

Presidenza del Consiglio dei Ministri



**BIOETHICAL CONSIDERATIONS ON
INVOLUNTARY EXCHANGE OF EMBRYOS**

11 JULY 2014

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Presentation

The matter brought to the NBC's attention concerns the exchange of embryos that occurred at the Pertini Hospital of Rome, where the embryos of a couple, obtained through a process of homologous fertilisation, were mistakenly implanted in the uterus of another woman who, in turn, with her husband, had undergone an analogous treatment and is at the moment of the writing of this document – carrying out a twin pregnancy.

Faced with this serious adverse event, which raises issues from a human, ethical and legal point of view, the Lazio Region Administrative Authority on May 6, 2014 asked the NBC to formulate an Opinion on this matter (see attached letter).

The NBC does not deal with the technical errors of the case, but it examines in general terms the emerging bioethical and biolegal aspects.

Some preliminary remarks on parenting and filiation within the context of Italy's current legal system are put forward.

There follows an articulated reflection on the arguments in favour of the parental subjects involved (gestational mother, genetic mother, genetic father, social or legal father) and although some members of the NBC for ethical and/or legal reasons consider one argumentative stance to be prevalent over another and highlight some critical aspects concerning the opposite viewpoint, they recognise the reasons and motivations of the other members.

Therefore, in this matter of involuntary exchange of embryos, the Committee deems appropriate not to express a bioethical 'preference' as to prevalence of one or the other possible parental figures concerned, being aware of the fact that whatever situation the children are raised in, the ethical dilemma remains open. Furthermore, there is a unanimous awareness of the tragic and dreadful nature of the events which are analysed herein and the human suffering they cause.

However, moving from the perspective of the interests of the future born, the weakest characters in this matter, the Committee formulates a series of recommendations: a) the right of those born to have two certain parental figures of reference; b) the need for the mentioned matters to be promptly dealt with, in such a way as to ensure that the children will have suitable family conditions appropriate for serene and balanced growth; c) the ethical hope that the compelling rationale of competing rights is set aside and that the families involved are able to access the dimension of responsibility and solidarity towards the children, even with the legal guarantee of non-exclusion (e.g. visitation rights); d) the right of the couples to become aware of the error and the children's right to know their origins (mode of conception and gestation), through appropriate counselling and support; e) the increase in safety procedures through specific protocols, by means of effective norms in order to avoid errors.

The document was drawn up by Lorenzo d'Avack, who coordinated the working group along with Assuntina Morresi and Laura Palazzani. The document was discussed in plenary session and approved by those present at the meeting: Profs. Amato, Battaglia, Canestrari, Caporale, Da Re, d'Avack, De Curtis, Di Segni, Garattini, Gensabella, Morresi, Palazzani, Proietti, Toraldo di Francia, Umani Ronchi, Zuffa.

The members not entitled to vote: Dr. Bernasconi, Conte, Petrini also gave their approval.

Profs. Caltagirone, Casonato, Dallapiccola, Frati, Neri, Nicolussi, Scaraffia not present at the discussion also expressed their support.

Prof. D'Agostino voted against, and submitted a personal remark. A further personal remark of dissent was written by Prof. Flamigni. Prof. Gensabella, following approval of the document, also sent a personal note.

The President
Francesco Paolo Casavola

Response

1. Introductory note

The matter brought to the NBC's attention concerns the exchange of embryos that occurred at the Pertini Hospital of Rome, where the embryos of a couple, obtained through a process of homologous fertilisation, were mistakenly implanted in the uterus of another woman who, in turn, with her husband, had undergone an analogous treatment and is at the moment of the writing of this document – carrying out a twin pregnancy.

Faced with this serious adverse event, which raises issues from a human, ethical and legal point of view, the Lazio Region Administrative Authority on May 6, 2014 asked the NBC to formulate an Opinion on this matter (see attached letter).

These adverse events are in principle always possible within the techniques of in vitro fertilisation whether homologous or heterologous. Awareness of the possibility of error, far from serving as a justification, should alert to the highest sense of responsibility of the medical personnel and other health professionals involved in these techniques in compliance with the security procedures provided by law.

The issues raised by these errors as regards filiation are particularly complex for ethical and juridical evaluation as they differ from case to case, depending on the defined situation. This complexity is made increasingly evident by the emergence, due to new technologies, of 'new paradigms' even with reference to the identification of filiation/parenting.

It is not the task of the NBC to deal with the specific case as regards its technical errors, rather to examine in general terms the bioethical profiles that emerge from these certainly uncommon events, which however, have also occurred in recent years in other countries.

At this point, several possibilities can be distinguished: be it that the exchange of embryos involves more than two couples or only two; be it that in all the cases a pregnancy was developed or that in some cases the embryos exchanged did not give rise to pregnancies. In the case, in fact, of an error leading to a pregnancy in both the women involved, the two couples would be in a symmetrical condition with different ethical and psychological issues.

For each situation there should then be differentiation for the case in which the discovery of the error occurs before birth and the one in which it occurs after birth. The moment in which the error emerges, in fact, plays a fundamental role in these matters: this moment could take place at a later period, when the newborn has already been placed within a family context with consolidated emotional relationships with the result that any other parental figure would seem foreign to him.

In the face of such a wide record of cases, the NBC has decided to deal only with the bioethical profiles of the case which actually occurred of the exchange of embryos involving two couples, where the error was discovered before birth and in which only one of the two women has become pregnant (following the transfer of embryos of the other couple). A situation in which there is at the same time the presence of a gestational mother and a genetic mother and their respective husbands or partners, all keen to become parents and take care of those born.

2. Some preliminary observations

With regard to parenting - in the face of errors with an exchange of embryos - it raises the ethical and juridical problem of how to relate to the splitting of motherhood (between genetic mother and gestational mother) and the related division of fatherhood (between genetic father and the social or legal father, husband or gestational mother's partner).

In general, the legal framework in our country has been based on the assumption that the natural mother is at the same time the genetic and gestational mother. Article. 269 of the Civil Code regulates maternity establishing that it can be proven by "showing that the person who claims to be the child is the same person as the "woman assumed to be the mother" actually gave birth to; but in the absence of proof of childbirth "proof of maternity can be given by any means".

Even the regulations on homologous MAP (L. 40: Rules on medically assisted procreation) have been designed according to this model. With heterologous fecundation, as now permitted by the Constitutional Court (judgment 162/2014), there may come to be two maternal figures: one genetic and the other gestational, however, only one of these, the gestational mother, will be the legal mother.

The legal attribution of paternity is linked to genetic identity. However, in case of the pregnant woman, being married, declaring in the birth certificate the child as being conceived or born during the marriage, the husband becomes the legal father (Art. 231 Civil Code). And in the presence of the status of being the child of another person (the husband of the pregnant woman) the genetic father can bring no action to disclaim or recognise the child.

Also for the paternal figure, a result of reproductive technology with donor gametes, genetic paternity may be terminated in favour of legal paternity.

From both the ethical and legal standpoint in the identification of maternity, and paternity, following heterologous MAP, there is the emphasis on the concept of voluntariness of the behaviour necessary for filiation, so as to allocate maternity and paternity to those parents, who, regardless of their biological contribution, want the child and accept to abide by the rules of professional ethics and the legal framework regulating MAP. Accordingly there is the rule that those who have given their informed consent to the procedure are the parents of those born and that disclaiming paternity and anonymity of the mother are not allowed (art. 9, paragraphs 1 and 2).

However, in the face of adverse events with an exchange of embryos in the process of homologous MAP, there is heterologous "by error" (the mother is carrying embryos genetically not hers or of her husband or partner) or a surrogate mother "by error "(genetic parents produce embryos that are implanted into the uterus of another woman who carries them through gestation) in a procedure lacking consent, which creates a situation of indeterminacy with regard to maternity and paternity. And the non-voluntariness (consent) to the heterologous fecundation or surrogate motherhood also implies that the rules mentioned above cannot be implemented.

Therefore, when we refer to the existing regulations, we must take account of the fact that its "rationale" is for a situation that does not provide for an error of this kind.

Also to be considered is:

- that in our case both couples, as a result of free and informed consent given at the time of accessing the technique, wanted to pursue a parental project, having expressed a desire to have children from their own gametes and the willingness to carry out pregnancy, and take on future obligations and duties from the very start;

- that the position of the couple from which the gametes originate is not comparable to that of male donor/female donor of gametes, who normally proceed in the knowledge that they will have no parental rights or obligations on the newborn;

- from a legal standpoint, even with the agreement of the couples according to current legislation, it is not possible to hypothesise the spontaneous handing over of the newborn from the gestational mother to the couple with a genetic link, neither is it possible to envisage the registration of birth of the newborn as the child of a woman who does not give evidence of her having given birth to it.

3. What importance is to be attributed to the gestational mother and the genetic mother

In this case the primary concern that emerges among the ethical and legal problems is whether the right of the gestational mother or the genetic mother should prevail.

a. Arguments in favour of the gestational mother.

Between the gestational mother and her unborn child there are undeniable bonds of a biological, psychological and sensorial nature, that are determined and consolidated during pregnancy. The gestation period confers therefore, to maternity a specific existential value, that is both biological and cultural which goes far beyond the mere provision of the uterus. These elements of "early attachment" distinguish motherhood from fatherhood, conferring it with all those dimensions not only biological and psychological but also social and symbolic that common language expresses when it speaks of the mother who by giving birth "brings into the world" a daughter or son (registering on the unborn child, day by day, a unique and personal "biography" beyond genetics and even beyond the influence also of regulation of genes). Therefore, even in the present case of the mother who is carrying the embryo of another woman, it is believed that the expectant mother acquires the status of mother in relation to the child.

Even from a psychological viewpoint, it is stressed that the pregnant woman, in the event that, against her will, she is not regarded as being the mother of the baby, she would face two difficulties: on the one hand that of carrying out the pregnancy in the awareness of a subsequent painful separation from the child at birth and on the other of an enforced detachment, from the very beginning of pregnancy, a problematic process the mental and physical consequences of which are not known in advance. For this woman childbirth is simply an "end" and not a "beginning". This could be a motivation (related to 'serious harm to physical and mental health') to induce the woman to abortion.

In addition, a recognised right of the genetic parents on the embryo could be interpreted as a legitimate interest in the good outcome of the pregnancy and with a consequent interference in the autonomy of a pregnant woman, to

her private life and the exclusive right that is recognised to her by law to take all the decisions relating to pregnancy.

As part of this contrast between the gestational mother and genetic mother causality also comes into play: whoever brings the baby to birth has directly caused the existence of this child and for the parents to be the cause of the child's existence is not a circumstance that can be easily overlooked.

For those who maintain these claims this makes it difficult, if not impossible, to think from the ethical and legal point of view that the child - after birth - can be taken from the gestational mother in an authoritative way, "by judgment".

b. Arguments in favour of the genetic mother.

In the present case a first argument in favour of genetic parenting is given by the fact that the gametes have not been "donated" for procreation by others but they have been collected (as is well known, in a way that is burdensome to the health of the woman) with the precise intention (informed and consensual) to achieve through technology the desire to have their "own" biological children.

In this sense, even from the point of view of causality, mentioned above, the couple have played a vital role by allocating their gametes to procreation: in total analogy to what has been said for those who bring the baby to birth, those who have provided their gametes have directly determined its existence, as without those embryos the pregnancy would not have developed.

Neither can the trauma faced by the genetic mother be ignored: It can no more be ignored even the trauma faced by the genetic mother: not having received the implantation of her own embryos because of an "adverse event", the knowledge of having one's own genetic children, without being able to live out the gestation period, build an emotional and social bond despite being aware of their identity, and conversely to see them grow up in another family.

In general, especially in the context of the debate on surrogate motherhood, in support of the genetic mother is a widespread thesis that the link between maternity and childbirth is, by virtue of assisted reproduction techniques better divisible and that, in and the hypothesis of gestational mother, the figure of the genetic mother can take on - according to some - the contours of a "female fatherhood", not considering pregnancy - despite its importance - the decisive factor for the construction of the parental bond. As in the case of paternity, the absence of pregnancy does not entail a decrease in the emotional intensity towards the newborn.

After failing identification with conception (with one's own oocyte), gestation and parturition, it follows that especially from the medical point of view, the mother should be considered to be the genetic mother, since she transmits, at the moment of the fusion of gametes her own genetic heritage. This circumstance is increasingly significant even in medical terms. It is possible then to wonder whether pregnancy with one's own oocytes cannot be lived out in an emotionally intense manner even by the genetic mother.

Should the gestational mother continue to be present after the birth of the child for its initial care needs, in order to protect the primary interests of the child, the bond of gestation may be gradually loosened and replaced by other acts of traditional care by the genetic parents: feeding protecting and educating the child.

4. What importance is to be attributed to the genetic father and the social or legal father

The Committee also notes that the discussion on the attribution of maternity should not erase the issue of paternity. In the cases discussed there is a certain genetic father and a possible legal or social father as he is the husband or partner of the gestational mother.

The error causes, therefore, also a splitting of genetic fatherhood from legal fatherhood which, remaining in the context of our legal system can hardly be remedied by ensuring the interests of all the parties involved.

As previously mentioned, in the case of a pregnant woman who is not married, paternity under the laws in force should be attributed to the genetic father, even though this would mean that the newborn lives in two families, in a manner determined by the court in line with so-called shared custody. It must be said that in this situation the child does not lose contact with the genetic mother, if she is married or cohabiting with the genetic father.

This is a hypothesis that can cause psychological and educational difficulties as between the genetic father and the gestational mother there would be no link of affection not even initially (unlike what can occur in separated or divorced families). And in this particular case - according to some - the definition of the parental couple would be completely defined by the child or even by the error that led to conception of the child. This would cause a paradoxical overturning of perspective: neither the family nor the couple would be strictly at the origin of the birth but the error of the exchange would determine in one way or another, the future of both the couples.

Conversely, assuming that the gestational mother is joined in marriage, according to current legislation legal paternity should be given to the husband this effectively deprives the genetic father and of responsible parenting. Should it be added to this specific case that the newborn were to be denied the right to knowledge of genetic paternity this could cause suffering. This situation could result in a successive application for the denial of paternity as accorded by law.

On the other hand it should be noted that according to this hypothesis value would be given to the presence of the husband of the gestational mother, his accepting and wanting to be a father and to his being emotionally attached to the gestational mother, his sharing the parental project, and after discovery of the error, his shared choice to continue the pregnancy.

In addition, the opposite hypothesis of not privileging legal paternity, could lead the gestational mother to terminate the pregnancy, so strong and extensive would the difficulties be of raising the newborn in keeping with the intent of the genetic father, also recognised as legal father and the possible tensions with her husband to whom no authority would be granted, for any reason over the child born to his wife.

Unfortunately, it must be remembered that we are in the context of a situation of "error" which must be dealt with, with the awareness that it is not always possible to completely "repair" damage.

5. Reasoning in the interests of those born

The ethical problematicity arising from the complexity of reconciling conflicting requirements, on the one hand the need to guarantee certain

parental reference points to the unborn as well as a family, while on the other hand assuring - as far as possible - the interests of those who have resorted to MAP, with the legitimate desire to have children.

All the arguments examined in favour of the gestational or the genetic mother, or the genetic father and the social/legal father appear to be reasonable under the ethical aspect. It should also be considered that the arguments in favour of maternity and paternity delineate the possibility of several parental reference points: the gestational mother and legal or social father, genetic mother and genetic father; but also gestational mother and genetic father. Although some components of the NBC consider prevalent one line of argumentation over the other for ethical and/or legal reasons and highlight some critical issues with respect to the opposite line, everyone recognises the reasons and motivations of the others.

Therefore, the Committee deems in this matter of involuntary exchange of embryos not to express a bioethical "preference" in relation to the prevalence of one or the other possible parental figures in the awareness that whatever situation the children grow up in, the ethical dilemma remains open. In addition there is unanimous awareness of the dramatic and tragic nature of the events that are analysed here and the human suffering that they activate.

The plurality of bioethical positions on maternity and paternity are a further reason that spurs the Committee to move from another perspective: that of the interests of those to be born, the weakest protagonists in this affair.

Parents, procreators, donors are the holders of relevant ethical and legal interests, but their protection is subordinated in relation to the realisation of the interests of the newborn. The pre-eminence of the interest of the minor is one of the general principles of national and international regulations in the context of filiation. Under this general clause it follows that the rights of the child are placed in a prominent position with respect to the interests and rights accorded to parents. Normative and jurisprudential references on the subject indicate a set of inviolable and non-negotiable guarantees of the child to be connected within the context of the rights relating to personality.

Should the cases in point arouse conflict between the couple, these will be resolved in fact by the judge based on the regulations in force, although the solution of the judging body will be made more difficult, considered that the prenatal life of the children and their births are the result of particular conditions, placed within the context of an error.

The Committee hopes that the legislator will provide criteria that can regulate this kind of situation involving maternal and paternal parenting, in the face of legislation that is no longer adequate to resolve emerging issues in the field of development and the applications of new reproductive technologies.

The Committee believes, however, to be able to make some recommendations.

a) It is a primary need for minors to be entitled to have two parental figures as certain reference points, with full ownership of legal responsibilities and in a position to exercise the right to choose with awareness and authority what they believe to be best for their children.

b) The events caused by exchange of embryos once the error is known, must be addressed promptly, in time to allow the children to have appropriate family circumstances suitable for serene and balanced growth, avoiding the traumas of separation or being placed into contexts perceived as foreign.

c) In order to safeguard the interests of those born, it is desirable that the compelling logic of competing rights be set aside and that the families involved access the dimension of "understanding feelings" of "care" and the ethics of responsibility and solidarity towards those born, who one day will have to deal with an error which made their origins uncertain and the context of family life. Notwithstanding the need for two parental figures as reference points, it is not desirable for one of the two couples to be excluded from the life those born.

Furthermore a number of reasons should, even through dialogic confrontation of the parties, favour the reciprocal exchange of "affectivity" towards the minors, so that the children can maintain a "meaningful relationship" with those who gave them life (in a genetic and gestational manner).

The trauma, the grief of separation suffered by the parents not recognised as such could be reduced by an awareness of the external error (for which the parents are not responsible) and the extraneousness of the genetic element of those born from the gestational one.

In addition, genetic mother and gestational mother, genetic father and legal father could consider "the greater suitability" of the embryos that gave rise to pregnancy compared to the others, that did not result in any pregnancy. An entirely qualitative element, but if certified, it would have favoured the development of the pregnancy. It is also possible that the pregnancy is not only connected to the embryos but also to the co-occurrence of a more suitable gestational mother in anatomical and bio-hormonal terms.

The awareness of the genetic parents and the gestational mother to have contributed to the birth of the children should constitute the reason for the generosity requested of the two family units to ensure the children have a serene life, conflict aside: this generosity could be strengthened through mutual gratitude, respect and collaboration placing the primacy of the interests of the children as a guiding criterion, this means not sharp-cutting the links between these children and, alternatively, between the genetic parents and the legal ones.

As in other family situations, in view of the interests of the minor, there are legal means to protect the child in the case of exclusionary behaviours that are prejudicial for them occurring in one family nucleus in relation to the other, for example by providing the right to visit. There could also be a spontaneous agreement between the parties involved, recognised by the judge according to the principle of the best interests of the child.

d) In the context of the rights of the child, there is also the additional and essential interest of the couples to know the error and for those born to know their origins (mode of conception and gestation) through filters and appropriate criteria (proportionality, sustainability, importance, relevance, etc.) and, if necessary with the aid of qualified specialist psychological counselling in the different stages of their growth, if it is deemed necessary.

The NBC has already had occasion to recommend, in another opinion (Knowing one's biological origins in heterologous medically assisted procreation, 2011) the right of the newborn to know the truth regarding their conception and their biological ancestry in its general aspects. It is all the more justified for the parents with whom those born live to be required to disclose to their children the truth about the manner of conception.

In these cases, the hypothesis of the child being denied the opportunity to know the personal details of the genetic parents and the gestational mother, is

undesirable. This full disclosure on the part of the centre where the procedure is recorded about the origins of the newborn and the couples involved in the error may be authorised by the competent judicial organs and is considered necessary not only for the reconstruction of the personal identity of those born, but also in order to allow the couples to promote the cooperation called for above.

e) Lastly, the NBC recommends that, with the spread of these techniques, there should be an increase in the safety procedures, by means of effective regulations in order to avoid errors. It highlights the need to strictly follow the regulations in terms of quality, safety and traceability on the biological material of human origin in particular gametes and embryos as drawn up by the European provisions transposed into Italian national law. While human error can never be completely avoided, at the same time it is only through compliance to the safety procedures that our regulations have drawn out with certainty and in detail that the likelihood of such errors occurring is minimised. The breaching of rules by facilities and regional administrations increases the probability of error of individual operators. Within such a delicate environment as that of in vitro fertilisation where human lives are at stake - couples, the unborn - every single "adverse event" can have serious and traumatic consequences which are extremely problematic from the ethical and legal viewpoint.

A further general aspect to be considered regards the ways in which the couples involved in this adverse event find out about it. Usually this occurs through normal monitoring of the health status of foetuses, particularly in order to exclude the presence of chromosomal Aneuploidy.

The literature on incidental findings during the course of genetic testing is extensive and the right to know or not to know is still a matter of debate. In these specific cases, the problem is even more complex as it relates to a type of information that may not have specifically been requested, involving other parents. However, it is expected to be in the interests of those born (any medical reasons and knowledge of their genetic origins) both in the interests of the gestational mother and the legal father, especially considering that the mother on the basis of the information obtained could have chosen to terminate the pregnancy.

The complexity of such circumstances recommend that the error should be communicated clearly and in a timely manner; it should not be the geneticist, alone, to assume the responsibility of identifying the most appropriate behaviour to be adopted towards the couples, entrusting it to a molecular report integrated by information provided in the post-test genetic counselling, rather, it is the Ethics Committee of the Centre, through carefully studied policies and procedures that should take charge and debate and decide the mode of communication that is most appropriate to the specific circumstances in the interests of the parties concerned.

Personal remarks

A personal remark by Prof. Francesco D'Agostino

I would like to explain in this note the reasons why I voted against (mine being the only vote against!) the document drawn up by the NBC on the well known adverse event, which took place at the "Pertini Hospital of Rome", as a

result of which a woman who had asked along with her husband and in full compliance with the Law 40/2004, to access homologous in vitro fertilisation, was implanted with two embryos in her uterus that were genetically generated by another man and another woman (and for them, however, heterologous embryo implantation did not lead to the start of a pregnancy).

I will summarise my comments in less than ten points.

1. The NBC has considered the ethical question of the conflict between biological maternity and gestational maternity to be undecidable. This is however a badly-posed question, because it does not exist on an ethical level, since the determination of maternity is not ethical but factual. Ever since the new techniques of MAP have enabled the multiplication of maternal figures (so now there is a common distinction between the genetic mother and the uterine mother and similarly both of these can be distinguished from the possible social mother) we must resign ourselves to the fact that there is no longer a unique mother figure (the same is true with reference to the male, since we cannot fail to distinguish, always within the context of MAP, the genetic father from a possible social father). Those who feel repugnance for the multiplication of maternal figures, seek to answer the question of who the true mother is within the most extreme practices of MAP, but they are asking themselves the wrong question, because in the context of manipulation of maternity all the women involved are true mothers, each one on her own level (even the social mother, who does not provide either the "oocyte, or lend her uterus for pregnancy, should be considered a true mother, because without her intervention the future child would neither have been conceived nor given birth to). The real question that should be asked is not who the true mother is, but which of the women who have contributed in different capacities to the process of procreation is to be ethically, socially and legally considered the mother.

2. The NBC declaring the "undecidability" of the case - has intentionally and explicitly limited itself to the bioethical level without entering into juridical and social evaluations; but assessing the merits of these evaluations, in my opinion, was and is one of its specific duties, seeing as one of its tasks is to develop recommendations for possible legislative acts (according to the precise dictates of resolution No. 6-00038 approved on 07.05.1988, by which the House of Representatives engaged the Government to establish the NBC).

3. The biojuridical solution to the case, however, does not appear particularly complex: taking the baby from the mother who will give birth to it, to give the child to the genetic mother, appears legally and socially absurd, not because the expectant mother is better entitled as a mother in relation to the genetic mother, but because the nine months of gestation (an accepted fact!) create links between the gestational mother and the unborn child that cannot physically be created (except in imagination) between the genetic mother and the unborn child. For the NBC not to want to elaborate these simple observations and call for a law to confirm in any case the status of mother to the woman who gives birth to a child, seems to me frankly unacceptable; especially since this overt non-decision seems to allude to the recognition, on the part of the NBC itself, of its institutional superfluity.

4. If it is established as a fundamental biojuridical principle that maternity which must obtain social recognition can only be gestational, it easily follows that in the best interests of the child the husband of the woman should nevertheless be recognised as the legal father of the unborn child, if, of course, he grants his consent.

5. Moreover, even stopping merely on the bioethical level, and intentionally excluding the biojuridical level, it seems very problematical to support, as the NBC does, that an ethical choice (any ethical choice!) is undecidable. It is possible to argue, in exceptional cases, that are extreme, or even simply very complex, that whoever has to choose is not able to do so or is not competent to do so: this is the traditional case, which, all things considered banal, where one feels the "need to resort to" the intervention of the wise, capable of bringing light into the darkness. A variation of this case is the one for which the elaboration of an extraordinarily complex ethical issue may take a long time, sometimes, unfortunately, even more time than is actually available, in a case that requires quick decisions (just as is the case of the adverse event at the Pertini). In the history of moral philosophy, those who love case histories have found themselves countless times faced with complexities of this kind. The NBC could have, with an act of the utmost intellectual honesty, recognised that they needed a long time to carefully investigate and resolve the issue; they could also have asked to integrate among its members other scholars with more and better skills than those of the institutional members of the Committee. They did not want to do so.

6. Nor can appeal be made to the category of tragedy to properly set this issue. Tragic is meant as the opposite of epic: while we witness in the epic the conflict between good and evil, between just and the unjust, or between right and wrong, in tragedy the conflict is always between good. Those who love Greek literature know just how dramatic the results of tragedies are; but they also know that, in principle, a solution to the conflict exists (even if, as happens so often in Euripides, the solution is often entrusted to the decisive words of a deity). There cannot fail to be a solution, because between the conflicts of good one will have to be axiologically prevalent over the other, since it is only on this condition that tragedy is credible. Otherwise, the only logical solution to the tragic conflict is the one that is entrusted to the prevailing force of one of its subjects in competition; but when a conflict is resolved by force its tragedy disappears and only the blind brutality of violence without good reason remains on the scene.

7. To believe, as the NBC did, that a matter (in our case, the ethical conflict between the two mothers) is in se and per se not resolvable introduces within bioethics, for the NBC is in some ways the institutional custodian of bioethics, a disquieting guest (as Nietzsche said), that is the germ of ethical nihilism. Nihilism can be absolute, when one does not believe in the existence of good and evil. Instead we may talk about moderate nihilism, when one considers that it is not within the possibilities of human reasoning to distinguish good from evil. The reduction of ethical issues and subjective, emotional, psychological, and utilitarian attitudes falls within the logic of nihilism. Via this reductionism it is quite possible, even for the nihilists, to unravel many ethical conflicts, but not through good use of ethics: e.g. by approaching the party that suffers most emotionally or that psychologically attracts greatest sympathy or the party with the most conspicuous interests at stake. But most of the time nihilism concludes with a judgment of non liquet (i.e. not clear): the formula that identifies, starting from Roman law to this day, in the theory of law the denial of justice by an incompetent or lazy judge who refuses to issue a judgment. Certainly, deciding is sometimes very difficult and produces conflicts and ideological lacerations: as shown by the very Latin etymology of the verb to decide, which takes us back to cutting. An honest decision, although very

painful, is however noble; a non decision is, instead, and unfortunately a sign of moral weakness (if not pusillanimity). Far too many times, the NBC has let itself be seduced by this temptation, which instead should be boldly rejected, restricting itself to merely recording the various ethical options existing within it, without taking any formal position either way.

8. Added to this is the fact that, believing it to be impossible to disembroil the ethical knot of the two mothers, the NBC sent the legislator, albeit indirectly, a potentially highly dangerous, although seemingly reassuring, message: any decision the legislator may take to guarantee the right to two parental figures to the children born as a result of "adverse events" will always be justified. The legislature is therefore relieved of the obligation to provide good reasons for its legislative choices or for its possible eventual inertia and indeed, if such an authoritative committee like the NBC is unable to formulate these good reasons, why should it be expected of a parliamentary assembly? Added to this ethical nihilism is a genuine legal nihilism, understood as the doctrine that insists on presenting legislative output not as based on the promotion of common good, but merely on the potestative will of those holding power.

9. I should add that the final considerations of the NBC, the exhortations to both couples to discard all confrontational attitudes and to operate for the overriding good of the children, are indeed very noble and beautiful. However, they are also, and unfortunately, very abstract, as generally are all the moral exhortations expressed by beautiful souls. I take note, following the work which has led, in the plenary session, to the unanimous approval of this document, with my one vote against, that currently all the souls in the NBC are beautiful, except mine.

A personal remark by Prof. Carlo Flamigni

While agreeing substantially with the NBC's Opinion on the involuntary exchange of embryos, I believe that certain aspects of this document could have been much more significant and I would like to add some brief considerations on what seem to me the most important points.

The Opinion makes clear that "it is not among the tasks of the NBC to deal with the specific case as regards its technical errors, but to examine in general terms the bioethical profiles that emerge from these events": this issue deserved better argumentation and the Committee could have transmitted a more realistic perspective of the human error: there is no doubt that this is a very troublesome event (even dramatic in some cases - but certainly not in this case) and it must be prevented by taking the utmost care, however, the inevitable connection with the arrival of new techniques and modern instruments of care as well as more generally with the advance of science, cannot be ignored. So, for example, in the Rome of the Caesars medical errors related to the administration of antibiotics and the doses of radiation were particularly unlikely: I understand that some people might consider banning these techniques, because of susceptibility, but I have the feeling that patients with pneumonia and cancer would be opposed to this. Moreover, those who can rely on a clinical experience of more than half a century certainly remember the times in which many women avoided giving birth in public hospitals because they were frightened by the possibility of the babies being exchanged in obstetric wards. I do not think that this "sensational" error in the Roman hospital would have raised as much disconsolate lamentation if it had occurred

in one of the Tobriand islands, where animism still predominates and where children are produced through the intervention of the spirit of their ancestors, or among Australian aborigines, who still believe the "wandering baby" legend.

In reality one cannot forget that the impact of human error is different depending on the context in which it occurs and that the assessment that it is given is heavily dependent on the historical moment and the benchmarks adopted for judgment. The specific human error that is the basis of the NBC's Opinion would have been given a different evaluation if a different kind of family model had been taken as valid. There are a number of kinds of family models which are widespread and sometimes in conflict with one another, this aspect should have been better considered. It is interesting to note in this respect that in 1890 William James wrote: "The natural institution of motherhood and fatherhood does not exist and is just a myth much emphasised in the West. It is a statement that focuses on a certain view of man, typical of our society, where science and medicine in particular, claim to have the key to our identity. One should instead reflect on the fact that this claim is just an illusion, or more precisely, the myth upon which, in the West, the image of motherhood and fatherhood has been based. In fact, in other parts of the world, other cultures have created very different myths regarding parenting. Therefore, as it is biologically true that pregnancy is the product of fertilisation of an ovum by a spermatozoon, in the same way it is wrong to derive any definition of fatherhood and motherhood, it is a symbolic definition and not a biological one. Plain common sense shows, however that, when a man and a woman are expecting a baby and say they have conceived it together, the biological evidence for this is difficult to obtain and it is usually just their word that asserts this as true and that the fecundating spermatozoon is not of a different origin." (Principles of psychology 1890). James went on to cite a large number of different models of family and concluded that the parents of a child are those indicated by society. Now as then, anthropologists and sociologists mainly agree in saying that our traditional model of parenting (which among other things, has long been in crisis for cultural reasons) is not the only one possible, as numerous empirical studies have long confirmed. In modern human society there can be traced different models of social inclusion of biological fact, different modes of thinking of how one can be a father and mother and it is therefore possible to imagine that even on this issue there is under way a clash of paradigms, with the consequences that are usual in such circumstances: the protest of those who are faithful to the old, the pressures those who support the new, the many (mostly useless) attempts at mediation.

Anthropologists and sociologists say, in essence, that the natural institution of motherhood and fatherhood is questionable, so that it calls into question the very existence of a true parental instinct, expressed in purely biological terms and believing rather that it represents if anything a myth which the West has emphasised. This myth focuses on a particular vision of man and claims to define our identity according to it. To imagine it possible to derive definitions of a purely symbolic nature from biological events, has, in reality, been proven to be totally wrong, as I believe everyone knows.

Today the error underlying the exchange has caused so much uproar because even in our society there is an ongoing conflict between the traditional family model and a new and different model, based on a paradigm that has been proposed to us for at least twenty years, connected with new ways of generating that call on the radical transformation of the relationships of kinship

and the way to consider filiation and parenting. In this regard, I can cite some interesting examples that cannot be ignored: in the USA a growing number of very young women leave their egg cells refrigerated with the intention of retrieving them 20 years later, thus escaping the social punishment that men continue to inflict upon women; in many laboratories there is experimentation with ectogenesis that will allow women to avoid the slavery of pregnancy; in many Infertility treatment centres ovum donation is automatically offered in a large number of circumstances and virtually no women refuse; in 2013 the US Supreme Court declared illegal the Defense of marriage act, which prevented the recognition of gay marriages. I'm not asking anyone to accept the hypothesis that this new paradigm is changing many things in the world, I am asking everyone not to ignore it and discuss it in view of its importance and the need to compare it with serenity to the present paradigm, already deeply disturbed by the new rules on voluntary abortion and divorce and the finding that millions of children are raised successfully by a single parent. It would also have provided the opportunity to examine the moral implications of the possible acceptance of this new model, an analysis that should take into consideration the observations of the Courts of Justice which tells us that ethical rules should be formed on the basis of changes in the common sense of morals and not in accordance with a presumed "natural law" or traditions that are no longer appropriate. I approve the contribution because it stands in continuity with what I pointed out, but I reiterate that if the NBC had examined the aspects of the problem that I have tried to highlight, its contribution to the current debate would have been significantly greater. My hope is that there is a commitment to do so with an outlook open to the innovation that scientific progress puts at our disposal.

A personal remark by Prof. Marianna Gensabella

While substantially adhering to the structure of the Opinion Bioethical considerations on the involuntary exchange of embryos, the writer wishes to propose some elements for argumentation and reflection on what has already been successfully exposed in the document.

The case of involuntary exchange of embryos whose Opinion examines its bioethical profiles raises for ethics and law issues of great complexity, both for their novelty, and for their differing from the will of the subjects whose interests it would like to protect. While supporting the conviction expressed in the Opinion of the extreme difficulty of deciding which interests must take priority, it is considered possible to indicate certain paths of reasonableness to find agreement, not least because their exclusion would undermine the interests of those involved.

First of all, it should be pointed out that here there will not be any priorities established between the two parental couples and their alleged right to the child: there is in fact no right to the child but the desire for parenthood, a licit desire, which can be called natural in the strong and full sense of the term, as it is the desire for life and birth. All four subjects involved in the case which examines the bioethical profiles are driven by this desire and resort to procreation techniques in the homologous form and therefore pursue a parental project following the traditional paradigm: a heterosexual couple married or cohabiting, that wants a child "of their own", according to a social/legal bond that also corresponds to the genetic one. All four have a desire, which can also

be described as a primary interest: for the embryos to be born. This interest on the part of the conceived is configured as the "right to life".

It is clear that this interest/right can be protected only by the pregnant mother, or the woman who has had, even through error, the implantation of the embryo. It is therefore necessary, regardless of any option of principle in favour of the gestational mother in relation to the genetic mother, to start from the latter's consent to parenthood, this is because, "in fact", the same error gives her, like any mother who discovers to be pregnant, the responsibility for the choice of saying yes or no to pregnancy. It is essential to start from her consent to the implant and make the most appropriate choices because that consent which is the "most part" of the responsibility of motherhood, is confirmed in a free and conscious manner, even after becoming aware of the exchange of embryos. As is pointed out in the Opinion in the part in favour of the gestational mother, any decision addressing an involuntary restitution of those born, would undermine her acceptance and encourage her refusal of pregnancy, which the current legal system allows.

But what are the choices facing "this" gestational mother? Though it is clear we must respect her as a person, and not regard her as a mere incubator, but give honour to her consent, what is not clear, given the splitting of the maternal figure made possible by new procreation techniques and the situation in which she finds herself, is, which "type" of maternity this can be related to? The involuntary change in the parental project pursued with her husband or partner is not comparable to the transition from a homologous IVF to a heterologous IVF: the embryos in her womb are not the fruit of heterologous and do not genetically belong to her or to her companion. This situation can not even be considered analogous to that of a "surrogate mother" - not foreseen by our legal system and bioethically highly controversial – that has given her consent to make her uterus available for the embryos of others: indeed at the time of the implantation she was pursuing "her" parental project, clearly and consciously directed to a homologous IVF. The condition which comes the nearest is the one, not provided for by our legal system, but foreshadowed by the NBC's Opinion in 2005, Adoption for the birth of criopreserved and residual embryos obtained by medically assisted procreation (MAP). In that Opinion, designed to meet the right to life of surplus embryos that are abandoned and the desire for parenthood of infertile couples, maternity takes the peculiar form of adoption before birth and for birth. The analogy with the gestational mother carrying, by error, in her womb embryos of another couple, leaves room for a certain difference: in her case the embryos are not "abandoned", but "exchanged" and yet still wanted by the genetic parents. The analogy, however, stands in regard to the intention for two reasons: to ensure the right to life of the embryos and fulfillment of one's desire for parenthood, which for women takes the peculiar form of passage through the body. It still stands in regard to the peculiar condition of having in her womb embryos that genetically- in contrast to heterologous IVF - are foreign to her and her husband/partner but they can be "adopted" by both. This would involve transforming the first consent to homologous IVF into a second consent for adoption before birth and for birth.

However, another option also remains open, which from the ethical point of view has its justifications: that the gestational mother chooses to continue the pregnancy as fostering for birth and prior to birth, fostering that is not only aimed at birth but that ends at birth. The special situation created by the error requires both ethics and law to move in new territory that is neither that of

homology, from which the parental project had commenced, nor that of heterologous or even that of a surrogate mother, being foreign to the parental project. This makes it possible to think of these two forms and the possibility that both may be supported by the agreement of the partner/husband who shared the parental project.

In the first case the gestational mother by adopting the embryos that are not hers, takes on the maternity and it does not seem possible, for the gestational bond on which the opinion focuses in the part in favour of the gestational mother, to separate this relationship in an authoritative manner. This solution is not included at present in our legal system, it is also excluded from bioethics which respects the "dignity" of the gestational mother as a person.

It should, however, leave open the possibility that the gestational mother, who considers important for her, her partner/husband or responsibly evaluates the genetic bond as important for the children, chooses to be the foster mother for birth and until birth. If the validity of this option is recognised on the bioethical front, one could think of solutions on the biojuridical front, given the exceptional nature of the situation, innovating compared to what is currently foreseen by the legal system and taking into account the wishes of the genetic parents to recognise those born; providing for the possibility at the moment of birth for the child not to be abandoned and therefore be in a state of adoption, but to be immediately recognised by the genetic parents. Again this possibility should not involve the anonymity of the mother, who, in the interests of the newborn regarding the truth about one's origins, should be able to be recognised/known as the person that consented to the birth.

The second priority concerns the protection of the interests of those born, from which the Opinion rightly proposes to start. To impose it, even prior to the law, is ethics itself and the principle of responsibility that finds in the parental paradigm its first, fundamental application. The Opinion highlights two fundamental interests of those born: one is to have a certain parental reference point and the other regards the truth about one's origins.

As regards the first, one must note how in the Opinion there is talk of "two parents" and not "a parental couple". The Opinion indicates in fact, without expressing preferences, three possibilities for parental reference points: the gestational mother and her partner or husband, the genetic parents, but even, following the parenting that could be recognised in the existing legal system, the gestational mother and the genetic father. This last possibility breaks the unity of the couple that embarked on the parental project and prefigures cross-parenting. The traditional parental paradigm, that has been a point of reference for the project of both couples, becomes radically transformed, but it is detrimental also to the interests of those born to grow up in "a" family. Who will the children live with? With the gestational mother or the genetic father? Their situation is similar to that of the children of divorced couples but with one difference, that is in no way small, the initial complete extraneousness of the parents.

The same parental project that has as its ethical reference not only the principle of responsibility but its application in a shared responsibility, thought out and experienced together, would be undermined from the start. The negative repercussions on all those involved seem evident: on the children who would lack a family environment that gives as far as possible shared educational reference points; on those who are recognised as parents, as they

would bear the suffering of living parenting that is on the one hand crossed with a stranger, and on the other that is separate from their partner; on their partners or spouses excluded from the parenting; These difficulties do not appear, in the opinion of the writer, surmountable and impose its exclusion, as it is clearly not feasible because detrimental to the interests of all those involved, the third hypothesis sees as a parental reference point the gestational mother and the genetic father.

Nor is it worth maintaining such a hypothesis only on the grounds that it would guarantee with certainty the possibility of "including" both of the parental couples, recognising as parent "one" of its elements. Indeed, there would be, in an attempt to include everyone, a splitting of the couple that gives rise to and supports the fulfillment of the parental project. It is as if to the involuntary splitting of motherhood between the genetic mother and the gestational mother one responds with the splitting of parenthood, which far from being an attempt to remedy the error, would only perpetuate the consequences.

The proper recognition of the double bond of those born with both parental couples must be achieved by other means, while protecting interests regarding the truth about origins and thinking, as a part of the Opinion suggests, of forms of emotional relationships between the child and the couple to whom parental responsibility is not recognised from the legal and educational standpoint: forms starting from "rights of access" that could be thought of and defined by means of new instruments utilised by biolaw as para-parental.

Salvatore Amato subscribed to this personal remark.

LAZIO REGION
Regional Health Directorate and Socio-sanitary Integration
Institutional Legal Regulations Area, and Interface with the Regional
Advocacy

Prot. No. 260 685
Rome, 06 May 2014

To the President of
The National Bioethics Committee
Prof. Francesco Paolo Casavola
Via Della Mercede, 96
00187 Rome

SUBJECT: The adverse event that occurred from the 4th to 6th
December 2013 at the hospital Sandro Pertini -ASL RMB

With reference to the very serious events that occurred at the hospital Sandro Pertini -ASL RMB in relation to Medically Assisted Procreation (MAP) and made the subject of news releases on the 12th and 13th April of last month, it is considered appropriate to report to the National Bioethics Committee the above adverse event presumably linked to treatment induced by ICSI (Intra Cytoplasmic Sperm Injection) practiced in the UOSD of Physiopathology of Reproduction and Treatment of Sterility at the Sandro Pertini Hospital on 4th December (pick up date) and 6th December 2013 (transfer date).

Following the above ICSI treatment one of the couples involved achieved a twin pregnancy and following several diagnostic tests performed at the laboratory Sant' Anna ASL RMA there was the subsequent discovery of the incompatibility of the DNA profiles of both parents with both fetuses.

In view of the legal and ethical implications related to the matter and the profiles of responsibility that can be configured, it is considered appropriate to send this communication along with the report and documentation acquired at the Pertini, already sent to the President of the Lazio Region (att. 1).

The foregoing so that the aforementioned Committee may issue an opinion or provide a response in accordance with the Regulations approved on November 28, 2008, as supplemented by the guide lines of 24 April 2009.

We remain available for any further clarification and/or supplements (which can be obtained directly from the Area Manager, Dr. Cristina Matranga, 06/51684274) awaiting your response.

With best regards

THE AREA MANAGER
(Dr. Cristina Matranga)
THE GENERAL DIRECTOR
(Dr. Flori Degrassi)