

CRIME or PUNISHMENT

Penal or Administrative Sanction Concerning Medical Liability in Medically Assisted Reproduction Techniques in the Iberian Context

PhD. João Proença Xavier¹

Human Rights Professor and Researcher at CEIS20UC - Centre for 20th Century Interdisciplinary Studies of the University of Coimbra, Portugal.
Rua Filipe Simões, 33, 3000-186 Coimbra

Abstract

The existing Portuguese and Spanish laws on medically assisted reproduction are in general not much different, but this study shows they go completely different ways with respect to medical liability and sanctions for the physicians or medical teams that perform them against these laws in Portugal and Spain. Our study describes both legislative solutions in terms of legal sanctions for medical wrongful actions in this matter. This is a comparative study between the Iberian laws on medically assisted reproduction – Law 14/2006, in Spain, and Law 32/2006, in Portugal – which analyses based on these 2 punitive approaches the solutions for medical liability justice in medically assisted reproduction techniques in the Iberian context. In our study, we show both legal solutions from a critic and constructive point of view, through a comparative analysis of the texts of the laws in question, showing that the Portuguese law on criminal and penal justice concerning wrongful medical conduct is very different from the Spanish administrative system sanctioning wrongful actions as regards medical liability in medically assisted reproduction techniques. We therefore conclude that in order for these systems of reproductive human rights in health to be protected and growth together in the future (as we suggest), the Spanish approach, which is more open and does not apply criminal sanctions to wrongful medical conducts at once, but rather first applies administrative sanctions to medical professionals and hospitals that perform them outside of the law, should indeed, in this field, influence more profoundly the Portuguese system. The latter has a more conservative approach that, in our opinion, should be similar to the Spanish one, because there really is not a scientific reason for handling medical conduct in Portugal and in Spain differently. In the former, the same conduct could easily constitute a criminal offence and imply imprisonment for the Portuguese physician, while in Spain the same conduct is only subject to a fine and administrative legal action. In conclusion, the criminalization of medical liability, in general, and in terms of medically assisted reproduction, in particular, does not help protect human and reproductive rights in health care.

Keywords: Medically Assisted Reproduction Techniques Liability, Comparative Iberian Medical Law, Penal Justice, Administrative Justice, Human Rights.

DOI: 10.7176/RHSS/11-11-04

Publication date: June 30th 2021

1. Spanish Law 14/2006/of 26 May

The Spanish legal system only began regulating assisted reproduction techniques with the introduction of Law 35/1988 of 22 November.

The Spanish law passed by the “Cortes Generales” and endorsed by King D. Juan Carlos I of Spain² was justified by the need to regulate the new assisted reproduction techniques which, since they came into being in the early 1970s, have opened up new possibilities for solving the problem of human infertility for a vast number of couples affected by this pathology.³

Spain was one of the first countries in its cultural and geographical circle to enact a law on this matter: “This need materialised early on with the approval of Law 35/1988 of 22 November on assisted reproduction techniques”⁴

“The important scientific progress in recent years, the development of new reproduction techniques, the increase in research potential and the need to respond to the problem of the fate of surplus pre-embryos called for

¹ PhD João Proença Xavier Postdoctoral Research Scientist from University of Salamanca (Spain)

Human Rights Doctor Professor and Researcher Integrated in CEIS20UC - Centre of Interdisciplinary Study of the 20th Century of University of Coimbra (Portugal).

² See Lledó Yague, F. “*Comentarios Científicos a la Ley sobre Técnicas de Reproducción Humana Asistida (Ley 14/2006, de 26 de Mayo)*”, Dykinson, Madrid, 2007.

³ See “Exposición de Motivos” [Explanatory Memorandum] in Law 14/2006 of 26 May.

⁴ See “Exposición de Motivos” [Explanatory Memorandum] in Law 14/2006 of 26 May.

a wide-ranging reform or revision of Law 35/1988 of 22 November”¹

It is true that the Spanish law of 1988 was supplemented by Law 45/2003 of 21 November, which authorised the use of pre-embryos that were frozen on the date of entry into force of this law for scientific purposes, but under very restrictive conditions.

“But while the law opened up this possibility, it established that no more than three oocytes could be produced in each reproductive cycle, making the ordinary practice of assisted reproduction techniques difficult by preventing the means from being put into place to achieve the greatest success with the least possible risk to the health of the woman, which was the main aim of the amended law”.² This law (45/2003) unveils another problem: the processing of cryopreserved embryos is done differently depending on the date on which they were generated.

Embryos frozen before November 2003, the date of entry into force of the law, may be used, *inter alia*, for research purposes, which was not permitted for those generated later, which could only be used for reproductive purposes of the user couple or to be donated to other women.

Following criticism of previous laws³ by the *Comisión Nacional de Reproducción Humana Asistida*, the Spanish Law 14/2006 clearly laid down its own scope of application, the concept of pre-embryo: “*This is understood as the in vitro embryo made up of the group of cells resulting from the gradual division of the oocyte from the moment it is fertilised until 14 days later.*”⁴

Also according to the indications of the European Council, the current Spanish law prohibits the cloning of human beings for reproductive purposes.⁵ Law 35/1988, which listed, by means of a closed list, the techniques which were known at the time, set the legal limits for such techniques, leaving out the new techniques discovered after the law was promulgated. The new law follows a much more open criterion, listing the techniques which, according to the state-of-the-art and clinical practice, can be carried out today. This avoids regulations being set in stone and enables the health authority to authorise and obtain a prior opinion from the *Comisión Nacional de Reproducción Humana Asistida*, (similar to the *Conselho Nacional de Procriação Medicamente Assistida* in Portugal – National Council for Medically Assisted Reproduction)⁶: “*the provisional*

¹ See also “Exposición de Motivos” [Explanatory memorandum] in Law 14/2006 of 26 May

² See also “Exposición de Motivos” [Explanatory Memorandum] in Law 14/2006 of 26 May.

³ See the opinion of the head of the Biology Department of the USP Institut Universitari Dexeus and member of the Catalan and national commissions for assisted human reproduction, in Boada Montse: - “The new Law on Assisted Reproduction” *EL País*, 13/06/ 2006 cit.: “*Assisted reproduction techniques have undergone significant developments in recent years and its regulation required a substantial revision. The new Law on Assisted Reproduction (Law 14/2006) repeals the previous laws, unifying them into a single regulation in accordance with the current reality. It introduces new therapeutical options such as the possibility of carrying out, with prior consent, a pre-implantation genetic diagnosis in combination with the determination of histocompatibility antigens for therapeutic purposes for third parties. This new technique is the way to solving the problem of various families who have a child affected by a disease that requires a bone marrow or cord blood transplant and who, through the birth of a healthy and compatible sibling, can try to cure it. It also allows in certain cases the freezing of oocytes and ovarian tissue for reproductive purposes, opening up the possibility of preserving fertility when it is compromised. The maximum period for cryopreserving oocytes and embryos is changed, leaving it to medical criteria without a fixed limit and giving couples the power to decide the future of their frozen embryos.*” Retrieved on 12/08/2014).

⁴ See Article 1(2) of Law 14/2006 of 26 May.

⁵ On this matter, see COUNCIL DECISION of 19 December 2006 concerning the specific programme “Ideas” implementing the 7th Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (Text with EEA relevance) (2006/972/EC) Article 3:

“1. All research activities carried out under the specific programme shall comply with fundamental ethical principles. 2. The following fields of research shall not be financed under this programme: — research activity aiming at human cloning for reproductive purposes, — research activities intended to modify the genetic heritage of human beings which could make such changes hereditary (4), — research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer. 3. Research on the use of human stem cells, both adult and embryonic, may be financed depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved. Any such application for financing must include, as appropriate, details of the licensing and control measures that will be taken by the competent authorities of the Member States, as well as information concerning the ethical approval that will be provided. As regards the use of human embryonic stem cells, institutions, organisations and researchers must be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved. 4. A revision of the fields of research referred to in paragraph 2 above must take place in the second phase of this programme, in the light of scientific advances. (2010- 2013).”

https://ec.europa.eu/research/participants/portal/doc/call/fp7/common/29935-ideassp_es.pdf

(Accessed on 30/08/2014)

⁶ See the current Portuguese Law, Chapter VI, Article 30, National Council for Medically Assisted Reproduction:

“1— Establishment of the National Council for Medically Assisted Reproduction, hereinafter CNPMA, which shall have the general power to decide on ethical, social and legal issues related to medically assisted reproduction (MAR).

2— The CNPMA’s tasks include:

- a) Updating scientific information on MAR and on the techniques regulated by this legislation;
- b) Establishing the conditions under which the centres where MAR techniques will be applied and where gametes or embryos will be preserved are authorised;
- c) Monitoring the activity of the centres referred to above, overseeing compliance with this law in coordination with the competent public bodies;
- d) Giving an opinion on the authorisation of new centres, and the conditions for suspending or withdrawing such authorisation;
- e) Giving an opinion on the establishment of stem cell banks and on the fate of the biological material resulting from their closure;

and supervised practice as an experimental technique; once its scientific and clinical evidence has been established, the Government may, by royal decree, update the list of authorised techniques.”¹

The new Spanish law on medically assisted reproduction also strengthens the role of the *Comisión Nacional de Reproducción Humana Asistida*² as regards these matters, and the registers and other information mechanisms that must be set up and improved in terms of public information as an essential element in the practice of these techniques. In addition to the registration of gamete donors and pre-embryos for reproduction purposes³, (as laid down by the new law), a register of the activity of assisted reproduction centres is also established.⁴

In the former, a register is made of the children born to each of the donors, the identification of couples or

-
- f) Establishing the guidelines related to the Preimplantation Genetic Diagnosis (PGD), pursuant to articles 28 and 29 of this law;
 - g) Assessing, approving or rejecting research projects involving embryos, pursuant to Article 9;
 - h) Approving the consent form for the recipients of the MAR techniques;
 - i) Providing information related to donors in accordance with and within the limits set out in Article 15;
 - j) Giving an opinion on the implementation of the MAR techniques in the National Health Service;
 - l) Gathering the information referred to in Article 13(2), carrying out the scientific treatment and assessing the medical, health and psychosocial results of the MAR technique;
 - m) Defining the format for the annual activity reports of the MAR centres;
 - n) Receiving and analysing the reports provided for in the preceding paragraph;
 - o) Contributing to the dissemination of techniques available and to the discussion on their applicability;
 - p) Centralising all relevant information on the application of MAR techniques, including the registration of donors, recipients, and offspring born;
 - q) Deciding, on a case-by-case basis, on the use of MAR techniques for the selection of an HLA match group for the treatment of serious diseases.

3— The CNPMA shall submit an annual report on its activities and on the activities of public and private services to the Assembly of the Republic and the Ministries for Health and Science and Technology, describing the state of play of the use of MAR techniques and making relevant recommendations as it sees fit, in particular on the legislative changes required to bring the practice of MAR into line with scientific, technological, cultural and social developments.”

¹ See also Article 20 of Law 14/2006.

² See Article 20 of Law 14/2006 of 26 May on the *Comisión Nacional de Reproducción Humana Asistida*

“Article 20: 1. The National Commission on Assisted Human Reproduction is the collegial body, of a permanent and advisory status, aimed at providing advice and guidance on the use of assisted reproduction techniques, contributing to the updating and dissemination of scientific and technical knowledge in this field, as well as to the drafting of functional and structural criteria of the centres and services where they are carried out. 2. The National Commission on Assisted Human Reproduction shall comprise representatives designated by the Government, the Autonomous Communities, the various scientific societies and entities, professional corporations and associations, and groups representing consumers and users, related to the various scientific, legal and ethical aspects of the application of such techniques. 3. The governing bodies of the general state administration and the Autonomous Communities, as well as any equivalent commissions that may be set up by the latter may request the report of the advice of the National Commission on Assisted Human Reproduction. The health centres and services where assisted reproduction techniques are applied may also request the report of the National Commission on issues relating to such application. In this case, the report must be requested from the health authority that has authorised the application of the assisted reproduction techniques by the corresponding centre or service. 4. The report of the National Commission on Assisted Human Reproduction is mandatory in the following cases: a) To authorise an experimental assisted human reproduction technique not included in the annex. b) For the occasional authorisation in specific cases of preimplantation diagnosis techniques not foreseen in this law, as well as in the cases foreseen in Article 12.2. c) To authorise therapeutic practices provided for in Article 13. d) To authorise research projects in the field of assisted reproduction. e) In the procedure for drafting general provisions that deal with matters provided for in this law or directly related to assisted reproduction. f) In any other legal or regulatory case. 5. The National Commission on Assisted Human Reproduction shall be informed at least every six months of the preimplantation diagnosis practices carried out in accordance with the provisions of Article 12.1. Similarly, it shall be informed on an annual basis of the data collected in the national donor registers and activity registers of the centres referred to in articles 21 and 22. 6. The counterpart commissions set up in the Autonomous Communities shall be considered as supporting and reference commissions of the National Commission on Assisted Human Reproduction and shall cooperate with the latter in the performance of its functions. 7. The members of the National Commission on Assisted Human Reproduction shall make a declaration of its activities and interests and refrain from taking part in the decisions and voting where they have a direct or indirect interest in the matter under consideration.”

³ This was already provided for in Law 35/1988 of 22 November.

⁴ See articles 21, 22, and 23 of Law 14/2006: National registers of assisted reproduction. Article 21. National Donor Register. “

1. The National Donor Register, attached to the Ministry of Health and Consumer Affairs, is the administrative register in which gamete and pre-embryo donors for human reproduction purposes are registered, with strict guarantee of confidentiality of their data. 2. This register, whose data will be based on those provided by the Autonomous Communities within its corresponding territorial scope, shall also register the children born to each of the donors, the identity of the recipient couples or women, and the original location of both at the time of the donation and of its use. 3. The Government, following a report from the National Health System Interterritorial Council and by means of a royal decree, shall regulate the organisation and operation of the national register. Article 22. National register of activity and results of assisted reproduction centres and services. “1. Whether associated with or independent of the previous register, the Government, by means of a royal decree and following a report from the National Health System Interterritorial Council, shall regulate the establishment, organisation and operation of a register of activity of assisted reproduction centres and services. 2. The register of activity of assisted reproduction centres and services shall disclose at least once a year the data on the activity of the centres, including the number of the different types of techniques and procedures which they are authorised to practice, as well as the success rates in terms of reproduction achieved by each centre for each technique, and any other data considered necessary so that users of assisted reproduction techniques can assess the quality of care provided by each centre. The register of activity of assisted reproduction centres and services shall also include information on the number of cryopreserved pre-embryos kept, if any, in each centre.” Article 23. Provision of information. “Centres practising assisted reproduction techniques are obligated to provide the authorities in charge of the registers referred to in the two preceding articles with detailed information for their proper functioning.”

women recipients, and the original location of both at the time of the donation and its use.

As for the latter, a record is made of the type of techniques and procedures used, success rates and other issues that serve to inform citizens about the quality of each of the centres. These data must be made public and published at least once a year. The number of pre-embryos kept in each centre or assisted reproduction service will also be indicated, thus eliminating the obligation established in the previous law to send the surplus embryos from the techniques performed to the National Centre for Transplants and Regenerative Medicine.

The new Spanish Law 14/2006 solves the problems raised by the previous legislation, eliminating the differences between embryos that were cryopreserved before the entry into force of Law 45/2003 and those generated thereafter as regards their fate: always subject to the will of the parents, and in the case of research, bound by restrictive conditions of authorisation, follow-up and monitoring by the corresponding health authorities.¹

This concludes the legislation, with a regime that characterises and defines the offences and sanctions for those who violate its rules and principles,² according to the guidelines below.

Sanctions (in Spain) are regulated in the new Spanish Law 14/2006 of 26 May on assisted reproduction techniques, in accordance with the provisions of Law 30/1992 of 26 November, of the Legal System applicable to Public Administration and of the Joint Administrative Procedure, and with Law 14/1986 of 25 April, the Spanish General Health Law. Assisted human reproduction offences shall be subject to the corresponding administrative sanctions, without prejudice to the civil and criminal liabilities which may be incurred.

When an offence or misconduct is involved and a criminal penalty applies, the administrative penalty will be excluded. Where the offence is proven, the penalty proceedings will be accompanied by the evidence from the Court. In penalty proceedings involving serious or very serious offences (*graves* or *muy graves*), the *Ley de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común* [law on the Legal System of Public Administration and Joint Administrative Procedure] and its related rules may be adopted. The measures to be taken, with an indication of the commencement of the proceedings, must be confirmed, amended or withdrawn in relation to the accused within 15 days of their adoption, and may be the subject of an appeal. However, these measures shall be without effect if the said time limit is not indicated in the relevant sanctioning proceeding (or if at the commencement of the proceeding there is no explicit indication of such measures). The sanctioning administrative body may establish (ancillary sanctions) fines of not more than EUR 1,000 per day if the accused fails to comply with the provisional measures that have been established. The Spanish Law on Medically Assisted Reproduction provides that the offender shall be liable for different offences when the fulfilment of the obligations provided for in this law corresponds to several persons acting jointly, in which case all those involved shall be jointly and severally liable for the offences committed and for the sanctions imposed. In accordance with Article 130.3 of Law 30/1992 of 26 November, "*the directors of the centres or services shall be jointly and severally liable for the offences committed by the biomedical teams dependent upon them.*"³

As regards the application of assisted reproduction techniques, offences in Spain today may be qualified as

¹See Health centres and biomedical equipment in Law 14/2006: Article 17. Qualification and authorisation of assisted reproduction centres: "All centres or services where assisted reproduction techniques or related activities are carried out, as well as gamete and pre-embryo banks, will be considered as health centres and services. They shall be governed by the provisions of Law 14/1986 of 25 April on General Health, in accordance with the regulations that govern them or in those of the public administrations with competence in health matters, and shall require a corresponding specific authorisation for the practice of assisted reproduction techniques." Article 18. Operating conditions of the centres and equipment: "1. *Biomedical teams working in these centres or health services must be specially qualified to perform assisted reproduction techniques, their complementary applications or scientific related activities, and will have the necessary equipment and means, to be established by royal decree. They will act in an interdisciplinary manner, and the director of the centre or service to which they report will be directly responsible for their actions.* 2. *The biomedical teams and the management of the centres of services in which they work shall incur in the relevant liabilities if they violate the secrecy of the identity of donors, in the event of malpractice in assisted reproduction techniques or the corresponding biological materials, or if, by omitting the established studies, the interest of donors or users are affected, or congenital or hereditary diseases are transmitted to the descendants, which can be avoided with that previous information and study.* 3. *The medical teams shall draft a clinical history and keep it strictly confidential, with all the details about the donors and users, as well as the signed consents for carrying out the donation or the techniques. The data in the medical records, with the exception of the identity of the donors, shall be made available to the recipient and their partner, or the child borne of these techniques or their legal representatives when they come of age, on request.* 4. *The biomedical teams shall carry out as many studies as are established by regulation for donors and recipients, and shall also complete the information protocols on the conditions of the donors or the activity of the assisted reproduction centres as may be established.*" Article 19. Performance audits. "*The assisted human reproduction centres shall be subject to external audits at the intervals established by the competent health authorities, which shall evaluate both the technical and legal requirements and the information transmitted to the Autonomous Communities for registration purposes, and the results obtained in their clinical practice.*" See also the explanatory memorandum of Law 14/2006: "The limits established in Law 45/2003 of 21 November on the generation of oocytes in each reproductive cycle are eliminated. These limits must derive exclusively from the clinical indications that may apply in each case."

² In a slightly different way, Chapter VII of the Portuguese law sets out the applicable "*Sanctions*", and is divided into four sections: "*Criminal Liability*", "*Administrative Offence*", "*Accompanying Sanctions*" and "*Supplementary Law*". The latter, in this case, is the Criminal Code/Criminal Law/Portuguese Criminal Law and the General Scheme for Administrative Offences.

³ See (end of) Article 25 of the Spanish Law on Assisted Human Reproduction Techniques.

muy graves, graves or leves [very serious, serious, or minor].¹

These offences are listed in Article 26(2) of the new Spanish Law on Medically Assisted Reproduction Techniques, Law 14/2006: minor offences in sub-paragraph a), serious offences in sub-paragraph b), and very serious offences in sub-paragraph c).²

This list, however, does not replace the need to consult the list of offences presented in Article 26(2) of the Spanish law in force (Law 14/2006, which is included in some footnotes in this research paper). Nevertheless, for information purposes only, we offer some examples of each type of offence as per Article(2)(a)(b) and (c) of the Spanish law on medically assisted reproduction techniques we have analysed:

- In accordance with the Spanish law, a minor offence is “*the non-fulfilment of an obligation or the violation of any prohibition set out in this law*”, where it is not considered or typified as a serious or very serious offence.
- In accordance with the Spanish law, a serious offence is, for example, the negligence by work teams of their legal obligations when treating users/recipients with these techniques, the omission of data, the lack of consent and the references required by law, such as the failure to carry out the medical history in each case, the breach of confidentiality of the donors’ details, the payment for the donation of gametes and embryos, or an financial consideration, the generation of more children per donor than legally permitted, the generation of more pre-embryos in each reproductive cycle than necessary, and in the case of in vitro fertilisation and related techniques the transfer of more than 3 pre-embryos to each woman in each reproductive cycle, among others referred to in the law.
- The Spanish law considers these to be very serious offences: allowing the in vitro development of pre-embryos longer than the limit of 14 days following the fertilisation of the oocyte (minus the time during which they may be cryopreserved), carrying out assisted reproduction techniques outside authorised centres, carrying out research with human embryos without complying with the legal limitations, the creation of pre-embryos with material from different individuals to be transferred to the woman recipient, the production of hybrids that use human genetic material (except in the case of permitted trials), as nuclear transfer techniques for reproductive purposes, and sex selection and other genetic modifications for non-therapeutic or unauthorised therapeutic purposes.

In addition, it should be recalled that, under Spanish law, very serious offences are extinguished after 3 years, serious offences after 2 years, and minor offences after 6 months.³

In Spain, the competent bodies of the Autonomous Communities and cities with autonomous status, as the case may be, are in charge of inspection and monitoring the procedures for examining and resolving these issues,

¹ See Article 26(2) of Spanish Law 14/2006, under heading “Offences: “*In addition to those foreseen in Law 14/1986 of 25 April, General Health Law, and those typified in the legislation of the Autonomous Communities, they are considered as minor, serious and very serious offences.*”

² See also Article 26.2 Sanctions “*a) A minor offence is the failure to comply with any obligation or the breach of any prohibition established in this Law, provided that it is not expressly typified as a serious or very serious offence. b) Serious offences: 1st – The violation by work teams of their legal obligations when treating the users of these techniques. 2nd – The omission of information or prior studies necessary to avoid harming the interests of donors or users, or the transmission of congenital or hereditary diseases. 3rd – The omission of information, consent and references required by this Law, as well as the lack of the medical history for each case. 4th – The failure to supply the health authority responsible for the functioning of the registers provided for in this Law with the information belonging to a given centre on an annual basis. 5th – The breach of confidentiality of the donors’ details set out in this Law. 6th – The payment for the donation of gametes and pre-embryos or their financial compensation contrary to the provisions of Article 5.3 and 11.6. 7th – Publicity or promotion encouraging the donation of human tissue and cells by authorised centres by offering compensation or financial benefits contrary to that provided for in Article 5.3. 8th – The generation of more children per donor than legally permitted resulting from the lack of diligence of the relevant centre or service in checking the data provided by the donors and, in case of the latter, the provision of false data in the identity or reference to other previous donations. 9th – The generation of more pre-embryos in each reproductive cycle than necessary, in accordance with clinical criteria to guarantee, within reasonable limits, the reproductive success in each case. 10th – In the case of in vitro fertilisation and related techniques, the transfer of more than 3 pre-embryos to each woman in each reproductive cycle. 11th – The continued performance of ovarian stimulation practices that may be harmful to the health of healthy donor women. 12th – Failure to comply with the rules and guarantees established for the transfer, import or export of pre-embryos and gametes between countries.*

c) The following are very serious offences: 1st – Allow the in vitro development of pre-embryos longer than the limit of 14 days following the fertilisation of the oocyte, minus the time during which they may have been cryopreserved. 2nd – The practice of any technique not included in the Annex or authorised as an experimental technique under the terms of Article 2. 3rd – The performance or practice of assisted reproduction techniques in unauthorised centres. 4th – Research with human pre-embryos in breach of the limits, conditions and authorisation procedures established in this Law. 5th – The creation of pre-embryos with male biological material from different individuals to be transferred to the woman recipient. 6th – The transfer to the woman recipient in one same act of pre-embryos originated from oocytes from different women. 7th – The production of interspecific hybrids using human genetic material, except in cases where testing is currently permitted. 8th – The transfer to the recipient woman of gametes or pre-embryos without the required biological guarantees of viability. 9th – The practice of nuclear transfer techniques for reproductive purposes. 10th – Sex selection or genetic modifications for non-therapeutic or unauthorised therapeutic purposes.”

³ See, in this regard, (end of) Article 24(5) of the Spanish Law on Assisted Human Reproduction Techniques.

as well as for serving these sanctions by letter to the offenders.¹

1.2 Comparison with the Portuguese Law

The Portuguese law, on the other hand, instead of classifying offences as minor, serious or very serious like its Spanish counterpart, establishes the conduct liable to criminal liability in its “Section I”², Articles 38 to 43, conduct liable to give rise to

It should be noted that the Portuguese Law is concerned with establishing the more serious offences in “Section I”, stating the criminal sanctions for offenders according to the infringement, namely imprisonment for up to 8 years for very serious conduct in this regard. As a mere example, what follows is the explanation of a number of very serious infringements of the Portuguese law on Medically Assisted Reproduction, Law 32/2006, which appear in this section of the Portuguese legal system, and their criminal categories, showing, in our opinion, that the Portuguese law on this matter is considerable distanced from the Spanish law we have characterised before.

As such, the application of MAR techniques outside authorised centres is punishable by imprisonment for up to 3 years; the application of MAR techniques to anyone under the age of 18, to incapacitated individuals or individuals with a mental condition is punishable by imprisonment between 2 and 8 years; harvesting genetic material of a man or a woman without their consent and using it in MAR is punishable by imprisonment; the transfer of an embryo obtained through nuclear transfer, “reproductive cloning”, except when necessary to apply the MAR techniques is punishable with imprisonment between 1 and 5 years; the same penalty applies to whoever implants an embryo obtained through embryo splitting; and, the creation of chimeras or hybrids for assisted reproduction purposes is punishable with imprisonment between 1 and 5 years. The Portuguese law on MAR, in turn, provides for a fine in the case of contents susceptible to be condemned as “administrative offence”³ in the amount of EUR 10,000 to EUR 50,000 (for natural persons) or the maximum fine up to EUR

¹ See also the Spanish Law 14/2006 on Assisted Human Reproduction Techniques, which specifies the maximum amounts and other penalties to which offenders are subject (see Article 27. Sanctions): “1. *Minor offences shall be punished by a fine of up to EUR 1,000; serious offences with a fine from EUR 1,001 to EUR 10,000, and very serious offences with a fine from EUR 10,001 up to one million euro. In the case of very serious offences within the meaning of Article 26(c)(2) and (3), in addition to the monetary fine, a decision may be taken to close the assisted reproduction centre or service wherein the assisted human reproduction techniques are performed. In the case of the serious offence defined in Article 26(b)(5), in addition to the monetary fine, the authorisation granted to the assisted reproduction centre or service may be revoked by the decision imposing a sanction. The amount of the sanction to be imposed, within the indicated limits, shall be established taking into account the risks for the health of the mother or of the pre-embryos generated, the amount of the possible benefit obtained, the degree of intentionality, the seriousness of the health or social alteration produced, the generalisation of the offence and the recurrence. 3. In any event, when the amount of the fine is less than the benefit obtained for committing the offence, the sanction shall be increased to twice the amount received by the offender. 4. If the same act or omission constitutes two or more offences, as defined in this Law or in other laws, only the offence that carries the highest penalty shall be taken into consideration. 5. The amounts of the fines shall be periodically reviewed and updated by the government by means of a royal decree.*”

³ See Criminal liability under the Portuguese law on Assisted Reproduction. SECTION I:

Article 34 (Authorised centres) “Anyone applying the MAR techniques outside authorised centres shall be punished by imprisonment for up to 3 years.” Article 35 (Recipients) “Anyone applying the MAR techniques in violation of the provisions of Article 6(2) be punished by imprisonment between 2 and 8 years.”

Article 36 (Reproductive cloning): See “Prohibited purposes”

Article 37 (Choice of non-medical characteristics) “Anyone using or applying MAR techniques to improve certain non-medical characteristics, namely the choice of sex, other than the cases permitted by this Law, shall be punished by imprisonment for up to 2 years or with a fine of up to 240 days.” Article 38 (Creation of chimeras or hybrids) “Anyone creating chimeras or hybrids for the purpose of MAR shall be punished by imprisonment between 1 and 5 years. Article 40 (Misuse of embryos)

“1— Anyone using embryos in scientific research and experimentation other than in the cases permitted by this Law through MAR shall be punished by imprisonment between 1 and 5 years. 2— The same penalty shall apply to those who transfer to the uterus embryos used in research and scientific experimentation other than in the cases provided for in this Law.” “Article 41 (Interventions and treatments) “1— The provisions of Article 150 of the Penal Code shall apply to interventions and treatments carried out using MAR techniques by a doctor or by another legally authorised person with the knowledge of the doctor in charge.

2— Interventions and treatments within the scope of MAR carried out without the knowledge of the doctor in charge or by anyone not legally qualified constitute offences against physical integrity of a person, punishable pursuant to the Penal Code according to the injuries caused, without prejudice to any other criminal classification. Article 42 (Harvesting and unauthorised use of gametes)

Anyone harvesting genetic material of a man or a woman without their consent and using it in MAR shall be punished by imprisonment between 1 and 8 years. Article 43 (Violation of the duty of secrecy or confidentiality) Anyone violating the provisions of Article 15 shall be punished by imprisonment for up to 1 year or with a fine of up to 240 days.” To this we add the new Article 43-A is added, on the new criminal reform influencing the Portuguese MAR law. 23rd AMENDMENT OF THE PENAL CODE (updated version) Article 4 – of Law 59/2007 of 04 September – Addition to Law 31/2004 of 22 July, to Decree-law 15/93 of 22 January, and Law 32/2006 of 26 July:

3 – Article 43-A is added to Law 32/2006 of 26 July (assisted medical reproduction), with the following wording:

“Article 43-A Criminal liability of legal persons and similar entities. Legal persons and similar entities shall in general be liable to the crimes provided for in this Law.” See Law 32/2006 of 26 July (updated in relation to the aforementioned decree.

Law 32/2006 of 26 June “misdemeanour” in its “Section II” in Article 44 and, at the end of “Section III”, the Portuguese law establishes ancillary sanctions which, as its name suggests, may be added to the main penalty.

Article 43-A

Criminal liability of legal persons and similar entities

500,000 (for legal persons) to those who: apply MAR techniques without the proper conditions, or outside authorised centres, or apply medically assisted reproduction techniques to those who are not recognised as recipients of the techniques, or apply MAR techniques without consent. However, the Portuguese law also provides for the possibility of ancillary sanctions to those convicted of a crime or to those convicted of a misdemeanour, provided for in Article 45 of Law 32/2006, which may be a court order, temporary disqualification from the practice, the exclusion from entitlement to benefits from the State, temporary closing of the establishment, termination of the authorisation to operate, and the public display of the sentence.

It should be noted that the Portuguese courts are responsible for the application of criminal law, so it is up to them to apply the sanctions referred to in this chapter, and to increase the “ancillary sanctions” mentioned above in a sentence involving a crime or administrative offence. In Spain, on the other hand, pursuant to the Spanish Law 14/2006 on Medically Assisted Reproduction [the *Ley Española de Procreación Medicamentosa Asistida*, the (administrative) bodies of the Autonomous Communities and cities with autonomous status are in charge of monitoring and inspecting these sanctions.

Conclusion

While the Portuguese Law on medically Assisted Reproduction determines that sanctions (in Portugal) are mainly of a criminal nature, implying criminal liability, the Spanish Law on Assisted Human Reproduction Techniques (although not excluding the possibility of criminal and civil liability for “offenders”) applies penalties primarily as a response to the offences which it considers “naturally” to be of an administrative nature.

Thus, in my opinion, the Portuguese Law on Medically Assisted Reproduction (Law 32/2006 of 26 July) relates much more to the criminalisation of offending conduct than the Spanish Law (Law 14/2006), given that in Portuguese Law these conducts are analysed from a criminal law point of view, which does not appear to be the case in the Spanish legal system.

We therefore conclude that in order for these systems of reproductive human rights in health to be protected and growth together in the future (as we suggest), the Spanish approach, which is more open and does not apply criminal sanctions to wrongful medical conducts at once, but rather first applies administrative sanctions to medical professionals and hospitals that perform them outside of the law, should indeed, in this field, influence more profoundly the Portuguese system. The latter has a more conservative approach that, in our opinion, should be similar to the Spanish one, because there really is not a scientific reason for handling medical conduct in Portugal and in Spain differently.

In conclusion, the criminalization of medical liability, in general, and in terms of medically assisted reproduction, in particular, does not help to protect human and reproductive rights in health care systems.

References

- Abellán, F. y Caro, J.S. (2009). *Bioética y Ley en reproducción humana asistida: Manual de Casos Clínicos*, Granada, Comares
- Alkorta Idiákez, I. (2003). *Regulación jurídica de la medicina reproductiva: derecho español y comparado*, Navarra, Aranzadi
- Arroyo |Amayuelas, Esther (2004). “Interpretación de testamento contraria a los Derechos Humanos”, in *Derecho Privado y Constitución*, 18, pp. 7 -87.
- Ara Pinilla, I., “*Las Transformaciones de los Derechos Humanos*”, Madrid, Tecnos, 1994.
- Assembleia da República Portuguesa (1992). “Questões de Bioética”, in *Coleção Temas 1*, Procriação Medicamentosa Assistida, Utilização do Embrião, Vol. II.
- Barbas, S. Marcos Neves (1999). “Aspectos Jurídicos da Inseminação artificial “post mortem”, in *Colectânea de Jurisprudência*, tomo II, 7º, pp. 21 – 24.
- Barbas, S. Marcos Neves (2000). “Da problemática jurídica dos embriões excedentários”, in *Revista de Direito e de Estudos Sociais*, Jan/Jun., pp. 103 – 113.
- Barbas, S. Marcos Neves (2006). “*Direito ao Património Genético*”, Coimbra, Almedina
- Cárcaba Fernández, M. (1995). “*Los problemas jurídicos planteados por las nuevas técnicas de procreación humana*”, Barcelona, J.M. Bosch
- Coelho, Pereira y Oliveira, Guilherme De (2003). *Curso de Direito da Família*, Vol. I (3ª ed.), Centro de Direito

Legal persons and similar entities shall in general be liable to the crimes provided for in this Law.

Amended by the following decree: Law 59/2007 of 04 September.

See Administrative offences in the Law Assisted Reproduction. SECTION II:

Article 44 (Administrative offences) “1— The following shall constitute an administrative offence punishable by fine between EUR 10,000 and EUR 50,000 in the case of natural persons, the maximum being EUR 500,000 in the case of legal persons:

a) The application of any NAR technique in violation of the conditions provided for in Article 4; b) The application of any NAR technique outside authorised centres; c) The application of any NAR technique in violation of the requirements provided for in Article 6; d) application of any NAR technique without the consent of any of the beneficiaries in a document complying with the requirements of Article 14(2) — Negligence shall be punishable, by halving the maximum amounts provided for in the preceding paragraph.”

- da Família, Coimbra, Coimbra Editora
- Conseil de L'Europe (1985). “*Le Droit au Respect de la Vie Privée et Familiale*”, Dossier sur les Droit de L'Homme, 7, Strasbourg
- Díaz, Martínez A. (2006). “*Régimen de la reproducción asistida en España: El proceso legal de reformas*”, Madrid, Dykinson S.L.
- Goday Vázquez, M. Olaya (2014) “*Régimen jurídico de la tecnología reproductiva y la investigación biomédica con material humano embrionario*”, Madrid, Dykinson S.L
- Gomes Cobacho, José António (2007). “*Comentarios a la Ley 14/2006 de 26 de Mayo, sobre Técnicas de Reproducción Humana Asistida*”, Madrid, Thomson Aranzadi
- Hidalgo Ordás, M.C.(2002). “*Análisis jurídico – científico del concebido artificialmente: En el marco del experimentación génica*”, Barcelona, Bosch
- Human Fertilisation and Embryology Authority (HFEA). (2005/2006). “*The HFEA guide to infertility and directory clinics*”
- Idiákez Itiziar, Alkorta (2003). “*Regulación Jurídica de la Medicina Reproductiva – Derecho Español y comparado*”, Navarra, Thomson Aranzadi
- Lledó Yague, F. y Ochoa Marieta, C. y Monje Balmaseda, O.(2007). “*Comentarios científico – jurídicos a la Ley sobre Técnicas de Reproducción Humana Asistida: Ley 14/2006 de 26 de Mayo*”, Madrid, Dykinson
- Mota Pinto, Paulo (2007). “*Indeminização em caso de “Nascimento Indevido” e de “Vida Indevida” (“Wrongful Birth” e “Wrongful Life”)*, in *Lex Medicinæ*, 4, 7
- Oliveira, Guilherme De (2004). “*Um Caso de Seleção de Embriões*”, in *Lex Medicinæ*, 1
- Oliveira, Guilherme De (2005). “*Beneficiários da Procriação Assistida*” in *Temas de direito da medicina*”, Coimbra, Coimbra Editora, pp. 31 – 58.
- Pérez Luño, A.E.(2006) “*La Tercera Generación de Derechos Humanos*”, Navarra, Aranzadi, 2006
- Raposo, Vera Lúcia (2014). “*O direito à Imortalidade – O exercício de direitos reprodutivos mediante técnicas de reprodução assistida e o estatuto jurídico do embrião in vitro*” Coimbra, Almedina
- Romeo Casabona, C., (Ed.) (2006), “*La cuestión jurídica de la obtención de células troncales embrionarias humanas con fines de investigación biomédica. Consideraciones de política legislativa*”, in *Revista Derecho y Genoma Humano*, 24, enero/julio, pp. 75/ss
- Serrão, D. (2003). “*Livro Branco - Uso de Embriões Humanos em Investigação Científica*”, Lisboa, Ministério da Ciência e do Ensino Superior
- Vale e Reis, R., “*O direito ao conhecimento das origens genéticas*”, Coimbra, Coimbra Editora, 2008.
- Vale e Reis, R. (2010). “*Responsabilidade Penal na Procriação Medicamente Assistida – Criminalização do Recurso à Maternidade de Substituição e Outras Soluções Criminalmente Duvidosas*”, in *Lex Medicinæ*, 7, 13
- Proença Xavier, João, (2012). “*Ensayo sobre la Problemática de los Embriones Excedentarios en la Reproducción Medicamente Asistida*”, Tesina Doctorado “*Pasado y Presente de Los Derechos Humanos*”, Salamanca

Legislation

- Instrument of Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of biology and medicine (Convention on human rights and biomedicine), done in Oviedo on 4 April 1997. <<http://www.boe.es/boe/dias/1999/10/20/pdfs/A36825-36830.pdf>> (December 30, 2015)
- Portuguese Law on Medically Assisted Reproduction, Law 32/2006 of 26 July fdunl.pt, <http://www.fd.unl.pt/docentes_docs/ma/tpb_MA_4022.pdf>. (Updated version Law 59/2007 of 4 September, Article 4 of Law 59/2007 of 04 September – Addendum to Law 32/2006, of 26 July), (December 30, 2015)
- <http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?artigo_id=930A0004&ni_d=930&tabela=lei_velhas&pagina=1&ficha=1&nversao=1> (December 30, 2015)
- Spanish Law on Medically Assisted Reproduction, Law 14/2006 of 26 May, (version included in the author’s thesis). <<http://www.bioeticaweb.com>> Law 14/2006 of 26 May on assisted human reproduction techniques (December 30, 2015)
- Head of State, “Boletín Oficial del Estado (BOE) [Official Journal] no. 126, of 27 May 2006. Reference: BOE-A-2006-9292 Consolidated text - Last amendment: 14 July 2015) (December 30, 2015)
- <<http://www.boe.es/buscar/pdf/2006/BOE-A-2006-9292-consolidado.pdf>> (December 30, 2015)