

Perspectivas

en Derecho y Genoma Humano

Number 12, December 2008

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

This issue is also published in Basque and Spanish

Opinion

The current state of affairs of Biolaw and Bioethics

The health and life sciences, since the second half of the twentieth century, are raising numerous questions about the validity of their applications and methodologies in order to increase its knowledge and make progress in health care services. But, above all, many times, innovations that are achieved in order to cure or prevent diseases, or even to improve or modify our reproductive capacities or other physical or mental faculties contribute to this perplexity. Knowledge and other similar techniques (biotechnologies) have also been applied to other living beings: animals, vegetables and microorganisms. In this manner, the human being has been faced with especially complex scenarios in very relevant matters for which it has not always found effective responses when contrasted with its traditional value systems.

In similar circumstances, in the early '70's of the twentieth century, a new methodological discourse arose, that although not completely new, had been seldom used before; it shall be accompanied by a new discipline, which, since its outset, has generated great power of attraction: Bioethics. In fact, Bioethics, is foremost, an Applied Ethics, aimed towards the health and life sciences (mostly, towards Medicine and Biology). However, the novelty presented by Bioethics is, as I mentioned earlier, its methodology: its interdisciplinary discourse, that is, to tackle a conflict from different and complementary perspectives that are offered by diverse disciplines: Medicine (both in its research as well as clinical dimensions), Biology (in its scientific and technical aspects), Ethics, Theology, Philosophy, Law, Economics, Sociology, etc. The result is an integration of these diverse perspectives, that when considered independently would have provided unilateral and incomplete approaches and solutions. Therefore, methodologically speaking, the aim is not to provide a mere sum of perspectives, but rather to achieve its integration, which will provide new approaches and all-inclusive solutions that have richer nuances.

Approximately at the same time, but certainly also pressured by the development of Bioethics

and the social demand to provide adequate answers to these applications, the advances in the Sciences and the technologies involved, Law begins to pay greater attention to these matters. It takes as reference the most recent contributions that arise from the theories and development of human rights in the international ambit.

Since then, in a parallel manner and frequently with that interdisciplinary approach, Bioethics and Biolaw have been constantly developing, having generated countless activity in very diverse means and formats. Currently, there are numerous publications and documents of different relevance that have been published. There are abundant congresses and meetings. Specialised courses and other university degrees have been developed and bioethics committees have been created with specific functions which are also very diverse. Conclusively, legislators and international institutions have passed laws, declarations and conventions of the up most transcendence.

It should come as no surprise that throughout these years (for the first time in 1984) works have been published which aim to systemise and make available to those interested, and to the public as a whole, the most meaningful aspects of the bioethical and legal thinking in a complete, didactic and rigorous manner. This way, the Encyclopedias on Bioethics are created, which are works of a collective, interdisciplinary and generally of a pluralist nature which aim to ease the access to all this knowledge in a simple and easy manner. Currently, we are aware of the existence of these types of works in several countries and languages (English, French, German and Italian). In order to mention only a few which have been most ambitious in their objectives as well as of a greater breadth (all are over one thousand pages, one over three thousand) and diffusion:

— *Encyclopedia of Bioethics* (U.S.A.), Warren T. Reich (Ed.) 4 vol., 1984; 6 vol., 2nd ed., 1995.

- *Encyclopedia of Bioethics* (U.S.A.), Stephen G. Post, 5 vol., Editor in Chief, 3rd ed., 2003.
- *Dizionario de Bioetica* (Italy), Salvino Leone / Salvatore Privitera, 1994.
- *Lexikon der Bioethik* (Germany), Wilhelm Korff / Lutwin Beck / Paul Mikat, 1998.
- *Nouvelle Encyclopédie de Bioéthique* (Belgium), Gilbert Hottos and Jean-Nöel Missa (Eds.), De Boeck Université, Brussels, 2001.

However, a work of this nature has been missing in the Spanish language, which is not easily understood, given the high level that this discipline is acquiring both in Spain as well as in Latin America, not to mention the high number of potential readers whose native language is Spanish.

There are many issues to be evaluated, such as: to verify at what stage we are at in these discourses, which have been or are at present the most controversial topics and emerging topics, which values, goods or rights have been involved or confronted and finally, which have been the solutions provided by Bioethics and which have been the social stances which have been crystallised in legal norms or which have been part of crucial legal decisions. These are the main objective of the new project of the Inter-University Chair: The Encyclopedia of Biolaw and Bioethics. A work envisaged and promoted by the Inter-University Chair in Law and the Human Genome, BBVA Foundation-Provincial Government of Biscay, University of Deusto and the University of the Basque Country. This ambitious project has been backed by and collaboration has been provided by the Roche Institute and Comares Publishing of Granada.

The members of the Inter-University Chair in Law and the Human Genome, comprising its Editorial Board, have identified the subject-matter entries that should be incorporated into the Encyclopedia, deciding the scientific, ethical or legal

approach, or all at the same time. Each section is written by a different author. In the end, a total of two hundred issues were selected, besides thirty more reference entries. Some were added—or deleted—as suggested by the authors who collaborated in this work. Issues such as biobanks, biometrics, stem cells, pharmacogenomics, individualised medicine, xenotransplantation are examples of the most recent developments; some, such as abortion, health care, euthanasia, organ transplant although already deemed as old issues in a debate, nonetheless maintain their interest and have new approaches; in sum, others, such as health care ethics committees, Bioethics training, Council of Europe, duty of care (precaution), principlism, risk, suggest multiple aspects that surround Biolaw and Bioethics.

The authors are all experts on the field which they are writing (and many of them with broader and more profound knowledge). In order for

the Encyclopedia to be as participatory as possible, each author was made responsible for only one area (except for some scientific or technical areas, which due to their brevity and their similarity, seemed most suited to grant several—two—to the same contributor). Each author was also made responsible in an individual manner of the given issue (there are no co-authors) so that each specialty is faithfully reflected. The aim of this compilation is not only to be known in Latin America, but, at the same time, to recognise the importance of the contributions that are being made in the region. For this, we have wanted, from the outset, to have a meaningful and qualified number of contributors of countries such as Argentina, Brazil, Colombia, Cuba, Costa Rica, Chile, Guatemala, Mexico, Peru, Uruguay, etc., as well as from our neighbour Portugal. Notwithstanding this, we must assume that for many reasons, not all the renowned specialists have been able to contribute to this work.

Therefore, this Encyclopedia of Biolaw and Bioethics is a collective work that is interdisciplinary and plural, as no indications have been provided to the authors other than those necessary to provide a uniformity of style throughout the work. At this time, it is only fair to recognise the enthusiasm, effort and generosity provided by all the invited authors in their acceptance to collaborate in a work of this nature, in which the individual effort is important and decisive in order to advance towards the final objective: a work that is the fruit of a collective task which interacts within itself. This is an added value of the work that truly enriches it.

Therefore, we believe that the soon to be published Encyclopedia shall fulfil an ambitious, pioneering and necessary endeavour in our cultural environment.

Carlos María Romeo Casabona

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

The Chair held a Congress entitled “Un asunto pendiente: el desarrollo de la normativa sobre biobancos”

The 31st of October the Inter-University Chair in Law and the Human Genome held a Congress entitled “Un asunto pendiente: el desarrollo de la normativa sobre biobancos” which was organised in collaboration with the Comité Ético de investigación Clínica de Euskadi and with the support of the Department of Education, Universities and Research of the Basque Government and the Ministry of Education and Science. Directed by Dr. Carlos María Romeo Casabona and coordinated by Prof. Dr. Aitziber Emaldi Ciri6n, the Congress had the participation of Augusto Silva, General Director of Advanced Therapies and Transplants of the Ministry of Health and Consumption, who addressed the Inaugural Conference entitled “Nuevas t6cnicas en la investigaci6n con c6lulas madre. C6lulas iPS”. Afterwards, we had the participation of Dr. V6ctor Gonz6lez Rumayor of the Health Institute Carlos III of Madrid; Prof. Dr. Sergio Romeo Malanda, of the University of Las Palmas de Gran Canaria; and Prof. Dr. Lorena Donoso Abarca, Director of the Centre for Studies in Computer Law of the University of Chile, who respectively addressed the following conferences: “Biobancos en Espa6a. Inter6s y panorama general”, “Biobancos y colecciones. Justificaci6n de la diferenciaci6n” and “Regulaci6n de los biobancos en Derecho comparado”.

In turn, during the second session, moderated by Prof. Dr. Beatriz P6rez de las Heras, Professor in European Community Law of the University of Deusto— had the participation of Mr. 6ngel Iguallada, Adjunct General Subdirector General of the Registry of Archives and Information Systems for the Agency for Data Protection of the Community of Madrid, as well as by Dr. Roberto Bilbao, Coordinator de R&D in Health Research of the BIO Foundation, who respectively spoke on “Derechos de los sujetos y biobancos” and on “Creaci6n, organizaci6n y acreditaci6n de biobancos”.

In the end, there was a Round Table focused towards the analysis of the “Controversias en la aplicaci6n de la esperada Ley de Investigaci6n biom6dica” and had the participation of the following Drs. Guillermo Alcalde Bezhold, Secretary of the CEIC of the Hospital de Santiago Ap6stol of Vitoria; Felipe Aizpuru Barandiaran, Secretary of the CEIC of the Hospital de Txagorritxu of Vitoria; Txema Gonz6lez de Castro, Member of the Basque CEIC; Iciar Alfonso Farn6s, Secretary of the Basque CEIC; and Prof. Dr. Pilar Nicol6s Jimenez, Researcher of the Inter-University Chair in Law and the Human Genome.

Meeting of the European Project “Poseidon”

6nigo de Miguel participated, from the 25 to the 27 of August of 2008, in the monitor-

ing meeting of the European Project “Poseidon” which took place in Paris. The global advances and the achievements of the *Work Package*, led by the Chair, were presented at the same time that measures were adopted on future undertakings.

Meeting of the European Project “Xenome”

The annual meeting of the European Project Xenome took place in Brussels during the 9th and 10th of September of 2008. This Project has the participation of different academic institutions as well as research centres of the majority of the Member States of the European Union. The aim is to study the implication of the xenotransplantation from a cross-disciplinary approach.

Workshop of the European Project “Privileged”

The Second *Workshop* of the European Project “Privileged” was held the 13 and 14 of November of 2008. In this Project, several research centres and academic institutions of the majority of the Member States of the European Union participate, in order to study how the individual rights and liberties are affected—specially, their right to privacy—in relation with the use of genetic information and biobanks for research purposes. In this *Workshop*, there was a detailed look at how existing regulations—especially, those related with the protection of personal data—understand and protect the aforementioned rights and how, in turn, these could be developed within the European Union.

Second meeting of the research members of the LATINBANKS Project in Mexico

During the 4th and 5th of July, in the Offices of the Institute for Legal Research of the Universidad Nacional Aut6noma of Mexico, the second meeting of the research members of the LATINBANKS Project. This new meeting, firstly, undertook a *meeting which was open to the public at large*, and secondly a *meeting of the members* in an internal meeting with the sole participation of the members of the project.

The open *meeting*, held during the morning of the 4th of July was entitled: “muestras biol6gicas y biobancos para investigaci6n biom6dica. Estado actual y retos del futuro” and had the participation and contribution both of members of the project, invited experts, as well as the public at large. The session was moderated by Dr. Emilssen Gonzalez de Cancino and was presented by Prof. Dr. Guillermo Sober6n of the National Commission for Bioethics of Mexico. The conferences presented during this time were the responsibility of Professors Carlos Mar6a Romeo Casabona, Ingrid Brena Sesma, Gerardo Jim6nez, Clara Gorodezky and J6rgen Simon, who respectively dealt with the following issues: “*Marco Jur6dico Internacional*”, “*Reporte de Biobancos en M6xico*”, “*Colec-*

ci6n y manejo de muestras biol6gicas en el Instituto Nacional de Medicina Gen6mica de M6xico”, “*Biobancos y bancos de c6lulas de cord6n umbilical: aspectos comunes y espec6ficos relativos a la investigaci6n en las implicaciones sociales, 6ticas y de regulaci6n*” and “*Aprovechamiento y reparto de beneficios econ6micos*”.

In turn, the *internal meeting of the members*—which took place during the afternoon of the 4th of July, as well as throughout the 5th of that same month—was inaugurated by Professors Carlos Mar6a Romeo Casabona and J6rgen Simon, coordinators of the Project and moderated by Prof. Lorena Donoso Abarca (Universidad de Chile). In order to analyse the functioning and the legal system of biobanks in Europe, the following Professors participated: Heike Bockmann and J6rgen Simon (University of L6neburg in Germany), Myriam Blumberg-Mokry (France), Carlos Mar6a Romeo Casabona (Inter-University Chair in Law and the Human Genome of Spain), as well as S6nia Fidalgo (Centre for Biomedical Law of the University of Coimbra of Portugal).

Subsequently, the Latin-American partners openly exposed the difficulties of their respective legal systems when trying to make compatible the advance of science with the respect for the interests of the agents involved in the activity of biobanks for biomedical research; in order to do so, the following professors participated: Carlos Valerio (Asociaci6n de derecho M6dico de Costa Rica), Ingrid Brena Sesma (Universidad Nacional Aut6noma de M6xico), Emilssen Gonz6lez de Cancino (Universidad Externado de Colombia), and Lorena Donoso Abarca (University of Chile). At the end, the reading of conclusions was made by Emilio Jos6 Armaza after the conclusion of the debate on the possible solutions and recommendations for the improvement of the systems as well as for the optimisation of the legal instruments for each of the countries which participated in the Project.

Lastly, the members agreed that the next meetings shall take place in the cities of Buenos Aires (Argentina) and finally in L6neburg (Germany); where the work shall continue centred in the objectives established by the Latinbanks Project in order to contribute in this manner towards the development of the Latin American society in relation with banks of biological samples aimed at medical research.

New project “Delincuencia Econ6mica. Nuevos instrumentos jur6dicos y econ6micos”

Dr. Carlos Mar6a Romeo Casabona, as Main Researcher, has been awarded a new research project entitled “Delincuencia Econ6mica. Nuevos instrumentos jur6dicos y econ6micos” by the Ministry of Science and Innovation for 2008-2010. The University of La Laguna and the University of the Basque Country are participants in this project.

Publications of the Inter-University Chair

Revista de Derecho y Genoma Humano/ Law and the Human Genome Review. Has published Issue No. 29, July-December 2008: *The inheritance rights of the child born from fertilisation postmortem* (Iniesta); *Human Tissue and Cells Regulation in Spain: looking at Europe to solve inner contradictions?* (Alkorta); *El embrión humano después de Dolly: Nuevas pautas para nuevos tiempos* (de Miguel); *La nueva Ley Orgánica 10/2007, de 8 de octubre, reguladora de la*

base de datos policial sobre identificadores obtenidos a partir del ADN. Aspectos procesales (Reverón); *New legal developments in xenotransplantation: the Spanish approach* (Romeo / Urruela); *Consentimiento, biobancos y Ley de investigación biomédica* (Seoane / Casado); *Investigaciones con células troncales embrionarias en Brasil y la (In)constitucionalidad del artículo 5.º de la Ley de Bioseguridad (Parte II)* (Freire De Sá / Luna Moureira); *The regulation of biobanks in Spain* (Nys).

Iñigo de Miguel Beriain, *La clonación, diez años después*

This monograph makes a juridical and ethical reflection on the incidence that the development of the transfer of nuclear cells has had, has and shall have in our societies, either through new ways of production of stem cells or directly, through the cloning of human beings.

Activities of the members of the Inter-University Chair

Carlos María Romeo Casabona has published the following works: "La Globalizzazione e il ruolo dinamico dei diritti umani in relazione ad una prospettiva comune per la biotecnologia umana"; "De los delitos informáticos al cibercrimen"; *Revista da Faculdade Mineira de Direito*; "La expansión del Derecho Penal en el campo de la biotecnología humana: últimas tendencias"; "La Ley de Investigación Biomédica: un nuevo mapa Normativo para la Investigación Científica en el sistema nacional de salud". Furthermore, he has been a speaker in several events: "Temas Fundamentais do Direito Penal Contemporâneo"; "Bioética e Direito"; "A estrutura monista do dolo: uma visao crítica" y "A investigação com as células-tronco e técnicas de clonagem: o debate jurídico actual"; "Diversidad cultural y principios del derecho penal"; "El delito imprudente"; "La Responsabilidad penal por manipulación genética"; "Imputación penal objetiva y la responsabilidad medica-sanitaria"; "Derecho penal y libertades en la red"; "La discusión actual sobre el contenido del dolo"; "Cómo dar una respuesta eficiente al desarrollo científico"; "Dilemas éticos y jurídicos al final de la vida"; "Derechos y libertades en Internet: los límites del Derecho Penal"; "Leyes genéticas y leyes humanas: control científico y penal de la vida"; "Actuación médica y eutanasia"; "Leyes genéticas y leyes humanas: control científico y penal de la vida".

Aitziber Emaldi Cirión has addressed the following conferences: "Las acciones de wrongful birth and wrongful life"; "Aspectos jurídicos da clonación en da investigação con embriões". Likewise, she has written several articles: "De la intimidad genética al derecho a la protección de datos"; "Human biological samples in research: juridical perspective"; "La investigación biomédica: Pilares sobre los que se asienta". She has directed the dissertation for the award of a diploma in advanced on "Consentimiento informado en el ámbito biomédico", September 2008.

Leire Escajedo San Epifanio has published her monograph entitled *Bioteknologiaren garapen osasuntsu eta jasangarria*, Elhuyar, 2008. She has also published the work "Reproducción Humana, Medicina genética y Derechos Funda-

mentales". Additionally, she has addressed the conference "Clonación humana, eugenesia y biobancos en la Carta de Derechos Fundamentales de la Unión Europea: ¿un acierto?". She has made a four week research stay at the Max Planck Institute (Germany)

Sergio Romeo Malanda has published the work entitled "Minoría de edad y aborto: algunas consideraciones sobre consentimiento y confidencialidad". Additionally, he has given the following conferences: "Desidia del legislador y retroactividad de la ley penal"; "Manipulación genética, culpabilidad y herencia"; "¿Protege el Derecho penal adecuadamente los intereses de los consumidores? Furthermore, he has been distinguished as an Honorary Professor of the University Nacional de San Agustín and of the University José Carlos Mariátegui, de Moquegua, Peru). He has also been the President of the Jury at the Academic Conference of Criminal Law Students: "Viejas y nuevas tendencias del Derecho Penal y la Criminología", Peru, July 10.

Pilar Nicolás Jiménez has become a member of the Editorial Board of the Review *Hereditary Cancer in Clinical Practice*. She has published the work entitled "Obtención y utilización de datos genéticos en la contratación de seguros. La difícil concreción de la prohibición de discriminación". Also, she has addressed the following conferences: "Biobancos y consentimiento informado en el ámbito de la Ley de Investigación Biomédica"; "Aspectos prácticos en el actual marco jurídico en la investigación con biomarcadores"; "Use of biological samples in scientific research. Consent and Biobanks"; "Los principios inspiradores de la legislación española sobre investigación en biomedicina y los problemas no resueltos por la ley 14/2007".

María Jorqui has published a bibliographical critique on the Manual of the Agency for Data Protection of the Community of Madrid. She has also published: "El diagnóstico genético preimplantatorio: breve apunte comparativo dentro del marco legal en Italia y España". She has drafted a report entitled "privacy protection in research using genetic data and bio-banks provided by the law of data protection (spe-

cifically as implemented under Directive 95/46/EC)", which was presented at the Second PRIVILEGED workshop.

Iñigo de Miguel Beriain has published the monographs entitled "La Clonación, diez años después" and "El poder en la era de la Globalización", both published by Editorial Comares. Additionally, he has participated in the drafting of three chapters in the new Manual of Philosophy of Law for Students of the UNED. Likewise, he has addressed the lecture entitled "Bioética, Derecho, Medicina y Ciencias de la Salud: campos de actualización de los Derechos Humanos". He has also published the work entitled "El concepto de embrión en la Ley 14/2007, de 3 de julio, de Investigación Biomédica".

Emilio José Armaza Armaza, has completed the research period for his Doctorate in Law: *Problemas actuales del Derecho Público y Privado en la Europa del siglo XXI* and has become, in November 2008 a professor of the III Edition of the Inter-University Master on Bioethics. He has published the first volume of the *Digesto de Derecho penal peruano, Fuentes Bibliográficas*, co-authored with Julio Armaza Galdos, Editorial Adrus, Arequipa, 2008; as well as the articles "La cuestión del bien jurídico en el delito de clonación", co-authored with Iñigo de Miguel Beriain in *Temas de Derecho Penal, Libro Homenaje a Luis Guillermo Cornejo Cuadros*, Editorial Adrus, Arequipa, 2008; "Consideraciones generales en torno a la responsabilidad penal del médico".

Inter-University Chair in Law and Human Genome

Staff:

Prof. Dr. Dr. Dr. h.c.mult. Carlos María Romeo Casabona (Director)
Dra. Aitziber Emaldi Cirión (Periodicals and Conferences Coordinator)
Dra. Leire Escajedo San Epifanio (Post-Graduate Studies Coordinator)
Dra. Pilar Nicolás Jiménez (Research Projects Coordinator)
Dr. Sergio Romeo (International Relations)
Dr. Iñigo de Miguel (Researcher)
Dra. María Jorqui Azofra (Researcher)
Lic. Emilio Armaza (Researcher)

Dra. Fátima Flores Mendoza (Advisor)
Dr. Ulises Hernández Plasencia (Advisor)
Dra. Amelia Martín Uranga (Advisor)
Dr. Esteban Sola Reche (Advisor)
Dr. Asier Urruela Mora (Advisor)

Leire Larrazabal Larraudogoitia
(Support Staff)

PO Box, 1
48080 Bilbao (SPAIN)
Tel.: + 34 94 413 92 87
+ 34 94 445 57 93
Fax: + 34 94 445 55 13
Email: llaraza@genomelaw.deusto.es
www.catedraderechoygenomahumano.es