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## COMMENTARY

# Italian Constitutional Court removes the prohibition on gamete donation in Italy



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**Abstract** In 2004, The Italian Constitutional Court prohibited treatments involving gamete donation, embryo donation, embryo cryopreservation (except under exceptional circumstances), and the transfer of more than three embryos. Basically three statements were made by the Court: the ban violates a couple's fundamental right to health, to self-determination and to have a child. Here, the consequences of such a decision and the legal challenges that ensued are discussed. 

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In April 2014, the Italian Constitutional Court ruled that Italy's prohibition on gamete donation in assisted reproduction treatments was unconstitutional. This was for three main reasons: first, the ban on gamete donation violated couples' fundamental right to have children; second, it also violated couples' fundamental right to self-determination, as a couple's decision to have a child is an expression of their right to self-determination; and third, it violated their right to health, which includes, according to the the World Health Organization's definition, a right to psychic health.

The Court also took account of the future child's interests in knowing their biological parentage (i.e. the child born out of fertility treatment). It noted that Italian law has resolved these issues in cases involving adopted children by granting adoptive parents a right to information about their adopted children, and suggested a similar solution will adequately protect the rights of children of fertility treatment.

The Court's decision focused on couples' best interests: more of them will now get access to the best fertility treatments they need.

Italian regulation of fertility treatment was historically very lax since its introduction in Italy in the 1980s, leading to so-called reproductive tourism (travel abroad for fertility

treatment), and menopausal pregnancies. But in 2004, the Italian Parliament, possibly provoked by damaging media coverage, approved 'Legge 40/2004' ([Repubblica Italiana, 2004](#)), which banned gamete and embryo donation, embryo cryopreservation (except under exceptional circumstances), and transferring more than three embryos, among other things.

These restrictions had two main consequences. Firstly, reproductive tourism reversed its course, this time with Italian couples moving to foreign countries for IVF treatment. A European Society of Human Reproduction and Embryology study found that most patients who decided to seek treatment abroad did so because of legal restrictions in their country of origin, and that almost 32% of them came from Italy. This exposes patients to significant costs, and, in some cases, increased risks ([Shenfield et al., 2010](#)). Secondly, the restrictions provoked negative reactions from patients and practitioners: patients feared that it decreased their treatment choices and chances of achieving a pregnancy, whereas practitioners warned that it was suboptimal, unethical, and would lead to 'mandatory malpractice' ([Benagiano, 2002](#)). The law's opponents challenged its controversial aspects in a referendum, which failed to reach the prescribed quorum

(Benagiano and Gianaroli, 2004). Their remaining option was to challenge the law in the Italian Constitutional Court.

Two considerations were relevant to their challenge in the courts. *Legge 40/2004* aimed to protect every life created by IVF. This is an impossible task, however, given the biologically low fecundability of the human species. In humans, a relatively high proportion (possibly up to 50%) of naturally produced embryos never generates a full-term pregnancy (Benagiano et al., 2010), a fact that has serious practical consequences for fertility treatment. Also, *Legge 40/2004*'s prohibitions detrimentally affected IVF results: in Italy the mean pregnancy rate per transfer decreased from almost 30% in 2003 to 25% in 2006 (Ferraretti et al., 2013).

Italian courts heard more than 30 challenges to various aspects of *Legge 40/2004*, deciding in various, and often inconsistent ways. In May 2008, the Italian Constitutional Court declared that the *Legge*'s ban on transferring more than three embryos was unconstitutional because it did not take account of the health of the woman receiving treatment. It also acknowledged physicians' right and obligation to treat each case individually according to the best treatment available, particularly when carrying out embryo cryopreservation for medical reasons (Benagiano and Gianaroli, 2010). The Court did not express any opinion on the prohibition of preimplantation genetic diagnosis (PGD).

Additional cases followed this Constitutional Court decision. In particular, the Civil Court of Salerno granted a couple access to PGD, and authorized the subsequent transfer of embryos free of mutations, recognizing for the first time a couple's right to a child (Tribunale Civile di Salerno, 2010). In 2012, in a case concerning a couple carrying the cystic fibrosis gene, the European Court of Human Rights ruled that Italy's ban on PGD violated Article 8 of the European Convention on Human Rights (Right to privacy and family life) (European Court of Civil Rights, 2012).

In 2010 and 2011, the Civil Courts of Milan, Florence and Catania questioned Italy's prohibition of treatments involving gamete donation. These courts referred their questions to the Italian Constitutional Court, which ruled that various aspects of the *Legge 40/2004*'s prohibition on treatments involving gamete donation were unconstitutional. In particular, the Court declared it unconstitutional to prohibit gamete donation treatments for couples who are sterile because of medical conditions (Corte Costituzionale della Repubblica Italiana, 2014).

The Court noted that the ban on gamete donation involves multiple constitutional issues, and therefore lawmakers must balance the protection granted to embryos against the other constitutional rights involved. Other relevant rights include a couple's right to form a family (regardless of the cause of their infertility), a couple's right to self-determination as expressed through their decision to have a child, and a couple's right to health, which includes their right to psychic health. The ban on gamete donation harmed all of these rights.

The Court also noted that Italy's ban on gamete donation had not existed for a long time. Italy introduced the ban in 2004, but, before that, 75 private clinics practised gamete donation treatments without limitations, and numerous public clinics carried out gamete donation treatments under limited conditions. What is more, the ban on gamete donation generated economic discrimination between patients who can move abroad for treatment, and those who cannot.

In passing its judgment, the Court took into consideration the interests of any future child of fertility treatment. The State Advocate General argued that the psychological health of any future child of donor gamete treatment was at risk, because of 'non-natural' parenthood, and a violation of a right to know one's 'genetic identity'. The Court dismissed these objections, drawing on the law on adoption, which grants adoptive parents the right to access information about their adopted child's biological parentage.

Importantly, the Italian Constitutional Court can declare legislation unconstitutional, but cannot amend their text. Italian law must now therefore clarify when it permits treatment involving donor gametes. Also, the present law does not consider a child's right to know his biological parents in an era of DNA testing. We currently speak of gamete donation as one concept, but it involves three separate treatments (the use of a germinal cell by a third party, egg donation, and sperm donation), which all raise different legal considerations. First and foremost, Italian law must clarify how it treats donor anonymity problems. Countries have increasingly allowed children of donor gametes access to information on their biological parentage (Pennings, 1997). This may reduce donors' willingness to donate gametes (Bernstein, 2012); however, any reduction in gamete donations may only be temporary (Daniels and Lalos, 1995). Additionally, egg donation is more technically complex and intrusive than sperm donation, and often involves participation of close relatives. It therefore raises ethical issues unknown to cases needing sperm donation (Benagiano and Mori, 2006). Furthermore, Italian law should guide courts on how to decide cases involving errors, for example where patients receive gametes intended for other patients. The current law declares 'foster-genitors' exclusive parents, thereby denying biological parents any rights in respect of these children. The situation is extremely delicate and complex, but it is unacceptable not to give any rights to biological parents in any case.

Finally, new Italian regulations must overcome a number of technical barriers before clinics can routinely offer gamete donation treatments. Primarily, procedures for procuring donor gametes must be specified. Not all countries allow clinics or patients to buy gametes from donors. Many donation programmes are based on voluntary donation of excess eggs by patients undergoing IVF treatment, in exchange for semen donation. This 'mirror exchange system' gives very good results, and proves that successful non-commercial gamete donation programmes are possible (Ferraretti et al., 2006). Moreover, practitioners will have to update their training before they can successfully carry out treatments involving gamete donation. Finally the National Health Service will have to clarify its role concerning treatments involving donor gametes.

At the time of publication, the debate on the practical application of donor techniques is still ongoing. Although the Ministry of Health is pursuing the elaboration of a Decree to regulate gamete donation, authoritative jurists and other scholars claim that this is not necessary as current regulations are sufficient to allow a safe and effective application of donor procedures.

Because of this confused context, one Regional Government (Tuscany) has already issued its own guidelines; several prominent specialists, however, are considering the possibility of carrying out treatments using existing provisions and the Constitutional court ruling.

In conclusion, the Italian Constitutional Court's ruling on *Legge 40/2004* represents a fundamental step forward for infertile patients and fertility practitioners. The Court's decision was based on a new vision of how to promote patients' best interests, and will grant more couples the right to access the best treatments available for their conditions. That said, the decision is unlikely to end the debate on fertility treatment in Italy: opposing sides will continue to use ethical and scientific arguments to promote or hinder further liberalisation of fertility treatment. Parties' communication strategies will continue to play a major role in raising consciousness on these issues.

## References

- Benagiano, G., 2002. *Una legge che impone la malpractice? Osservazioni di un ginecologo sulla proposta di legge* [A law that mandates malpractice? A gynaecologist's commentary on the proposed legislation]. *Bioetica* 10, 561–563.
- Benagiano, G., Gianaroli, L., 2004. The new Italian IVF legislation. *Reprod. Biomed. Online* 9, 117–125.
- Benagiano, G., Mori, M., 2006. Oocyte donation: legal and ethical aspects. *Reprod. Biomed. Online* 13 (Suppl. 1), 17.
- Benagiano, G., Gianaroli, L., 2010. The Italian Constitutional Court modifies Italian legislation on assisted reproduction technology. *Reprod. Biomed. Online* 20, 398–402.
- Benagiano, G., Farris, M., Grudzinskas, G., 2010. The fate of fertilised human oocytes. *Reprod. Biomed. Online* 21, 732–741.
- Bernstein, G., 2012. Unintended Consequences: Prohibitions on Gamete Donor Anonymity and the Fragile Practice of Surrogacy (December 18, 2012). *Indiana Health Law Rev* (Symposium, 2013), Forthcoming; Seton Hall Public Law Research Paper No. 2190992. Available at SSRN: <<http://ssrn.com/abstract=2190992>> (accessed 22.05.2014).
- Corte Costituzionale della Repubblica Italiana, 2014. Sentenza 162/2014 [Ruling 162/2014]. <[http://www.sanita.ilsole24ore.com/pdf2010/Sanita2/\\_Oggetti\\_Correlati/Documenti/Giurisprudenza/PROCREAZIONE\\_SENTENZA.pdf?uuid=0934bbbe-f121-11e3-bba7-cc9c088df17f](http://www.sanita.ilsole24ore.com/pdf2010/Sanita2/_Oggetti_Correlati/Documenti/Giurisprudenza/PROCREAZIONE_SENTENZA.pdf?uuid=0934bbbe-f121-11e3-bba7-cc9c088df17f)> (accessed 22.05.2014).
- Daniels, K., Lalos, O., 1995. The Swedish insemination act and the availability of donors. *Hum. Reprod.* 10, 1871–1874.
- European Court of Civil Rights, 2012. *Costa and Pavan versus Italy*. Ban preventing healthy carriers of Cystic fibrosis from screening embryos for in vitro fertilisation, despite existence of right to therapeutic abortion in domestic law. Violation. Judgement 54270/10, 28 August 2012 no. 155. <[http://www.echr.coe.int/Documents/Annual\\_report\\_2012\\_ENG.pdf](http://www.echr.coe.int/Documents/Annual_report_2012_ENG.pdf)> (accessed 20.05.14).
- Ferraretti, A.P., Pennings, G., Gianaroli, L., Magli, M.C., 2006. Semen donor recruitment in an oocyte donation programme. *Hum. Reprod.* 21, 2482–2485.
- Ferraretti, A.P., Goossens, V., Kupka, M., Bhattacharya, S., de Mouzon, J., Castilla, J.A., Erb, K., Korsak, V., Nyboe Andersen, A., The European IVF-monitoring (EIM), and Consortium, for the European Society of Human Reproduction and Embryology (ESHRE), 2013. Assisted reproductive technology in Europe, 2009: results generated from European registers by ESHRE. *Hum. Reprod.* 28, 2318–2331.
- Pennings, G., 1997. The 'double track' policy for donor anonymity. *Hum. Reprod.* 12, 2839–2844.
- Repubblica Italiana, 2004. *Legge 40/2004*. Norme in materia di procreazione assistita [Law 40/2004. Norms in the field of assisted procreation]. *Gazzetta Ufficiale della Repubblica Italiana*, Serie generale 45:5–12 (24 February 2004).
- Shenfield, F., de Mouzon, J., Pennings, G., Ferraretti, A.P., Andersen, A.N., de Wert, G., Goossens, V., 2010. ESHRE Taskforce on Cross Border Reproductive Care. Cross border reproductive care in six European countries. *Hum. Reprod.* 25, 1361–1368.
- Tribunale Civile di Salerno, 2010. Ordinanza 9 gennaio. Sentenza sulla legge 40/2002. Guida al diritto, 2010; fasc.9, p. 60.

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