

Ideological conflicts leading to regulation of investigation with embryonic stem cells

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Abstract

Human stem cells, particularly embryonic, have huge therapeutic potential to many degenerative diseases, so they are the subject of intense research in many countries. Because obtaining human stem cells involves the use of zygotes obtained by in vitro fertilization, when they arrive in the blastocyst stage, ethical issues arise that some groups considered insurmountable; in Mexico to date it has not been possible to establish a law or rule that regulates the issue. The purpose of this paper is to discuss the ideological conflicts that have led to this situation, and about the light a judgment delivered by the Inter-American Court of Human Rights may shed on a democratic and secular legislation. (Gac Med Mex. 2015;151:256-60)

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Introduction

Human stem cells, particularly embryonic stem cells, have an enormous therapeutic potential in many degenerative diseases and, therefore, are the subject of intense research in a large number of countries. Although techniques for transforming adult cells into cells with embryonic features have been developed in the last 8 years, embryonic stem cells remain as those with the highest potential, not only from the therapeutic point of view, but also to understand cell differentiation processes occurring during development, whose alterations are often causative of diseases, including cancer. Since obtaining human embryonic stem cells involves the use of zygotes obtained by IVF, once they reach the blastocyst stage, ethical issues are raised, which some groups consider unsurmountable. As of

today, it has not been possible for a law or regulatory standard to be established in Mexico. The purpose of this work is to discuss the reasons for this situation, in the light of certain decisions taken by international organizations and to propose some solution from the legal point of view.

Current legislation

The General Health Statute stipulates that health establishments involved with the handling of progenitor or stem cells require a health authorization (art. 315) and must have an internal transplantation committee available (art. 316); that trading cells (any kind) is prohibited (art. 327) and that a special permit is required to extract them from national territory (art. 317). This law also refers to the use of placental blood to obtain

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stem cells for therapeutic or investigational uses (art. 321Bi), but there is no precept in this legal text referring to the use of embryonic stem cells for research.

Conversely, penal law, in the Penal Code for the Distrito Federal (CPDF), establishes sanctions for anyone who uses egg cells or sperm with purposes other than those authorized by the donors¹. The text induces to think that the regulation allows for donors to authorize the use of their germ cells for the creation of blastocysts useful for research. However, this deduction is limited by the text of article 152, fraction II from the same code, which penalizes anyone who fertilizes eggs with purposes other than human procreation². This text implies the tacit prohibition to produce embryos for investigational purposes, which is clearly an activity intended for purposes other than procreation.

On the other hand, fraction III of the same article 152 sanctions with the same penalization anyone who creates human beings by clonation or who performs genetic engineering procedures with illicit purposes. This precept clearly penalizes reproductive clonation; however, the second part of the article is not that clear, since we don't know which the illicit purposes of, for example, a genetic engineering procedure might be. Knowing the objective of every procedure would be necessary to determine its illicit or licit nature. ¿Which authority should be responsible for determining which technique is illicit and which licit? ¿Which parameters or legislation should be followed to rate the illicit nature? In the absence of legislation providing satisfactory answers, it will be the judge who will be responsible for qualifying the licit or illicit nature of genetic engineering techniques, but we wonder if a judge is prepared for this.

The lack of sufficient legislation implies risks. Scientists ignore if their actions will be socially accepted or not, and even if they might be regarded as a crime. The decision will correspond to public servants of the Ministry of Health and, ultimately, to the judges, who will

have to resolve on the illicit nature of the procedure without a regulation to support their decision. This legal uncertainty has generated that in Mexico no research with human embryonic stem cells is carried out.

Why has research with this type of stem cells not been legislated in Mexico?

The answer relates to the position assumed by conservative groups: since research with embryonic stem cells involves the destruction of blastocysts, they equate them to embryos that, according to their position, are already human beings, they are persons. In the Latin American panorama, positions on the moment life begins and, therefore, the moment the duty of the State to protect it begins are clearly defined. The position of the Catholic Church³ is unequivocal: "Human life has to be held as sacred because since its beginning it is the fruit of God's creative action and nobody under any circumstance can assume the right to directly kill an innocent human being"⁴. This premise leads to the conclusion that human life must be absolutely respected and protected since the moment of conception⁵. Additionally, the Church prescribes that "the inalienable rights of the person have to be recognized and respected not only by believers but also by the civil society and political authority"⁶.

During the decade of 1960, the Catholic Church experienced a true institutional and ideological renewal in the American continent, which forced to review much of the postulates that political actors had held on it for the previous one and a half century⁷. Its position on reproductive issues is clear from a precise moment on, October 12, 1992, which is when the General Conference of the Latin American Episcopacy took place. The then Pope John Paul II set the bases of a very conservative ideology and strategy specifically directed to

1. CPDF, art. 149.

2. CPDF, art. 154

3. To know the positions of the Protestant Church and Judaism, please refer to *La reproducción humana asistida: un análisis desde la perspectiva biojurídica*, by Héctor Mendoza (México: Universidad Autónoma de Nuevo León/Editorial Fontamara; 2001).

4. Congregación para la Doctrina de la Fe: "Las enseñanzas del magisterio", en *Instrucción Donum vitae sobre el respeto de la vida humana naciente y la dignidad de la procreación*, Introducción, punto 5, Ciudad del Vaticano; 22 de febrero de 1987. [Internet] Available in: http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_sp.html.

5. Since the first moment of his existence, the human being should see his personal rights respected, including the inviolable right of every innocent being to life. 2273 2

6. S. S. Juan Pablo II, Joseph Ratzinger, et. al.: *Catecismo de la Iglesia católica: teología moral, 3.ª parte: La vida en Cristo, 2.ª sección: Los diez mandamientos, capítulo 2.º: Amarás a tu prójimo como a ti mismo, art. 5: El quinto mandamiento*, 2.ª versión corregida, Ciudad del Vaticano: agosto de 1997. [Internet] Available in: http://www.vatican.va/archive/catechism_sp/p3s2c2a5_sp.html.

7. Ernesto Boholavky: *Laicidad en América Latina*, Colección de cuadernos Jorge Carpizo para entender y pensar la laicidad, UNAM, Instituto de Investigaciones Jurídicas, Cátedra Universitaria Benito Juárez, Instituto Iberoamericano de Derecho Constitucional; 2013, p. 25.

governments and political parties ideologically related to the Catholic Church. Since then, the function of both has been to promote initiatives of laws according to the principles of the catholic faith and, on the contrary, to stop those that are adverse⁷. Unfortunately, in Latin America these postures have a very strong political presence and dominate public policies and legislation, pretending to rule life not only of their believers but also of the entire population⁸.

In turn, since the beginning of the decade of 1970', liberal thought, based on scientific positions, has generated and emphatically proposed a different concept on the consideration that has to be paid to the embryo during its development, especially before being implanted in the uterus. Thus, Diego Gracia's posture is supported by the argument that the embryo is a being in process, and that it can not be regarded as a new being until constitutional sufficiency is achieved⁹. In the same sense, Juliana González maintains that the embryo in the pre-implantation status is not more than a potential life and that if left alone it will not survive, even if it contains the human genome¹⁰. Similarly, Ricardo Tapia considers that, from the scientific point of view, the human being, the person, is the result of ontogenic development when it reaches the stage of physiological autonomy and, as long as the brain cortex is not developed, we cannot talk about human life, although, of course, there is life, just as there is in an organ that can be transplanted. Prior to that stage of development, the embryo's life does not substantially differ from that of any cell, organ or tissue of a living multicellular organism¹¹.

Position of the Inter-American Court of Human Rights

With regard to this apparently endless discussion, there is a new position posed by the Inter-American Court of Human Rights. In November 2012, this court passed sentence on the case *Artavia Murillo and others versus Costa Rica*. Although the case refers to assisted

fertilization, it has great impact with regard to the notion of conception, and to the treatment that has to be given to blastocysts prior to implantation in the maternal uterus.

The sentence is quite comprehensive and addresses very interesting issues, but for the purposes of this work, I will concretely refer to the interpretation of article 4.1 of the American Convention for the Protection of Human Rights, which states: "Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception". The terms *person*, *conception* and *in general* have been used in countless judicial decisions at all levels and in general provisions of laws. This multiplicity of meanings, which in addition are conflicting, has generated a great deal of confusion and uncertainty. The most radical positions led the Court tribunal not to restrict itself to solve the presented controversy, but, in use of its attribution as official interpreter of the American Convention, it decided to carry out the legitimate interpretation of the "person", "human being", "conception" and "in general" concepts contained in the aforementioned article 4.1.

The Court underlined that two different readings of the term *conception* stand out: some understand it as the moment of egg fertilization by the spermatozoid, which generates a new cell, the zygote, that carries the necessary instructions for the embryo to develop; conversely, others consider conception as the moment of implantation of the blastocyst, formed in the traject from the Fallopian tube, in the inner wall of the uterus, since it is then that the blastocyst gains access to all hormones and other elements required for its development.

The expert Fernando Zegers¹² referred to the *Diccionario de la Real Academia de la Lengua Española*, which defines *conception* as the action and effect of conceiving (conceiving as the female becoming pregnant). The word *conception* refers explicitly to pregnancy, gestation, which starts with implantation of the embryo. Conception or gestation is an event of

7. Alicia Miyares: "Derechos sexuales y reproductivos en América Latina.", in *Pensamiento Iberoamericano Feminismo, género e igualdad*, no. 9, 2.ª época, Madrid: Agencia Española de Cooperación Internacional para el Desarrollo (AECID)/Fundación Carolina; September 2011.

8. Florencia Luna, "Infertilidad en Latinoamérica. En busca de un Nuevo Modelo", in *Revista de bioética y Derecho*, number 28, May 2013, p. 38.

9. Quoted by Juan Ramón Lacadena. Word *embrión* in the *Enciclopedia de bioderecho y bioética*, *op. cit.*, pages 728 and subsequent.

10. Juliana González: "Embrión humano y dignidad humana", in *Células troncales: aspectos científicos-filosóficos y jurídicos*, coordinated by Ingrid Brena, México: Universidad Nacional Autónoma de México/Instituto de Investigaciones Jurídicas; 2005, p. 71.

11. Ricardo Tapia: "La formación de la persona durante el desarrollo intrauterino desde el punto de vista de la neurobiología", in *Conciencia latinoamericana*, April 2009, vol. XVII, no. 16, México: Red Latinoamericana de Católicas por el Derecho a Decidir, p. 23-25.

12. Fernando Zegers Hoshild is a surgeon that has occupied many posts both in his country (Chile) and international organizations: he is president of the International Committee for Monitoring ART and member of the Research Project Review Panel of the WHO Special Program on Reproduction.

the woman, not of the embryo. Conversely, to fertilize is a different action, which is the union of the male reproductive element with the female one to give origin to a new being, a definition that so far has not changed. So, we are dealing with two different terms that shouldn't be mixed up. This is also the position of the World Health Organization (WHO)¹³ and the International Federation of Gynecology and Obstetrics (FIGO)¹⁴.

So, the Court, from a secular position, considered that, although some groups insist on seeing full human life in fertilized eggs, based on notions associated with conceptions that confer certain metaphysical attributes to embryos, these judgments should not prevail over scientific literature when interpreting the scope of the right to life enshrined in the American Convention for the Protection of Human Rights, since this would imply imposing some type of specific beliefs to persons who do not share them. The court considered that if the embryo is not implanted in the body of the woman, as it happens in the case of using it for investigational purposes, its possibilities for development are null, since when not receiving the necessary nutrients it will not be in an adequate environment for its development. Therefore, the term *conception* must be understood from the moment of implantation on, and this is the reason why the court ruled that, before this event, article 4 of the American Convention is not applicable.

On the other hand, the Court undertook the review of numerous international documents to investigate if the intention of protecting prenatal life was therein established. After reading the American Declaration of the Rights and Duties of Man, the Universal Declaration of Human Rights and several sentences passed by the European Court of Human Rights, the Court found intention of the States to recognize the embryo as part of the human race with potentiality, but without recognizing it as a person with the right to life.

The analyzed documents and evidences allowed for the Court to infer that the purpose of article 4.1 of the Convention is to safeguard the right to life without being an absolute right whose protection can justify denying other rights. In the same sense, the Supreme Court of Justice of the Nation of Mexico, on August 28th 2008, resolved on the unconstitutionality claim and de-

clared that from the fact of life being a necessary condition for the existence of other rights, it cannot be validly concluded that life must be considered as being more valuable than any of those other rights.

On the other hand, the issue of the embryos' right to life was perhaps one of the most sensitive topics analyzed during the procedure. Taking this into account, the Court found it disproportionate to pretend absolute protection of the embryo with regard to a risk that is common and inherent even in processes where the IVF technique does not intervene. Based on this position, the Court decided to share Zeger-Hochschild's concept, for whom differentiating the meaning of "protecting the right to life" from that of "warranting the right to life of cell structures that are governed by mathematical and biological laws that are beyond any social or legal regulation" is fundamental from the biomedical perspective.

Reflections on the sentence

The democratic and secular spirit conveyed to the sentence of November 2012 represents a big step towards the construction of liberal thought on reproductive rights in the American continent, but it also makes way to possible permissiveness in the research with embryonic stem cells. Article 4 official interpretation will with no doubt permeate doctrine and legislations, as well as judicial decisions, but it will correspond to international law specialists analyzing the significance of the interpretation and its degree of compulsoriness for signatory States of the American Convention.

Adverse reactions to the interpretation

Those who think that the sentence, with its solid arguments, provides a scientific vision on IVF application never cease to be surprised when we see conservative currents insisting on their arguments, not acknowledging those of the sentence at all. The Costa Rica State itself has failed to comply with the Court's resolution, *i.e.*, it has failed to regulate IVF owing to the attitude of conservative representatives. Some documents, including the Guanajuato Declaration on *in vitro* Fertilization¹⁵,

13. Mechanism of action, safety and efficacy of intrauterine devices: Report of WHO Scientific Group, Technical Report Series 753, Geneva: WHO; 1987.

14. Definition of pregnancy. Recommendations on ethical issues in obstetrics and gynecology, London; 2000.

15. Suscribed in April 2013 in the city of Guanajuato (Mexico) by a group of people dedicated to bioethics, including physicians, philosophers, academic biologists and jurists.

insist on identifying conception with fertilization and maintain that, for international instruments on human rights, the embryo is the holder of the rights therein enshrined. These documents prove that scientific knowledge does not want to be listened to, with a dogmatic position superimposed on it. The fight for legislation and interpretation of laws based on scientific and not ideologic or religious knowledge is still going to be a long one.

Towards a regulation for research with stem cells

Opposing positions have cancelled the possibility of legislatively advancement in order for research with embryonic stem cells to be conducted¹⁶. In Mexico, political parties have presented initiatives to the Senate of the Republic and the House of Representatives¹⁷. Conservative members of the Partido Revolucionario Institucional (PRI), but also currents of the Partido Acción Nacional (PAN), are aligned for absolute prohibition, which entails not even allowing for embryos left over from IVFs to be frozen and possibly used in investigations; liberals and left parties have proposed the use of embryonic stem cells for research. None of the presented initiatives has been approved, especially owing to different considerations on when life begins and, in consequence, from which moment on it must be juridically protected.

We are in favor of a regulation in Mexico on research with stem cells, but legislators must act with a democratic and secular spirit, without forgetting the importance of

respecting freedom of research, which only can be exercised in a secular State that doesn't admit religious impositions or obstacles, and where adequate conditions are created for this freedom to be exercised. Trying to impose a religious or moral conception, even if it is shared by the majority of the population, seriously threatens freedom of conscience, thought and belief¹⁸.

Research with embryonic stem cells has to be, of course, subjected to certain limitations, but there is a large difference between establishing restrictions when these are justified and not excessive, and imposing a categorical prohibition or not legislating at all. Legislation must be supported by scientific information that allows for respectful coexistence to be constructed, directed towards the development of science with the benefit of mankind in mind. There is no justification for any religion to try to stop or restrict freedom of research and less so to support these actions on values created by some church that, even though they are respectable, they are not shared by the entire society. A State that calls itself democratic, must watch over for this interference not to be perpetrated.

In the presence of legal voids, the Law is responsible for signalling the limits of what is socially acceptable and give certainty on things that are forbidden and those that are allowed. Legislative work must be carried out with great sensitivity in order to avoid restricting such a valuable activity as scientific research directed to reduce pain, cure diseases and warrant more dignified life conditions to the human being, but in the same way, it must protect human rights and values considered by society as worthy of protection.

16. In some cases, ultraconservative positions are observed, such as that of the Buenos Aires Province where the legal entity of "tutor of embryos" was created in 2004; this justice officer must watch over for the embryos and control that fertility clinics do not disregard them; see Florencia Luna, *op. cit.*, page 41.

17. In the current term, a project of law created by the Partido de Acción Nacional is trying to be promoted.

18. Diego Valadés: "Eutanasia. Régimen jurídico de la autonomía vital", in *Derechos humanos, aborto y eutanasia*, Valadés D y Carpizo J, México, Instituto de Investigaciones Jurídicas, UNAM, 2008, p. 81.