby be a person), even without manifesting all, always and in the maximum degree the said characteristic features.

According to another concept, developed particularly by some modern Authors, that of person is instead a *concept* defined by a certain set properties or functions (such as the ability to think, self-consciousness, self-determination, interpersonal communication, symbolic representation). Like all concepts, it results in an abstract class of bodies which, *irrespective* of their ontological nature, may be *declared* to be people - according to the definition of person stipulated in this way - as long as they are capable of exercising the functions described in the requirements. Since a certain being can exercise the functions to which a person is *reduced* in variable quantities and to different degrees, it follows that we can be more or less of a person, that we can become or cease to be one, and that, whilst it is possible that some human beings are not

persons, can instead be persons (although to a lesser extent) various animals. In the extreme, even artefacts (such as robots) could be considered a person if, one day, they were able to show behaviours such as those listed in the definition of person (2).

2.3 Both approaches have been analysed and discussed. The Committee decided not to accept the second approach because in effect it reintroduces, surreptitiously, the legitimacy of a *discrimination* among human beings, on the basis of possessing certain features or functions. Even though, at least apparently, these are the highest and most characteristic capacities of the human nature, it still remains true that human nature cannot be *reduced* to them, and that humans would therefore not be discriminated against on the basis of what they *are*, but what *they have* or *can do*, according to a catalogue of requirements that are identified not only, in effect, ambiguously but also arbitrarily.

It has therefore been recognized that being a person, in an ontological sense, is a simple consequence of having a *rational nature* and that, since rationality is a requirement of human nature, the mere possession of a *human nature* implies that every human individual *is a person*, even though some more complex features of this rational nature may occur only after an appropriate process of evolution, be more or not fully prevented by accidental circumstances, and in some cases even diminish or disappear.

2.4 In the context of philosophical discussions, the respect due to human beings is very often based on the particular *dignity* due to the person in the name of his/her elevated nature, or the special functions it is capable of. However, it is also widespread and present within the Committee - the conviction that the duty of respect towards all humans appears to be sufficiently motivated even without using a concept as complex and controversial as the *philosophical* person. It would be sufficient, for example, to consider man as the product of a long biological and cultural evolution, which has placed him at the centre of our planet and allowed him to change the territory for his benefit - for better or for worse -, thus giving him, in effect, a particularly important position. Those who prefer this intellectual attitude emphasize that all that matters for ethical purposes, really, is to determine whether the embryo is entitled to being treated as a person, that is, in the way in which we agree that the beings of our species who undoubtedly have the status of "persons" (using the term in its *common* meaning) should be treated.

2.5 As a result of the foregoing considerations, it has emerged in the Committee that - whether we want to refer to the philosophical concept of person set out in paragraph 2.3, or whether we prefer to adopt the more philosophically nuanced point of view stated in paragraph 2.4 - the matter can be expressed in a more neutral way with the question, "is the human embryo an individual with human nature or not?" Despite appearances, this is not a futile question, when we carefully examine the concepts appearing in it. In fact, this question is sometimes posed, in the literature on the subject, with regards to the early stages of embryonic development, when it is possible to think that the embryo, although it can be classified as "human" because it is an organism belonging to the species *Homo sapiens*, cannot yet be said to have a fully developed human *nature*. Several authors, in addition, state that in this phase

the embryo does not have individuality, in the sense of being a human with an already clear *identity*. The Committee has therefore proceeded to reflect on these two issues separately.

3. The fully human nature of the embryo

3.1 The philosophical issue

That the embryo may not yet have a fully human nature is a philosophical thesis that is not new. It is indeed known as the theory of the so-called "later vitality", supported by various Authors in the history of philosophical anthropology: it is based on the assumption that a certain degree of preparation of the biological "matter" must be reached, in order for it to contain the "form" that characterizes the human being's *rational nature*. This notion, as well as being based on a certain model of embryogenesis that is today scientifically out-dated, also tends to satisfy certain metaphysical and theological concerns, which are no longer part of the framework of understanding adopted today. It is therefore more reasonable to accept that an individual will have his/her nature and stay with it as long as it retains his/her individual identity (rather than thinking that he/she can "change nature" during his/her development). This allows, in particular, to choose even just one (or few) of the *distinctive* characteristics of this nature, like traits of *identification*, which make it possible to assign this nature at a given entity, even though it does not show (or not yet) a number of other perhaps more "qualifying" of characteristics of this nature.

3.2 The contribution of biological knowledge to the solution of the problem of the embryo's nature

While in the past the "visible" characteristics allowing the distinction between a human being and a non-human being were of morphofunctional (and therefore not obvious from the beginning of embryonic development), today genetics allows us to take the DNA as the depository of the characteristics that accompany every living thing from the first to last moment of their history. For what concerns us, each embryo derived from the fusion of human gametes has, since the phase of his/her zygotic creation, a DNA that contains *specifically human* sequences. These are uncontroversial biological data, that allow us to give the embryo a *human nature* since fertilization, also because the DNA is the bearer of a development program that (if the embryo will be regularly implanted in the maternal womb) will lead to the formation of a full human being, or, exceptionally, of more human individuals (in other words, the development is endogenous and could not lead to different results).

4. The issue of the embryo's individuality

4.1 The issue of the embryo's *individuality* is very complex because of the many meanings of the word "individuality". This cannot be clarified by simply using the standard philosophical definition of "individual": an entity with intrinsic unity (*indivisum in se*) and distinct from any other entity (*divisum a quolibet alio*). In fact, according to this definition, an isolated generic human cell is

properly recognized as an *individual*, and we also cannot deny that it has a human nature. However, no-one would say that such a cell is a "human individual" (but the term "cellular individuality" would rather be used). Similarly, each of the gametes, male and female, is a separate entity (as gamete), but certainly not a human being. In the case of the fertilized egg cell (in which there is potential for development and differentiation absent in other cells, including gametes) the question of whether this "individuality" can be established as that of a "human individual" can instead be sensibly asked. The *direct* answer to this question is very controversial and difficult. In fact, the transition from gametes to zygotes is *not instantaneous*, as is generally the case in biological processes, where it is not only difficult, but in a sense impossible, to identify the exact moment when there is a complex transition. For those who think that the early embryo is a human being, the transition from gametes to zygotes is a very early *event* that already means the creation of a new being who is individually determined, who will develop without discontinuity. For those who do not believe that he/she is already a human being, this transformation is only the first of a series of changes, during which there are other *events* that may be considered particularly significant in order to determine the individuality of the embryo as "human being", because only these would lead to the complete *individual determination* of the embryo.

4.2 *The most significant biological data for the debate on the embryo's individuality*

The stages of embryonic development are analytically reported in a working paper, previously discussed by the Committee, summarised in this final exposition (4). In it are reported 23 stages that, over the 56 days from the moment of fertilization, define the chronology of embryonic development (on the 57th day starts the *foetal* period). Important moments of that chronology can be considered the following:

- During the *first stage*, in the first day of fertilization, the two genomes of the parents (coded gene pools of DNA sequences in chromosomes), already in common in the cytoplasm from the moment of fertilization, join to form the zygote;

- During the *second stage* (2nd and 3rd day) the first mitotic divisions of the zygote and the formation of the morula (2-16 cells) take place and the activity of transcription of genetic information contained in the zygote starts, which expresses the specific characteristics of the individual;

- During the *third stage* (4th and 5th day) the blastocyst is formed (64 cells): cells derived from the zygote, which up to this moment are "totipotent", namely, each one can express the complete genetic programme of a human individual, from this stage they lose their property in the sense that only their integration can express this program;

- During the *fourth stage* (6th day) the blastocyst begins to implant in the uterine wall and at the cellular level there is more interaction between embryo and maternal organism, already present in the biochemical-endocrinological environment in the tuba;

- *Stages 5* (from the 7th to 12th day) and *6* (from the 13th to 15th day) define very important biological processes: on the one hand, the blastocyst comes to completion and the embryonic component is clearly distinguishable

from the extra-embryonic one, which will result in the formation of membranes (placenta, amnion, yolk sac, umbilical cord); on the other, the line or the primitive streak appears (on the 14th-15th day) which allows the identification of the craniocaudal axis, the extremities, the dorsal and ventral surfaces, the right-left symmetry, in other words, the construction plan for the embryo. The appearance of the primitive streak marks the *upper limit* for the division of twins, an impassable limit except in extremely rare pathological cases (such as those Siamese twins or the "parasite" twin). The presence of one or more primitive streaks therefore indicates the development, already determined, of a single or multiple genetically identical individuals. The embryogenesis data for the various types of monozygotic twins (bichorial diamniotic, monochorial diamniotic and monochorial monoamniotic) in fact suggest that the *cellular* precursors of the primitive streak, as a morphologically noticeable structure, differentiate from each other at an earlier stage than that in which the process can be seen, a corresponding phase, for the later event of the 8th-9th day (5).

Therefore, the moment of no return for the formation of multiple twins should happen before the usually reported estimates, based on morphological evidence;

- The *eight stage 8* (18th day) characterizes the appearance of the neural plate, which will develop into the central and peripheral nervous system.

The above information allows us to state that:

a) every individual has a genome different from that of another, if this other is not his/her identical twin; therefore it can be certainly identified as belonging to the human species and his/her *genetic identity* is guaranteed from the moment of fertilization. However, genetic identity and individual identity are not necessarily comparable conditions. In fact, two distinct individuals can share the same genetic material (as monozygotic twins), and the same individual can be formed by genetically different cells (like a chimeric organism).

b) the development of the human embryo is continuous and directed, according to a program that is entirely contained in his/her DNA, expressed in a regulated way, and also modulated by the environment in which it develops, through mechanisms that are not well understood yet.

4.3 For these reasons, the chronology of embryonic development, as summarized previously, not offering an immediate and direct answer to the problem of the *moment* in which human individual identity is established, has given rise to different interpretations of this chronology, present in the abundant literature on this issue. These can be attributed to two main lines of thought.

a) *Immediate origin of personal life*

According to one line of thought, the beginning of a fully individual human life is placed at the moment of fertilization. The following arguments are brought (in summary) in support to this thesis: already at the first stage of embryonic development we can find all the genetic information needed to complete the person's development programme; this development programme is characterized by three important biological properties: the *coordination* of

various structural and regulation genes; the *continuity* in the formation of the organism; the *slow development* of a unique personal project that goes from simple structure to more complex structure (6).

b) *Later origin of personal life*

One line of thought different from the previous one also reworks the abovementioned biological information, to state that the embryo in an *initial period* of development *does not* have the features that make a person. This period is defined differently depending on the feature (or features) taken as those defining the person:

(i) from fertilization to the start of implantation (6 days), during which the cells are certainly totipotent, namely, able to generate a distinct individual (7);

(ii) after fertilization at the end of the implantation and the appearance of the primitive streak (14 days), a period leading to the formation of the plan construction for the embryo and the first and even rudimentary organization of a central nervous system (8); this period should be considered over by the 8th-9th day if, instead of the morphological criterion represented by the appearance of the primitive streak, we consider cellular differentiation, as stated in paragraph 4.2;

(iii) from fertilization to the 18th day, period after which the neural plate appears and, with it, the first sketch of the brain and nervous system that, once developed, can control the sensitivity to pain (9).

Point of view (iii) ~ assumed by those who stress that for the person to exist, *in addition to the requirement of individual identity*, there's *also* the need of a rational nature and believe that the embryo does not possess such nature until the moment in which there are the minimal anatomic-physiological *conditions* to exercise rationality, that is, the first elements of the nervous system. This objection is not considered valid by those who distinguish the possession of a given nature from the ability to carry out its functions, a possibility which may well take a certain time to mature for the formation of their respective anatomic-physiological *conditions*. Positions (i) and (ii) regard instead the problem of *individual identity* and the relevance that, in this context, the characteristic of totipotentiality (of each single cell, or groups of cells) can have, as well as the impossibility of the formation of monozygotic twins.

Up to a T time, following fertilization, cells derived by subsequent divisions of the zygote, although grouped together and interconnected in a specific biological unit, are *totipotent*, which means that *each* of them (in a first phase) or *groups of them* (later) may give rise, with successive specializations, to *any* organ or embryonic or non-embryonic tissue, and even to the development of a complete human being. This occurs naturally in very low percentage of cases (monozygotic twins), but it can also be achieved artificially. Conversely, during this time it is possible to obtain, by fusing two morulas of totipotent cells, one morula capable of continuing the normal development and lead to a single individual. Once the T time has passed, by contrast, the cells' totipotency (intended in both senses mentioned above) disappears, and the individual (or individuals) formed preserve their *identity*, in the sense that they cannot be subdivided into other individuals, nor joined with them. That's why the embryo's individual identity should only be asserted from the time of reaching this irreversibility.

4.4 Individuality and individual identity

As we can see from examining the arguments summarised here, the problem highlighted in this second line of thought is not simple individuality, but rather the more complex *individual identity*, a characteristic that is also stated in the classic definition of person, when we require for it to be an individual *substance*, that is, an individual that remains him/herself and only him/herself throughout his/her existence. This is the reason why we search for a *criterion* to ascertain such identity.

A criterion that is today considered particularly appropriate to ascertain individual identity is *re-identification*: faced with an adult, it is normal to admit that he/she is a *human being*, and it is not difficult to say that “it was till him/her” at birth, and also a few months before birth: his/her “individual identity” is (ideally) guaranteed by this possibility, even though only theoretical, of *re-identification* (10). How far back can we go with such a criterion? Maybe as far back as the moment in which *his/her* DNA is formed? It is difficult to say so, because although it is true that every living individual has during all his/her existence the same DNA (at least in the composition of its chemical elements), it is not true that a certain DNA belongs *only* to a certain individual. In fact, monozygotic twins have (for what we can see with the techniques that are currently available) the same DNA, although they are *distinct* individuals. But even disregarding the case of monozygotic twins, the probability of finding two genetically identical individuals is not null. The only *certain* point we can regress to is that at which it is no longer possible to get his/her identity from something that “was not him/her” (because it could have resulted also in his/her monozygotic twin), or making it flow into something that “is no longer him/her” (as it would at the same time also be “another” merged with him/her) (11).

The Authors who state that the creation of personal individuality (and therefore the relative identity) occurs at the moment of fertilisation, proposed some “biological models” in order to answer the objections mentioned above. In particular, they state that the fact that the zygote has the chance to develop in one or more genetically identical individuals can be interpreted in light of the knowledge on the processes of agamic reproduction by fission or gemmation, which can be observed in unicellular and pluricellular animal and vegetal organisms. This would imply, in the case of twins, recognising to each of the twins a full individual human nature since their creation. In the gemmation model, this creation would happen at different times: the first of the twins would acquire his/her definite identity at the exact moment of fertilisation, and the other, instead, at the moment of the division into twins. In the fission model, the first individual, identifiable in the zygote, would exhaust his/her vital cycle after a few cellular generations, when, for a symmetric process of separation of the single cells or groups of cells, new individuals are formed. Naturally, the two models can be adapted also to multiple twins.

In the same way, the fusion of two early embryos, made up by totipotent cells, which would lead to the formation of a single embryo, capable of developing only in one individual, can be interpreted as the completion of one or two individual vital cycles. In the first case, an already existing individuality would be maintained, and a second individuality would merge with it; in the second, a new individuality would be formed following the fusion of two pre-existing individualities (12).

Similar *interpretations* consist in the proposal of models that, although not based on direct empirical proof, are logically consistent and biologically plausible, as they are based on analogies with known characteristics for the vital cycles of different organisms, in which asexual reproduction is either the rule or it happens at times instead of sexual reproduction. The production of multiple human embryos, for a symmetric process of fission, has recently had an experimental verification (13).

5. Conclusions about the embryo's ontological status

With what we have stated above, we can consider the analysis of the problem of the ontological status of the human embryo as concluded, an analysis based on the outcomes of biological research, interpreting them in the light of the pertinent philosophical categories. The *unanimous* conclusions are the following:

5.1 No ontological suggestion considers the embryo as an object, as his/her material and biological nature puts him/her amongst the being belonging to the *human species*;

5.2 The status of individual is recognised to the product of conception, at least starting from the moment before the appearance of the primitive streak, in which the capability of division in one or more embryos, or of reconstitution into a single embryo, following the fusion of two embryos, is irreversibly lost.

5.3 Before this stage, the embryo's individual identity is – at the current state of scientific research – a controversial issue, although it cannot be denied that he/she has the ontological status of a specifically organised biological human nature, as well as exactly and autonomously aimed at producing one or more clearly discernible human beings.

It's important to observe that the *logical* reason for this controversy can be identified in the fact that the re-identification criterion, which has been used to discuss the moment when we can *state* the presence of individual identity, is only a criterion, that is, a condition that is *sufficient*, but not necessary. This means that there could be an individual identity even if we don't have adequate ways to verify it. Therefore, the ontological interpretation of the biological data ends up being influenced by the interpreter's *moral* options, that is, by the way in which he/she feels *in conscience* to have to behave towards the embryo from the moment of fertilisation. If he/she recognises him/her as another human being, the lack of a differentiating criterion to recognise this ontological status would not be sufficient to contradict his/her moral attitude. On the other hand, if he/she does not recognise him/her as a human being, the lack of such criterion would appear to support his/her internal conviction. This fact explains the statement, already made at the beginning (and which will be discussed again in the following point), that the ontological discussion, although very *relevant* with regards to the ethical issue, does not exhaust it, and this also explains why, regarding the controversial point, there are also within the Committee positions that mirror the fundamental thesis present in the international debate and mentioned above:

(a) It prevails, within the Committee, the thesis according of which the embryo's personal identity is present since fertilisation. For some, this identity can be stated with certainty; for others it has a high level of plausibility. From a practical point of view, both derive from this the duty to treat the embryo as having a personal identity since fertilisation;

(b) Other members, considering the unclear character of the ontological analyses, highlight that the concepts of genetic and epigenetic development, evolutionary continuity, applicable to the embryo as intrinsically aimed at becoming a complete human being, present strong difficulties with regards to the possibility of thinking about a precise moment, defined in the embryo, for the appearance of personal identity. Therefore they believe that the issue essentially cannot be decided, but they recognise that the embryo has the right to be treated *like* a person, namely, in the way in which we agree we must treat all the individuals of our species when there are no doubts about their nature of persons;

(c) Particular resonance in the Committee has the position according to which we can state the full creation of the human embryo's personal identity after the formation of the zygote, indicating as the latest moment the 14th day from fertilisation, or at least the 8th.

6. Moral considerations

6.1 The results of the ontological investigation, in order to determine moral obligations, must be integrated by adequate *axiological* considerations, namely, by attributing to the highlighted ontological structures a precise connotation of value, such that it imposes certain *duties* to our *responsibility*. Today, there is widespread agreement in recognising a very high value to the *person*, maybe even the highest from a moral point of view. For this reason the Committee has explicitly agreed with the recognition of a primary moral value to the *human being*, considered in its *substance*, and as such recognisable in every *human being* in all the phases of his/her existence. It has not deemed necessary to explain this agreement, as this is a principle that already has adequate foundation in different ethical perspectives. On the basis of this recognition, we deduce the *duty to respect* and *protect* every human being, which translates in favouring his/her fullest pursue and exercise of the capacities and functions possessed. A human being can not have reached yet, or not being actually able to exercise, or having lost the ability to carry out certain "functions" typical of the person, without for this reducing his/her *dignity* of person. Simply, he/she will not have the *right* to the protection of such functions, as they are absent. In the case of the individualised embryo, this means that there is no moral obligation (and it would make no sense) to treat him/her "as if" self-aware, free, self-determined, able to communicate and use symbolic imagery. However, there is an *intrinsic duty* to protect his/her *existence* and *integrity*, compared to which the other duties are simply *derivatives* from the characteristics of his/her nature and effective degrees of their manifestation.

6.2 As much as these ontological considerations are very important to frame the issue of moral obligations in the treatment of the embryo, they are not the only foundation for these obligations. In particular, the moral conscience of each individual feels forced by the so-called "golden rule" of morality: "don't do

to others what you wouldn't want to be done to you", where the "others" are like us. Well, since each of us was an embryo – and went through the "early" phase of their embryonic development – we cannot but feel that the embryo is *like us*, and find in this fact reason enough to adopt an attitude of respect and care towards him/her. And this, independently from the fact that we can apply to him/her the philosophical categories (also often controversial) of person or individuality.

This spontaneous way of feeling expresses the awareness of the fact that the embryo is not an entity with a random nature, but an organism with a human nature, who should – at least in principle – be born as the consequence of a free action: an adequate reason, this, to state that it involves our freedom. It is intrinsically *destined* to develop until the birth of a complete human being, towards whom we have to be (*we must be*) responsible. This, according to the Committee, is the only *morally* correct attitude we can have towards the embryo and, better than many ontological subtleties and "segmentations", makes us perceive that he/she is not an *object*. From this comes how abhorrent it is (because it twists their *meaning*) the thought of creating embryos to use as research materials, whilst it can allow a positive view of the creation of embryos for procreative purposes, within a project of responsible care and love, which can also involve certain aspects of artificiality. Naturally, we must then consider the bioethical issues regarding specifically assisted procreation, which are not within the scope of this analysis, and that are the object of another document.

7. Moral duties

7.1 The Committee unanimously believes that the human community has precise, strong and binding moral duties of care towards the embryo, and this in a measure that does not necessarily depend on the outcomes of the philosophical discussion about whether the embryo is a person or not. It becomes therefore essential to identify these duties and establish their typology, not forgetting that an ethical duty loses a lot not of its vitality, but of its efficacy, when it is defined so that it makes its applicability in real behaviours uncertain. The consequence is that also the *duties* burdening man, in view of pursuing the said values, can be in conflict and we can only resolve this if we accept that, case by case, the weight of the values at play is differentiated, according to a *moral judgement* which determines which duty should come first, and in what measure.

In moral philosophy, this situation is often analysed using the distinction between *absolute* duties and *prima facie* duties (which in English could be translated as the difference between binding and non-binding duties) (14). It is defined as *absolute* a duty that has to be respected unconditionally, regardless of what other values could be sacrificed and what consequences could derive from it. Instead, it is defined as *prima facie* a duty that *morally binds* us to respect it (and therefore cannot be confused with a hypothetical imperative, which requires us to do a certain thing if we want to pursue a certain aim, which is in itself not morally binding). However, such moral obligation, emerging "first of all", can be non-binding if, in a certain concrete situation, is in conflict with other duties believed to be morally more binding, and gives way to them. For example, the ethical imperative "do not kill" is considered *prima facie*, rather than absolute, when we admit that killing in self-defence is morally acceptable.

The abovementioned distinction is useful also in the study of the problem that interests us, because determining the morally fitting treatment of the embryo in certain concrete situations is not diversified only on the basis of the fact that we are ready or not to recognise the status of person to the embryo, or at least the moral obligation to treat him/her as a person, but also of whether this obligation is intended as an *absolute*, or a *prima facie* duty.

7.2 Those who state that the embryo must be protected in an *absolute* manner, say that any harmful manipulation, and even more so his/her suppression, must be categorically forbidden. This position is very common among those who recognise the status of person to the embryo, and it leads us to extend the moral duty of protection to any stage of embryonic development. In fact, even if there were uncertainties about the fact that in a certain early phase the embryo is not a person yet, the doubt that he/she might be is enough to force us (according to the *tutoristic* ethical principle) to abstain from harming him/her, in any way and circumstance, given the fact that the duty to protect him/her is absolute.

7.3 Those who state that the duty of protecting the embryo is only *prima facie* believes that, in certain situations where different values are in conflict, even the suppression of embryos – within well-defined and narrow limits – can be ethically admissible.

A typical case is that in which, for example, a genetic test on the embryo's DNA reveals the presence of a serious pathology, so that the exceptional suffering of the person destined to be born and his/her parents is certain. It is then ethically in conflict putting on the same level the duty to avoid such burden of pain and the duty to defend the life of an embryo in his/her first stages of development; it could therefore not be morally condemnable – according to the supporters of this position – to opt for the suppression of the embryo's life.

It is necessary to observe that this position can be taken (and it is often taken in fact) also by those who recognise the status of person to the embryo, although it is more easily taken by those who do not recognise this status to the embryo (at least in certain initial phases of his/her development). In the case mentioned, in fact, it is obvious that those who are convinced that the embryo is a person from the moment of fertilisation, could have very strong moral issues in suppressing him/her, for example, also in the presence of a serious pathology, whilst this *prima facie* duty would appear less binding if he/she was convinced that the embryo is in a state of development in which his/her personal identity is not yet defined (even without denying other, more general but weaker reasons that still force us to respect the embryo). This position, which implies the recognition of the duty to protect the embryo as a *prima facie* duty, the binding force of which is *differentiated* according to the overall circumstances, amongst which also the level of conviction about the ontological status of the embryo in the various stages of his/her development, is shared by various Committee members.

8. Unanimous bioethical conclusions

In bioethical literature, other cases of conflicts of values and, therefore, of duties, are also identified. They derive, in particular, from the consideration of

situations in which the embryo can be implicated and that, on the other hand, involve legitimate interests and responsibilities which we have the *duty* to take into account. In these situations there can be conflicts between the duty to protect the embryo considered only *in itself*, and other rights or duties that come from the *relationship* of the embryo with other people. The Committee has not explicitly discussed these wider contexts, in which the *bioethical* issues involve more complex *ethical* issues, and it is also aware that the bioethical conclusions, should they inspire precise *legal* regulations, should be integrated not only with ethically wider perspectives, but also with all that series of mediations that notoriously involves the move from the moral to the technically legal point of view. It has therefore only come up with some “bioethical conclusions” more closely linked to the problem of the ontological status of the embryo, which was the explicit object of study, in light of the moral criteria taken into consideration and believe to be sufficient to justify them.

The ethical arguments presented above allow us to draw some conclusions that the Committee unanimously wants to recommend. They are the following:

8.1 They are to be believed to be *morally illicit*, because they damage the dignity of the embryo as belonging to the *human nature*, also regardless of his/her more specific characteristic of person:

8.1.1 The *in vitro* creation of human embryos for the only purpose of using them for experimental research, or for commercial or industrial uses;

8.1.2 The multiple creation of genetically identical human beings by twin fission or cloning;

8.1.3 The creation of chimeras using human embryos;

8.1.4 The creation of man-animal hybrids;

8.1.5 The transferral of an animal's embryo in the human uterus or of a human embryo in an animal's uterus.

The Committee is different in recognising as *illicit*:

8.1.6 The suppression and any form of harmful manipulation of embryos, even at the pre-implantation stage of development;

8.1.7 The diagnosis on pre-implantation embryos, indiscriminately finalised to the suppression of embryos;

8.1.8 experimentation on embryos, as in effect it implies their suppression;

8.1.9 The *in vitro* creation of embryos for whom we have no intention of proceeding to the implantation into the maternal uterus.

This difference is discussed in the following point 9.

8.2 They are to be believed to be *morally acceptable*:

8.2.1 Eventual therapeutic interventions, still at the experimental phase, carried out on the embryo, when they are finalised to the protection of the embryo's life or health. In this case, the deontological rules for children apply, in particular with regards to the free and informed consent;

8.2.2 Experimentation for non-therapeutic purposes on dead embryos, obtained from spontaneous or induced abortions, as long as the parents give their free and informed consent and the independence between the medical personnel and/or the institutions that practice voluntary abortion and those that carry out the experimentation, is ascertained.

9. Differentiated bioethical conclusions

Within the Committee there are different positions regarding the recommendations on the protection of *pre-implantation embryos*.

9.1 *Pre-implantation diagnosis*

9.1.1 Those for whom the embryos' protection is an *absolute* duty believe that all forms of pre-implantation diagnosis aimed at *any* choice involving the suppression of the embryos are *morally illicit* (for the reasons already recalled in point 7.2).

9.1.2 Those, however, for whom the protection of the embryo is a *prima facie* duty and *differentiated* in its applications, believe that the prenatal diagnosis on pre-implantation embryos aimed at knowing particular pathologies and even being able to choose, in the presence of particularly serious reasons, to not proceed to the implantation of such embryos, is *morally licit*.

The supporters of this moral admissibility also highlight that this is, according to them, the *only* morally admissible case. In particular, they are unanimous in not recognising the moral legitimacy of discriminating between embryos aimed, for example, at selecting their sex, or other characteristics that are not linked to the future onset of serious pathologies. They also believe that the choice of whether to proceed or not to the discriminatory suppression must be left to the morally responsible free choice of the future parents, and it cannot be the object of legal impositions.

9.1.3 *Embryonic reduction*

The Committee, in this document, did not tackle the problem of the so-called "embryonic reduction" (that is, the suppression in the maternal uterus – in the case of multiple pregnancies – of one or more of the developing embryos, in order to ensure the positive outcome of the pregnancy), as this problem will be adequately tackled in a document regarding pregnancy, which is already being drawn up by the Committee. In said document we will carry out an adequate reflection on the conditions of the children born through assisted fertilisation. There are worrying data in literature, not only for the increase in twins and multiples, and there are no adequate *follow-up* studies of these children. The Committee already recalls the need for polycentric studies on this issue.

9.1.4 *Trials on the embryo implanted in the uterus*

For similar reasons, in this document we do not consider the trials on the embryos in the uterus, an issue that will be tackled in other documents being drawn up by the Committee.

9.2 *"Abandoned" embryos*

A particular problem is that of the so-called "*abandoned*" embryos, that is, cryopreserved embryos, which are produced in excess during practices of assisted fertilisation, and that are not destined to being transferred because the respective parents do not want it anymore and they are against them being used for assisted procreations in other couples.

With regards to the situation under examination, the Committee believes that the respect for the embryo's life should have priority on other values and that, therefore, suitable legal tools are necessary to guarantee *supernumerary embryos* a chance of life and development. For example, the law could take away the availability of these embryos to the couple that accepted their creation, but no longer wants to accept their transferral into the uterus, and establish that, during a fixed period of time (which should be established taking into account the available scientific data relative to the possibility of a reasonable preservation of the embryos from the point of view of their use for reproductive purposes), they are frozen and made available also to other couples intent on ensuring their transferral. Once this period of time has passed, at the end of which the vitality of the embryo could already be considered as deteriorating, these cryopreserved embryos, by now "abandoned", would be considered no longer *supernumerary*, but rather biologically *unsuitable for transferral*. Their situation would therefore be similar to that of the embryos (fresh and cryopreserved) who are unsuitable for transferral for a variety of reasons.

The main alternatives put forward with regards to the destiny of such embryos (each of which should in any case be the object of precise legal regulations) are: leaving them to die spontaneously whilst frozen; suppress them; allowing their use in research.

9.2.1 Some Committee members believe, as a consequence of the *absolute* respect due also to the pre-implanted and cryopreserved embryo, that such abandoned embryos – as they are not dead – *cannot* (morally) be used for experimentation or other purposes, but must be preserved in a frozen state until their natural extinction. Those who support this position are aware that this idea can involve the moral duty to preserve the cryopreserved embryos for a very long period of time, but they see in this situation, objectively worrying, the only ethically coherent way to face a situation that, in their view, should never have happened.

9.2.2 Other Committee members, having as a moral as well as legal criterion the values of the protection of health and scientific research, the meaning of which is individual as well as social, believe that we can *morally accept* experimentation for basic or applicative research on:

9.2.2.1 fresh embryos objectively judged to be unsuitable for transferral, applying to their use the conditions in force for the removal of organs from brain dead individuals. In effect, it would be about considering these embryos as "cell donors", instead of organs;

9.2.2.2 cryopreserved embryos, as long as the term fixed for their preservation for reproductive purposes has passed, and as long as their further development is not protracted beyond the time in which, in the case of normal development, such embryos could have been implanted. The legitimacy of this type of experimentation should in any case be subordinated to the following conditions:

(a) The guarantee that the parents' decision of not wanting the implantation of the embryo in the mother's or another woman's uterus is firm and taken completely independently from the scientific purposes of the research project for which the embryo could be used;

(b) Ascertaining that the personnel and/or institution in which the living embryos are created and/or preserved are not directly involved in their use for experimentation or research purposes, even applicative (for example, production of reagents, medicines, etc.);

(c) Ascertaining the scientific validity of the research project, previously evaluated by expert committees entrusted with the task, from which also comes the fact that trials on human embryos cannot be given up;

(d) Advertising and control both of the institutions where these trials are carried out, as well as the results deriving from them;

(e) The safeguard of the right to conscientious objection by the researchers who are members of the *team* involved in the trials.

Those who support this position highlight that the moral admissibility of what said in point 9.2.2.2 is based on the fact that abandoned cryopreserved embryos exist today in great quantities and they are therefore destined in any case to extinction, which makes it more morally acceptable to achieve from their situation particularly high aims, rather than the simple loss of their existence. Another reason, which is put forward by some, is that, given their early stage, there can be with regards to these embryos the doubt about whether they have achieved the stage of personal identity, which means that we cannot state with certainty that we are experimenting on human beings.

In addition, the Committee believes that the situation presented in the abovementioned point must be considered exceptional and transient, and that the respect due to the embryo also in the first phases of development should lead to regulations prohibiting the creation of supernumerary embryos in practices of assisted procreation, encouraging the research, which is already being carried out, of other ways to satisfy those needs (the moral legitimacy of which has already been discussed in the mentioned document on assisted procreation) that are today satisfied by cryopreserved embryos.

10. Conclusions

The Committee has unanimously come to recognise the moral duty to treat the human embryo, since fertilisation, according to criteria of respect and protection that must be adopted towards human beings who are recognised as persons, and this regardless of whether we attribute to the embryo from the beginning, and with certainty, the characteristic of person in its technically philosophical sense, or whether this characteristic can be attributed only with a high level of plausibility, or that we prefer not to use the technical concept of person and refer only to their belonging to the human species that cannot be contested to the embryo from the first instants and does not change during his/her subsequent development.

The Committee has unanimously deduced a series of recommendations about the *morally illicit* treatment of human embryos, at any stage of their development:

- The creation of embryos for experimental, commercial or industrial purposes;
- The multiple creation of genetically identical human beings by twin fission or cloning;
- The creation of chimeras;
- The creation of man-animal hybrids;
- The transferral of human embryos in an animal uterus or vice versa.

Some Committee members believe that the illegitimacy is unconditional also in the following cases:

- Suppression or harmful manipulation of the embryos;
- Pre-implantation diagnosis indiscriminately aimed at the suppression of the embryos;
- The *in vitro* creation of embryos not intended to be implanted in the maternal uterus.

The Committee has unanimously considered *morally legitimate*:

- Eventual therapeutic interventions trialled on embryos, when they are aimed at protecting their life and health;
- Trials on dead embryos obtained from abortions.

Some Committee members believe that the moral legitimacy extends to some precise cases, namely:

- The creation of embryos for reproductive purposes;
- The decision of not implanting embryos when, following the pre-implantation diagnosis, they are affected by serious malformations of genetic pathologies;
- The use of fresh or cryopreserved embryos who are biologically unsuitable for implantation for experimental or therapeutic purposes;
- The use of "abandoned" cryopreserved embryos for experimental or therapeutic purposes, as long as their further development does not go beyond the term in which, in case of normal development, they should be implanted.

The full recommendations of the cases summarised here, as well as the conditions to respect in some of them, will be discussed in other NBC documents, which will be published soon. The Committee also felt that it would not have made sense, in this document, to indicate if a certain point of view was believed by the majority or by a minority of its members, as the presentation of the ethical positions must take into account all the arguments, the value of which does not depend on the number of those who support them, but by an intrinsic judgement of their validity.

NOTES

1. This is the famous definition given by Boezio in the VI century: “*persona est naturae rationabilis individua substantia*” (Cf. *Contra Eutychen et Nestorium*, 1-3). It is offered in the context of a theological discussion, and it is a sort of final destination for the philosophical-theological doctrinal elaboration of centuries. Criticised and discussed in a variety of ways by a number of medieval authors, it was accepted by Thomas Aquinas, who elaborated a very rich interpretation of it, stressing, in particular, the characteristic of self-determination and the capability of self-reflection. Given that it is general and compact, it was accepted even outside the theological context, and it therefore became a kind of commonly accepted, standard definition of the concept of person; in this sense it can be considered “classic”.

2. These various notions are often called “functionalist”, as they are different from the classical notion that is “substantialist”. They have emerged as a consequence of the progressive erosion that the concept of substance has suffered in modern thought, starting with Descartes, Locke and, especially, Kant. In characterising the various realities, the concept of “function” has come to the fore and, in particular, this has happened also with regards to the person, so much so that even many contemporary “personalistic” philosophies avoid presenting the person as a substance, preferring to insist on certain characteristics or functioning relationships believed to be particularly significant. For a short but significant historical analysis of the different notions of person in the Italian language, we refer to Enrico Berti’s contribution, “Il concetto di persona nella storia del pensiero filosofico”, in AA.VV. *Persona e personalismo*, Lanza Foundation, Gregoriana Ed., Padova, 1992, pp. 43-76. The presentation of the themes linked to the notion of person under “Person” and similar, in the *Historisches Worterbuch der Philosophie*, Band VII, pp. 269-364, is very detailed. Significant examples of functionalist notions of person, with the respective ethical effects, are: D. Parfit, *Ragioni e persone*, Il Saggiatore, Milano, 1989; P. Singer, *Etica pratica*, Liguori, Napoli, 1989; HT Engelhardt Jr., *Manuale di bioetica*, Il Saggiatore, Milano, 1991. A critique of the functionalist notions of person can be found in E. Agazzi, *The Ontological Status of the Human Embryo*, a working document of the National Bioethics Committee in 1995.

3. The incongruity of separating the concept of human being from that of person is analysed, in the context of a substantialist notion, in the work by E. Agazzi, “L’essere umano come persona”, in E. Agazzi (ed.), *Bioetica e persona*, Angeli, Milano, 1993, pp. 137-157.

4. L. De Carli (with the contribution of G. Berlinguer, A. Bompiani, C. Flamigni, E. Sgreccia), *The Status of the Human Embryo: biological data and issues*, a working document of the National Bioethics Committee in 1995.

5. Cf. CE Boklage, “On the timing of monozygotic twinning event. Twin research 3”, in *Twin Biology and Multiple Pregnancy*, Alan R. Liss inc., New York, 1981, pp. 155-165.

6. Cf. L. De Carli, "La persona negli stati di confine: le indicazioni della genetica", in C. Viafora (ed.), *La bioetica alla ricerca della persona negli stati di confine*, Gregoriana ed., Padova, 1994, pp. 43-52; A. Bompiani, "La nascita dell'individuo, della persona e della personalità nel contesto della riflessione bioetica", in *Rivista Italiana di Pediatria*, 21 (1995), pp. 579-594; A. Serra, "Per un'analisi integrata dello 'status' dell'embrione umano. Alcuni dati della genetica e dell'embriologia", in S. Biolo (ed.), *Nascita e morte dell'uomo*, Marietti, Genova, 1993, pp. 55-108.

7. The data on the totipotentiality of the single cells of the embryo after the first divisions can be gained by experiments on animals. See for example: JS Nicholas and BV Hall, "Experiments on developing rats II: The developments of isolated blastomeres and fused eggs", in *Journal of Experimental Zoology*, 90 (1992), pp. 441-459. The 6th day is by some indicated as the moment in which individuality starts, as, coinciding with it, the first direct connections with the maternal tissues and therefore, the interactions necessary for a complete development of the organism are established. See F. Abel, "Nascita e morte dell'uomo: prospettive della biologia e della medicina", in S. Biolo (ed.), *Nascita e morte dell'uomo*, Marietti, Genova, 1993.

8. Cf. A. McLaren, "Prelude to embryogenesis", in *Human embryo research: yes or no?*, The Ciba Foundation, Tavistock London, 1986, pp. 5-23; E. Lecaldano, "Questioni etiche sui confini della vita", in A. Di Meo e C. Mancina (ed.), *Bioetica*, Laterza, Bari, 1989, pp. 32-35. See also the authors, cited in the following note 11, relative to the non-immediate appearance of human individuality.

9. Cf. M. Lockwood, "When does a life begin?", in M. Lockwood (ed.), *Moral Dilemmas in Modern Medicine*, Oxford, Oxford University Press, 1985, pp. 9-31; M. Lockwood, "Warnock versus Powell (and Harradine): when does potentiality count?", in *Bioethics* 2 (1988), pp. 189-213; HM Sass, "Hirntod und Hirnleben", in HM Sass (ed.), *Medizin und Ethik*, Stuttgart, 1989, pp. 160-183. See also P. Singer, *Etica pratica*, Laterza, Bari, 1982, p. 122.

10. A significant presentation of the application of this criterion can be found in the work of a known representative of the Oxford school analytical philosophy in the: Peter Strawson, *Individuals*, Methuen, London, 1959.

11. Amongst the many authors belonging to different philosophical trends, who believed that they had found in totipotentiality, in the possibility of creating monozygotic twins, and in that of obtaining chimerical individuals, reasons to doubt, or even deny, the appearance of the embryo's individual identity before a certain T time (differently indicated), we mention: NM Ford, *When did I Begin?*, Cambridge, Cambridge University Press, 1988; J. Fuchs, "Seele und Beseelung im individuellen Werden des Menschen", in *Stimmen der Zeit*, 207 (1989), pp. 522-530; KV Hinrichsen (ed.), *Humanembryologie*, Springer, Berlin, 1990; TA Shannon, AB Walter, "Reflections on the Moral Status of the Pre-Embryo", in *Theological Studies*, 51 (1990), pp. 603-626; R. McCormick, "Who or what is the Pre-embryo?", in *Kennedy Institute of Ethics Journal*, 1 (1991), pp. 1-15; M. Lockwood, "Tissue donors and research subjects to order: some Kantian concerns", in *Revue internationale de philosophie*, 193 (1995), pp.

265-284; C. Flamigni, "Embrione e feti umani: sperimentazioni e donazioni", in S. Rodotà (ed.), *Questioni di bioetica*, Laterza, Bari, 1992, pp. 165-181; M. Mori, *La fecondazione artificiale*, Laterza, Bari, 1995, chapter III. The intention of non-recognising to the embryo an individual identity before a certain stage of development has led some authors to coin the term "pre-embryo" to indicate such early status. Although recommended also in some other official document (e.g. by the *Medical Research Council* in London, in a 1985-86 report), this term has not been universally accepted and is used, in practice, only by those who believe that the embryo is not a human being before a certain moment in time.

12. Cf. M. Alikani, N. Noyes, J. Cohen, Z. Rosenwaks, "Monozygotic twinning in the human is associated with the zona pellucida architecture", in *Human Reproduction*, vol. 9/7 (1994), pp. 1318-1321. See also the works, already mentioned in note 4, of L. De Carli (with the contribution of Berlinguer, Bompiani, Flamigni, Sgreccia) and A. Serra (and other publications by this author).

13. Cf. R. Kohlberg, "Human Embryo Cloning Reported", in *Science*, 262 (1993), pp. 652-653; HW Jones, RG Edwards, GE Seidel, "On attempts at cloning in the human", in *Fertility and Sterility*, 61 (1994), pp. 423-426.

14. This distinction was introduced by the English philosopher WD Ross, author of two important works: *The Right and the Good*, Clarendon Press, Oxford, 1930 e *Foundations of Ethics*, Clarendon Press, Oxford, 1951. It is very useful in the discussion of the conflict between duties, and it is largely adopted by contemporary ethics. For a critical analysis we can see: E. Agazzi, *Il bene, il male e la scienza*, Rusconi, Milano, 1992, pp. 269-272.

ADDITIONAL DECLARATION BY SOME NBC MEMBERS

The signatories of this declaration – recognising the effort made to welcome and reconcile the different ethical instances existing today in the debate on the identity and status of the human embryo – feel the need to express more broadly their convictions on the most crucial point in the debate, relative to the embryo's nature of human being since fertilisation, with the bioethical consequences that this point of view involves.

Although they don't question the biological concept of totipotentiality, which characterises the embryo's cells in the very first phases of his/her existence, they don't believe that this biological data can in any way be in contrast with the fact that *the zygote has an individual identity since fertilisation*. It's at the moment of fertilisation that the substantial change happens and that a new human being, with an individual and unique genetic make-up, is created, which allows him/her to be an active subject in his/her creation and intrinsically autonomous in his/her continuous, gradual and coordinated growth.

The fact that the zygote contains the necessary and sufficient genetic information to determine – during the period of the cells' totipotentiality – the development not only of one but, eventually, also of more twin individuals, must be interpreted as a process of multiplication, or as a model of agamic reproduction by gemmation (as in the hydra). *This implies, in the case of twins, that we must recognise a full individuality to each of the twins from the moment of their creation: the first of them gaining his/her definitive identity at the moment of fertilisation and the other, or others, at the moment, instead, of the twin fission.*

The loss of the so-called totipotentiality during the very early stages of development does not give the zygote a quality it did not have until then – that is, the quality of a real individual – but it takes away only one further possibility: “reproducing”.

In the same way, the fusion of two embryos (hybridization) in the so-called totipotent phase – from which only one embryo or individual could derive – can be interpreted as the “death” of one of the two individualities that are fusing and it would therefore conclude its very short vital cycle, without it altering the individuality, already present, of the other embryo.

On the basis of these uncontroversial scientific considerations, the signatories of this declaration believe that it is irrelevant to wait for the loss of totipotentiality in the embryo's cells – or even the appearance of the so-called “primitive streak” – and the eventuality of the occurrence of the rare phenomena of twins or hybridization, in order to be able to proclaim its human individuality. And therefore we believe as unfounded all the bioethical options that, starting with another opinion, consider it legitimate to reduce the protection of the embryo – called “early embryo” or “pre-embryo” or “pro-embryo” – in the first stages of development. And we also recall the fact that the pre-embryo theory, suggested within the *Warnock Committee*, was believed by many to be a way of supporting the possibility of experimenting on embryos.

We observe that the 14th day period is in any case scientifically wrong, as it is by now known that dichorial twins receive their destiny of separate development in the 4th day; monochorial diamniotic between the 5th and 6th day; monoamniotic monochorial around the 7th day; and that there is no relationship between the possibility of twins and the formation of the primitive streak in the 14th day. Therefore, the supporters of the theory of the “early” embryo – which

is not referred to in any modern text of biology, but it only appears in the literature dedicated to assisted procreation – should limit the concept of early embryo to a much earlier moment than the 14th day, namely, between the 4th and the 7th day.

The signatories of this declaration believe, in addition, that the concept of “individuality” should be used properly.

Individuality does not imply indivisibility and non-reproducibility, but rather existing as a whole, separate from others (*individuum = indivisum in se = divisum quolibet alio*). The embryo is, therefore, an individual since fertilisation and his/her intrinsic unity can be expressed with the *unum* – represented by his/her cellular nature, by the coordination of his/her early reactions, by totipotentiality – and *the aliquid*, determined by a rigorously individual genetic message, different from any other, including that of eventual twins.

A further consideration must be made. The fact that the reading of the phenomenon of twins as agamic procreation, and of the phenomenon of hybridization must be believed to be scientifically based (and on this agree also those who do not approve of it), must in any case impose the obligation to have a tutioristic ethical attitude towards the embryo from the moment of fertilisation. It seems after all evident that the possibility, although not very frequent, that an embryo can produce others by twin fission, genetically identical – in reality different in some parts of the genome – makes their use or suppression within the first weeks since fertilisation even more unacceptable, because they are potentially bring more damage, implying the possible suppression of twins, that is, the development of more human beings, each with his/her unique individuality.

Given, at this point, that:

- 1) We cannot separate the concept of human individuality from that of person;
- 2) The individuality of the human embryo coincides in objective (ontological) reality with the human person;
- 3) Each human person, in his/her unique singularity, does not exist if not through his/her body;
- 4) Physical life therefore acquires a fundamental value for personal development and the formation of other values;
- 5) Each man, as such, has a dignity that gives him/her a higher value and makes him/her worthy of respect;
- 6) The behaviour to have towards the human person can be said moral only and as long as it conforms to his/her nature and identity, in the sense that it respects them and never contradicts them;

The signatories of this declaration believe that *the human embryo must always be considered and treated, from the moment of fertilisation, on the basis of the ethical value of human person and that the simple doubt of suppressing*

or damaging the human person – even in an embryo in the first phases of development – forces us to abstain from doing so.

This tutoristic criterion is worthy of being completely adopted, as it is founded *in primis* not on axiological options, but on scientific facts, based on experimental and objective data that are not susceptible of alternative interpretations.

The signatories of this declaration therefore agree in believing that is scientifically and ethically inadmissible to distinguish between “early embryos” (before the 14th day) and “embryos” (after the 14th day): the first must be given exactly the same protection as the second.

Consequently, integrating the bioethical considerations formulated in this document, they stress that we must consider:

1) Illicit the suppression, including embryonic reduction and any form of embryonic manipulation even before the 14th day of development;

2) Illicit any non-therapeutic trial on embryos from the first moment of their formation, namely, also on the so-called “early embryos”;

3) Illicit the suppression and any form of manipulation of frozen and/or residual embryos, who must be considered alive although not suitable for implantation;

4) illicit the *in vitro* creation of embryos, especially when there no certainty that they will be transferred in a woman’s uterus.

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CLARIFICATIONS BY SOME NBC MEMBERS

1. The document elaborated by the Committee has been the outcome of long and tiring discussions and it reflects the attempt to incorporate different points of view. Although we appreciate the mediation effort that it represents and we agree with its general principles, we also believe that it is necessary to better clarify, as other colleagues have done, our thoughts about it. We have experienced a certain discomfort regarding the philosophical issues raised within the Committee, so we want to express our perplexities (which probably attest to our ignorance) on the problem of the definition of person and on the ethical aspects associated with it, which constitute a major part of the document.

2. Is an embryo a person? This is a very complex question, and even insidious, because the term “person” has a great variety of uses and meanings, which depend on the way in which the concept of person has been intended in different ways and elaborated in the history of thought.

To try and understand the possible causes of confusion, let’s pretend that one day we read in a scientific journal that the apes that are closest to us from an evolutionary point of view are much more intelligent and emotively complex than we think today. Let’s then imagine that someone asks if an ape for this reason must be considered a “person”.

We could treat this as a philosophical issue and try and perfect our idea of what actually is a person to decide if apes, on the basis of our new information, can be candidates to obtain this title. This type of point of view obviously requires an “ontological” definition, which in the western philosophical and theological tradition is expressed referring to an “*individual substantia rationalis naturae*”, an individual substance with a rational nature (S. Boezio). Today we don’t talk about substance anymore, but the terms used, like “rationality”, “self-awareness”, “symbolic activity”, “physical activity”, etc., refer, in any case, if not to substances, to properties that transcend the physical-organic world.

We could, alternatively, analyse the same issue of the apes practically, and ask ourselves if we should treat them, on the basis of the new knowledge, the way we treat human beings, recognising their right to life, and, therefore, evaluating as ethically inappropriate to suppress them for experimentations and reduce them to slavery. We could also think that the two points of view are linked: if the monkeys are persons in the philosophical sense, they should be treated in the same way as other people; if, instead, they are not people in that sense, then they should not be treated as such. But it seems evident that the two points of view, the philosophical and the ethical, are not necessarily linked.

Further clarifying our thought, it seems to us in any case that both points of view are radically fragile: the philosophical one when it wants to base a high concept like that of person on a philosophy of nature, which today is more than ever in crisis; the purely ethical point of view, for the fact, that it appears clearly devoid of the foundation it needs. We believe, therefore, that, given the rational impossibility of identifying the moment in which a human being effectively becomes person, he/she can be treated from the beginning as he/she was, or on the basis of a religious involvement, considering that he/she has been created, according to the scriptures, directly from God in his image (as some of us believe) or, on the basis of a cultural conviction, considering that he/she is the product of a long biological evolution that put him/her at the centre of our

planet and allowed him/her to change, for better and for worse, the territory in which he/she lives (as other believe, without being contradicted by the first).

In light of this point of view, we could resolve the abovementioned issue of the apes. The most realistic hypothesis is that we could not consider them persons and however we could establish that their sentient nature and their rational structure allowed them to be treated as persons in some important ways, a treatment that human beings reserve for each other; but even if we should consider them “persons”, which on the basis of a mere philosophy of nature could not be excluded, as their rational nature is not very different from humans, it would not follow that human beings are not “right” (but it would be clearer and honest to say “interested”) in treating them as they treat each other.

3. Whatever the definition of person, difficult in any case, as we have observed and explained, the Committee has unanimously stated that the simple fact that from the fusion of the gametes of two different people, and through the development of an embryo, human life goes into an individual with a human nature (another person), this simple fact gives the embryo the right to be protected as a human person, that is, as a being the life of whom is recognised as a primary value that is completely different from the protection we owe to the embryo of a mouse or other animal.

We believe, however, that it is scientifically and culturally inappropriate to identify the embryo with a completely formed individual. In particular we believe that, as all the evaluations relative to the embryo cannot disregard his/her radically relational context that identifies it, the moral duties we have towards him/her cannot be considered as absolute, if we don't want to drastically distance them from this context. The distinction between *prima facie duties* and *absolute duties*, highlighted in the document, reflects the completely normal eventuality that the duties towards the embryo are in conflict with the duties towards other human beings. In this eventuality of conflict between equally significant duties, we believe that the imperatives of respect towards the embryo are relative: “*you must, unless the situation is such that it allows an exception to the general rule*”.

4. We ask ourselves how to behave towards embryos that are: a) affected by serious pathologies; b) supernumerary products, when they can be studied for the purpose of treating a serious pathology in humans. The value of the embryo's life is in conflict respectively with: a) the certain suffering of the man who will be born and/or his future parents; and b) the possibility of advancing the knowledge that can derive from the study of embryos destined in any case to die.

In these very particular situations: faced with the type a) conflict we don't feel that we can morally criticise the parents who oppose the re-implantation of the embryo affected by the serious pathology, neither do we believe that the legislator can impose this or any other type of re-implantation. In particular, from an ethical point of view we don't feel that we can expect from others a heroic behaviour that maybe we (and we guess many of us: if we are honest) would not be able to bear. Faced with a type b) conflict, which is even more particular, we believe that the simple suppression of embryos *who would be lost in any case* cannot leave us ethically indifferent, if their study can determine important advancements in knowledge and in the applicative outcomes aimed at the progress in human health conditions: in these cases it is

to the control, not only ethical, of this situation, that we need to pay our outmost attention.

This said, we want to clarify that our assessment of the moral and legal legitimacy of the abovementioned experimentations is limited to embryos who are not beyond the threshold of the 14th day; this, not because we believe that such a day is ontologically and biologically discriminating – biology does not and cannot give any certainties about exclusively ontological deadlines -, but because before the implantation of the nervous tissue in the developing embryo, it should exclude, not so much his/her individuality, but his/her conscious and rational nature.

5. We move now to a more general consideration. It is absolutely necessary to any human cohabitation not only the existence of well-founded behavioural rules, but also observing them: with this we want to highlight that, as we have said, the ethical rationalism, both secular and theological, encounters the same aporias, the most evident of which is that there is no moral precept for any circumstance and it does not allow for exceptions and the choice of which does not belong to a conscious assessment of the consequences. Since this assessment can only lead to probable solutions, entrusted to the judgement of each individual conscience, religious or not, the ontological arguments referred to the embryo seem deprived of any purely rational ethical foundation. On the other hand we believe that no man, even the most profoundly religious one, would base the truth of his theology only on the efficacy of the moral deriving from it, as it should be the theology, or the truth taken from the faith, to establish the moral.

This observation puts us in front of one of the hottest crossroads of the contemporary era. Facing it, we have the impression that the search for absolutely consistent behavioural rules is tragically difficult in a secular and pluralistic society like ours. If it is true, in fact, that the validity of an ethics is measured by the aims it pursues, then the ethical propositions seem necessarily exposed to the loss of our universality.

6. In conclusion:

We fully agree with the document's statement that the human embryo has the right to be treated as a person, namely, in the way in which we agree that all creatures of our species should be treated. This statement for us:

6.1 *does not mean* that the protection we owe the human embryo, who is the manifestation of a human life within another human life, should be identical to that owed to the man who has already been born, or that the embryo must be considered since conception as an individual by right;

6.2 *means*, instead, that the embryo, since conception, must be considered as a human individual to whom the law is due to guarantee the most favourable conditions of development and birth, and that, for such individual nature, he/she must be safeguarded from sacrifices, not justified by the need to protect his/her interests or those of the adult person containing him/her, or who is destined to contain him/her.

We fully agree with the document's statement that the human embryo must be given the highest dignity, even when he/she has not reached the ability to carry out certain functions typical of the person and that he/she should, therefore, be surrounded by the strongest possible duties of respect. This statement, for us:

6.3 *does not mean* that the personal duties towards the human embryo must always be considered absolute: namely, that they must be considered, always and automatically, prevalent compared to any other type of duty and existential interest that is in conflict with them;

6.4 *means*, instead, that the absolute duty to safeguard the embryo's life stops where it goes against the manifestation of needs of protection of the mother's physical and psychological health, as the choice between caring for her health and saving the embryo's life is entrusted to hers and the father's responsibility, when one cannot be conciliated with the other.

We completely agree, finally, with the hope formulated by the document that no embryos are created for the only purpose to subject them to experimentations and research and that the production of supernumerary embryos is strictly limited. This hope for us:

6.5 *does not mean* that research and experimentation on human embryos must always and in any case be morally illicit and, consequently forbidden;

6.6 *means*, instead, that:

a) research and experimentation must not be allowed for the only reason that the couple from whom the embryo comes does not allow the implantation;

b) supernumerary embryos who are not re-implanted should be frozen before the 14th day, in order to favour, in this way, the eventuality of their re-implantation;

c) supernumerary embryos that are not re-implanted during the legally anticipated freezing period, who are in a situation in which it is now impossible to safeguard their life (so-called "abandoned embryos"), can undergo practices of therapeutic experimentation, as long as it undergoes the rigorous conditions, in method and aim, listed in the document.

ALBERTO PIAZZA
SERGIO STAMMATI
MAURO BARNI
RENATA GADDINI
PIETRO RESCIGNO

PERSONAL REMARK

Looking at the document of synthesis drafted by Prof. Agazzi, we however find some ambiguities that are obviously due to the multiplicity of the ethico-philosophical components of the NBC, but that can give way or give way to some statements, when suggesting to put certain points in the minutes, which can twist the scientific data towards conclusions of ethical judgement that are not always justified. Consequently, the following additional statement is suggested:

1. The general problem

The problem of the nature of the human embryo has been an object of debate since classical philosophy, whilst the opportunity to define the so-called *status of the human embryo* is born from the technological progress of bio-medicine, both in the sector of human fertilisation, as in experimental research, with diagnostic and therapeutic perspectives.

The moral considerations regarding what is legitimate and what instead must be avoided or forbidden resent, in a few other sectors as much as in this one, of the profound convictions about the value of a new life.

To the questions posed, biological research does not give, and it must not give, exhaustive answers but only provide points of discussion, on which it is possible to formulate further conjectures from a scientific point of view and fix instead some shared ideas on the most important ethical values and rules. The definition, for example, of *embryo* as the product of the conception in its initial phases, does not deal with whether or when the embryo is an individual and/or person and of when he/she must be given adequate consideration and protection.

2. Conventional terminology and principles

When we have wanted to tackle embryological knowledge with moral instances, as it happened in the United Kingdom within the *Warnock Commission* (1984), we have in the end decided – the majority of us – to adopt a *term of convenience*, that is, resulting from an agreement of those present, on the fact that before the 14th day of life we talk about a *pre-embryo*, namely, a vital entity we owe generic respect to, but not the care we owe the *embryo*.

There is no doubt that the terminology adopted with regards to pre and post 14th day does not have any scientific foundation for the meaning we want to give to that day or to the histophysiological structures that can be identified on that day, at most, we should use the term “individual” or “person” when the multicellular complex is made up of cells the vitality of which is linked to mutual relationships, that is, at the moment – between 16 and 64 cells – in which the separation of cells does not create the individual. And this happens at the 3rd-4th day with the formation of the *blastocyst*.

To take this road – namely, to link ethical consideration to the advancement of knowledge in molecular embryology – means wanting to derive philosophical or ethical principles from scientific observations, which instead belong to different spheres. It is not by accident that the issue is discussed with surprising logic since Aristotle, who distinguishes ethical

behaviours in relation to the fact that there is life (*zoe*) or not, without knowing nothing about embryology the way we intend it today.

From all this comes that it is arbitrary to fix a temporal limit (the 14th day) below which the embryo must be seen as a “little pile of cells” on which we can carry out for example research activity without any particular regulations, if not a generic respect. In the same way, it is arbitrary to deduce moral principles from useless considerations on the division of the *morula* (2-16 cells) in 2 or more individual identities or on the re-aggregation of cells at this stage.

3. The substantial respect for the human embryo

Without using the support of each scientific particular, which always presents a temporary knowledge, it must be stated that the substantial respect for the human being is due since the beginning, regardless of the stage of development, and that therefore experimentations or biotechnological manipulations are ethically unacceptable, and they will be so at least until such procedures, with definite limits of certainty, will not be finalised by concrete therapeutic aspects (event that is definitely far from the current technological capabilities).

It seems instead more difficult to tackle some secondary issues deriving from fertilisation practices, like the FIVET, that common conscience accepts if aimed at bypassing obstacles to fertility due to various pathologies, even if these techniques or their variants are strongly discussed by religion and pose in any case relevant problems of moral legitimacy in relation to the interest of the future child (FIVET for parents over a certain age; frozen embryos to use in the case of one partner's early death; etc.).

4. Ethical limits of biological applications. Parliament's invitation to promulgate laws

Certainly some possibilities offered by biotechnologies are not acceptable from an ethical point of view: this is the case of the *embryo splitting* (the division of a morula in two separate entities, one to freeze in order to obtain a future twin in case of a future need to donate organs or tissues). On this path, technological utilitarianism can suggest the most disparate variants: so it must be stated, in principle, that every method that tends to the instrumental use of human life at any stage must be refused.

In addition, regarding the problem of the *so-called in excess embryos*, it must be said that the practice to create embryos not destined with certainty to implantation is morally questionable but, certainly, it is reprehensible when we proceed to in excess implantations and the subsequent suppression of the embryos already implanted in the uterus, or we proceed to using the embryos for non-procreative purposes.

On the basis of these principles, it is necessary for the Parliament, the most appropriate authority to take up the discussion started by the previous legislature, to fix strict limits, so that the human being is given a substantial respect at any stage of development, together with a substantial protection of the rights of the future child.

LUIGI FRATI

STATEMENT

In approving the document, I state that I am amongst those who, strongly proposing to consider the embryo as a person since conception, agree with the thesis discussed in paragraph 7.2, according to which any harmful manipulation of the embryo and even more so his/her suppression, must be categorically forbidden; even if there are uncertainties about his/her personal status, the doubt that the embryo might be a person is enough to make us abstain from harming him/her and, in positive, to treat him/her as a person in any circumstances. In this sense I agree with all those parts of the document where the absolute protection of the embryo is put forward.

However I state my preference to argue the difference between the ethical points of view that lead to differentiated bioethical conclusions, in a different way from the document. The investigation must not be, I believe, between absolute and non-absolute (or "*prima facie*") duty to protect the embryo, but rather between recognising or not the duty to treat the embryo since the beginning as a person. The general principle of the protection of the person in fact is compatible with the well-known exceptions to the prohibition to kill (for example for self-defence). Instead, to admit exceptions to the duty of protection, like the selective pre-implantation diagnosis (for serious pathologies) or the experimentation of certain surviving embryos, means not recognising the duty to treat the embryo as a person: such exceptions are not in fact applied to the adult person and there is no reason to lower the legal force of this duty only towards a growing human life.

PAOLO CATTORINI