



# ANNUAL REPORT OF ACTIVITIES

# 2011

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## INTRODUCTION

In 2011, the Spanish Bioethics Committee (SBC) (*Comité de Bioética de España*) focused its activity on the discussion and final approval of two documents, namely, an *Opinion on Conscientious Objection in Medical Care* and a *Report on Synthetic Biology*.

The Committee decided to address the matter of conscientious objection in the health-care sphere, bearing in mind that Spain's Organic Act 2/2010 on Sexual and Reproductive Health and Voluntary Interruption of Pregnancy (*Ley Orgánica de salud sexual y reproductiva y de la interrupción voluntaria del embarazo*) expressly recognises the need to bestow the status of law on conscientious objection to abortion. The SBC itself, in its *Opinion* on the above Act, urged that conscientious objection be regulated so as to ensure the rights of public health system users and draw up a more detailed definition of cases in which conscientious objection would be lawful, not only as regards interruption of pregnancy but also vis-à-vis health care in general. The *Opinion* takes an in-depth look at the legal and ethical grounds for recognition of conscientious objection, and, in its final recommendations, lists the points that any future statutory regulation should take into account.

Secondly, within the framework of the joint meetings annually held by the Spanish Bioethics Committee and the Portuguese National Ethics Committee for Life Sciences (*Conselho Nacional de Ética para as Ciências da Vida/CNECV*), discussion centred on and approval was given to a report on a field which has come to be called, "Synthetic biology", and which relates to all manner of research undertaken with a view to creating living multicellular organisms in the laboratory. Even at a stage when the future of such research, as well as its specific application, is still very hazy, it is essential to pay heed -from the very outset- to any possible dangers, keep scientists alert as to their responsibilities, and avoid causing confusion by disseminating less than rigorous news and information about the matter. The report in question is the first to be issued by two European Bioethics Committees and seeks to afford a suitable framework for future debates.

One of the goals of any national bioethics committee is to furnish material that will go to form opinion on problems which should properly be in the public arena. The two documents cited above also have this function and, to different degrees, can help render deliberation more realistic on issues that will have to be regulated, or alternatively, simply call for interdisciplinary consideration in the light of possible results. In 2011, the SBC held two-monthly plenary meetings, preceded in every case by a Steering Committee meeting. Although the internal debates of these sessions have a value *per se*, by providing an opportunity for different points of view to be aired and weighed against one another, the committee members' efforts would be to no avail if their internal debate did not, in turn, enrich the effective development of bioethics in this country.

All national bioethics committees are currently raising the same issues, and it is salutary that this exchange of different points of view transcends the strictly national scope. Since its inception, the SBC has maintained close ties with various European

committees, and attends the scheduled meetings that are held at both a European and a world level.

Victoria Camps  
Chairperson

## COMPOSITION OF THE SPANISH BIOETHICS COMMITTEE

Title VII of the Biomedical Research Act 14/2007 of 3 July (*Ley de Investigación Biomédica*) sets up the Spanish Bioethics Committee as an *independent, collegiate, consultative body, concerned with matters relating to the ethical and social implications of Biomedicine and Health Sciences* (Article 77).

*The Committee's functions are as follows (Article 78):*

- a) issuing reports, proposals and recommendations for state and regional public authorities on issues having relevant ethical implications;*
- b) issuing reports, proposals and recommendations on matters relating to such ethical and social implications of Biomedicine and Health Sciences as the Committee may deem relevant;*
- c) laying down the general principles for the drawing-up of codes of good scientific research practices, which are to be implemented by Research Ethics Committees;*
- d) representing Spain at supranational and international fora and bodies involved in Bioethics;*
- e) drawing up an annual report of activities; and,*
- f) any others with which it may be tasked by the regulations implemented hereunder.*

Similarly, Title I of the Science, Technology & Innovation Act 14/2011 of 1 June (*Ley de la Ciencia, la Tecnología y la Innovación*) also makes reference to the Spanish Bioethics Committee, on establishing the separation of functions between the Spanish Research Ethics Committee and the Spanish Bioethics Committee.

*Creation of the Spanish Research Ethics Committee (Article 10) for the purposes of:*

*2.b) laying down general principles for drawing up codes of good practices for scientific and technical research, which shall include the resolution of conflicts of interest between public and private activities. Such codes are to be developed by Research Ethics Committees and the Spanish Bioethics Committee; and,*

*2.c) representing Spain at fora and supranational and international bodies involved in research ethics, save in matters of bioethics, in which case representation of Spain will fall to the Spanish Bioethics Committee.*

## MEMBERS



**Chair**

### **Victoria Camps Cervera**

Victoria Camps is a Doctor of Philosophy and Professor of Moral and Political Philosophy at the Autonomous University of Barcelona. She was an independent senator for the PSC/PSOE from 1993 to 1996, and acted as advisor to the Catalan Audiovisual Council from 2002 to 2008. She chairs the Víctor Grifols i Lucas Foundation (Barcelona), is a member of the Catalan Bioethics Committee, and has published a number of books on ethics, political philosophy, bioethics and education.



**Deputy Chair**

### **Carlos Alonso Bedate**

He holds degrees in Philosophy from the University of Alcalá de Henares, and in Theology and Biology from the University of Granada, as well as a Master's Degree in Genetics from the University of California (USA). He is a doctor of Sciences and *ad honorem* Professor of Research at the Molecular Biology Centre of the Spanish Council for Scientific Research (*Consejo Superior de Investigaciones Científicas - CSIC*) at the Autonomous University of Madrid. Carlos Alonso has sat on numerous national and international bioethics committees.



**Secretary  
(vested with the  
right to speak but  
not to vote)**

### **Javier Arias-Diaz**

Dr. Arias-Diaz is Professor of Surgery at Madrid's Complutense University, Specialist (Consultant) in surgery at the San Carlos Clinical University Teaching Hospital, Co-ordinator of the Surgical Infection Committee of the Spanish Association of Surgeons, Subdirector-General of Cellular Therapy and Regenerative Medicine at the Carlos III Institute of Health (*ISCIII*), Director of the National Bank of Stem Cell Lines (*Banco Nacional de Líneas Celulares/BNLC*), Chairman of the ISCIII Research Ethics and Animal Welfare Committee, and Member of the Board and representative of the Ministry of Science & Innovation on the Council of Europe's Steering Committee of Bioethics (CDBI). He is the author or co-author of more than 150 papers in scientific journals, with a total impact factor of over 180 and a Hirsh index of 15.



### **Carmen Ayuso García**

Carmen Ayuso holds a Doctorate in Law from the Autonomous University of Madrid), and is associate head of the Genetics Department and Sub-director of Research at the Jiménez Díaz Foundation (Madrid).



### **Jordi Camí Morell**

A Doctor of Medicine and specialist in Clinical Pharmacology, Jordi Camí is currently Professor of Pharmacology at the Pompeu Fabra University (Barcelona), and Director-General of the Barcelona Biomedical Research Estate (*Parque de Investigación Biomédica de Barcelona/PRBB*) and the Pasqual Maragall Foundation. He is a member of the Health Advisory Board (Ministry of Health). Until 2005, he held the post of director of the Barcelona Municipal Medical Research Institute (*Instituto Municipal de Investigación Médica/IMIM*). In 2000, he was awarded the Narcís Monturiol Medal for scientific and technological merit.



### **María Casado González**

María Casado is a Doctor of Law, and the Resident Professor of Legal, Moral and Political Philosophy at the University of Barcelona (UB). She is director of the UNESCO Chair of Bioethics at the University of Barcelona, director of the UB-PCB Bioethics and Law Observatory Research Centre, and co-ordinator of the Catalanian Regional Authority's Consolidated Bioethics, Law & Society Research Group, the Bioethics and Human Rights Thematic Network, and the Bioethics Joint Teaching Network. In addition, she holds the Narcís Monturiol Medal awarded by the Catalanian Regional Authority for contribution to scientific and technological progress, and is a member of the Board of Directors of the International Association of Bioethics, the Catalanian Bioethics Advisory Committee and the National DNA Committee.



### **Yolanda Gómez Sánchez**

Yolanda Gómez is a Doctor of Law, a Professor of Constitutional Law at the National Distance Education University, a holder of the Jean Monnet Chair of the European Union, and an advisor to the European Agency of Fundamental Rights. Until 2008, she was a member of the UNESCO International Bioethics Committee. She is a specialist in fundamental rights, the author of numerous publications in the field of bio-law, and is the PhD- and specialisation-programme director in these same subjects.



### **César Loris Pablo**

César Loris is a Doctor of Medicine and specialist in paediatrics. He is Chairman of the Aragonese Clinical Research Ethics Committee and Head of the Paediatric Nephrology Department at Zaragoza's Miguel Servet University Teaching Hospital.



### **José Antonio Martín Pallín**

José Antonio Martín is a Supreme Court judge, a permanent member of the Canary Islands Institute of Studies, a member of both the International Secretariat of Jurists for Amnesty and Democracy in Paraguay and the Hispano-German Association of Jurists, and has undertaken a number of special missions on human rights on behalf of Amnesty International (Venezuela, Mexico, Peru). He was awarded the 1996 *Jurista* Prize by Madrid's Complutense University.



### **César Nombela Cano**

César Nombela holds a degree in Pharmacy and Chemical Sciences as well as a doctorate from the University of Salamanca. He is Professor of Microbiology at the Pharmacy Faculty of Madrid's Complutense University, and has been Chairman of the Spanish Council for Scientific Research and the Scientific & Technological Research Ethics Advisory Committee of the Spanish Foundation for Science & Technology (*Fundación Española para la Ciencia y la Tecnología/FECYT*) at the Ministry of Education & Science. Currently, he is director of the Extraordinary Chair of Genomics and Proteomics, sponsored by the pharmaceutical company, Merck, Sharp & Dohme. Until 2003, he was a member of UNESCO's International Bioethics Committee.



### **Marcelo Palacios Alonso**

Marcelo Palacios is a specialist both in General Surgery (recognised by Germany's Westphalian Chamber of Medicine and the Medical Education Council), and in Traumatology and Orthopaedics (Medical Education Council). He sat as a Member of Parliament from 1982 to 1996. Among his other posts, he chaired the Special Committee for the Study into *in Vitro* Fertilisation & Human Artificial Insemination of the Lower House of Parliament and drafted the Committee's final report. Dr. Palacios has acted as Chairman of the Bioethics Committee of the Council of Europe and is the founder of the International Society of Bioethics (SIBI).

### **Carlos María Romeo Casabona**



Carlos María Romeo is a Professor of Criminal Law and Director of the Inter-University Chair of Law and the Human Genome, at the University of Deusto and the University of the Basque Country. He holds doctorates in both law and medicine, is a member of the Committee for the Supervision and Monitoring of Human Cell and Tissue Donation & Use, the Bioethics Advisory Committee of the Basque Country (*Euskadi*), the Bioethics Steering Committee of the Council of Europe, the Ethics Committee of the Human Genome Organisation, the European Research Area Board (ERAB) of the European Commission, and is Chairman of the Basque Country Clinical Research Ethics Committee. He has received six honorary doctorates.

### **Pablo Simón Lorda**



Pablo Simón took his Doctorate in Medicine at the University of Santiago de Compostela and has specialised in Family and Community Medicine. He is currently a lecturer in bioethics at the Andalusian School of Public Health (Granada). He holds Master's Degrees in Bioethics from Madrid's Complutense University and in Health Service Administration and Management from the Pompeu i Fabra University (Gaspar Casal Foundation). In addition, he has a seat on the Andalusian Regional Ethics and Research Committee.

## ACTIVITIES UNDERTAKEN:

### PRINCIPAL RESOLUTIONS PASSED BY THE SBC IN 2011

- Approval of the 2010 Annual Report of Activities
- Carlos Alonso Bedate's attendance at the 17<sup>th</sup> Forum of National Ethics Councils (NEC Forum) in Brussels on 20 September on behalf of the Spanish Bioethics Committee.
- Approval and publication of the document entitled, "Conscientious objection in Medical Care".
- Organisation of the 2<sup>nd</sup> meeting of the Spanish Bioethics Committee and Portuguese National Ethics Committee for Life Sciences in Barcelona on 23 and 24 October 2011.
- Approval and publication of the document on "Synthetic biology", jointly drawn up by the Spanish Bioethics Committee and Portuguese National Ethics Committee for Life Sciences.
- Resolution to hold the third meeting of the Spanish Bioethics Committee and Portuguese National Ethics Committee for Life Sciences, scheduled for autumn 2012 in Oporto.
- Commencement of activities with respect to the drawing-up of a report on end-of-life health care.

### PLENARY MEETINGS OF THE COMMITTEE

During 2011, the following plenary meetings of the Spanish Bioethics Committee were held:

- 14 February 2011
- 11 April 2011
- 13 June 2011

- 13 September 2011

## MEETINGS OF THE STEERING COMMITTEE

During 2011, the Steering Committee held the following scheduled meetings:

- 25 January 2011
- 24 March 2011
- 26 May 2011
- 6 September 2011
- 15 November 2011

## MEETINGS WITH OTHER ETHICS COMMITTEES

### 24 October 2011

As agreed at the first meeting in Lisbon, the 2<sup>nd</sup> Meeting of the Portuguese National Ethics Committee for Life Sciences and the Spanish Bioethics Committee was held in the city of Barcelona.

At this meeting, the following topics were addressed:

- *Synthetic biology*: a document drawn up by both committees, and presented by Ana Sofia Carvalho (CNECV) and Carlos Romeo Casabona (SBC)
- *Ethical aspects in the computerisation of health data*: an issue addressed by the Portuguese National Ethics Committee for Life Sciences and presented by Rosalvo Almeida, Jorge Sequeiros and Lucília Nunes.

Yolanda Gómez was scheduled to present the topic, *Benefits for the patients in biomedical research*, on behalf of the SBC. Nevertheless, this presentation could not go ahead as planned, due to the speaker being indisposed.

It was agreed that a third meeting, envisaged for autumn 2012, would be held in Portugal.

## ATTENDANCE AT NATIONAL AND INTERNATIONAL EVENTS

**1<sup>st</sup> International Seminar on Bioethics, Biomedicine and Law**, held at the Carlos III Institute of Health (*Instituto de Salud Carlos III/ISCIII*) in Madrid on 5-6 May 2011 and co-ordinated by the National Distance Education University (*Universidad Nacional de Educación a Distancia/UNED*) and the ISCIII Animal Research Ethics and Welfare Committee.

The Seminar's general goal was to take an in-depth look at relevant problems in the sphere of bioethics applied to health sciences. The fact that legal systems have incorporated specific provisions to govern relations in the field of health sciences as well as the necessary setting-up of bioethics committees in clinical medicine and research, justifies the three-pronged scientific, bioethical and legal stance adopted by this seminar.

Attending the event were, Yolanda Gómez Sánchez in her capacity as Chair of the Organising Committee, Javier Arias Díaz, also a member of the Organising Committee, and Carlos Alonso Bedate.

**17<sup>th</sup> NEC Forum** held in Brussels on 20 September. The topics addressed were as follows:

- the formulation of a better definition of the notion of responsible research;
- the sharing of information on how respect for fundamental rights has been incorporated into national and international research, and the innovation of programmes and initiatives in other regions of the world; and,
- the discussion of the inclusion of ethical considerations in research and innovation worldwide.

It was agreed that Carlos Alonso Bedate would attend on behalf of the SBC.

**7<sup>th</sup> World Bioethics Congress, held under the aegis of the International Society of Bioethics (*Sociedad Internacional de Bioética - SIBI*)** in Gijón from 19-22 September 2011.

The overall theme of the Congress was "Environment and sustainable development: bioethical aspects". At the venue, a wide spectrum of topics was addressed, including climate change, sustainable development and food security, in all cases from a bioethical standpoint.

The Congress was organised by Marcelo Palacios Alonso, Chairman of the International Society of Bioethics, and was attended by Victoria Camps Cervera and Carlos María Romeo Casabona.

**1<sup>st</sup> Bioethics Congress: Ethical Aspects in research and clinical practice**, organised by the ISCIII Animal Research Ethics and Welfare Committee.

As this Congress was a continuation of previously held conventions on Ethical Aspects of Biomedical Research, the topic areas addressed were not confined to research but extended to health care and bioethics in general.

Insofar as the round tables were concerned, issues of maximum interest were chosen, whether in research (including the problem of incapacity to give informed consent and medical-research risk insurance cover) or in health care (including electronic medical records, conscientious objection and end-of-life decisions).

The Congress was attended by Javier Arias Díaz in his capacity as Chair of the Animal Research Ethics and Welfare Committee, Victoria Camps Cervera, Carmen Ayuso and Carlos Alonso Bedate.

## DOCUMENTS APPROVED IN 2011

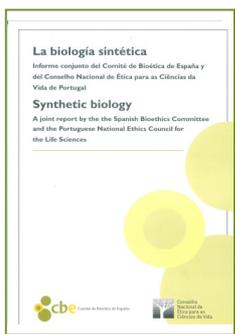
### *Opinion of the Spanish Bioethics Committee on Conscientious Objection in Medical Care*



The document analyses the legal doctrine on the right to conscientious objection in medical care, as well as the ethical-philosophical grounds underlying the advisability of regulating such objection in a State that guarantees the right to freedom of thought and, at the same time, the right of public system end-users to be duly attended. It establishes in which cases objection corresponds to the exercise of religious and ideological freedom, and lays down the guidelines to be taken into account by any future regulation. The Opinion was approved by a majority at the plenary Committee session held on 13 September 2011.

### *Synthetic biology*

#### *Joint report of the Spanish Bioethics Committee and the Portuguese National Ethics Committee for Life Sciences*



This document provides a summary of the scientific scope of and challenges posed by synthetic biology in its different applications in the treatment of diseases and in the field of biosecurity. Special stress is laid on scientists' responsibility and on the rigour and prudence that should accompany news about scientific innovations, so as to prevent counterproductive misunderstandings and alarm. Finally, consideration is given to the ethical and legal limits of the patent covering the creation of living multicellular organisms in a laboratory.

This report is the result of collaboration between the Spanish and Portuguese Bioethics Committees, which jointly approved the text at the meeting held on 24 October 2011.

## WORK IN PROGRESS

2011 marked the commencement of activities pertaining to the following issues:

- 1) Benefits and rights of patients in biomedical research.
- 2) Umbilical cord banks.
- 3) Bioethical aspects of death with dignity.

## DOCUMENTS PUBLISHED



### **Opinion of the Spanish Bioethics Committee as to the Organic Bill on Voluntary Interruption of Pregnancy**

7 October 2009



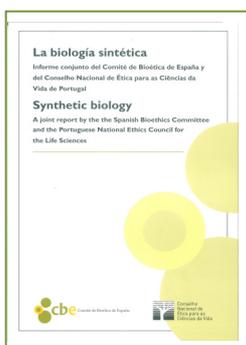
### **Recommendations for implementation of Good Scientific Practices in Spain**

12 April 2010



### **Opinion of the Spanish Bioethics Committee on Conscientious Objection in Medical Care**

13 October 2011



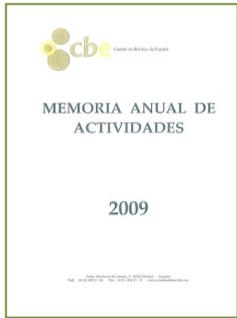
### **Synthetic biology**

### **Joint Report of the Spanish Bioethics Committee and the Portuguese National Ethics Committee for Life Sciences**

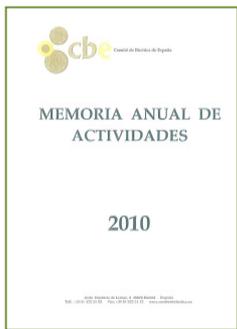
24 October 2011

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## ANNUAL REPORT



### **2009 Annual Report of Activities**



### **2010 Annual Report of Activities**

