

Publications of the Inter-University Chair

Revista de Derecho y Genoma Humano/Law and the Human Genome Review. Has published issue number 25, July-December 2006, with the following content: Una oportunidad para la investigación y la bioética (Francisco Gracia Navarro); Diagnóstico genético embrionario y libertad reproductiva en la procreación asistida (Fernando Abellán); Biobancos poblacionales: un análisis jurídico a partir de las experiencias islandesa y estonia (Roberto Andorno); El Preámbulo de la Declaración Universal sobre la Bioética y los Derechos Humanos de la UNESCO (Héctor Gros Espiell); Bionociencia y bionanotecnología. Aspectos sociales y éticos (Manuel Martín Lomas); El delito de manipulación genética con fines de clonar seres humanos. Una contribución al estudio jurídico-dogmático del nuevo artículo 324 del Código penal peruano (I) (David Rosario Mendiguri Peralta); The issue of constitutional law legitimacy on "human assisted reproduction" between reasonableness of the choices and effectiveness of the protection of all involved subjects (Simone Penasa); Biotechnology and Law: Biotechnology Patents. Special

considerations on the inventions with human material (Jürgen Simon); Biomedical research with human embryos: Changes in the legislation on assisted reproduction in Spain (Jaime Vidal Martínez); El concepto de dato personal relativo a la salud en la ley orgánica de protección de datos personales (Jesús Rubí Navarrete); La bioética desde una perspectiva social: European Biopolitics Conference (Miguel Ruiz-Canela López); Oocyte donation for reproduction and research cloning-the perils of commodification and the need for European and international regulation (Ingrid Schneider)

Carlos M. Romeo Casabona/Aitziber Emaldi Cirión/ Leire Escajedo San Epifanio/Pilar Nicolás Jiménez/Sergio Romeo Malanda/Asier Urruela Mora, La Ética y el Derecho ante la biomedicina del futuro, Universidad de Deusto, Bilbao, 2006

This publication is the most recent result of the research activities of the members of the Inter-University Chair BBVA Foundation-Provincial

Activities of the members of the Inter-University Chair

Carlos Romeo Casabona was awarded another Doctor Honoris Causa. This time, it has been granted by the University Privada de Moquegua, Peru. He has coordinated the book entitled *El cibercrimen. Nuevos retos jurídico-penales, nuevas respuestas político-criminales*, Comares, Granada, 2006, in which he published the article "De los delitos informáticos al cibercrimen. Una aproximación conceptual y político-criminal". He has also published the article "Alcance y objetivos de la Declaración Universal", in the book *La Declaración Universal de Bioética y Derechos Humanos de la UNESCO* (coordinated by Héctor Gros Espiell and Yolanda Gómez Sánchez), Comares, Granada, 2006. He has given, among others, the following lectures in the Congress: "Manejo de Información y Consentimiento Informado en Materia Médica y de Investigación Científica. Aspectos Jurídicos, éticos y responsabilidad", organized by the Centro de Estudios sobre genética y derecho de la Universidad de Externado de Colombia, 26-28 July 2006; "Repercusiones jurídico-científicas de la reproducción asistida" in the Summer Course "Biociencia, conciencia y derecho ¿conflicto o relación?", organized by the University Pablo Olavide de Sevilla (11-15 September, 2006); "XVIII Jornades Jurídiques Biotecnologia i Prèti", organized by the University of Lleida (26-27 October, 2006); "Biotecnología humana, transculturalidad, globalización y derecho", in the Congress *Un Diritto per il futuro. Teorie e modelli dello sviluppo sostenibile e della responsabilità intergenerazionale*, organized by the Università Degli Studi di Parma (30 November- 2 December); Finally, he has been the director and speaker in the "II Jornadas Nacionales de Comités de Ética Asistencial", organized by the International University Menéndez Pelayo in collaboration with the Consellería de Sanitat of the Valencian Government and the Valencian School for Health Studies (16 and 17 November, 2006). As Spanish Delegate, he participated in the plenary session of the Bioethics Committee of the Council of Europe (Strasbourg, 20-23 November). He addressed a conference entitled "Declaración Universal sobre Bioética y Derechos Humanos" in the headquarters of Osakidetza in Vitoria-Gasteiz (18 and 19 of December).

Aitziber Emaldi Cirión has published the following works: "Derechos de los pacientes en la comunidad autónoma de la Rioja: especial referencia a las instrucciones previas", *Anuario Jurídico de La Rioja, Anales del Convenio Universidad de la Rioja-Parlamento de La Rioja*, nº 10, 2006; "Trasplantes de donantes vivos", *Revista Federación Nacional Alcer*, nº 138, October-nov-dec., 2006; *Women's Reproductive Rights*, (Widows/ Alkorta/ Emaldi-Cirión, editors), Plaggrave, Great Britain, 2006. Additionally, she has given the following lectures: "Personal Rights on human biological samples for research: A few examples of biobank" (Birmingham, September 21-22); "Personal Rights over human biological samples" (San Petersburg, October 5-8); "El consejo genético", at the University Carlos III (Madrid, December 1).

Leire Escajedo San Epifanio has participated as professor in the course entitled "Formación en

Trazabilidad de Alimentos, Tecnologías y Sistemas de Gestión", held in October 23-26, 2006 in La Concha de Villaescusa (Cantabria) which was organised by the Centro de Estudios de la Administración Pública de Cantabria (CEARC) and coordinated by AZTI-Tecnalia. She taught the following courses: "Problemas ético-sociales y jurídicos de los OGM" y "La situación de los OGM en Europa, de iure y de facto". Additionally, she has published a monograph entitled *El Medio ambiente en la crisis del Estado Social: su protección penal simbólica*, Comares, Granada 2006. In this book, the author looks at the complaint that the measures undertaken by Criminal Law have had more a symbolic or political efficacy rather than legal. This book deals in depth with the reach of criminal law in matters related with political-criminal matters as well as criminological and dogmatic matters on the criminal protection that is currently being provided to the environment.

Amelia Martín Uranga participated the last month of August in the Curso de la Universidad Internacional Menéndez Pelayo in Santander, which was organised by the Instituto de Salud Carlos III, on the Plataformas Tecnológicas Españolas de Medicamentos Innovadores y de Nanomedicinas. She gave a lecture on September over this same topic in the Jornada sobre Investigación Biomédica en el VII Programa Marco de I+D de la UE at the Centro de Investigación Principe Felipe in Valencia. She participated on October in the VII Congreso de Ciencias Farmacéuticas y XXVI Simposio de AEFI en Madrid. As a member of the Committee on Research Ethics of the Instituto de Enfermedades Raras del Instituto de Salud Carlos III she participated in the writing of a document entitled "Recomendaciones sobre los aspectos éticos de las colecciones de muestras o bancos de materiales humanos con fines de investigación biomédica", which will be Published soon.

Pilar Nicolás Jiménez has addressed the following lectures: "Los derechos del paciente en investigación genética", in the course *Genética, Derecho y Sociedad*, UIMP (A Coruña, 17 of July); "Aspectos Ético Legales de la Información Genética", First Congress of the Units of Hospital Genetic Counselling (Madrid, 18 of October); "Aspectos éticos y legales de la huella genética", in the 1st *International Seminar on DNA fingerprint in Europe*, University of the Basque Country (Leioa, 26 October); "Aspectos éticos y legales del consejo genético" in the symposium *Cáncer Familiar y Consejo Genético* (Murcia, 17 de noviembre); "Aspectos legales del genoma humano", in the Congress *Medicina regenerativa y células madre. Nuevas fronteras terapéuticas* (Badajoz, 22 November); "El consentimiento de los sujetos", *Jornada sobre investigación con muestras biológicas* (Barcelona, 27 November); "Pautas en la elaboración de un Consentimiento informado en estudios de farmacogenética" in the Course *Perspectiva actual de la Farmacogenética* (Santiago de Compostela, 15 December).

Asier Urruela Mora has joined, since September 2006, as an Assistant Professor Doctor, The Criminal Law, Philosophy of Law and History of Law Department at the

Government of Biscay in Law and the Human Genome, University of Deusto, University of the Basque Country, which obtained the UD-Santander Group Research Award in its first prize announcements in the year 2005. The book has several chapters, in each, dealing with a social matter of special social, ethical and legal relevance that has been raised by the biomedical advances.

This work continues the line drawn in the objectives which were the basis for the foundation of the Chair in 1993 and which have been consolidating throughout its almost 14 years of life: to foster the research in the ambit of the ethical and legal implications of biomedicine, of human genetics in particular and the dissemination of its results.

University of Zaragoza. He has published an article entitled "La investigación con células madre en el contexto europeo. ¿Resulta posible el consenso?", in the *Revista Portuguesa de Directo da Saúde Lex Medicinæ*.

He was a speaker in September 2006 in the III Peruvian-Spanish meeting of Criminal Law held in the city of Arequipa (Peru) which was organised by the Universidad Nacional de San Agustín with the lecture entitled "Modernas Aportaciones al debate en torno a la fundamentación material de la culpabilidad". At the Universidad José Carlos Mariátegui de Moquegua (Peru) he lectured on "Nuevos retos del Derecho Penal en la sociedad del riesgo". During his stay in Peru, Asier Urruela Mora was named Honorary Professor of the Universities Nacional de San Agustín de Arequipa and José Carlos Mariátegui de Moquegua. On the 23-27 of November, he taught at the Universidad Autónoma de Ciudad Juárez (México) in the Graduate Courses entitled "Nuevas tendencias de la política criminal en el siglo XXI", the module on the criminal protection to prenatal life. On the other hand, in the Congreso entitled "Retos y realidades en el Sistema Nacional de Salud de España", organised by the Dirección General de la Agencia de Calidad del Sistema Nacional de Salud (Ministry of health and consumer affairs), held the 15-16 of November in the auditorium of the Universidad Carlos III (Madrid), he gave a lecture on the "Planteamiento legal de los Sistemas de Notificación en el ordenamiento jurídico español". Lastly, the 17 of November 2006, he taught the module entitled "Aspectos éticos y legales de la investigación. Terapias génicas. Usos de la información genética" in the Health Law Masters of the Universidad de Castilla la Mancha at the Law School of Albacete.

Iñigo De Miguel Berian has made the following lectures: "Investigación genética y principio de precaución", in the summer course entitled "Avances en medicina y Derecho Penal", organised by the University Autónoma de Madrid (25 and 26 of September, 2006); "Tendencias en la Unión Europea sobre las posibles soluciones jurídicas frente a los dilemas relacionados con el inicio de la vida, las investigaciones científicas y sus aplicaciones biotecnológicas", in the Primer Congreso Internacional de Derecho Médico-Sanitario, held in Bogota, Colombia, (12-14 of October 2006); "Relaciones y diferencias entre la bioética y el derecho médico-sanitario", in the Primer Congreso Internacional de Derecho Médico-Sanitario, held in Bogota, Colombia, (12-14 of October 2006); and "La nueva normativa en investigación biomédica", addressed within the Seminar on New Legislative Policies in Spain in relation with biomedical research organised by the Inter-University Chair in Law and the Human Genome, held in the UPV-EHU in Bilbao on November 2006. He has also published, as co-author with professor Romeo Casabona the work entitled Alcance y objetivos de la Declaración Universal sobre Bioética y Derechos Humanos in GROS ESPIELL, H. and Y. GÓMEZ SÁNCHEZ, *La declaración Universal sobre la Bioética y los Derechos Humanos de la UNESCO*, Madrid-Granada: Comares-Universidad Europea de Madrid. Pages 223-250.

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Perspectivas

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Inter-University Chair BBVA Foundation-Provincial Government of Biscay in Law and the Human Genome. University of Deusto, University of the Basque Country

Director: Prof. Dr. iur. Dr. med. Dr. h.c. mult. Carlos María Romeo Casabona

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Editorial

Opinion

Presentation of the Universal Declaration on Bioethics and Human Rights



This last 10th of November of 2006, The Inter-University Chair in Law and the Human Genome held an act of presentation of the Universal Declaration on Bioethics and Human Rights which was approved by the UNESCO on the 19th of October, 2005.

The approval of the Universal Declaration on Bioethics and Human Rights has, without a doubt, meant a true milestone in the history of contemporary Law, specifically in the approximation of International Law towards an important area of human activity that up until 10 years ago had received no mention in this supranational ambit: the medical sciences, the life sciences and the technologies that, bearing relation to both, can be applicable to human beings. Parting from International Law, its influence on the law of the States is foreseeable as well as inevitable.

Given the special transcendence of this new international text, the Inter-University Chair in Law and the Human Genome has taken a series of initiatives aimed at its dissemination, as a means for its promotion.

The following people were present in the inaugural act of this presentation of the Declaration of the UNESCO, which was held in the head quarters of the BBVA Foundation in Bilbao (from left to right in the photograph): Iñaki Goizelaia Ordorika, Vice Rector of the Bizkaia Campus of the University of the Basque Country, Vicente Gutiérrez, Manager of the BBVA Foundation, Gabriel María Inclán Iribar, Health Minister of the Basque Country and José Luis Ávila Orive, Vice Rector of the University of Deusto and Carlos Romeo Casabona, Director of the Chair in Law and the Human Genome .

Further information on the contents of this act can be found within the news section of this Issue.

Merits and Flaws of the new Law on Assisted Reproduction Techniques

Introduction

The modern technological and scientific advances, especially in the fields of biomedicine and biotechnology, have made possible, among others, the developments and use of alternative reproduction techniques to those of natural conception. The novelty and indubitable use of these techniques made obvious the need to regulate them. Spain was one of the first nations in the world to do so, with Law 35/1988, of the 22 of November, on Assisted Reproduction Techniques. This Law was slightly modified by Law 45/2003, of the 21st of November, which also regulated the use of surplus in vitro embryos from assisted reproduction techniques for their use in research. Both of these laws have been recently repealed and substituted by Law 14/2006, of 26 May, on Assisted human Reproduction techniques (henceforth, LAHRT). The object of this law, as is established in its article 1, is to regulate: a) the application of assisted human reproduction when scientifically accredited and clinically indicated; b) the application of the assisted human reproduction techniques in the prevention and treatment of diseases of a genetic nature, always when there are sufficient diagnostic and therapeutic guarantees; and c) the events and requisites in the use of gametes and cryopreserved human pre-embryos.

The new LAHRT respects, in essence, its predecessor in all that is relative to the participants in assisted reproduction techniques (donors and contracts for donation, users of the techniques, legal establishment of filiation, etc.), though slight modifications can be seen. Some dispositions in relation with cryopreservation of embryos, pre-implantation diagnosis and the research with gametes and human pre-embryos are also novel. In other cases, as will be seen, the non-modification of some of the precepts has already begun, a few months after its approval and entry into effect, to pose some problems in its practice and its revision has been foreseen in the short run. In the following, reference will be made to some of the most noteworthy matters provided in this new Law or that are meaningful, precisely, for not being taken into account.

Assisted reproduction techniques and marriages of people of the same sex

Beginning with the absences, it is noteworthy the use that the new Law makes of the assisted human reproduction techniques when dealing with homosexual couples. Article 6.3 is very similar to its equivalent in Law 35/1988 (also article 6.3).

However, we must bear in mind that the LAHRT has been approved subsequent to law 13/2005 of 1 July, whereby the Civil Code is modified in relation to the right to marry.

Obviously, before this reform, it was clear that both the filiation by nature as well as by adoption were only possible for heterosexual couples. Since this reform caused by the aforementioned Law on the concept of marriage, the determination of the filiation in reference to homosexual couples must be equal to that made in relation with heterosexual couples, always when nature so permits. This way, there is no problem in order to determine a filiation by adoption in relation with a homosexual couple, both in the case of two men or two women. When the filiation is based on nature, this shall be impossible in the event of two men, but can't be discarded when dealing with two women, as for example when one of them has undergone a procedure of assisted reproduction with semen from a donor. The question is, whether in such circumstance, it is possible to establish the filiation of both members of the couple by nature or whether it would be necessary to recourse to the adoption by the person who didn't use the techniques.

According to article 6.3 LAHRT, "if the woman is married, then the consent of the husband is necessary, except if they are legally or de facto separated and are shown to be so in a satisfactory manner (...)". According to article 8.1 of this same law "neither the woman progenitor nor the husband, when they have provided their formal, previous and express consent to a specific fertilisation with the contribution of a donor or donors, can challenge the marriage filiation of the born child as a consequence of such fertilisation". This drafting, that uses the term "husband" in a manner that is not unconscious, seems to exclude the possibility that the female spouse of the user of the techniques can be automatically considered the legal mother of the child born in this manner from her spouse. In these cases we would have to use the corresponding procedure of adoption.

We state that this drafting is not an error by the legislator, who could have forgotten the new regime of marriage, because they have indeed taken into account the possibility that there exist marriages between people of the same sex in other parts of this Law. In this manner, for example, art. 11.5 LAHRT, in reference to the use of pre-embryos states that "previous to the generation of the pre-embryos, the consent must have been given by the woman, or in the event that the woman is married to a man also by the man". Furthermore, this was also made

manifest during the parliamentary process of approval of the law, for example by the Parliamentary Group Izquierda Verde-Izquierda Unida-Iniciativa per Catalunya Verds who presented in the Parliament two amendments (number 22 and 23) proposing the substitution of the term “husband” by that of “spouse” in order to fit it within the new regulation on marriage. Along the same lines was amendment no. 38 by the Parliamentary Group Esquerra Republicana. Subsequently, during the passage of this Law in the Senate, there was another request to modify such on the same ground (amendments 13 and 15 filed by the Parliamentary Group Entesa Catalana de Progrés).

According to our opinion, this regime seems to be incoherent and lacking all legal logic. However, in practice, some judges have already admitted the registration of the female spouse of the biological mother as the legal mother, without making recourse to the aforementioned process of adoption. In fact, an application that is a little forceful of the current legislation on the determination of the filiation contained in the Civil Code and on the law of the Civil Registry would make possible such a solution, given that both legal texts establish that the maternal and paternal matrimonial filiation shall be legally established by the registry of the birth alongside that of the marriage of the parents. Furthermore, one can't forget that the final purpose that inspired Law 13/2005 has been the full equality among heterosexual and homosexual couples. In fact, the additional first disposition of this Law states that all “the legal and regulatory dispositions that bear some reference to the marriage shall be understood as applicable independent of the sex of their components” The problem lies in that the regulation in reference to the presumption of paternity has a true meaning when dealing with a marriage between a man and a woman. An interpretation of the existing regulation in the previously aforementioned sense would use the pre-existence of a marriage of two women as a “presumption of maternity” of the couple of the biological mother. In the case of de facto couples, this presumption does not exist, so therefore the only legal mechanisms to which the female companion of the person who underwent the assisted reproduction techniques could clearly use in order to determine the filiation of the child born in this manner is through the adoption process.

In this way, independent of the value judgement of this legal stance whereby a sole woman can have access to the assisted reproduction techniques, as well as the placing on the same level as the heterosexual and homosexual unions for all purposes, it seems evident that the establishment of the filiation of these couples must be done in an identical manner to those, either through the interpretation that has been made (as the courts have already done), or through what seems most advisable in accordance with the principle of legal certainty, through a legal reform that will establish it in an express manner. To this respect, an amendment of the Draft Bill of a regulating law on the registry corrections in relation to the sex of the persons, will foreseeably modify the existing LAHRT in the aforementioned sense. Specifically, this will be done by including a new section 3 in article 7 with the following content: “When the woman is married with another woman and is not separated either legally or de facto, then the latter shall be able to manifest before the Registrar at the Civil Registry of the family domicile, that she consents that when the child of the couple is born, that there be established in her favour the filiation of the newborn”. However, there is no reference to non-married couples.

Post mortem paternity

As a general rule, both the repealed as well as the actual legislation (in both cases, in art. 9.1) established that the reproductive material of a man must be in the uterus of the woman in the date of his death in order to legally establish the filiation between the child born from the application of the assisted reproduction techniques and a deceased man. Nonetheless, if there exists previous consent by the male, his reproductive material could be used after his death in order to fertilise his couple (art. 9.2 LAHRT). The first difference between this new Law and the earlier is that the time period in which this biological material can be used is extended from 6 to 12 months. The second difference, more relevant, is

that it aims to provide a clear solution to situations such as the one we are going to set out in the following.

In the year 2000, a couple began the process to undergo an in vitro fertilisation treatment. Both members of the couple, in December of the same year, granted their consent in order to proceed to the transfer of embryos, thereby beginning the pharmacological process. However, the same day that the transfer was going to take place, the husband died due to a traffic accident. However, the spouse decided to continue with the process of the transfer of embryos, which happened in May 2001, resulting in her pregnancy. After the birth of her daughter, February 2002, the mother went to the Civil Registry to register her child. The judge responsible for the Civil Registry rejected the registration of the filiation of the father alleging that through the fertilisation as such had been made during the life of the husband, there was no documented express desire for the pregnancy to be undertaken after his death. The woman appealed this decision to the General Office of Registrars and Notary Publics, which, in its resolution of 24 September, 2002, ruled in favour of the decision of the examining judge.

In order to avoid that these types of situations happen again, the legislature has included a new paragraph in art. 9.2 LAHRT, according to which, “there is a presumption that the consent is granted in reference to the earlier paragraph [consent in order for the reproductive material to be used in the 12 months following the death in order to fertilise his wife] when the surviving member would have undergone a process of assisted reproduction that has already begun for the transfer of pre-embryos that were constituted before the death of the husband”.

Pre-implantation Diagnosis

The techniques of preimplantation genetic diagnosis are of a very recent clinical application. In Spain, the first gestation via a preimplantation diagnosis was achieved in 1994, when the selection of the sex of the descendant was chosen by a couple whose wife was the carrier of haemophilia. Its final objective is to reach to good term the pregnancies with genetically healthy embryos. This technique is specially suited for those couples that, for family antecedents of serious genetic diseases, bear the risk of having genetic or chromosome alterations in the embryo.

The LAHRT allows the practice of these techniques of preimplantation diagnosis in order to: a) detect serious hereditary diseases, of early onset and not capable of post natal cure in accordance with the actual scientific knowledge, in order to select the embryos of the non-affected pre-embryos for use in the transfer; and b) in order to detect other alterations that could compromise the viability of the pre-embryo.

In any case, the principal novelty of this new Law in reference to the repealed legislation can be found in section 2 of article 12 that authorises “the application of the techniques of pre-implantation diagnosis (...) when the aim is to undergo together with the determination of the antigens of the histocompatibility of the in vitro pre-embryos for therapeutic purposes for third parties”. The law requires an express authorisation, to be done on a case by case basis, by the corresponding health authority, which previously must have the favourable report of the National Commission on Assisted Human Reproduction that must evaluate the clinical, therapeutic and social characteristics of each case. That is, the LAHRT permits to select those embryos that, besides not being carriers of the genetic disease, are genetically compatible with a third (usually a sibling) in order to be able to successfully undergo a transplant (for example bone marrow). The National Commission on Assisted Human Reproduction has already received several requests along these lines, some of which have received a favourable report.

Research with human pre-embryos

Lastly, it is necessary to highlight the regulation set in the LAHRT related with the research with human pre-embryos. Truly, it is not the first time that this matter is dealt with, but this new law shows

some novelties in relation with diverse matters that are both in Law 35/1988 as well as Law 45/2003, both repealed.

In the first place, it clearly defines the concepts of pre-embryo, understood as the in vitro embryo that is made up of the resulting group of cells from the progressive division of the oocyte from its fertilisation until 14 days after (article 1.2 LAHRT). In this way, though it subsequently prohibits the cloning of human beings for reproductive purposes (article 1.3 LAHRT), this Law is not applicable to research with embryos, created in a different manner to fertilisation, for example, when using the technique of somatic cell nuclear transfer (the incorrectly labelled “reproductive cloning”). This matter is expected to be regulated in a future law on Biomedical Research that is currently in parliamentary process of approval.

In the second place, the research with surplus embryos from assisted reproduction techniques (prohibited in Law 35/1988 if dealing with viable embryos) was authorised via Law 45/2003, but only in relation to the embryos that were cryopreserved earlier to the enactment of such (November 2003) and always under very restrictive conditions. This limitation of research with those pre-embryos prior to the entry into effect of the Law had its theoretical reason for being, as the legislator had in mind that after the entry into effect of Law 45/2003 there wouldn't stop being any more surplus embryos. Therefore, it established the limitation to produce a maximum of three oocytes in each reproductive cycle, a number that matched with the number of embryos that according to the Law can be transferred to a woman. But as was soon shown, this didn't stop having surplus embryos (for example, if after the in vitro fertilisation, the woman rejects the transfer or is deemed inviable). Additionally, that made more difficult the daily practice of the assisted reproduction techniques as it impeded to make available the means to achieve greater success with the least amount of risk possible for the health of the woman.

The new LAHRT eliminates the difference that had been established between the cryopreserved embryos previous to a certain date and the rest. Furthermore, the limits that had been established in Law 45/2003 for the generation of oocytes in each reproductive cycle have likewise been eliminated. These are limits that must derive in an exclusive manner from the clinical indications that exist in each case.

The research or experimentation with surplus pre-embryos that come from the application of the assisted reproduction techniques shall only be authorised if certain requisites are met, as for example, to have the written consent of the couple or of the woman; that the embryo has not been developed in vitro beyond 14 days after the fertilisation of the oocyte, subtracting the time in which it could have been cryopreserved; or that the research be undertaken in authorised centres or by qualified teams

Furthermore, the research must be undertaken on the basis of a project that is duly presented and authorised by the corresponding health authorities, after a favourable report by the National Commission on Assisted Human Reproduction, if dealing with projects of research related with the development and application of assisted reproduction techniques, or the corresponding entity if dealing with other research projects related with the obtaining, development and use of cell lines of embryonic stem cells. The corresponding entity at present is the Commission for the Follow-up and Control on the donation and use of human tissues and cells (second additional clause of the LAHRT), though the draft bill of the Law on Biomedical Research sets that this entity be replaced by the Commission on Guarantees for the Donation and Use of Human Cells and Tissues.

Of course, the donation for research purposes is only one of the possible uses of the cryopreserved embryos, others are, in accordance with art. 11.2 LAHRT, are, their use by the woman or her spouse (in marriages between two women), the donation for reproductive purposes or the cease of its conservation without other use.

Dr. Sergio Romeo Malanda

News on the Inter-University Chair in Law and the Human Genome

A Seminar entitled “Nuevas políticas legislativas en España en relación con la investigación biomédica” was held

The Inter-University Chair in Law and the Human Genome held on the 9th of November a Seminar on “Nuevas políticas legislativas en España en relación con la investigación biomédica. El proyecto de Ley de investigación Biomédica”, which was held in two sessions and was moderated by Dr. Ingrid Lilian Brena Sesma, coordinator of the Núcleo de Estudios Interdisciplinarios en Salud y Derecho of the Universidad Autónoma de México, by Prof. Dr. Pilar Canedo Arrillaga, profesor of Private Internacional Law at the University of Deusto (Bilbao), by Prof. Dr. Edorta Cobreros Mendazona, Profesor of Administrative Law at the University of the Basque Country (San Sebastián), and by Dr. Dora Jiménez Ortiz, Chief of the Unit of Clinical Management of Pharmaceutical and Health Products of the Donostia Hospital (San Sebastián).

The Seminar began with some introductory conferences which offered a general overview on biomedical research from a science and legal perspective. Prof. Dr. José Luis García López, Research Professor of the CSIC and president of the Spanish Society of Biotechnology (Madrid) spoke on “la situación de la investigación biomédica en España”. Prof. Dr. Rosa Ruiz Lapeña, Profesor of Constitutional Law of the University of Zaragoza, disserted on the “Derechos fundamentales en la investigación biomédica”. Following these interventions, the rest of the panel analysed the different headings of the sections of draft bill on Biomedical Research.

Prof. Dr. Aitziber Emaldi Cirión, Professor of Bioethics and Law at the University of Deusto (Bilbao) and researcher of the Inter-University Chair in Law and Human Genome, spoke on the “principios generales en la investigación biomédica”. Prof. Dr. Asier Urruela Mora, Assistant Professor of Criminal Law at the University of Zaragoza expounded on the theme of “Investigaciones que implican procedimientos invasivos en seres humanos”. The last intervention of the first session was by Dr. Iñigo de Miguel Beriain, postdoctoral research fellow of the Basque Government in the University of the Basque Country and Professor-tutor of the UNED University (Madrid).

The second session had the interventions of Prof. Dr. Carlos Maria Romeo Casabona, Professor of Criminal Law at the University of the Basque Country and Director of the Inter-University Chair in Law and the Human Genome, who disserted on the “Obtención y uso de células y tejidos de origen embrionario humano y de otras células semejantes”; Dr. Pilar Nicolás Jiménez, researcher of the Inter-University Chair in Law and the Human Genome, spoke on “Análisis genéticos”; Dr. Sergio Romeo Malanda, postdoctoral research fellow of the Centre for Law and Genetics of the University of Tasmania (Australia), spoke on “Muestras biológicas y biobancos”. The Seminar was closed by Prof. Dr. Leire Escajedo San Epifanio, Associate Professor of Constitutional Law of the University of the Basque Country, with a presentation on “El Comité de Bioética de España”; and by Angel Rodrigo Bravo, Subdirector General of Normative of the Ministry of health and consumer affairs (Madrid), whose theme was “Promoción y coordinación de la investigación biomédica”.

Current state of affairs of the research projects

The European Project EURECA held a workshop from the 5th to the 7th of October in St. Petersburg entitled “Delimiting the research Concept and research Activities”. The Chair participated with a conference. Following the seminar, the main coordinators of the project held their annual meeting in order to deal with future matters.

On the other hand, there was a meeting of the participants in the European project Biotethed in Heidelberg (Germany) in the month of November. The Chair participated in the definition of the activities to be developed in the coming months as well as the organisation of the management of the project in order to achieve such ends.

New European Project: XENOME

The Inter-university Chair participates in the European project XENOME, whose purpose is to study the possibility of the clinical application of the xenotransplantation following new lines of research. The first meeting of the work group was held in Padua the 19-20 of November. The Chair will co-ordinate two modules. The first one is dedicated to the dissemination of the results of the project, while the second is in reference to the study of the ethical, legal and economic aspects of the xenotransplantation. The project co-ordinator is Prof. Emanuele Cozzi of the University of Padua. The following universities are also part of this project: University of Coimbra (Portugal), Università degli Studi di Milano (Italy) and Universidad Panteion (Greece). Its duration is five years.

“The legal implications on the use of biological samples in biomedical research and biobanks” project

The web of the Chair will soon have available an area dedicated to “The legal implications on the use of biological samples in biomedical research and biobanks”. This work continues a line of research of the Chair in this field, that with the same name, was financed by the Basque Government during 2005-06. This area will include national, international and comparative legislation as well as bibliographical information and doctrinal articles.

Act of presentation of the Universal Declaration on Bioethics and Human Rights

Conference on the Bioethics Declaration

The presentation of the Universal Declaration on Bioethics and Human Rights held the 10th of November, had diverse experts who contributed in a session that was moderated by Prof. Dr. Francisco Javier Quel López, Professor of Public International Law, Dean of the Law School of the University of the Basque Country, San Sebastián. Dr. Hector Gros Espiell spoke on “La Declaración Universal: su importancia e incidencia en el desarrollo del Derecho Internacional”. Dr. Roberto Andorno (Ex-Member of the Internacional Comité on Bioethics of the UNESCO), dealt with the theme on “La dignidad humana como fundamento de la Bioética y los derechos en la Declaración Universal”. Prof. Dr. Yolanda Gómez Sánchez, (Member of the International Committee on Bioethics of the UNESCO) spoke on “La naturaleza jurídica de los principios de la Declaración Universal”. Prof. Dr. Carlos M. Romeo Casabona and Dr. Iñigo de Miguel Beriain disserted on “Los objetivos de la Declaración Universal”, while Dr. Ingrid Brena Sesma, Coordinator of Instituto de Investigaciones Jurídicas, UNAM, México, spoke on the “Perspectiva de la Declaración Universal en Iberoamérica”.

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adopted by the UNESCO, as well as the text translated to Basque by the corresponding services of the University of Deusto, which has been officially accredited in this language by the Basque Institute for Public Administration (IVAP).

With this new initiative, the Inter-University Chair in Law and the Human Genome aims to contribute, from its academic function established in its foundational charter, to serve its social surroundings and to collaborate to the utmost in the international institutional ambit.

Publication of the Instituto Roche on the Declaration of the UNESCO

Professor Carlos María Romeo Casabona has coordinated a publication by the Instituto Roche, in collaboration with the Chair in Law and the Human Genome entitled “*Hacia una Bioética Universal: La Declaración Universal sobre Bioética y Derechos Humanos de la UNESCO*”.

The humanist vocation with which the Instituto Roche was established has once again been highlighted with this opportune and on-target initiative, which means an assumption of the growing importance that the Declaration on Bioethics and Human Rights is going to have in the coming years. This publication also helps to contribute to its dissemination in the Spanish speaking world, for which it has had the contribution of authors of exceptional recognition and international prestige, such as: Héctor Gros Espiell, “Significado de la Declaración Universal sobre la Bioética y los Derechos Humanos de la UNESCO”; Carlos María Romeo Casabona/Iñigo de Miguel Beriain, “Ámbito de aplicación de la Declaración Universal sobre Bioética y Derechos Humanos”; Roberto Andorno, “El respeto de la dignidad humana en el ámbito biomédico según la Declaración de la UNESCO”; Yolanda Gómez Sánchez, “Los principios de igualdad, no discriminación y no estigmatización en la Declaración Universal de Bioética y Derechos Humanos”; Pilar Nicolás Jiménez, “La medicina individualizada frente a la Declaración Universal sobre Bioética y Derechos Humanos”; Sergio Romeo Malanda, “Impacto de la Declaración Universal de la UNESCO sobre Bioética y Derechos Humanos en el ordenamiento jurídico español”; Ingrid Brena Sesma, “Perspectiva de la Declaración Universal en Iberoamérica”.

Report for the Ministry of Health and Consumer Affairs

The Chair in Law and the Human Genome has written a report for the Ministry of health and consumer affairs on the legal viability of the setting up of a notification system and a registry of incidents and effects or adverse events, that will include a proposal for legislation that can be used as a basis for the drafting of a specific legal regulation on this matter by the Ministry.

The creation of a system of notification and registry of incidents and adverse events is one of the aims included within the Quality Plan for the National Health System (SNS), within the framework of the works underway by the Ministry in order to improve all aspects related with the safety of the patient. These kind of systems are destined to learn from the errors and to avoid their repetition. For this reason, it is necessary to design and develop systems of voluntary communication, that are anonymous, confidential and not punitive, for which there is the need, at times, to improve the current legislative system.

For the undertaking of this study, an analysis of the existing legislation and current bibliography in this field, both at the national as well as international level, will be done. Interviews with experts in this matter will also be held.

The edition that was presented in this act included the official text in Spanish which was