IN VITRO VERITAS?
THE NEW ITALIAN HUMAN FERTILISATION AND
EMBRYOLOGY ACT 2004:
LEGAL ISSUES BETWEEN BALANCE
OF INDIVIDUAL INTERESTS
AND SOCIAL PRIORITIES

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1. - Introduction

After a very long time (about 15 years) the Italian Parliament, on 19th Feb 2004, enacted the first and long awaited for Human Fertilisation and Embryology Act. The statute try to regulate biomedically assisted reproductive technology that is now available only to very limited groups, being legally married couple based and hetero-centric in its approach. This Act attracted much criticism both from juridical and political point of view. The statute, two months ago, was submitted to a popular referendum to modify some controversial aspects but the vote (largely in favour of the proposed modifications) was not valid as only 25% of voters expressed their opinion. The Act is, as consequence, full in force but the socio-political and juridical debates are yet strong and far from an ending. The principal questions, indeed, seems to be if the statutory law, as a instrument of social control pursuing policy priorities, should regulate and restrain even private life’s aspects and the individual’s rights and if should inspect, limit and restrict the scientific research.


The Italian Human Fertilisation Act was one of the “priorities” of the centre-right Government majority and it was enacted after a very short Parliamentary debate. Furthermore the usual support of Parliamentary Commission and panel of “experts” was very weak while their works were fast especially if confronted with the works of precedent Commissions that take about 10 years to lead a … then “aborted” proposal. The first impression is that this statute was enacted more to give a political answer to part of the electorate and public opinion (especially the Catholic oriented part and who was afraid of the unlimited scientific and technological developments) vigorously asking for a “legal regulation” of human fertilisation services and practices than on the basis of a precise, accurate analysis of the problems and their juridical implications and, specifically, of the real needs and expectations of the actual Italian society. It seems, in other words, that the Government and the Parliament majority wanted to enact on in vitro fertilisation “a” statutory regulation instead of “the” statutory regulation.

The most important point and provision of this statute are:

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2 In Italy, the “referendum” is valid only if at least 50% of voters express their opinion.
a) the statute ensure the fundamental individual rights of each subject and of the conceived;

b) the medically assisted reproduction is legally permitted only if there is no therapeutic alternative to the sterility; the infertility, even if it is due to natural or unexplained reasons, must be certified by a doctor;

c) the heterologous artificial fecundation has been forbidden;

d) only adult couples (with legal capacity) of different sex, legally married or living together (de facto couples), in a potential fertile age, both of them living at the moment of fecundation are entitled to ask for the medically assisted reproduction. This, in other words, means that same sex couples have been excluded from access to artificial reproduction techniques. Furthermore this means that no post-mortem treatment is admitted and, also, that the fecundation is barred when the age of the applicants (both of them or only one, it is not clear) is out from the potential fertility status, i.e. for the woman when she is in menopause;

e) the applicants must express their consent in writing. The consent must be “informed” (i.e. there is an obligation for the doctor to show and explain all the consequences, including the legal and psychological ones). It is not possible to repeal the consent after the ovule’s fecundation;

f) the artificial fecundation must be executed according to the medical standards and it is up to the doctor to choose times and methodologies but the statute imposes the respect of “graduality” principle (i.e. the time and method less invasive from the psycho-physical point of view of the patient) and suggests to carry on a single and simultaneous implant of all the produced embryos: these embryos must be limited to three for each procedure while their cryo-preservation or suppression is not allowed unless it is the unavoidable consequence of “a serious and documented circumstance of absolutely necessity and unforeseeable at the time of fecundation” and, of course, it will impracticable to proceed to the implant in uterus in a very short time, as soon as possible;

g) last but not least, any kind of test or experiment on embryos is absolutely prohibited like the production of embryos for researches, uses or purposes different from the reproductive finality; this will include, of course, clonation and genetic manipulation as the creation of hybrids but inhibit also the researches on stem cells.

Of course the statute provide for some sanctions: it is a crime to research on embryos and it is a crime cloning a human being but is also a crime to create more then 3 embryos for each procedure or not proceed to the implant in uterus as soon as possible. Who carry on heterologous fecundation should pay only a fine even if very heavy (about 450,000 euros); it will be so again in case of same sex couples or couples non legally married or not living together or … not living at all (post-mortem fecundation).

3. – The criticism from a “technical” point of view.

As already said this statute is particularly weak just from a “juridical” or technical point of view. In certain circumstances the statute will be not applicable in particular according to some erroneous or misleading provisions.

In my opinion, with mention to the depicted points, we can observe:

a) the generic reference to “individual rights” and to the “rights of the conceived” is only pleonastic and not conclusive: indeed there is no indication that the graduation of individual rights provided in our legal system is modified by this new statute, nor that a new particular “legal personality” -i.e. the power to be considered as human being with rights and duties according to the law- is grant to the conceived. This topic will be discussed in depth.
b) In case of infertility due to natural causes or unexplained reasons there is a need of a medical certification to grant the access to the artificial reproductive practises. According to the Guidelines and Rules of Practise of the Health Ministry, a couple is infertile when there is no pregnancy after a year or more of regular non-protected sexual intercourses. Furthermore the Guidelines entrust the doctor (and in particular family doctor or general practitioner) with the duty of certify the “natural infertility”. It is frankly difficult to understand in which way the doctor would “check and control” if the couple had unprotected sexual intercourses for more than a year and if they do so with daily (or more) regularity!

c) The prohibition of the heterologous fecundation is a choice of policy but it has not a foundation on private law rules: indeed, if we look at the rules of our civil code, there are provisions on “natural” filiation in order to protect children (and their parents) born outside of the marriage or born as consequence of an “adultery”, even if that birth was planned with the agreement and consent of all the parties. Furthermore there is today a obviously possibility, according to the European rules (the Blood’s case it is emblematic of the question) to ask for “heterologous” treatment on a great number of Medical Centre all over the Europe.

d) Again a question of policy is evident on the prohibition for same sex or not legally married or living together couples to ask for medical assisted reproduction. The rules seems to be against European provision for equality and non-discrimination but it is possible to argue that in Italy there is a Constitutional “pre-eminence” of the “paramount” interest of children to be raised in a “real family” or to be brought up in a nurturing environment conducive to their full development. This argument needs a deep analysis too. From a merely technical point of view we can observe that the “letter” of the rule is really misleading: in a Country like Italy were the “letter” of the statutory law is paramount and where all the interpreters should respect it (we have only one source of law, i.e. the statutes!) words are very important. The rule grant the possibility to ask for a medical assisted reproduction to “legally married” or “living together” couples with no further prescription: from a literal point of view a legally married coupled, in this case, may be even the couple made by a men and a woman both of them legally married … with the respective partners!

e) The request of a “informed consent” is again a question of policy: it seems that far from protect the “consumer” rights to make his choose freely and with a complete evaluation of “pro and cons”, the statute suggest to doctors to “discourage” the practice: according to the Guidelines the doctor must explain the “alternative” possibility to have recourse to adoption or affiliation, then the juridical discipline of the medical assisted reproduction, the bio-ethical problems linked to the artificial insemination. Only after that the doctor shall explain in full the “technical” aspect of the practise. It is one more difficult to imagine how a “Clapham Common” doctor, usually not so expert in legal or philosophical questions, should give in a complete and correct way the requested information. If the precedent experiences (in similar cases) were true probably the couple will sign a written agreement … with no reading. Notwithstanding this is not the real problem on this part of the statute. The most controversial point is the “impossibility to revoke consent after the ovule’s fecundation”. The provision (art. 6) is in contrast with the right of the father and of the mother to not procreate: this right is granted till a pregnancy starts; a pregnancy starts when there is the implant in uterus. Furthermore the rule of art. 6 of UFEA is in contrast with the fundamental (and Constitutionally granted) right of the individual to refuse any medical or invasive treatment. It will be impossible to proceed to an artificial fecundation if the woman refuses to be treated … unless we imagine a kind of legalised (artificial) rape. The statute, cautiously, says no word on this point.

f) A very difficult point is the limited possibility to proceed to the creation of not more than three embryos that should be implanted in a single and simultaneous way. The rule seems to be very critical from a medical point of view. So that the same statute on the same article let the doctor deciding case by case, even if in presence of “serious and documented unforeseeable
circumstances of absolute necessity”: this may be, for instance, the case in which the embryo’s development is pathological affected and the mother (or the father) will refuse to carry on the implant. The point is not so simple and we have some different judicial decisions that it is necessary to study in depth.

g) The policy argument comes back on the prohibition of any kind of test or experiment on embryos. We can, at least, agree on the ban of human cloning or genetic manipulation to create hybrids but it is more difficult understand why scientists must refrain to make their researches if, as the research on the stem cells, this seems to be useful for the knowledge and fight against diseases.

Again we can note that all the provisions of the Italian statute are enforceable only in Italy; the European Union legal system let, today, people to receive medical assistance, even for artificial reproduction, from any centre in whatever part of the Union. It is extremely significant that from March 2004 onwards in Italy at least 3,610 couples (i.e. three times the precedent number) were bound to leave their Country requiring in foreign specialised centres the assistance and the support for artificial fecundation that is denied in Italy. But perhaps the Italian legislator policy … is intended to solve the crisis of tourism.