García San José, Daniel, “Epygenetic: new challenges for fundamental rights”, *IUS ET SCIENTIA*, 2015, Vol. 1, No. 1, pp. 79-92.
DOI: http://dx.doi.org/10.12795/IETSCIENTIA.2015.i01.06

Epygenetic: new challenges for fundamental rights.

Epigenética: nuevos desafíos para los derechos fundamentales.

Dr. Daniel García San José. Ass. Professor of Public International Law. University of Sevillle, Spain dagarcia@us.es

Keywords: Epigenetic and Protection of fundamental rights - Informed consent - Huge Data bases and screening - Doctrine of proportionality

Palabras clave: Epigenética y protección de derechos fundamentales - consentimiento informado- Mega bases de datos y tratamiento masivo de datos - Doctrina de la proporcionalidad

Abstract: Based on the work done to date by the R+D project DER 2010-14896, this article seeks to identify the new challenges posed by epigenetic for fundamental rights at international, European and national order. Epigenetics refers to the possible alterations in the expression of genes of an individual by various environmental conditions (epimutations). These are reversible and thanks to new technologies for data processing, predictable. This opens the door to better treat many diseases but it also carries risks on some fundamental rights (right to privacy and genetic determination, the right to non-discrimination) because heritable epigenetic changes in the structure and organization of DNA affect information concerning not only to a specific individual but also to others (family, community or group associated with environmental conditions that cause a certain epimutation). International law on the issue is almost nonexistent. At European level, apart from a few Recommendations of the Council of Europe, the Directive 95/46/EC and the draft EP and the Council Regulation on the protection of personal data, still in process, do not give an adequate response to these challenges. That inadequate European regulation is particularly problematic considering threats to fundamental rights in the field of private law relations (labor relations, insurance contracts of life and health) due to advances in computer processing of information in large epigenetic databases. The proposed research should be conducted, from an international and comparative approach to Law, combining an empirical-inductive method with another logical-deductive, and articulated through various methodological techniques. The general objective pursuid is to provide a legal basis from a multidisciplinary, cross-cutting and integrated approach that allows establish a common legal framework in Europe facing the new challenges posed by epigenetic to protection of fundamental rights.

Resumen: Partiendo del Proyecto de I+D DER 2010-14896, buscamos identificar los nuevos desafíos que la epigenética plantea para los derechos fundamentales en el ordenamiento internacional, europeo y nacional. La epigenética hace referencia a las posibles alteraciones en la expresión de los genes de un individuo por diversas condiciones medioambientales (epimutaciones). Éstas son reversibles y gracias a las nuevas tecnologías de tratamiento de datos, predecibles. Se abre la puerta al tratamiento de graves enfermedades pero también a riesgos en algunos derechos fundamentales (a la intimidad y a la autodeterminación genética; a no sufrir discriminación) pues la epigenética indica cambios heredables en la estructura y organización del ADN e incluye información concerniente no sólo a un individuo concreto sino también a terceros (grupo familiar y comunidad o colectivo asociado a las condiciones medioambientales que provocan cada epimutación). La normatividad internacional sobre la cuestión es casi inexistente. A nivel europeo, al margen de algunas Recomendaciones del Consejo de Europa, la Directiva 95/46/CE y el Proyecto de Reglamento del PE y del Consejo relativo a la protección de datos personales, aún en tramitación, no dan una respuesta suficiente a estos desafíos. Resulta particularmente problemático en el ámbito de las relaciones jurídico-privadas (relaciones laborales, contratos de seguros de salud y vida, entre otros) debido al tratamiento informatizado en grandes bases de datos epigenéticos de millones de individuos sin su consentimiento. Desde una aproximación de Derecho internacional y comparado, utilizando un método positivista sociológico complementado con dos técnicas metodológicas, empírico-inductiva y lógico-deductiva, respectivamente, pretendemos establecer un marco jurídico común en Europa frente a los nuevos desafíos que la epigenética plantea para la protección de los derechos fundamentales.

1. Introduction.

In the R + D + i National Plan of the Spanish Ministry of Science and Innovation (MICINN) (current MINECO) entitled "European legal framework for biomedical research and cellular reprogramming transfer" DER2010-14896, 2010-2014, we have studied the informing principles of biomedical research on human embryos in Europe with the intention of identifying a corpus juris europaeum on two issues that in recent years have been troubling lawyers in connection with the implications of this sector of Sciences of life for society, what could be the subject of such research and by what procedures?, one hand and what legal protection by way of patents should be given to the results of this research? The premise from which we started in this research was twofold: first, assumed that science always moves faster than the law which can only give tentative and often imperfect answers to the challenges posed by everyday scientific discovery (SAN JOSE GARCIA, RGLJ, 2012, 8). On the other hand, we assumed that the approach as jurists to study the eventual answer to scientific advances should be done from the biolaw; that is, from a new legal perspective characterized by three notes: firstly, taking as a reference national, international and supranational standards; secondly, adopting a multidisciplinary acknowledge that several legal areas are concerned at this regard and, thirdly, accepting the integrative rather reductionist nature of the convenient approach; that is, not ruling out a priori ethical and moral considerations but neither conditioning our analysis thereof (SAN JOSE GARCIA, 2010, 10).

2. New challenges to fundamental rights posed by scientific advances: epigenetic data.

In recent years, coinciding with the life of the research project above referred, there have been new developments in biomedical research so that issues that until recently were dormant or in the background have become more relevant. This applies to the new challenges to fundamental rights posed by scientific advances (LLANO ALONSO, 2014, 33) and in particular epigenetic can be understood as "the study and analysis of changes in the functions of the genes that are heritable and do not involve changes to the original DNA sequence, which means determining the alternative expressions of the same gene "(GARCIA CAVAZOS, 2003, 58). Thus epigenetic indicates heritable changes in DNA structure and organization which are not, nevertheless, an alteration of the nucleotide sequence, gene expression and modified lead heritable changes in phenotype (GARCIA ROBLES, 2012, 61). These genetic changes are produced by various environmental conditions (epimutations) and are heritable in families, hence the interest of science to know how they are made to better treat and even prevent diseases such as schizophrenia, depression, neurological disorders and even cancer (BEDREGAL, 2010, 367).

Epigenetic explanations can bring in diseases that until now had no clear origin and involve substantial changes in medical practice by allowing prescribe from a drug based on the genetic background of the patient (GARCIA CAVAZOS, 2003, 59). However, epigenetics involves several challenges for fundamental rights from multiple viewpoints. A mere illustration, and the current state of knowledge, we will refer only to two fundamental rights: the right to privacy of genetic information and the right to non-discrimination (for genetic reasons). Regarding both fundamental rights, a close up of challenges is motivated by the specific nature of epigenetic information. As noted above, the epimutations, being heritable in families, are therefore predictable and preventable. At present, epigenetic data provide information on the health of an individual, on their future health and even on the present and future health of their children.

The specificity of the information about an individual can bring epigenetics is linked to the question of the ownership of the fundamental rights concerned. Being an intimate information and therefore protectable as part of the privacy of genetic information of a specific person, the truth is that - thanks to the massive data bases and computer processing of these data-, epigenetic open access to sensitive information of an individual, their families, and even a larger group to which that individual belongs, for example, a community, an ethnic or racial group.

Another order of epigenetic challenges to fundamental rights concerns what is the weight to be given to those risks for fundamental rights coming into play when legitimate interests in a democratic society as the fight against crime are at stake (CARUSO FONTÁN, 2012, 135). In this vein, calls attention in the field of biomedical advances by epigenetic research, how the right to be informed (TORRES CAZORLA, 2014, 41) about genetic data between authors invoke an individual who consented to participate in a particular medical test but that, in turn, relate to others- usually, his/her family who has not given consent (GÓMEZ RIVERO, 2007, 43). It also increases the risk to third parties outside the household, for epigenetic information refers to features common to groups or groups of individuals whose fundamental rights are most threatened if possible in their capacity of vulnerable groups (LLANO ALONSO, 2013). Also in the biomedical testing is a principle accepted that not always must be respected the right to privacy of epigenetic information of an individual when the disclosure of that information may be relevant to the health or life of others, relatives, for instance (MONIZ, 2004, 103).

In the above examples it seems easy to admit that it is possible and convenient to consider interference with the exercise of fundamental rights when it is deemed as a necessary interference in a democratic society and thus proportionated to the legitimate aim pursued. At other times, however, the scenario is not so far-sighted, providing gray areas. Consider, for example, in the acquisition and processing of epigenetic information in the field of private law relations, particularly in labor relations and in the context of life insurance and health.t is common practice to conduct biomedical testing in workplaces to establish, for example, whether or not employees are likely to be affected by certain type of disease related to their working conditions (DESMOND and GARDNER, 2001,435 and ff.).

Increasingly frequent are the judicial pronouncements in which the employer has been convicted for violating the privacy of genetic information of their employees. Even though, it can be very difficult to prove that an employer uses epigenetic data from employees to fix working conditions of these and even for the termination of their employment. Moreover, the approach followed so far by the Spanish and European courts -condemn unauthorized access to the genetic information of employees by their employers- appears not to be sufficient in the field of epigenetics and the following example may be instructive.

Imagine an employer requires its employees to provide voluntarily data about their eating habits, hobbies, whether drink, smoke or if they practice some kind of sport. Some employees may want to share that information if they practice any sport and maintain a healthy lifestyle. Other workers, however, might be uncomfortable revealing that information. Although it is voluntary yielding these data, the mere fact of allowing that it could be requested by the employer, is putting at risk of stigmatization and discrimination part of employees under the generalized conviction that "anyone who does not want to provide personal data, undoubtedly, is hiding something". These risks outlined in the field of labor relations are manifested also in the field of life and health insurance.

3. Insufficient legal regulation for protecting epigenetic data.

The amazing thing about the challenges that epigenetic is posing for the exercise of certain fundamental rights is that international and national regulation of treatment and collection of private data seems not having duly considered epigenetic data, for example, being a regulation that does not include epigenetic data on its material scope and excluding from the personal sphere of protection other people (relatives, for instance) apart from the subject directly interested in the protection of his/her epigenetic data. A preliminary reading of the existing rules or under development is evidencing this point, except for an error on our part. See in this regard in the context of the Council of Europe, Recommendations of the Committee of Ministers: R83(10) On the protection of personal data used for scientific research and statistics[1]; R86(1) On the protection of personal data used for purposes of social security[2]; R89(2) On the protection of personal data used for employment purposes; R97(5) On the protection of medical data[3]; R2002 (9) On the protection of personal data collected and processed for the purposes of insurance[4]; R2004 (17) On the impact of information technology in health care[5]; R2006(4) On the research on biological materials of human origin[6]. You can also see Convention No. 108

---

[1] https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=602986&SecMode=1&DocId=680204&Usage=2

[2] https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=1894447&SecMode=1&DocId=688622&Usage=2

[3] http://www.coe.int/t/dghl/standardsetting/dataprotection/EM/EM_R(97)5_EN.pdf

[4] https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=543727&SecMode=1&DocId=295736&Usage=2

[5] https://wcd.coe.int/ViewDoc.jsp?id=802853&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383

[6] https://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383

concluded within the Council of Europe in 1981, for the protection of individuals with regard to automatic processing of personal data[7].

In the context of the European Union, the same conclusion is drawn from the examination, for example, of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995, On the protection of individuals with regarding the processing of personal data and the free movement of such data[8]; Directive 2002/58/EC On the processing of personal data and the protection of privacy in the electronic communications sector[9]; Directive 2006/24/EC On the retention of data generated or processed in connection with the provision of electronic communications of public access or of public communications networks[10] by which is modified Directive 2002/58/EC; Framework Decision 2008/977/JHA of the Council of November 27th, 2008 On the protection of personal data processed in the framework of police and judicial cooperation in criminal matters[11]; see also the European Parliament legislative resolution of 12 March 2014 on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 - C7-0025/2012 - 2012/0011(COD)[12], to replace Regulation 45/2001 of the European Parliament and of the Council of 18 December 2000[13].

---

[7] http://conventions.coe.int/Treaty/en/Treaties/Html/108.htm

[8] http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

[9] http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:201:0037:0047:en:PDF

[10] http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:105:0054:0063:EN:PDF

[11] http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:350:0060:0071:en:PDF

[12] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0212+0+DOC+XML+V0//EN

[13] (whose state of processing can be found at http://www.europarl.europa.eu/oei/popups/ficheprocedure.do?reference=2012/2011(COD)&l=en)

4. A proposal for a new comprehensive normative framework.

Thus, in the present state of knowledge, as a specific continuation phase of the research project referred at the very beginning of this paper, we propose the basis for a new comprehensive normative framework departing from the relevance of some of the reporting principles of biomedical research identified European level not only with regard to human embryo research (GARCÍA SAN JOSE, 2013, 151 et seq.):

a) the *principle of the integrity of people and the protection of the dignity and identity of the human being* in any biomedical research involving interventions on human beings, as well as genetic tests, genetic treatment of personal data and of biological samples of human origin that are used in research;

b) The *principle of self-autonomy of the individual* as the basis of the specific consent granted and previous to obtain epigenetic information;

c) The *right to non-discrimination* and *the principle of confidentiality* by any person in the exercise of duties accessing to personal information of others;

d) The *freedom of scientific research and production counterbalanced with other fundamental principles in presence,* always under independent supervision, and also taking into consideration ethical aspects;

Our hypothesis is that following a logical deductive approach from the four principles identified at European level, it can be obtained through an empirical-inductive approach complementary to the above, the keys to an international normative framework (Biolaw international) concerning the need for international standards of protection of fundamental rights in all aspects of the impact of advances in life sciences in society that require a response from the law, particularly in the specific area epigenetic challenges posed to certain fundamental rights such as the right to privacy of genetic information and the right to non-discrimination for genetic reasons.

The general objective pursued in the envisaged research can be broken down into the following three specific targets:

1. Analyze the main doctrinal and jurisprudential pronouncements contributions of Spain, Europe and America have denounced in recent times the risks and problems of epigenetics for fundamental rights (in a clear, but not exclusive, two, the right to privacy of genetic information and the right to non-discrimination), with the possible proposed solutions to these challenges.

2. Examine critically and determine the validity of the main policy instruments in place or under development, such as the proposed European data-protection regulations taking into consideration the progress and gaps in this area in the light of the results obtained the examination of doctrine and national and comparative jurisprudence.

3. Anticipate possible policy proposals lege thanks to the massive data bases and computer processing of these data-ferenda for the European legislator and Spanish in the light of the results obtained in the first two years of the project and that can serve as inspiration for the conclusion of an international treaty on the treatment and protection of epigenetic data, non existing at present, that can be ratified by the largest possible number of States in the international community.

5. Conclusion.

Starting from the premise that science always moves faster than the law can only give late, precarious and tentative answers to the challenges it poses to society, the hypothesis defended in this paper is that epigenetic challenges for fundamental rights have not been taken into account in a proper way by the national, European and international legislation. We think it is possible to make a map of these challenges from an approximation of international and comparative law, combining an empirical-inductive method with another logical-deductive under a multidisciplinary research covering different areas such as International Law, Constitutional Law, Criminal Law and Litigation, Commercial Law, Labor Law and Philosophy of Law.

The general objective of this prospective research should be to bring a legal basis from a multidisciplinary, cross-cutting and integrated approach that allows setting up a common legal framework in Europe facing the new challenges posed to epigenetic protection of fundamental rights. This general objective is broken down into three specific objectives: 1st. Analyze the main doctrinal and jurisprudential pronouncements contributions of Spain, Europe and America have denounced in recent times the risks and problems for epigenetics Fundamental rights. 2nd. Examine critically the validity of the rules in force or in preparation, such as the proposed European data-protection regulations considering the progress and shortcomings in this area in the light of the results obtained by examining the doctrine and jurisprudence and compared. 3rd. Anticipate possible policy proposals for the European and Spanish legislator can serve as inspiration to conclude an international treaty on the treatment and protection of genetic data -inexistent at present, which could be ratified by the largest possible number of States the International Community.

6. References.

Bedregal, Paula *et al.*, “Aportes de la epigenética en la comprensión del desarrollo del ser humano”, *Revista Médica de Chile on line*, 2010, No. 138, pp. 366-372.

Caruso Fontán, María V., “Bases de datos policiales sobre identificadores obtenidos a partir del ADN y derecho a la intimidad genética, *Revista de Ciencias Jurídicas y Sociales,* 2012, Vol. 15, No. 1, pp. 135-167.

Desmond, James y Gardner-Hopkins, K., “Unemployable genes: genetic discrimination in the workplace”, *Aukland University Law Review*, 2001, Vol. 9, No. 2, pp. 435-468.

García Cavazos, Ricardo, “Epigenética: una explicación de las enfermedades hereditarias”, *Perinatol Reprod. Hum,* 2003, No. 17, pp. 57-60.

García Robles, Reggie *et al.*, “Epignética: definición, bases moleculares e implicaciones en la salud y en la evolución humana”, *Revista Ciencias de la Salud,* 2012, Vol. 10, No. 1, pp. 59-71.

García San José, Daniel, *European Normative Framework for biomedical research in human embryos,* Thomson Reuters, Aranzadi, 2013.

- "De la bioética al bioderecho. Retos para el jurista español". *Revista General de Legislación y Jurisprudencia,* 2012, No. 1, pp.7-28.
- García San José, Daniel, *International Bio law,* Laborum, Murcia, 2010.

Gómez Rivero, Carmen, “Los límites del deber de sigilo del médico en las situaciones de riesgo: especial referencia al ámbito de la genética”, *Revista de Derecho y Genoma Humano,* 2007, No. 26, pp. 43-90.

Llano Alonso, Fernando Higinio, “El hombre y la técnica en Ortega y Gasset”, *Nuevas Tecnologías y Derechos Humanos* (Director: Antonio E. Pérez Luño), 6/7, Tirant lo Blanch, Valencia, 2014, pp. 31-56.

- “El derecho al desarrollo en el sistema de derechos humanos: entre los derechos de la personalidad y la actividad de Estado”, *Anuario de Filosofía del Derecho*, 2013, Vol. 29, pp. 367-395.

Moniz, Helena, “Privacy and intra-family communication of genetic information”, *Revista Derecho y Genoma Humano,* 2004, Vol. 21, pp. 103-124.

Torres Cazorla, Isabel, “Legislación interna española y biomedicina : una aproximación a los recientes avances experimentados respecto al derecho a ser/no ser informado” en *Bioderecho Internacional y Europeo. Desafíos actuales (Sánchez Patrón, J.M., Coordinador).* Tirant lo Blanch, Valencia, 2014, pp. 41-66.

Normative Texts

Council of Europe

Recommendation of the Committee of Ministers 83(10) on the protection of personal data used for scientific research and statistics, available at https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=602986&SecMode=1&DocId=680204&Usage=2 last visited 14th November 2015.

Recommendation of the Committee of Ministers 86(1) on the protection of personal data used for purposes of social security, available at https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=1894447&SecMode=1&DocId=688622&Usage=2 Last visited 14th November 2015.

Recommendation of the Committee of Ministers 89(2) on the protection of personal data used for employment purposes, available at ***

Recommendation of the Committee of Ministers 97(5) on the protection of medical data, available at http://www.coe.int/t/dghl/standardsetting/dataprotection/EM/EM_R(97)5_EN.pdf Last visited 14th November 2015.

Recommendation of the Committee of Ministers 2002 (9) on the protection of personal data collected and processed for the purposes of insurance, available athttps://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=543727&SecMode=1&DocId=295736&Usage=2 Last visited 14th November 2015.

Recommendation of the Committee of Ministers 2004 (17) on the impact of information technology in health care, available at https://wcd.coe.int/ViewDoc.jsp?id=802853&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383 Last visited 14th November 2015.

Recommendation of the Committee of Ministers R2006(4) on the research on biological materials of human origin, available at https://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383 Last visited 14th November 2015.

Convention No. 108 concluded within the Council of Europe in 1981, for the protection of individuals with regard to automatic processing of personal data, available at http://conventions.coe.int/Treaty/en/Treaties/Html/108.htm Last visited 14th November 2015.

European Union

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995, on the protection of individuals with regarding the processing of personal data and the free movement of such data, available at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML last visited 14th November 2015.

Directive 2002/58/EC On the processing of personal data and the protection of privacy in the electronic communications sector, available at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:201:0037:0047:en:PDF last visited 14th November 2015.

Directive 2006/24/EC On the retention of data generated or processed in connection with the provision of electronic communications of public access or of public communications networks, available at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:105:0054:0063:EN:PDF last visited 14th November 2015.

Framework Decision 2008/977/JHA of the Council of November 27th, 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters, available at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:350:0060:0071:en:PDF Last visited 14th November 2015.

European Parliament legislative resolution of 12 March 2014 on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement

of such data (General Data Protection Regulation) (COM(2012)0011 - C7-0025/2012 - 2012/0011(COD), available at http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0212+0+DOC+XML+V0//EN, to replace Regulation 45/2001 of the European Parliament and of the Council of 18 December 2000, whose state of processing can be found at http://www.europarl.europa.eu/oei/popups/ficheprocedure.do?reference=2012/2011(COD)&l=en) Last visited 14th November 2015.