

Perspectivas

en Derecho y Genoma Humano

Number 27, June 2016

Inter-University Chair - Provincial Government of Biscay
in Law and the Human Genome

University of Deusto, University of the Basque Country UPV/EHU

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ISSN: 2386-6896

Legal Deposit: BI-1491-2014

This issue is also published in Spanish

Publisher

A time of changes

This is a period characterised by changes. And although some of them are imposed from outside the creative field, the real scientist, whatever the discipline that he/she professes, is always attentive to the environment and to what might affect his/her intellectual reflections. That is what makes him/her different from those involved only in the vicissitudes of everyday life. He/she is not interested in these things, and sometimes he/she even recklessly does not pay attention to them.

Thus, it is logical that the constant scientific and technological advances interest us as researchers at the Inter-University Chair in Law and the Human Genome, as this interest has been our main characteristic since the Chair was established twenty-three years ago. We have been pioneers in understanding that an interdisciplinary and multidisciplinary approach to the issues related to Law, Science and Technology was necessary, as soon we saw that only from this methodological perspective could we properly focus on those issues and therefore propose reasonable solutions. Our collaboration with other groups, research centres, national institutions and international organisations, as well as the opportunity to contribute directly to the drafting of legal instruments and also international treaties, have enabled us to enjoy a privileged vantage point to detect new scientific and technological challenges and this has made us pioneers in the scientific debate from the legal perspective. This is demonstrated also by the numerous seminars and publications that we have carried out, especially in recent years, and that will continue in the future. A few years ago we started to foresee external changes, and for this reason we opened



new production lines: the collection '*Derecho, Ciencia, Tecnología e Innovación*' (Law, Science, Technology and Innovation), which began in 2009, and the web platform www.bioderecho.eu. Moreover, we move forward, because this capacity remains our irreplaceable domain. The Encyclopaedia on '*Bioderecho y Bioética*' (Biolaw and Bioethics), published a few years ago in two volumes, roughly two thousand pages with the collaboration of about two hundred twenty Spanish, Portuguese and Latin American authors, and well received by the scientific community, will be published in a new online and open version that will be

constantly updated. It is a new challenge and a new effort for the Chair. In addition, the *Law and the Human Genome Review*, which over twenty-two years has published 44 volumes with a high impact factor, will be published online, as well as our Newsletter '*Perspectivas*'. Moreover, more initiatives will be communicated soon.

Science and technology are not only the object of our intellectual interest, but also working tools that we take advantage of in order to continue being useful to society.

Opinion

The new technological and scientific challenges of using clinical data. Opportunities and legal implications*

1. Big Data on Health. Technological challenges and opportunities

The health field has increasingly collected and stored more data about a higher number of citizens. How this clinical documentation of citizens throughout their lifetime is stored has recently undergone a transformation. It has evolved into a computerised system to facilitate health system management and patient care, providing the possibility of applying new technological tools. Big data on health refers to the existence of large amounts of information, providing the opportunity to add value to its integrated analysis with the aim of 'extracting information hidden or unexpected correlations, non-deductible or inferable with conventional analysis methods' (Spanish Data Protection Agency).

In 2008, the scientific journal *Nature* devoted an issue to this subject and its editorial warns that researchers need to adapt their institutions and practices in response to torrents of new data, and need to complement smart science with smart searching. Five years later, in *JAMA*, an article was published with the explicit title 'The inevitable application of big data to health care'.

Moreover, numerous studies on the economic possibilities offered by this new scenario have been already carried out. A good example of the most cited is the big data study: 'The next frontier for innovation, competition, and productivity' (McKinsey Global Institute, 2011). This study predicts that big data applications in the health field could pose a 300,000 million dollar profit for the US health system and 250,000 million euros for the European public health system. New market opportunities and high savings for public health services and health policies are now possible by analysing big data on health, which facilitates, for example, improving health coordination ('Big Data in digital Health', Rock Health Foundation, 2012. <http://www.slideshare.net/RockHealth/rock-report-big-data>).

Facing this new context, the European Commission has recommended reusing administration data as an engine for social development (see the report 'Towards a thriving data-driven economy'), particularly in the health system (e-Health Task

Force Report, 'Redesigning health in Europe for 2020').

2. Legal implications

The regulation applicable to this matter entails a complex and heterogeneous legal framework: there is general data protection legislation, specific to clinical documentation, sectorial on the organisation of the health system and public health, particularly on information management in specific areas such as clinical trials, post-authorisation studies or invasive biomedical research samples or genetic data management. Moreover, we must also consider the international and regional regulation, in addition to other legal standards that are also very important. We should also take into account the decisions and opinions of the data protection authorities and the reports of the Working Group on Article 29 of the Directive; and we must remember that the new Regulation 2016/679 on General Data Protection will be enforced on May 25, 2018.

Based on this regulatory framework, it is necessary to reflect on the following key issues in order to design implementation models for the big data on health:

A. First, due to new technological perspectives, the identifiability of the subject is not static and therefore the data protection system can become insufficient or excessive.

B. Secondly, the knowledge that citizens may have about the potential uses of clinical documentation is a parameter that should be evaluated while establishing the legitimacy of their use for purposes other than healthcare or in novel contexts, from the concept of 'compatible purpose': in its opinion n. 3/2013, the Working Group on Art. 29 has held that in order to determine when the use of certain data is compatible with the purpose for which they have been stored, the criterion of predictability by those potentially affected should be considered.

C. Although health data can be examined without the consent of the owner when the purpose is the healthcare of the patient and when this information is managed by persons under obligation of secrecy, there is no consensus on the possibility to find authorisation for other

purposes in the sectoral regulations – on clinical documentation, biomedical research, organisation of health systems or public health management.

D. The possible significance of the principle of solidarity and social responsibility in this field has not been sufficiently analysed, which has been discussed in Bioethics but not so much in Biolaw.

E. The meaning of the concept 'scientific interest' and the significance of the duties corresponding to the public authorities in relation to the promotion of science and the protection of the health of the individual citizens as well as the population in general (Articles 43 and 44 of the Constitution) should be addressed in this area.

F. The inclusion of subjects and institutions involved in the treatment of data within the corresponding legal categories to establish rights and obligations is of particular interest in relation to the rules for international assignments and management in the cloud (in this regard, the Opinion n. 5/2012 on Cloud computing of the Working group on Article 29 poses the problem and offers some general solutions).

G. The need to coordinate management policies refers to the institutions that can provide authorisation, verification and monitoring of the processes.

On the other hand, an evaluation system of the legitimacy of access to databases by the so-called Data Access Compliance Offices (DACO) - which are not accredited committees, but are bodies comprising people with highly specialised skills for that assessment - is spreading. Their status must be clarified. The Agencies for Health Technology Assessment are also controlling the management of big data on health, and we should not forget that the Data Protection Authorities have powers to authorise exceptional treatment of health data, as well as international transfers. In short, there are different possibilities of control and authorisation and the appropriateness of the various ways should be assessed from a legal perspective, while also considering their efficiency.

Pilar Nicolás

* These reflections are part of the Memory Project *Big-Dat-Ius* (University of the Basque Country. Ref.: DER2015-68212-R), funded by the Ministry of Economy and Competitiveness (MINECO). Members of the Project: Guillermo Alcalde (Osakidetza), Iciar Alfonso (Osakidetza), Itziar Alkorta (UPV/EHU), Elena Atienza (UPV/EHU), Iñigo de Miguel (UPV/EHU), Aitziber Emaldi (University of Deusto), Miriam Méndez (Hospital Clínic), Pilar Nicolás (-PR- UPV/EHU), Iñaki Pariente (University of Deusto), Mercedes Puente (Roche Institute Foundation), Carlos Romeo (UPV/EHU), Leire Sánchez (BIOEF) y Nuria Terribas (Grifols i Lucas Foundation).

Inter-University Chair News

Workshop "Knowledge, Communication and Personalized health: Navigating the digital landscape"

On 18 February 2016, the Inter-University Chair organized the international workshop entitled "Knowledge, Communication and Personalized health: Navigating the digital landscape", coordinated by I. De Miguel. The workshop took place in the University of Deusto. Its main purpose was to develop a scientific debate on the reliability of scientific-medical information available on line, as well as discuss new possible strategies in order to control, manage and communicate health-related knowledge to patients. To this end, prestigious experts attended as guest speakers from various countries: Anna Lydia Svalastog (Norway), Srecko Gajovic (Croatia), Andrea Perin (Italy/Spain), and Joachim Allgaier (Austria).

First Seminar of the BioTerr Project in Granada

On 16-18 March 2016, in collaboration with the Faculty of Law of the University of Granada, the Inter-University Chair in Law and the Human Genome organized the first seminar linked to the BioTerr Project (Bioterrorism and Biosecurity: Basis to structure new penal instruments to face

the biological threats). The "International Seminar on Biosecurity & Bioterrorism" has been directed by M^a Ángeles Cuadrado Ruiz (Research member of the Project and Professor of Criminal Law at the University of Granada) and coordinated by Emilio José Armaza Armaza (Principal Researcher of the Project at the University of the Basque Country and Lecturer of Criminal Law at the University of Deusto). The presentations have been given by the following invited experts: Armando Segura Naya, Jesús Bobo, Horacio Micucci, Fátima Flores Mendoza, Rocío Cobo, Tomás Navarro Blakemore, Adoración Valiente Méndez, M^a José Espona, M^a Ángeles Cuadrado Ruiz, Ana M^a Ambrosio, Emilio José Armaza Armaza, Fernando Guarnateme Sánchez Lázaro. Antonio Peña, Francisco González Palmero and Eduardo Raúl Gauna moderated the seminar sessions. More information: www.bioterr.eu

XXIII International Congress in Law and the Human Genome

On 11 April 2016, the XXIII International Congress in Law and the Human Genome took place in the *Bizkaia Aretoa* of the University of the Basque Country (UPV/EHU). This edition was dedicated to

the evolution of Biotechnology and its legal-ethical implications (Bioethics and Biolaw). The opening session has been held by C. M. Romeo Casabona (Chair Director), Amaia Maseda (*Vicerrectora de Investigación y Transferencia*, University of the Basque Country) and Gema Tomás (*Decana* of the Faculty of Law, University of Deusto). The Conferences were assembled into two main sessions. The opening presentation on "Genetic engineering in humans" has been delivered by Dr. Raúl Mallaina (Co-secretary of the Social Affairs, Health and Sustainable Development Committee at the Parliamentary Assembly of the Council of Europe). More information available on line at:

www.bioderecho.wordpress.com/23congreso

Sixth Meeting of the Executive Committee of the e-ENERCA Project

On 22 April 2016, the sixth meeting of the Executive Committee of the e-ENERCA Project took place in Barcelona. The Committee members presented and discussed the development of different tasks envisaged and plans for the next months. The project ends in September 2016. More information available on line at: www.enerca.org

Publications of the Chair

Law and the Human Genome Review, No. 44.

***Tecnologías convergentes: desafíos éticos y jurídicos*: C. M. Romeo Casabona (Ed.), Inter-University Chair in Law and the Human Genome - Comares, Bilbao-Granada, 2016, 238 pp.**

Activities of the members of the Chair

Carlos María Romeo Casabona co-directed the thesis "El Derecho a la Eutanasia activa: una perspectiva global de los derechos que asisten a pacientes en etapa terminal y su análisis en México", by Tonantzin G. Torres Navarro, Universidad Autónoma de Baja California Sur (Mexico), being also member of the academic board. He co-directed also the doctoral thesis entitled "Las respuestas del Derecho a las nuevas manifestaciones de dopaje en el deporte", by Elena Atienza, Faculty of Law, University of Deusto, which achieved the highest academic record. Prof. Romeo has been president of the academic board of the doctoral thesis presented by Miguel E. Valerio Jiminián, "Nuevas técnicas de control social: Análisis jurídico de las bases de datos de ADN", which achieved the highest academic record. He has taught in the Master on "Derecho de las Telecomunicaciones y TICs" at the Carlos III

University and in the Master on Criminology of the Pablo de Olavide University. He attended the meetings of the Guarantees Commission for the donation and use of human tissues and cells, the Farmindustria Code on Personal Data Protection in the field of Clinical Research and Pharmacovigilance, Spanish Bioethics Committee. Prof. Romeo has been also: member of the "3rd meeting of the Strategic Group entrusted with follow-up to the Conference on Emerging Technologies and Human Rights", Council of Europe, Paris; national representative of the "Committee on Offences relating to Cultural Property (PC-IBC)", Council of Europe (Strasbourg). He took part in the following international events: the Regional Seminar on Dangerous Offenders which took place in Yerevan, Armenia, on the Recommendation on Dangerous offenders adopted by the Committee of Ministers of the Council

of Europe on 19 February 2014; the seminar on "Medical Liability and patient's rights", University of Macao (China), giving the presentation "Medical Liability: Criminal issues; and Measures of Preventing Adverse Events in hospitals"; the Workshop "European Law and Vietnamese Law on donation, removal and transplantation of cells, organs and surrogacy", *Deutsches Recht Zentrum*, Hanoi Law University (Vietnam); "Die Aufgabe des Rechtsanwalts vor und im Strafverfahren", Bar association of Hanoi; "Recht der Organverpflanzung: Die Spanischen und Deutschen Modelle", *Goethe-Institut* in Hanoi (*DAAD und Deutsche Botschaft in Hanoi*). He has been member of the Scientific Advisory Board in the meeting of the European Project ERINHA-2 (Paris). In Spain, he took part as guest speaker in the international workshop "El futuro de la Bioética contra la exclusión y la pobreza", University of Va-

Activities of the members of the Chair

lencia; in the “Jornada Formativa de Actualización para los miembros de la Comisión Asesora de Bioética del Principado de Asturias”; in the congress “Bio.Iberoamérica: Biotecnología, Integrando Continentes” (Salamanca); in the working group “Recomendación para decir ‘Lo siento’ tras un evento adverso”, Ministry of Health. On 30 March 2016, during the IX Edition of the “Día Nacional del Trasplante”, Prof. Romeo received the “Carlos Margarit” award by the National Foundation for “Enfermos y Trasplantados Hepáticos”.

Aitziber Emaldi Cirión has authored the following articles: “Consideraciones bioéticas y jurídicas sobre la biotecnología con fines eugenésicos”, *Acta Bioethica* 1; “El derecho al libre desarrollo de la personalidad y la libertad reproductiva”, *Derecho y pobreza*. She took part in the “Máster en Derecho de la Salud CESIF-Europharlaw” (Madrid), in the “Máster de Bioética” of the Universidad Pontificia de Comillas; in the Doctoral Program “Derecho Económico y de la Empresa”, University of Deusto. She taught in two post-graduate programs on Bioethics and Law for health professionals in San Sebastián, “Fundación Onkologikoa Fundazioa”. She has been co-director of the doctoral thesis defended by E. Atienza, entitled “Las respuestas del Derecho a las nuevas manifestaciones de dopaje en el deporte”, achieved the highest academic record (*Cum Laude*). She has been member of the academic board of the doctoral thesis “Los delitos relativos a la pornografía infantil y juvenil cometidos a través de Internet”, defended by Christian Scheechler, University of Deusto. She is member of the following research projects founded by the Spanish Economy and Competitiveness Ministry: “Uso de datos clínicos ante nuevos escenarios tecnológicos y científicos (big data). Oportunidades e implicaciones jurídicas (BIGDATIUS)” and “KONTUZ!-2 Responsabilidad causal de la comisión por omisión”.

Pilar Nicolás Jiménez authored the article entitled “Spanish regulation on Biobanks”, *The Journal of Law, Medicine & Ethics*, No. ed. by Bartha Knoppers and Mark Rothstein. She took part in the “II Jornada Multidisciplinar Educativa en Cáncer de Mama Hereditario”, organised by Geicam and Solti; in the “Jornada de formación sobre protección de datos” University of

Alcalá de Henares; in the “IX Conferencia Anual de las Plataformas de Investigación Biomédica”; in the “Congreso Asociación Nacional de Comités de Ética de la Investigación”; in the “IV Conferencia Internacional de la Cátedra Google de Privacidad, Sociedad e Innovación, Big data, ciberseguridad e innovación tras las reformas europeas de protección de datos”; in the “Curso avanzado en Medicina Personalizada”, organised by the “Sociedad Española de Farmacogenética y Farmacogenómica”; and the “Curso de Verano sobre Biobancos”, University of Alcalá de Henares.

Iñigo de Miguel Beriain has been nominated member of the group of experts of Ethics and Scientific Integrity within the ‘Science with and for Society’ Programme, Horizon 2020 (SwafS-Ética). He has authored the book chapter “Synbio and IP rights: looking for an adequate balance between private ownership and public interest”, in J. Boldt (Ed.), *Metaphors, Worldviews, Ethics, and Law*, Springer, 2016. He has given the presentation entitled “Far Beyond Nation-State: empowering people in the globalization era”, Jagiellonian University of Cracow, Faculty of Law (March 22). He has coordinated the workshop “Knowledge, Communication and Personalised Health: navigating the digital landscape” (News). He has been member of two academic boards of doctoral thesis in the UNED and of eleven academic boards at the University of the Basque Country.

Emilio José Armaza Armaza has co-authored - together with E. Atienza - the book *El dopaje en el Derecho Deportivo actual: análisis y revisión bibliográfica*, Reus, 2016; the book chapters “Las torturas y otros delitos contra la integridad moral” and “Delitos contra la seguridad colectiva I. Delitos de riesgo catastrófico. Incendios”, in C.M. Romeo Casabona et al. (Coords), *Derecho Penal. Parte Especial*, Comares, 2016. He has coordinated the *V International Seminar on Biosecurity & Bioterrorism* (see News). He has been moderator of the communications panel “Intervenciones genéticas y derechos fundamentales”, *XXIII International Congress in Law and the Human Genome* (see News). He has given the following presentations: “El tratamiento penal del quebrantamiento de una medida

de cuarentena”, *V International Seminar on Biosecurity & Bioterrorism*; “Algunos problemas jurídicos y éticos en materia de bioseguridad y bioterrorismo”, *Inter-University Master in Bioethics and Biolaw*, University of La Laguna (June 18).

Elena Atienza Macías has defended the doctoral thesis entitled “Las respuestas del Derecho a las nuevas manifestaciones de dopaje en el deporte”, University of Deusto, *Mención Internacional and Cum Laude*. She co-authored - together with E.J. Armaza - the book entitled *El dopaje en el Derecho Deportivo actual: análisis y revisión bibliográfica*, Reus, 2016. She co-authored the article “O tratamiento jurídico dos complementos alimentares no contexto da dopagem desportiva”, *Revista Debater a Europa*, together with A.P. Myszczyk. She is member of the Management Committee of the ISCH COST Action “European Medicines Shortages Research Network - addressing supply problems to patients (Medicines Shortages)”.

Andrea Perin has been member of the e-Enerca Project, as postdoctoral researcher of the University of the Basque Country. He authored the article entitled “La contribución de la víctima y la imputación objetiva del resultado en la teoría del delito imprudente”, *Revista Electrónica de Ciencia Penal y Criminología*, and the book chapter “Conocimientos científicos, tecnologías convergentes y Derecho penal”, in C.M. Romeo Casabona (Ed.), *Tecnologías convergentes: desafíos éticos y jurídicos*, Inter-University Chair in Law and the Human genome-Comares, 2016. He has given the following presentations: “Reliance on scientific-medical knowledge in social and juridical contexts”, Workshop “Knowledge, Communication and Personalized health: Navigating the digital landscape” (News); “Scienza e diritto penale” (together with C. Valbonesi, University of Florence), University of Trento (May 26); “Ética, Bioética, Derecho, Bioderecho: Límites y comunidades”, at the Inter-University Master in Bioethics and Biolaw, University of Las Palmas de Gran Canaria (January 29). He has received the “best PhDs of the Academic Year 2013-2014” award by the University of Trento (May 14).

Inter-University Chair in Law and the Human Genome

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