Editorial

The new Italian IVF legislation

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Abstract

Last February, the Italian Parliament gave final approval to a new Law regulating assisted reproduction technology. The new legislation fell short of the expectations of infertile couples and of all specialists in the field. There are three problems with the new Italian law: they involve social issues, human rights and the application of technology. The present paper focuses on the fact that the new rules infringe upon basic human rights and the proper application of IVF technology, because they mandate procedures that are against the best interest of the woman seeking pregnancy. The main point of controversy is the combination of a mandatory limit of three embryos for transfer, and an obligation to reimplant all produced embryos; cryopreservation of excess embryos is prohibited. Obviously, this decreases the chances of most women to achieve pregnancy, while at the same time it increases the number and complexity of procedures they need to undergo and may expose some to an unacceptable increase in the risk of multiple pregnancy. The new law is inspired by the desire to protect every newly produced embryo; this is a commendable aim, although it is in total opposition to a law passed over 25 years ago that liberalized voluntary termination of first trimester pregnancies. This means that today Italy has a law that protects every early, pre-implantation embryo, and another that allows the ‘suppression’ of every post-implantation one. From a technical point of view, given the low level of human fecundity, the only way to prevent the ‘loss’ of even one pre-implantation embryo is to simply ban IVF altogether, an option that Italian legislators obviously did not have the courage to opt for. The tragedy is that Italian infertile couples are now confronted with new rules that not only severely limit the ability of physicians to correctly apply IVF technology, but are so confused that, depending on the interpretation, anyone may try to nullify the main ideological premise upon which the entire law has been structured.

Keywords: assisted reproduction, Italy, IVF, legislation

After more than a decade of bitter debates and of opposing views and after probably more than a dozen different proposals, on 19 February 2004 the President of the Republic of Italy finally promulgated Law 40/2004 ‘Norms on the matter of medically assisted procreation’ (Repubblica Italiana, 2004). A translation of the most relevant articles of the new Law is presented at the end of this editorial (see Appendix).

After such a long wait, Italy was entitled to better legislation; what was offered instead is an instrument that mandates procedures that would be considered ‘malpractice’ in most western countries (Benagiano, 2002).

It is recognized that the beginning of life is, in absolute terms, the most delicate and ethically loaded topic to regulate and that democratically elected parliaments have a right to legislate about the socio–cultural milieu in which assisted reproductive technology should be practised (Benagiano and Farris, 2003). This right, however, cannot extend to mandate medical practices that are deleterious to the patient, because they severely limit her chances of achieving pregnancy, while at the same time increasing the number and complexity of procedures she needs to undergo, and may expose some women to an unacceptable increase in the risk of multiple pregnancy. The extreme sensitivity of the matter to be regulated should have promoted a full and detailed debate within the parliament and outside, with the aim of ‘fine tuning’ the provisions of the law, even within the overall philosophy inspiring it. What happened was the exact opposite: the debate within the civil society was full and detailed, but the proposed text went through the Health Commissions and the main floors of the two Houses without modification; in other words, the text remained totally ‘locked’ and ‘impenetrable’ to change throughout the entire procedure, which took 2 years. Those promoting the legislation have defended this ‘locked-in’ approach on the grounds that opening up the text to modification would have meant postponing its approval indefinitely. This reasoning is flawed for the very simple reason that the text is clearly imprecise and confused even within the confines of its inspiring principles.

There are three orders of problems with the new Italian law; they involve social issues, human rights and the application of technology. This editorial does not intend to discuss the social consequences of this legislation (namely the problem of ‘access to assisted reproduction’), although they are important and far reaching; rather it will concentrate on the fact that the new rules infringe upon basic human rights and the proper application of IVF technology.

There is one overarching philosophy that inspires and conditions the new bill: the sanctity of human life from its inception. This is a most commendable position and the majority of Italians would, in principle, agree; in principle,
since not only has Italy a liberal abortion law, but this was subjected to and withstood a popular referendum some 20 years ago. Because of this reality, the ‘IVF Law’ had to be harmonized with the ‘Abortion Law’ and this was done in Article 14, paragraph 1 that specifically states: ‘Embryo cryoconservation and suppression are forbidden; however, the provisions of the Law of 22 May 1978, No. 194 stand valid’. Now, Law 194/78 gives a pregnant woman the power to request termination of her pregnancy within 90 days since her last menstrual period; this means that today there is a law that protects every early, pre-implantation embryos, and another law that allows the ‘suppression’ of every post-implantation one! It is certain that the way in which two totally opposed concepts can be contemporarily applied will become a legal nightmare.

As already stressed, the new legislation aims at preventing the loss of any early human embryo, although it says nothing about the status of a fertilized ovum. The fundamental objection to this philosophy is of a theoretical nature: human fecundity rarely exceeds 0.3 (e.g. Vessey et al., 1976; Balakrishnan, 1979; Wang et al., 2003); this means that nature ‘wastes’, in the very early stages, an absolute majority of all fertilized human ova (Benagiano and Pera, 1992). Since at least 60% of human embryos never reach the stage of a ‘recognized’ pregnancy, how can assisted reproduction be applied without ‘wasting’ a single one? Under these circumstances, the only viable option for Italian legislators would have been to simply ban IVF; something they obviously did not have the courage to do (Benagiano, 2002). In this respect, the Costa Rican law that prohibits IVF altogether is more coherent (Republica de Costarica, 1995).

Thus, Italian legislators have refused to draw the sole logical conclusion that stems from their ideological premise and results have been disastrous. Only a few examples will suffice to convince any person of good will, independently of her/his ethical views, of the need to modify this text.

Article 6, paragraph 1 of the law is named ‘Informed consent’ and deals with the procedures to be utilized to ensure that both partners express their will to undergo the procedure ‘jointly, in writing to the physician in charge’. This paragraph continues by stating: ‘the decision can be revoked by each of the subjects indicated in the present paragraph up to the moment of ovum fertilization’. This means that Law 40/2004 strips the woman (and, indeed, both partners) of the right to change her mind after the time of oocyte retrieval, with a major infringement of a basic human right: freedom of treatment, while contemporarily Law 194/78 gives the same woman every right to abort the pregnancy later on.

Another apparent violation of a basic human right, that to privacy, is contained in Article 11, which, in paragraph 1, states: ‘With a decree by the Minister of Health, a national registry is created at the Higher Institute of Health (the National Institute of Health) of the structures authorized to apply techniques of medically assisted procreation, of embryos formed and of those born out of the application of said techniques’. The entire article says nothing about the protection of the identity of those born through IVF, who apparently have no right to anonymity, since their names must be inserted in a national register. Similarly, nothing is said about the protection of the identity of the women submitting to IVF. In sheer contrast to this lack of attention of Italian legislators, the British Human Fertilization and Embryology Act (1990) mandates that disclosure of information which identifies anybody given treatment in an IVF clinic, even when the patient consents to it, is prohibited (Human Fertilisation and Embryology Authority, 1993).

Article 16, named ‘Conscientious objection’, specifically exonerates ‘health personnel and those exercising auxiliary health activities’ from participating ‘in the procedures for the application of techniques for medically assisted procreation’; in other words, it authorizes any medical or paramedical person to refuse to take part in any assisted reproduction procedure that he/she may object to on ethical grounds. This provision has been inserted to ‘protect’ individuals who, on ethical grounds, object to IVF as a whole; an identical clause also exists in the Law that instituted legal termination of pregnancy in 1978. In the case of induced abortion, however, the procedure is simple enough that any gynaecologist can perform it. Therefore, at the time, it was argued that without the right to conscientious objection, physicians might be forced by hospital administrations to perform an act they could not ethically carry out. When dealing with assisted reproduction, the provision may be theoretically valid in the case of paramedical personnel; for specialists involved in IVF, however, this clause is clearly redundant, since IVF is definitely a technology that requires specific training: it seems highly unlikely that those totally opposed to it would become so competent in its practice to be ‘forced’ to perform the procedures. Therefore, ironically, the only specialists who might avail themselves of the conscientious objection clause are those who believe that, by applying the law, they may harm the patient! Many such specialists are now finding themselves in an impossible situation; they trained in techniques that cannot be properly applied, therefore, ethically, they may be forced to refrain from performing IVF in certain circumstances and refer couples for whom the restrictions placed by the new legislation pose a medical problem, to centres outside Italy. Article 16, however, does not allow a ‘selective conscientious objection’: either you accept the law as it is and apply it to all couples, or you cannot practise IVF.

The difference between exercising a conscientious objection in the case of voluntary abortion and in that of IVF is underlined by one fact: in 1978, some 80% of all gynaecologists availed themselves of the right to object. Although the 3 months provided by the new law to object are not yet over at the time of writing, there is no record of anyone who has exercised the right to conscientious objection with regard to IVF!

Article 14, paragraphs 1 and 2, forbids: ‘embryo cryoconservation’, ‘embryo suppression’, and ‘to create a number of embryos exceeding that strictly necessary to a unique and contemporary implant (transfer), at any rate, never to exceed three’.

To anyone even vaguely familiar with IVF technology, the inescapable conclusion is that in all cases, Italian law permits fertilization of only three oocytes and mandates the transfer of all three possible embryos. This is unacceptable on medical grounds; on the one hand, fertilizing only three oocytes will impair the chances of success of an older woman, since
fertilization rates decline with age (Lim and Tsakok, 1997) and the best results are obtained when there is retrieval of between six and 10 oocytes (Melie et al., 2003); on the other hand, transferring three embryos may be excessive in the case of a young woman (Jones, 2003). The law does not mention zygotes; this may be because those writing the text presumed that ‘a zygote is an embryo’, when obviously, this is not the case; indeed, as pointed out by Ford (1988), a well known and respected Catholic theologian, even in philosophical terms, there is hardly an ontological continuity between a zygote and an embryo. Therefore, in all honesty, it is difficult to argue that the clause in the law that forbids embryo cryoconservation automatically applies to freezing of zygotes. It is not known whether the Guidelines mandated by the new law will clarify this point; however, they cannot fill the legal vacuum created by an imprecise text.

In order to illustrate the technical consequences of applying the new law, a mathematical model has been created to simulate a situation in which 1000 oocytes are retrieved from 100 women. The simulation is based on real results obtained at S.I.S.M.E.R. and stored in their database (Ferraretti, Gianaroli and Magli, unpublished data). Using this model, a number of hypotheses have been tested.

The first test evaluated the effect of increasing the number of oocytes that can be fertilized from three to five. Data shown in Table 1 indicate that this measure would be sufficient to substantially increase the number of expected live births with a minimal risk of ending up with ‘redundant’ embryos; these could easily be cryopreserved with, again, minimal risk of not being utilized. Although for 100 women, differences are either not significant or of borderline significance, if the calculations are carried out for 200 patients, differences reach statistical significance.

The second hypothesis considered the option of cryoconserving oocytes, which is not prohibited by the present law; as everyone involved in IVF knows only too well, this procedure unfortunately does not yield satisfactory results (e.g. Picton et al., 2002). Data presented in Table 2 confirm the very poor results to be expected when freezing supernumerary oocytes. Whereas results would be better when freezing 70 rather than 50 oocytes, the difference in the number of babies to be expected from the two groups would be only an average of 2.3 and 1.6.

The third hypothesis attempted to verify the consequences of freezing zygotes. This is an intriguing option since, as already mentioned, the law ignores the fact that zygotes and embryos are two separate entities. Table 3 shows that it would have been sufficient for the law to expressly allow the cryoconservation of pronuclear zygotes to significantly increase the efficiency of the procedure. Table 3 compares the expected number of babies to be born from 100 thawed oocytes to those calculated for the thawing of 100 pronuclear

<table>
<thead>
<tr>
<th>Number of fertilized oocytes</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryos transferred on day 3</td>
<td>110</td>
<td>148</td>
<td>185</td>
</tr>
<tr>
<td>Average number of embryos transferred per patient</td>
<td>1.1</td>
<td>1.5</td>
<td>1.8</td>
</tr>
<tr>
<td>Implanted embryos</td>
<td>22</td>
<td>29</td>
<td>37</td>
</tr>
<tr>
<td>Average number of babies expected to be born</td>
<td>19</td>
<td>25.5</td>
<td>32</td>
</tr>
</tbody>
</table>

$\chi^2 = 2.9$ for 1000 oocytes: not significant.
$\chi^2 = 3.8$ for 100 patients: borderline significance.
$\chi^2 = 8.2$ for 200 patients: $P = 0.05$.

<table>
<thead>
<tr>
<th>Group 1 Inseminated</th>
<th>Group 1 Cryopreserved</th>
<th>Group 2 Inseminated</th>
<th>Group 2 Cryopreserved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oocytes per cycle</td>
<td>3</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Transferable embryos</td>
<td>110</td>
<td>70</td>
<td>185</td>
</tr>
<tr>
<td>Implanted embryos</td>
<td>22</td>
<td>7</td>
<td>37</td>
</tr>
<tr>
<td>Births</td>
<td>19</td>
<td>2.3</td>
<td>32</td>
</tr>
<tr>
<td>Total babies born</td>
<td>21.3</td>
<td>33.6</td>
<td></td>
</tr>
</tbody>
</table>

$\chi^2 = 2.7$ for 1000 oocytes: not significant.
$\chi^2 = 5.8$ for 2000 oocytes: $P < 0.025$. 

Table 1. Results to be expected from embryo transfer according to the number of fertilized oocytes for women ≤38 years old.

Table 2. Expected clinical outcome after cryopreservation of three fertilized oocytes and seven unfertilized oocytes (group 1) or five fertilized oocytes and five unfertilized oocytes (group 2) for women ≤38 years old.
zygotes. Results are significantly better for thawed zygotes at the level of 200 oocytes.

Indeed, freezing pronuclear zygotes yields sufficiently good results to warrant a comparison between cryopreservation of embryos and that of pronuclear zygotes. A case was therefore simulated in which all 10 oocytes retrieved from each woman are inseminated; in the model, half of the resulting embryos are immediately transferred and the remaining five are cryopreserved; this situation was then compared with the alternative in which, after inseminating all the oocytes, an average of 3.5 per cycle are kept in culture, whereas the remaining ones are cryopreserved at the pronuclear stage. Results are illustrated in Table 4; in the case of embryo freezing, the resulting cumulative percentage of babies born would be 33.6%. This figure is significantly lower than that to be obtained when freezing pronuclear zygotes; in this scenario, representing a situation allowed by the German law, the cumulative percentage of babies to be born is an excellent 55%.

These calculations show that, with minor changes, the present law could have been substantially improved without betraying the guiding principle of respect for the beginning of life.

There is one final, sad comment to be made: even those who played a major role in drafting the legislation and in carrying to completion its approval are now busy making sure that the text is not applied according to its ‘most logical’ interpretation. Here too, an example will show how confused this position is.

During the final stages of the parliamentary debate (in fact, 9 days before the text became law) the Chamber of Deputies passed a motion (Camera dei Deputati, 2004) that reads:

‘The Chamber (of Deputies), in view of the fact that:
– according to Article 4, access to medically assisted procreation techniques is allowed only in cases of sterility or infertility that are medically certified;
– Article 13, paragraph 1, stipulates that clinical and experimental research on embryos is only permitted if the aim is therapeutic and

Table 3. Expected clinical outcome after cryopreservation of oocytes and pronuclear zygotes respectively.

<table>
<thead>
<tr>
<th></th>
<th>Oocytes</th>
<th>Zygotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Oocytes cryopreserved</td>
<td>100</td>
<td>–</td>
</tr>
<tr>
<td>Survival (%)</td>
<td>54</td>
<td>65</td>
</tr>
<tr>
<td>Fertilized (%)</td>
<td>31</td>
<td>65</td>
</tr>
<tr>
<td>Zygotes cryopreserved</td>
<td>–</td>
<td>100</td>
</tr>
<tr>
<td>Survived (%)</td>
<td>–</td>
<td>51</td>
</tr>
<tr>
<td>Percentage of generated embryos</td>
<td>20</td>
<td>44</td>
</tr>
<tr>
<td>Day 3 transferrable embryos</td>
<td>10</td>
<td>35</td>
</tr>
<tr>
<td>Number of implanted embryos</td>
<td>1</td>
<td>6.3</td>
</tr>
<tr>
<td>Babies expected to be born</td>
<td>0.33</td>
<td>4.6</td>
</tr>
</tbody>
</table>

$\chi^2 = 6.0$ for 200 oocytes: $P < 0.025$.

$\chi^2 = 34.4$ for 1000 oocytes: $P < 0.001$.

Table 4. Number of babies expected to be born after insemination of five oocytes, versus insemination of all generated oocytes and the culture of five pronuclear zygotes.

<table>
<thead>
<tr>
<th></th>
<th>Cryopreservation of surplus oocytes (&gt;5)</th>
<th>Cryopreservation of surplus pronuclear zygotes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inseminated</td>
<td>Frozen</td>
</tr>
<tr>
<td>Number per cycle</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Fertilized</td>
<td>350</td>
<td>155</td>
</tr>
<tr>
<td>Survived</td>
<td>270</td>
<td>-</td>
</tr>
<tr>
<td>Embryos</td>
<td>260</td>
<td>100</td>
</tr>
<tr>
<td>Transferable</td>
<td>185</td>
<td>50</td>
</tr>
<tr>
<td>Implanted</td>
<td>37</td>
<td>5</td>
</tr>
<tr>
<td>Expected births</td>
<td>32</td>
<td>1.6</td>
</tr>
<tr>
<td>Cumulative birth rate</td>
<td>33.6</td>
<td>55</td>
</tr>
</tbody>
</table>

$\chi^2 = 8.1$ per 100 cycles ($P = 0.005$).

$\chi^2 = 4.7$ per 1000 oocytes ($P = 0.05$).
diagnostic, allowing the so-called ‘pre-implantation diagnosis’; -- couples bearing genetic diseases transmissible to the offspring, if not sterile, could not have access to said techniques; binds the Government to adopt, within the guidelines to be established in accordance with Article 7, opportune initiatives aimed at permitting access to medically assisted procreation also to said couples, even if not sterile and, in application of Article 14, paragraph 1, to allow, with the consent of the couple, the non-transfer of the embryo in the uterus’.

As already pointed out, Article 14, paragraph 1 states: ‘Embryo cryoconservation and suppression are forbidden; however, the provisions of the Law of 22 May 1978, No. 194 stand valid’. Therefore, if one takes the position that Article 14, paragraph 1 allows the application of the ‘abortion law’ in the case of a pathological embryo, it finds itself obliged to accept that the same Article equally allows the ‘non-transfer’ of supernumerary embryos, provided the couple consents. This is because Article 14 does not contain any limitation.

It seems, therefore, that by applying the provision of Article 14, paragraph 1 in the manner mentioned in this Motion, specialists could easily fertilize five oocytes, because, even if the procedure yields five embryos, technically, by applying the power given to her by Law 194/1978, the woman could simply decide the ‘non-transfer’ of the embryos produced in excess. At any rate, it should be pointed out that this and other motions passed by the parliament carry very little real weight and can, for all practical purposes, be ignored when issuing the Guidelines.

Also connected with the application of Law 194/78 is paragraph 4 of the same Article 14, which dictates: ‘With regard of the present law on medically assisted procreation embryo reduction is forbidden, except in those cases provided for in the law of 22 May 1978, No. 194’. Here again, there is no indication that Law 194/78 poses any restriction on embryo reduction during the first trimester.

In conclusion, Italy is today confronted with new legislation that not only severely quenches the ability of physicians to correctly apply assisted reproduction, but which is so confused that, depending on the interpretation, anyone may try to nullify the main ideological premise upon which the entire law has been structured. As Schopenhauer once pointed out, mankind cannot get on without a certain amount of absurdity.

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Appendix. Law 40/2004: Translation of the most relevant articles

This translation follows as closely as possible the letter of the Italian legal text. Words in italics have been added for clarity.

Title I: General principles

Article 1

1. With the aim of facilitating the solution of reproductive problems consequent to human sterility and infertility, it is permitted to utilize medically assisted procreation, under the conditions and according to the modalities prescribed in the present law, that ensures the rights of every involved subject, including the one to be conceived.

2. Resorting to medically assisted procreation is only permitted when there are no other therapeutically effective means to remove the causes of sterility or infertility.

Article 2

1. The Minister of Health, having consulted the Minister of Education, Universities and Research, can promote research activities on the pathological, psychological, environmental and social causes of sterility and infertility phenomena and facilitate the interventions necessary to remove them, as
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well as on ways to reduce their incidence; the Minister can also promote studies and research on techniques of cryoconservation of gametes and can furthermore promote campaigns of information and prevention of sterility and infertility phenomena.

2. For the purposes specified in subsection 1, the present law authorizes the maximum expenditure of 2 million euro, starting in 2004.

3. Description of the financial means.

Article 3

Description of the modifications necessary to Law 405/1975. These are unrelated to IVF.

Title II: Access to techniques

Article 4: Access to techniques

1. It is permitted to utilize techniques of medically assisted procreation only when the impossibility to otherwise remove the impediments to procreation has been established and, in any way, this utilization is limited to cases of unexplained sterility and infertility documented through a medical act, as well as to cases of sterility or infertility established and certified through a medical act.

2. Techniques of medically assisted procreation are applied on the basis of the following principles:

a) gradually, in order to avoid resorting to interventions with a more profound degree of technical and psychological invasiveness for the persons to whom they are destined, thereby following the principle of lower invasiveness;

b) through informed consent, to be realized according to article 6.

3. It is forbidden to utilize heterologous techniques of medically assisted procreation.

Article 5: Objective requisites

1. Whereas what is established by Article 4, subsection 1, remains valid, access to medically assisted procreation is granted to couples made up of persons of different sex having reached the age of majority, married or living together, of potentially fertile age and both living.

Article 6: Informed consent

1. To achieve what is spelled out in subsection 3, before starting and during each phase of application of techniques of medically assisted procreation the physician informs the subjects referred to in Article 5 on the methods, bioethical problems and possible health-related and psychological side effects that may arise out of the application of said techniques, on the probabilities of success and on the risks deriving from them, as well as on the relevant juridical consequences for the woman, the man and the infant to be born. The couple must be made aware of the possibility to start procedures to adopt or receive in custody a child, according to the law of 4 May 1983, No. 184 and subsequent modifications, as an alternative to medically assisted procreation. Information contained in this subsection and those relating to the degree of invasiveness of techniques for the woman and the man must be provided for each applied technique and in such a manner as to guarantee the formation of a conscious and consciously expressed will.

2. In the event of a private, authorized structure, couples must be informed with clarity of the economic cost of the entire procedure.

3. The will of both subjects to access medically assisted techniques is jointly expressed in writing to the physician in charge of the structure, according to modalities defined by a decree of the Ministers of Justice and Health, to be adopted according to Article 17, subsection 3, of the law of 23 August 1988, No. 400, within 3 months of the day in which the present law went into effect. A minimum term of no less than 7 days must be observed between the manifestation of the will and the application of the technique. The decision can be revoked by each of the subjects indicated in the present paragraph up to the moment of ovum fertilization.

4. Notwithstanding the requisites indicated in the present law, the physician responsible for the structure (the centre) can decide not to proceed to medically assisted procreation exclusively for medical-health motives. In such an eventuality, he must provide the couple with written motivation of the decision.

5. At the time of accessing medically assisted procreation techniques, clear and explicit mention must be made to those requesting it, of the juridical consequences of Article 8 and Article 9 of the present law.

Article 7: Guidelines

1. The Minister of Health, availing himself of the Higher Institute of Health (the National Institute of Health), and having received the opinion of the Higher Health Council (the National Health Council), defines with a decree to be issued within 3 months of day in which the present law went into effect, guidelines containing indications about the procedures and the techniques of medically assisted procreation.

2. The guidelines mentioned in subsection 1 are mandatory for all authorized structures (centres).

3. Guidelines are periodically updated, at least every 3 years, taking into account the technical–scientific evolution, using the same procedure outlined in subsection 1.

Title III: Applications regarding the protection of the infant to be born

Article 8: Juridical status of the newborn

1. Those born out of the application of techniques for medically assisted procreation possess the status of legitimate children or of recognized children of the couple that has expressed the will to avail itself of said techniques according to Article 6.
**Article 9: Prohibition to disavow paternity and anonymity of the mother**

1. In the event that there is utilization of heterologous techniques of medically assisted procreation in violation of the prohibition made in Article 4, paragraph 3, the spouse or the common law spouse whose consent can be presumed from conclusive actions, cannot exercise the disavowal of paternity provided for in Article 235, first subsection, numbers 1 and 2 of the civil code, as well as the right to impugn provided for in article 263 of said code.

2. The mother of the infant born through application of techniques of medically assisted procreation cannot exercise the right to request not to be nominated, according to Article 30, subsection 1, of the regulations mentioned in the Decree of the President of the Republic of 3 November 2000, No. 396.

3. In the event of an application of heterologous techniques in violation of the prohibition specified in Article 4, subsection 3, the gamete donor does not acquire any juridical parental relation with the newborn and cannot request to exercise upon her/him any right, or be subject to any obligation.

**Title IV: Regulations concerning structures authorized to apply medically assisted techniques**

**Article 10: Authorized structures**

1. Interventions of medically assisted procreation are carried out in public and private structures (centres) authorized by Regions and registered as mentioned in Article 11.

2. Regions and the Autonomous Province of Trento and Bolzano define with appropriate acts, within 3 months of the day in which the present law went into effect:

   a) technical–scientific and organizational requisites of the structures (centres);

   b) characteristics of the personnel of the structures (centres);

   c) criteria to determine the duration of authorizations and of cases in which the same can be revoked;

   d) criteria for carrying out controls on the implementation of applications of the present law and on the continuing presence of technical–scientific and organizational requisites possessed by structures.

**Article 11: Registry**

1. With a decree by the Minister of Health, a national registry is created at the Higher Institute of Health (the National Institute of Health) of the structures (centres) authorized to apply techniques of medically assisted procreation, of embryos formed and of those born out of the application of said techniques.

2. The registration is mandatory.

3. The Higher Institute of Health (the National Institute of Health) collects and diffuses, in collaboration with Regional Epidemiological Observatories, information necessary to ensure transparency and public knowledge of techniques of medically assisted procreation adopted by centres and of results obtained.

4. The Higher Institute of Health (the National Institute of Health) collects petitions, information, suggestions, proposals of scientific societies and users concerned by medically assisted procreation.

5. Structures (centres) mentioned in the present article are bound to provide Regional Epidemiological Observatories and the Higher Institute of Health (the National Institute of Health) data necessary to enact Article 15 as well as any other information necessary to carry out the control and inspection functions of competent authorities.

6. Description of financial means.

**Title V: Prohibitions and sanctions**

**Article 12: General prohibitions and sanctions**

1. Whoever for whatever reason utilizes for procreative purposes gametes of subjects extraneous to the couple requesting assisted reproduction techniques, in violation of what is prescribed in Article 4, subsection 3, is punished with an administrative sanction of between 300,000 and 600,000 euros.

2. Whoever for whatever reason, in violation of Article 5, applies techniques of medically assisted procreation to couples whose members are no longer both alive or when one of the members is a minor, or composed of subjects of the same sex, or non married or living together, is punished with an administrative sanction of between 200,000 and 400,000 euros.

3. To ascertain the requisites mentioned in subsection 2 the physician utilizes a declaration signed by both requesting subjects. In the event of false declarations Article 76, subsections 1 and 2 of the Unified Text of Rules and Regulations in Matters of Administrative Documentation, mentioned in the President of the Republic Decree of 28 December 2000, No. 445, is applied.

4. Whoever applies techniques of medically assisted procreation without having obtained the consent with the modalities specified in Article 6 is punished with a monetary administrative sanction of between 5000 and 50,000 euros.

5. Whoever for whatever reason applies techniques of medically assisted procreation in structures (centres) different from those mentioned in Article 10 is punished with a monetary administrative sanction of between 100,000 and 300,000 euros.

6. Whoever in whatever form realizes, organizes or publicizes gamete or embryo trading or surrogate motherhood is punished with a jail term of between 3 months to 2 years and a fine of between 600,000 and 1 million euros.

7. Whoever in whatever form performs a process aimed at
creating a human being stemming out of a single cell of departure, in the final analysis identical in its nuclear genetic content to another human being alive or dead, is punished with a jail term of between 10 and 20 years and a fine of between 600,000 and 1 million euros. In addition, the physician is punished with a lifelong exclusion from practising the profession.

8. The man and the woman to whom techniques are applied in the eventualities mentioned in subsections 1, 2, 4 and 5 cannot be punished.

9. It is mandated that anyone in one of the health professions who has been found guilty of one of the illicit acts referred to in the present article, except for that provided in subsection 7, be suspended for 1 to 3 years from exercising her/his profession.

10. The authorization granted according to article 10 to the structure (centre) in which one of the practices prohibited in the present article has been performed, is suspended for 1 year. In the event of multiple violations of that mentioned in the present article or of a repetition, the authorization can be revoked.

Title VI: Measures for the protection of the embryo

Article 13: Experimenting on human embryos

1. Any experiment on every human embryo is prohibited.

2. Clinical and experimental research on every human embryo is permitted on condition to pursue exclusively therapeutic and diagnostic purposes connected to it and aimed at the protection of the health and development of said embryo and only in cases when no alternative methodologies exist.

3. In any event, the following are prohibited:

a) Production of human embryos for research or experimentation purposes or, at any rate, for purposes different from that provided in the present law;

b) Any form of eugenic selection of embryos or gametes or intervention that, through techniques of selection, manipulation or in any way through artificial procedures, are directed at altering the genetic content of the embryo or of the gamete or that are aimed at predetermining its genetic characteristics, with the exception of interventions with a diagnostic and therapeutic purpose, according to paragraph 2 of the present article;

c) Cloning interventions carried out through nuclear transfer or early division of an embryo or of ectogenesis whether aimed at procreating or for research;

d) Fertilization of a human gamete with the gamete of another species and the production of hybrids and chimerae.

4. Violation of the prohibition spelled out in subsection 1 is punished with a jail term of between 2 and 6 years and a fine of between 50,000 and 150,000 euros. In the event of violation of prohibitions contained in subsection 3, the penalty is increased. Attenuating circumstances concurrent to aggravating circumstances spelled out in subsection 3 cannot be considered equivalent or prevalent in respect to the latter.

5. Suspension of between 1 and 3 years from exercising the profession is mandated for any person in a health profession sentenced for one of the misdemeanours mentioned in the present article.

Article 14: Limitations to the applicability of techniques on embryos

1. Embryo cryoconservation and suppression are forbidden; however, the provisions of the Law of 22 May 1978, No. 194 stand valid.

2. Techniques of embryo production, taking into consideration technical–scientific evolution as well as that provided in Article 7, subsection 3, must not create a number of embryos exceeding that strictly necessary to a unique and contemporary implant (transfer), at any rate, never to exceed three.

3. If embryo transfer in the uterus cannot be carried out for serious and documented reasons of 'force majeure' having to do with the health of the woman and impossible to predict at the time of fertilization, it is permitted to cryoconservate the embryos in question up to the date of transfer to be carried out as soon as possible.

4. With regard of the present law on medically assisted procreation embryo reduction is forbidden, except in those cases provided for by the law of 22 May 1978, No. 194.

5. Subjects referred to in Article 5 are informed of the number and, upon request, on the health status of the embryo produced and about to be transferred in the uterus.

6. Violation of one of the prohibitions or obligations spelled out in the preceding paragraphs is punished with a jail term of up to 3 years and a fine of between 50,000 and 150,000 euros.

7. It is mandated that those individuals in a health profession sentenced for one of the crimes mentioned in the present article be suspended from exercising the profession.

8. It is permitted to cryoconservate male and female gametes, in the presence of written, informed consent.

9. Violation of that mandated in subsection 8 is punished with a monetary administrative sanction of between 5000 and 50,000 euros.

Title VII: Final and transitory dispositions

Article 15: Reporting to Parliament

Spells out how.
Article 16: Conscientious objection

1. Health personnel and those exercising auxiliary health activities are not obliged to participate in the procedures for the application of techniques for medically assisted procreation disciplined by the present law when raising a conscientious objection through a preventive declaration. The declaration of the person objecting must be communicated within three months of the date in which the present law went into effect to the director of the Local Health Unit Agency or of the Hospital Agency, in the case of employees of said agencies; to the health director in the case of persons employed by authorized or accredited private structures (centres).

2. Objection can always be revoked or be proposed outside the term spelled out in subsection 1, although in this case the declaration becomes effective only after 1 month of its presentation to the organisms spelled out in subsection 1.

3. Conscientious objection exonerates health personnel and those exercising auxiliary health activities from carrying out procedures and activities specifically and necessarily directed at determining the intervention of medically assisted procreation and not from assistance before and after the intervention.

Article 17: Transitory dispositions

This article specifies procedure to begin the application of the law.

Article 18: Fund for techniques of medically assisted procreation

This article specifies a 6.8 million euro fund to facilitate access to those authorized.