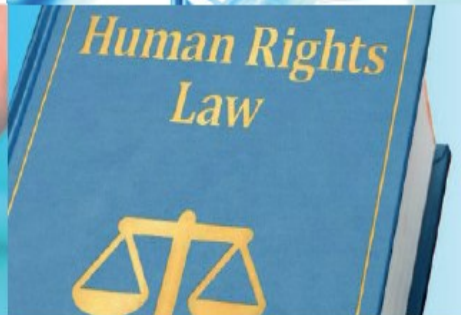


# 20TH ANNIVERSARY OF THE OVIEDO CONVENTION: Relevance and Challenges

20<sup>th</sup>  
ANNIVERSARY



International Conference organised  
by the Committee on Bioethics (DH-BIO)  
under the auspices of the Czech Chairmanship  
of the Committee of Ministers

24 - 25 October 2017  
Room 1, Palais de l'Europe,  
Strasbourg

## Proceedings



**Chairmanship of the Czech Republic**  
Council of Europe  
May – November 2017

**Présidence de la République tchèque**  
Conseil de l'Europe  
Mai – Novembre 2017

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE



## TUESDAY 24 OCTOBER 2017

### 9.30 SESSION I - OPENING

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*Chair:* [Dr Beatrice Ioan](#) (Romania), Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe

- ▶ [JUDr Radek Policar](#), Deputy Minister for Legislation and Legal Affairs, Czech Republic
- ▶ [Ms Gabriella Battaini-Dragoni](#), Council of Europe Deputy Secretary General
- ▶ [Ms Nada Al-Nashif](#), UNESCO Assistant Director-General for Social and Human Sciences

### 10.10 Keynote speeches

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- ▶ The Oviedo Convention: An achievement and a starting point  
[Dr Octavi Quintana](#) (Spain), Director of the Partnership on Research and Innovation in the Mediterranean Area (PRIMA), European Commission; former Chair of the Council of Europe Steering Committee on Bioethics (CDBI)
- ▶ How to protect Human rights in the face of current biomedical developments? The significance of the Oviedo Convention  
[Prof. Dr. Dr. h.c. Ludger Honnefelder](#) (Germany), Professor emeritus of Philosophy, Friedrich-Wilhelms University, Bonn; former member of the Council of Europe Steering Committee on Bioethics (CDBI)
- ▶ An ethics of integration: Novel biotechnologies and human dignity  
[Prof. Sheila Jasanoff](#) (USA), Pforzheimer Professor of Science and Technology Studies, Harvard Kennedy School, Harvard University

### 11.30 Coffee break

### 12.00 Objectives of the conference

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- ▶ [Prof. Dr Zvonko Magic](#) (Serbia), Chair of the Preparatory Group for the Conference

### 12.10 International case-law in bioethics: Insight and foresight

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- ▶ Outcome of the high-level seminar organised on 5 December 2016 at the European Court of Human Rights  
[Mr Hans-Jörg Behrens](#) (Germany), Vice-Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe

*Questions/Discussion*

### 12.40

### LUNCH BREAK

**14.30 Signing Ceremony of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (CETS 203) by the Czech Republic**

**14.45 SESSION II - EVOLUTION OF PRACTICES IN THE BIOMEDICAL FIELD**

**Rapporteurs**

- ▶ [Ms Isabelle Erny](#) (France), Head of the Bioethics and Patients' Rights Division of the Division of Users' Rights and Legal and Ethical Affairs at the General Secretariat of the Directorate-General for Health, Ministry of Solidarities and Health; member of the DH-BIO
- ▶ [Prof. Constantinos Phellas](#) (Cyprus), Vice Rector for Faculty & Research University of Nicosia, Chairman of the Cyprus National Bioethics Committee; member of the Bureau of the DH-BIO

**14.45 Autonomy – Consent and Privacy**

**Chair:** [Ms Ina Verzivoli](#) (Albania), Chair of the Ad hoc Committee for the Rights of the Child (CAHENF) of the Council of Europe

- ▶ Challenges raised by the evolution of practices for children rights  
[Dr Kavot Zillen](#) (Sweden), LL.D and postdoctoral researcher, Faculty of Law, Stockholm University represented by [Dr Santa Slokenberga](#)
- ▶ Action(s) to be undertaken at intergovernmental level to address the identified challenges  
[Prof. Dr Ton Liefwaard](#) (Netherlands), Professor of Children's Rights/UNICEF Chair in Children's Rights, Law School, Leiden University

*Discussion*

**Chair:** [Mr Miroslav Mikolášik](#), Member of the European Parliament and Chairman of the EPP Working Group on Bioethics and Human Dignity

- ▶ Challenges raised by the evolution of practices for elderly persons  
[Prof. Ana Sofia Carvalho](#) (Portugal), Director of the Bioethics Institute, Universidade Católica Portuguesa (IB-UCP)
- ▶ Action(s) to be undertaken at intergovernmental level to address the identified challenges  
[Prof. Antonio Cherubini](#) (Italy), Director, Geriatrics and Geriatric Emergency Care, IRCCCS-INRCA, Ancona

*Discussion*

**16.45 Coffee break**

### 17.15 Equity of access to health care

*Chair/Moderator: [Ms Brigitte Konz](#) (Luxembourg), Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe*

- ▶ Effectively exercising a right to protection of health: common or individual challenges?  
[Ms Marit Frogner](#) (Norway), Member of the European Committee of Social Rights (ECSR) of the Council of Europe (Rapporteur for Article 11 of the European Social Charter)
  
- ▶ **Round table**  
[Dr Rogelio Altisent](#) (Spain), Director of academic projects on the Clinical Ethics and Professionalism Chair, University of Zaragoza; [Ms Liliane Maury Pasquier](#) (Switzerland), Chair of the Committee on Rules of Procedure of the Parliamentary Assembly of the Council of Europe; [Ambassador Santiago Oñate Laborde](#) (Mexico), Permanent Observer to the Council of Europe, Mission of Mexico to the Council of Europe; [Dr Ucha Vakhania](#) (Georgia), Executive Director of the “Coalition Homecare in Georgia”

*Discussion*

18.15 End of day 1

WEDNESDAY 25 OCTOBER 2017

## 9.00 SESSION III - NEW SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS

### Rapporteurs

- ▶ [Dr Anne Forus](#) (Norway), Senior Adviser, Department of biotechnology and health legislation, The Norwegian Directorate of Health, member of the DH-BIO
- ▶ [Dr Tina Garani-Papadatos](#) (Greece), Lawyer, National School of Public Health, member of the DH-BIO
- ▶ [Prof. Stefano Semplici](#) (Italy), Professor of Social Ethics, Department of Literature, Philosophy and History of Art Studies, University of Rome Tor Vergata; Chair of the Bioethical Committee of the Italian Society of Pediatrics; former Chair of the International Bioethics Committee of UNESCO

### 9.00 Genetics – Genomics

*Chair:* [Prof. Milan Macek](#) (Czech Republic), Head of Department of Biology and Medical Genetics, Charles University, Prague

- ▶ Sequencing and analysis: Human rights challenges raised by scientific and technological developments  
[Prof. Anne Cambon Thomsen](#) (France), Emeritus Research Director, Paul Sabatier University, Toulouse; member of the European Group on Ethics in Science and New Technologies, European Commission
- ▶ Principles at stake – Action(s) to be undertaken at intergovernmental level to address the identified challenges  
[Prof. Bartha Knoppers](#) (Canada), Director of the Centre of Genomics and Policy, Faculty of Medicine, McGill University, Montreal

### Discussion

*Chair:* [Dr Petra de Sutter](#) (Belgium), member of the Council of Europe Parliamentary Assembly

- ▶ Modification of the human genome: Human rights challenges raised by scientific and technological developments  
[Prof. Jonathan Montgomery](#) (United Kingdom), Professor of Health Care Law, University College, London; former Chair of the Nuffield Council on Bioethics; member of the European Group on Ethics in Science and New Technologies, European Commission
- ▶ Principles at stake – Action(s) to be undertaken at intergovernmental level to address the identified challenges  
[Prof. Ewa Bartnik](#) (Poland), Professor of Genetics, Faculty of Biology, University of Warsaw; member of the International Bioethics Committee of UNESCO

### Discussion

## 10.40 Coffee break

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## 11.10 Brain technologies

*Chair: [Mr Jean-Yves Le Déaut](#) (France), former member of the Council of Europe Parliamentary Assembly*

- ▶ Human rights challenges raised by scientific and technological developments  
[Prof. Nikola Biller-Andorno](#) (Switzerland), Director of the Institute of Biomedical Ethics and history of medicine, Center for Medical Humanities, University of Zürich
- ▶ Principles at stake – Action(s) to be undertaken at intergovernmental level to address the identified challenges  
[Prof. David Winickoff](#) (OECD), Senior Policy Analyst, Secretary of the Working Party on Bio-, Nano- and Converging Technologies (BNCT)

*Discussion*

## 12.00 Information technologies/NBIC and Big data

*Chair: [Ms Tesi Aschan](#) (Sweden), Vice-Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe*

- ▶ Human rights challenges raised by scientific and technological developments  
[Ms Antoinette Rouvroy](#) (Belgium), The Research Centre in Information, Law and Society (CRIDS), Namur University; member of the Ethics Advisory Group of European Data Protection Supervisor
- ▶ Principles at stake – Action(s) to be undertaken at intergovernmental level to address the identified challenges  
[Ms Alessandra Pierucci](#) (Italy), Chair of the Council of Europe Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)

*Discussion*

## 13.00 LUNCH BREAK

## 15.00 SESSION IV – PAVING THE WAY FOR A STRATEGIC ACTION PLAN

### 15.00 Priority issues and action proposals

*Moderator: [Prof. Dr. med. Christiane Woopen](#) (Germany), Professor of Ethics and Theory of Medicine, University of Cologne; member of the International Bioethics Committee of UNESCO; Chairperson of the European Group on Ethics in Science and New Technologies, European Commission*

- ▶ **Round table**  
[Prof. Nikola Biller-Andorno](#) (Switzerland), on behalf of WHO, Director of the Institute of Biomedical Ethics and History of Medicine, WHO Collaborating Center in Bioethics, University of Zurich; [Prof. Jean-François Delfraissy](#) (France), President of the National Ethics Committee; [Dr Lyalya Gabbasova](#) (Russian Federation), Adviser to the Health Minister; [Ms Paula Kokkonen](#) (Finland), former emeritus Chairperson of the National Advisory Board on Health Care Ethics, former Chair of the Council of Europe Steering Committee on Bioethics (CDBI); [Ms Brigitte Konz](#) (Luxembourg), Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe; [Dr Petra de Sutter](#) (Belgium), member of the Council of Europe Parliamentary Assembly

## 16.30 CONCLUSIONS OF THE GENERAL RAPPORTEUR

- ▶ [Dr Siobhan O'Sullivan](#) (Ireland), Lecturer in Healthcare Ethics and Law, Royal College of Surgeons; Vice Chair of the European Group on Ethics in Science and New Technologies, European Commission

## 17.00 SESSION V – CLOSING

- ▶ [Dr Beatrice Ioan](#) (Romania), Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe



**BIOGRAPHICAL NOTES**

**ABSTRACTS**

**FULL TEXTS**

## CHAIR

### Dr Beatrice Ioan, Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe



*Beatrice Gabriela Ioan is Professor of Legal Medicine and Bioethics at "Grigore T. Popa" University of Medicine and Pharmacy of Iasi, Romania, as well as its Vice-Rector of institutional strategy. She is senior physician at the Institute of Legal Medicine of Iasi, Romania. She graduated from the Faculty of Medicine in 1993 and received her PhD degree in 2003 at the University of Medicine and Pharmacy of Iasi, Romania. She also graduated from the Faculty of Psychology in 2002 and from the Law Faculty in 2012. In 2004 she completed the Master of Art Program in Bioethics at Case Western Reserve University, USA, and in 2013 the Master du Droit et Gestion de la Santé at Institut Catholique de Rennes/Université*

*Montpellier, France. She joined the DH-BIO as a member in 2007 and is presently its Chair. She also joined the International Bioethics Committee (IBC) of UNESCO in 2016. Moreover, she is the Chair of the Bioethics Commission of the Romanian College of Physicians, member of the Discipline Commission of the Romanian College of Physicians, and member of several research ethics committees in Romania. Her research interests in Bioethics are: death and end of life issues, organ transplantation and research ethics. She participated in European and national research projects, she is the author and co-author of several scientific papers, books and book chapters on Bioethics and Legal Medicine.*

## JUDr Radek Policar

### Deputy Minister for Legislation and Legal Affairs, Czech Republic



*Radek Policar holds the JUDr. degree from the School of Law at the Masaryk University. He also completed the advanced state exams in the field of labour law at the same institution. Furthermore he studied at the Institute for Postgraduate Education in Health Services in the field of health law. Until this day he regularly attends congresses, conferences and seminars on health law as speaker. Radek Policar published two books and numerous articles on law and management in health services.*

*In the years 2000-2004, Radek Policar worked at the Public Procurement Department and later as the deputy director of Legal Section of the University Hospital Brno. Later he served as the head of Legal Department and as the deputy director for Legal Services and HR at the Masaryk Memorial Cancer Institute in Brno. Besides he was the head of the Institute of Social Medicine and Public Health at the Masaryk University in the years 2013-2014.*

*Since the year 2015, Radek Policar serves as the Deputy Minister for Legislation and Legal Affairs at the Ministry of Health of the Czech Republic.*

oOo

Dear ladies and gentlemen,

By a lucky chance the Czech Republic has been honoured to chair the Committee of Ministers of the Council of Europe in present months thus allowing me to say a few words at the beginning of such an amazing conference, where we commemorate 20 years since the adoption of the Convention on Human Rights and Biomedicine.

The Czech Republic belongs among the states that ratified the Oviedo Convention shortly after its adoption. Since I have dedicated almost 20 years of my career to medical law, my professional life is strongly connected with the application of the Oviedo Convention in my country.

After all, for me the celebration of the Convention's anniversary does not end with this conference. The capital city of the Czech Republic, Prague, will host our national conference to commemorate the 20th anniversary. And just as we welcome here today the top European experts, next week we shall meet the top Czech experts – professors and high court judges in Prague. When I saw the list of persons willing to give presentation, I came to a conclusion that this would be the best represented conference dedicated to the medical law held in the Czech Republic in last 20 years. Thus, I am pleased to say that the 20th anniversary of the adoption of the Oviedo Convention is, indeed, a very inspiring event.

Full title of the convention that brought us all here today is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Applications of Biology and Medicine. Human dignity then represents the central value, from which all other rights of patients arise.

Two weeks ago I saw a drama written by a German lawyer, Mr Ferdinand von Schirach, called Terror. It is a remarkable contemporary play based in Germany that narrates a judicial proceeding. At the end of every play, each spectator in the audience – as a member of an imaginary jury – votes either guilty or not guilty. The decisive point which distinguishes you from being pro-prosecution or pro-defence is whether or not you are a supporter of the human dignity principle.

I am afraid that most of the people do not understand the term “human dignity”. They do not understand, what it exactly means. Despite the fact that in many countries human dignity represents the key principle protected by their constitutions and human rights guaranteed by the constitution, the term represents something that is incomprehensible to the majority of people. Our major effort should focus on assimilation of those high values standing behind the Oviedo Convention to the language of people in our countries. We should also try to contribute to a better understanding of the key international law documents and thus to their better fulfilment in everyday life.

Lot of European countries fight with the rise of populists' and I am afraid it is also due to the fact that we are not able to explain the values standing behind our constitutions, among others also in the field of biomedicine.

The Oviedo Convention tries to set the balance in the relationship between patients and healthcare professionals. And that does not go well all the time. We should, however, guarantee such a key advancement not only by changes in our national legislation, but most of all by actual changes in practice. Not only future doctors and other healthcare professionals within their pre-graduate education, but also current medics within their lifetime education, must realise, what legal standards there are for patients' care, what are the patient's rights and healthcare professionals' duties that need to be kept.

The whole Europe should, on long-term bases, aspire to set up correct incentives, in order for the key values of the Convention on Human Rights and Biomedicine to be respected.

When I look at the list of the countries that signed and consequently ratified the Oviedo Convention, I have to admit, it is a remarkably long list. I also see, however, the list of those countries, which until this day do not want to be bounded by this Convention, and I ask myself why.

The situation is even more sad in a case of the Additional protocols. In this case I have to admit that my country – the Czech Republic, has yet signed only the Additional Protocol on the Prohibition of Cloning Human Beings.

I have been in my current position at the Ministry of Health for little over 2 years. Last year when I discussed with my colleagues the Czech chairmanship of the Committee of Ministers, I asked them why we had not signed the other Additional protocols just yet. And I found that all the obstacles remaining from the past had been overcome. So we took the remaining three Additional protocols and we asked all sections at the Ministry one question: Tell us why we should not sign these additional protocols. It turned out to be a well-placed question.

To make a long story short, our Permanent Representative to the Council of Europe will sign the Additional Protocol concerning Genetic Testing for Health Purposes this afternoon. I apologise to our

## Session I - Opening

Ambassador - that we brought more work his way, but I am convinced that these are the right steps. Its ratification procedure can take several months due to internal procedures in my country, but this should be rather easy and our decision to join the Additional protocol and to ratify it should not be reversed. This Additional protocol has been so far ratified only by 4 members of the Council of Europe and as such it could not come into force yet. I am glad that ratification by my country – the Czech Republic is the last step needed to allow the Additional protocol to become effective.

The Czech Republic will take all steps necessary to sign the Additional Protocol concerning Biomedical Research in the following months and I believe, we will take the same approach towards the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin within foreseeable future.

Ladies and Gentlemen, please, give a thought to whether our approach is or is not the right one. Please, give a thought to why your country has not signed and has not ratified the Convention or its Additional protocols and in case you do not know, just as I did not know why a year ago, then when you return home after this conference, ask the competent persons. And if I could recommend, do not ask them why you should sign the Convention and its Additional Protocols, ask that person why have not we done so already.

I am convinced that the Convention on Human Rights and Biomedicine and its Additional Protocols are the right means to set up the standard of rights and duties in health care. I am convinced that they represent the standard, which should be guaranteed to all the people in Europe and other countries that endorse values agreed upon by our European civilisation, with the human dignity on top and freedom, justice and solidarity following closely.

Allow me to express hope that despite the state of ratification of individual documents, we, here in Europe, agree on values standing behind the discussed documents.

Allow me to express hope that the aim of all member states of the Council of Europe, also thanks to solid foundations in the form of the European Convention for the Protection of Human Rights and Fundamental Freedoms, is to guarantee the highest possible, and increasing standard of not only healthcare services, but also of rights connected to healthcare to all people in Europe.

Allow me to express hope that Europe, and hopefully not only Europe, will keep such approach also during the times when it faces new challenges, be it new technologies, new intra-political or international changes.

Former Czech president and a great philosopher, late Václav Havel said: Hope is not the conviction that something will turn out well, but *the certainty* that something makes sense – regardless of how it turns out.

Thank you for your attention.

## Ms Gabriella Battaini-Dragoni

### Council of Europe Deputy Secretary General



*Mrs Battaini-Dragoni has served as the Council of Europe's Deputy Secretary General since 2012 and was re-elected in June 2015. She oversees the implementation of the Secretary General's reform agenda, in line with the decisions and priorities of the Committee of Ministers. Her priorities include shaping the Programme and Budget to guarantee member States value for money, while ensuring that the Organisation's activities have maximum impact in advancing democracy, human rights and the rule of law. She also oversees the Council of Europe's staff policy. Before taking up her post, Mrs Battaini-Dragoni held a number of positions within the Organisation.*

*In 2001 she became the first female Director General in the Organisation's history, in charge of Social Cohesion.*

*Between 2004-2011, she served as Director General of Education, Culture and Heritage, taking the Council of Europe's work into new terrain by introducing programmes on democratic citizenship, intercultural learning and human rights to schools, youth projects and other cultural spaces.*

*In 2011 Mrs Battaini-Dragoni established the Directorate General of Programmes (ODG-PROG), enabling greater decentralisation of activities to the field. Under her leadership a new system was created to mobilise extra-budgetary resources in a sustainable and long-term perspective.*

*Mrs Battaini-Dragoni has published widely on a range of issues relating to the Council of Europe's mission, including social rights and the role of intercultural dialogue in modern democracies.*

*She holds a degree in foreign languages and literature from the University of Venice and a diploma from the Institut Européen des Hautes Etudes Internationales, University of Nice. She was born in Brescia, Italy and is married with three children.*

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Vice-Minister,

Deputy Director General,

Ladies and gentlemen,

Dear colleagues,

*"A shared ethics that exalts the human person and his or her responsibility".* That is how Alcide de Gasperi, Minister of Foreign Affairs of Italy and one of the founding fathers of European integration, described the common European heritage.

It is through the notion of human dignity, the cornerstone of the whole human rights edifice, that law and ethics intertwine.

The European Convention on Human Rights crystallised this link between human rights and ethics. And the Oviedo Convention, whose 20<sup>th</sup> anniversary we are celebrating today, did it again, this time in the field of biology and medicine.

At that point, some began to talk about a "new generation" of rights.

For the work carried out by the Council of Europe in this context was ground-breaking and led to the adoption of what is still, to this day, the only binding international legal instrument in this field. I am sure the drafting of the Oviedo Convention will be recounted in greater detail by the other speakers of this session.

What I would like to focus on here are the reasons that prompted the Council of Europe to turn its attention to bioethics and why the approach and framework provided by the Council of Europe have been crucial in this process.

Developments in the field of science and in particular medicine have brought and continue to bring great improvements for humankind. The second half of the 20<sup>th</sup> century was a period of remarkable progress, namely in terms of both transplantation and genetics. In this field in particular, whose basic principles were laid by Gregor Mendel in the Czech Republic over 150 years ago, technological improvements and the advancement of knowledge have paved the way for a better understanding of diseases and the development of new treatments.

The increased scope for intervention and controlling human life associated with these developments very soon sparked concerns about the implications that any improper use of this potential could have for human dignity and integrity. Hope was at times mingled with worry.

Gradually, a collective awareness emerged of the need to prevent any such abuses and to use these advances solely for the benefit of present and future generations.

As stated in the preamble to the Convention, *"progress, human benefit and protection can be reconciled as a result of an international instrument devised by the Council of Europe in line with its vocation."*

## Session I - Opening

Developments in the fields of biology and medicine, indeed, raise key issues concerning both individuals and our societies as a whole. These issues involve common basic principles – the core principle of human dignity, but also protection of autonomy, protection of the integrity of the human body, and the principle of justice. The case for an overarching approach becomes evident in this context.

It was the concern to protect these fundamental principles that guided the drafting of the Oviedo Convention – a process that produced a set of principles which have become the common European legal heritage in the biomedical field.

A legal instrument that does not provide answers to all ethical issues – that is not its intention.

A Convention whose content does not constitute the lowest common denominator either.

But a framework convention, forming a bedrock of principles that reflect shared human rights values, and on which states can draw. Principles that are open to scientific progress and recognise their importance, but whose aim is to counter possible abuses.

This Convention is the culmination of a complex process involving highly sensitive issues. A process which would not have succeeded without constructive co-operation between all the relevant bodies and stakeholders. Co-operation whose success was notably underlined by the Parliamentary Assembly, which guided and supported this process, in its opinion on the final draft.

Praising this process, the Parliamentary Assembly rapporteur (Mr Palacios) spoke of “the calm, but positive way in which disagreements have been expressed”, and indeed the importance of remaining calm and positive when dealing with such sensitive issues cannot be overstated.

The aim of protecting fundamental values and progress, and the emphasis which the Council of Europe places on dialogue, were crucial here. And remain so today.

20 years on, this Convention has become a benchmark not only within Europe but also worldwide. The high-level seminar on international case-law in bioethics, held in December 2016, confirmed this. The reference to the Convention in the UNESCO Declaration on Bioethics and Human Rights and the provisions of the EU Charter of Fundamental Rights are a further testament to its importance.

This is a cause for celebration, as are the advances in biomedicine and the improvements in human health that we have seen over the past 20 years.

Given the extremely rapid – sometimes dizzying – speed with which science and technology and their potential applications for human beings are developing, however, the concerns which informed the drafting of the convention 20 years ago are still highly relevant today.

Today's celebrations are also an occasion to remind ourselves of the need for constant vigilance in relation to any development that could pose a threat to fundamental human rights.

It sometimes seems as though old certainties are crumbling; traditional boundaries are becoming blurred; the driving forces and key players are changing.

Developments in science and technology can be seen as a continuum yet one wonders whether perhaps we have now reached a new, unusually critical stage, given the possibilities for controlling or even modifying human life that their potential applications afford.

The time has come for debate, one that concerns all citizens.

As pointed out in Article 28 of the Convention, “*Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications.*”

Ethics committees can play a key role here. The fact that representatives from several of these national committees as well as ethics bodies at European and international level are present here today seems to me to be very important in this context.

Providing courses on ethics, not only for the professionals concerned but also for teachers and the public at large, likewise helps to raise much-needed awareness of these issues.

The Council of Europe is doing its bit here. The development of a course on the basic principles of bioethics for legal and health care professionals, under the HELP programme, meets this requirement.

Ladies and gentlemen,

The issues that you are going to be discussing today are central to the Council of Europe's remit. Since the 1980s, it has maintained constant vigilance in this area. Through its mission, but also by promoting dialogue and discussion, it has paved the way for the adoption of the Oviedo Convention, which brings us here today.

The Czech Republic's decision to make this conference one of the priorities of its Chairmanship of the Committee of Ministers of the Council of Europe shows the relevance and importance of our Organisation's work in this area. And I would like to thank the Czech Republic for that and for its decision to sign, at this conference, the Additional Protocol to the Oviedo Convention concerning genetic testing for health purposes. We can only hope that signature is swiftly followed by ratification, so that the Protocol can enter into force. A fitting symbol for the country which gave us Gregor Mendel!

More than ever, the basic principles laid down in this Convention and the kind of dialogue cherished by the Council of Europe are essential in order to address the new human rights challenges raised by science and technology.

Protecting human rights and encouraging advances in biomedicine for the benefit of humankind also means building trust.

I am confident that this conference will contribute to these objectives and provide a sound basis for the action that will need to be taken in response to the priorities identified. I wish you every success.

## Ms Nada Al-Nashif

### UNESCO Assistant Director-General for Social and Human Sciences



*Nada Al-Nashif took up her duties as Assistant Director-General for Social and Human Sciences at UNESCO on 16 February 2015.*

*She is the holder of a BA in Philosophy, Politics and Economics (1987) from Balliol, Oxford University and a Master's in Public Policy (1991) from the Kennedy School of Government, Harvard University.*

*Prior to joining UNESCO, she served (2007-2014) as Assistant Director-General/Regional Director of the International Labour Organization's Regional Office for Arab States, based in Beirut, Lebanon. Previously she worked at UNDP, where she started her UN career in 1991, serving in Libya (1992-1995), Lebanon (2000-2004), Iraq (2003) and at Headquarters*

*in New York (1995-2000, 2005-2006).*

*As a development economist and practitioner, she serves in an advisory capacity on several boards, notably the Boards of Trustees of Birzeit University and the Human Development NGO, Taawon.*

## Dr Octavi Quintana (Spain)

**Director of the Partnership on Research and Innovation in the Mediterranean Area (PRIMA), European Commission; former Chair of the Council of Europe Steering Committee on Bioethics (CDBI)**



*Octavi Quintana is a physician by training, specialist in Critical Care and MPH. After 10 years working as an attending physician he started on management positions in the health care system in Spain including director of the Malaga Regional hospital and deputy director general of the SNS (National Health Service). He started working in the CoE in 1986 as delegate of Spain in the CAHBI which later became the CDBI. He served as chair for a couple of years during the drafting of the European Convention on Bioethics. He left the Council of Europe in 2000. In 1996 he was appointed as member of the European Group of Ethics advising the President of the European Commission where he served until 2001 when he*

*was the vice chair. In 1993 he started working on Humanitarian Aid with an NGO mainly in the Great Lakes Crisis in 1994-7, in Bosnia in 1996-8, and in Kosovo in 1999.*

*On 2002 while he was the director for International Affairs of the Ministry of Health in Spain he was appointed as director for Health Research at the European Commission where he has been since as director of Energy Research and director of the European Research Area.*

*Since last month he is the Director of a R&I program with Mediterranean countries called PRIMA.*

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Excellencies, distinguished guests, dear colleagues and friends, Ladies and Gentlemen,

it is a pleasure to be here today, at the occasion of the twentieth anniversary of the European Convention on Human Rights and Biomedicine of 1997, the Oviedo Convention. It is not only an occasion to celebrate, it is an important opportunity to critically assess the achievements of the Conventions as well as - most importantly - reflect on what is needed to keep the Convention relevant, alive and impactful. And indeed, the programme of this conference is designed to inform the Council of Europe as to its next steps. So thank you for inviting me on this occasion, I feel very honored to have been invited as former Chair of the Steering Committee on Bioethics (CDBI).

According to some, the Oviedo Convention is 'the best current example of how to promote the protection of human rights in the biomedical field at a transnational level'.

While this might be true, I would like to give you a flavor of the discussions that took place at the time - as I believe there is much to be learned from these discussion as well as the history of the convention when it comes to the nature of research- and bio-ethics in general, as well as the possibilities and limits as to arriving at binding, 'eternal' rules in the area of biomedical law.

I first served as Spanish representative in the Ad Hoc Committee of Experts on Bioethics (CAHBI), the 'precursor' of the CDBI created in 1985, and in the beginning we sought over several years to come up with ground rules to guide scientific research in humans. While at first we focused on the area of genetic research, we realized that a much wider area would need to be elaborated. And then, instead of having different texts of interrelated issues, the very ambitious idea of developing one single Convention, the first legally binding international instrument setting European standards in the area of biomedicine, took shape.

As to the wider context, it is important to keep in mind that bioethics as well as research ethics as disciplines did not have the status in academia they have today, and the 'bioethical landscape' and structures enacting its principles were rather weak at time: while ethics and research committees existed in some countries, their methodologies were quite disparate, and National Ethics Councils for example were by no means the standard, for example.



In 1990, CAHBI was tasked to 'examine the possibility of preparing a framework convention, open to non-member States, setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences.' And the shift of name of the committee is significant – the AD HOC committee became a 'comite directeur' precisely because it was evident that the ethical deliberations accompanying the changing practices and scientific progress would indeed be necessary.

Coming up with a framework was an extremely ambitious endeavor, to say the least: very quickly, we – experts acting as state representatives with clear and strict instructions from our home countries – were faced with the impossible task to reconcile opposing points of view on a range of subjects.

For example, the discussion as to status of the embryo in scientific research, proved to be an extremely difficult discussion, and it represented a turning point as it made us understand that in some areas all we could best hope for would be a minimal standard: and indeed, all we could agree on in

'Article 18 – Research on embryos *in vitro*' is the following:

1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
2. The creation of human embryos for research purposes is prohibited.

Our difficulties in coming up with substantial agreements in some areas were by no means accidental of course: they were the result and expression of fundamentally incommensurable points of views and even 'world-views', of philosophical, religious and moral nature, informed by historical experiences.

As a way of seeking to overcome these difficulties, all the while respecting these deeply held diverging convictions, the Parliamentary Assembly recommended in 1991 to elaborate "a framework convention comprising [...] general principles and additional protocols on specific aspects", and the CAHBI (thereafter CDBI) came up with a first draft in July 1992, open for public consultation.

The result in terms of content we came up with you will all be very familiar with. So let me just name its main characteristics: the Oviedo Convention represents a binding instrument at the intersection of human rights and health law, it takes a comprehensive approach to bioethics, and it is a framework instrument which defines minimum agreements. As to the implementation of the convention: it is the responsibility of each state, and it is also up to the states to provide for appropriate judicial protection detailed in the convention.

The fact that the Convention describes minimum agreements is key when it comes to assessing the Convention: this 'minimalist approach' was chosen in face of the impossibility to come to a more substantial agreement in terms of content, and cannot be interpreted as an expression of a 'liberal bioethics', legitimizing what is not prohibited.

What did we manage to agree on back then?

For the first time in history, a framework was established, based on ethical principles derivative of and designed to safe-guard human rights in the area of biomedicine and biomedical research. – for example, the principle of informed consent, and most importantly in my view, the principle of freedom of research.

And it is important to note that in our discussions we understood the principle of freedom of research to be a fundamental one, which could not be arbitrarily be restricted but which needed to weighed against other principles. And while at individual level we uphold the 'right not to know', the freedom of research as basic right itself has not been challenged.

The final text was adopted by the Committee of Ministers in November 1996, and opened for signature in Oviedo, Spain, in April 1997. After the fifth ratification by Spain, the Convention entered into force in December 1999. Today, the Convention has been signed ratified by 29 states. Some countries still chose to abstain, and for very different reasons – some because the Convention is thought to be too permissive in some areas, and others because they think it is too restrictive.

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Ultimately, the text of the Convention was the result of a pragmatic approach, without which we probably would not have managed to come up with a text at all. This is also reflected in Article 27 which foresees that each signatory state has the right to come up with a 'wider measure'.<sup>1</sup> The Convention thereby leaves it up to subsidiarity, so that each country takes its own decision, while not imposing its standards on others either.

Another dividing line worth mentioning amongst the drafting group members of the Convention concerned our meta-views as to what bioethics is supposed to achieve: while some of us argued that the bioethical reflection was to provide definite limits and prohibitions, others upheld the view that the bioethical endeavor would be best understood as a common methodology which would allow, based on key principles, to frame and inform the discourse in society which is to accompany our ever evolving practices, scientific and technological advances in the biomedical sciences. Still, while we held different views on this, in the end it was foreseen – applying the precautionary principle as it were - that the Convention be periodically reviewed, and amended if necessary (Article 32), which I believe is a rather modern way of approaching a Convention.

Now, if I may do some expectation management - trying to answer the question as to the impact of the Convention in detail would be an entire academic research project in itself.

When reflecting on the lessons learned though, it is worth looking into areas in which the Convention foresaw a strict prohibition – that is Article 18 and the prohibition of human cloning [insert article/cite it]:

At the time of drafting of the Convention, we were not even in the position to foresee the creation of human embryonic stem-cell lines, nor the creation of 'Dolly' or the CRISPR-Cas technology and the multiplicity of possibilities it holds. Now while we cannot infer from this that strict prohibitions in the area may never be justified, what it does tell us though is that prohibitions in specific cases may be time-limited: as our scientific and technological knowledge changes, new and unforeseen possibilities of interventions emerge, as well as changing practices which may in turn impact on our values, deeply held beliefs, as well as what counts as convincing argument, and ultimately bring about paradigm shifts as to our practical judgments in the area of bioethics and research ethics.

Ultimately, I think **bioethics might be best understood as being a culture of limits**: its challenge and first aim is to align fundamental principles and our deeply held beliefs with the evolving practices in the biomedical field and the possibilities brought about by research. Or to put it differently: the role of bioethics should be to accompany progress in these areas and keep these in an 'reflective equilibrium' with our deeply held beliefs and fundamental principles. For this reason, the role of bioethics should and has always been, to foster the public debate. The aim is not necessarily be to bring about agreements, but spelling out the arguments, all the pros and cons, as well as their implications, in a first instance.

To provide just two examples:

1. Advances in the area of artificial reproduction, which challenges the notion of father-hood, motherhood as well as family-hood. Here the role of bioethics is to spell out the rights at stake, the implications it has, and to put these up for discussion in the public sphere – not so much to arrive to a definite conclusions, but as to enable an informed public dialogue which spells out all the relevant implications.
2. Another example this audience will be acutely aware of, is the area of gene editing – a very clear example bioethics needs to accompany the progress science and delineate again, refine and assess weighing fundamental ethical principles what is permitted and what is not.

A recommendation adopted just recently by the Parliamentary Assembly of the Council of Europe (12 of October) states that 'recent discoveries related to the human genome have opened the door to new opportunities and unprecedented ethical concerns. On the one hand, this improved knowledge of our make-up as human beings brings with it welcome potential to diagnose, prevent and eventually cure diseases in the future. On the other hand, it raises complex ethical and human rights questions,

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<sup>1</sup> Article 27 – Wider protection

None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.

including – but not limited to – unintended harm which may result from the techniques used' and including 'their potential abuse for enhancement or eugenic purposes.'

While the scientific community considered some of these techniques as not “safe”, leading to a de facto moratorium, other techniques, like pronuclear transfer technology (the “three-parent” technique) - used to avoid maternal inheritance of mitochondrial disease, have been applied and resulted in the birth of two babies (one of them for reasons other than the treatment of mitochondrial disease). Deliberate germline editing in human beings crossed a line articulated in Article 13 of the Oviedo Convention which states that : “An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modifications in the genome of any descendants”.

The recommendation calls for an assessment of the ethical and legal challenges raised by genome editing technologies by the CDBI, in the light of the principles laid down in the Oviedo Convention, and recommends the development of a framework 'which is able to balance the potential benefits and risks of these technologies aiming to treat serious diseases, while preventing abuse or adverse effects of genetic technology on human beings'. It also recommends to foster a broad and informed public debate in the area.

It is worth noting that this recent recommendation exemplifies and mirrors the principles invoked, as well as the methodology – the weighing of principles - and stresses as well the importance of the need for a public debate – all elements of the Oviedo convention drafted over 20 years ago and still valid today.

In which way has the Convention provided 'a starting point', and still provides one today? I believe the Convention has provided 'a starting point' by setting out basic principles, exemplifying itself a methodology in bioethics and research ethics, and – I believe this is very important - by insisting on the need for continued public debate. Moreover, the Convention foresaw mechanisms as for its review and its further evolution, taking into account the inherent open-endedness of the sciences and evolving practices.

As to the achievement of the Convention, let me highlight just one area which I am most familiar with – the area of research: The Convention has given rise to a much more structured landscape in the area of research ethics, it inspired national legislations in the area and thereby brought about a much more harmonized approach - within the member States and signatories of the Convention, and certainly within the EU. It brought about the creation of institutions, methodologies and processes for the review and monitoring of research projects, therefore enabling and ensuring researchers – and especially those working in the area of 'frontier research' – that their research takes place based on sound ethical principles. And while not all cases of frontier research may always be covered by national laws – the Convention has the beauty of having brought about a methodology based on which difficult cases may be assessed.

The Oviedo Convention has provided a key reference text providing the ethical rules governing promotion of research by several EU research programmes. Without a harmonized approach and structures for ethical review at national level, it would be impossible to promote research at EU level – within the EU and world-wide – on a sound ethical and legal basis.

And this harmonized approach would probably not exist if it weren't for this Convention. Last but not least, I believe the Convention also provided an impetus and paved the way for establishing new National Ethics Councils, many of which have a mandate to foster public debate in the area. [UNESCO DECLARATION OF BIOETHICS, WHO]

**Now, as to what would be my best hope for the future of Convention, and what could help make it come true?** The Convention came to bear fruit and is inherently dependent upon the well-functioning of democratic institutions and laws which – despite some worrying developments in the world – we still take for granted.

While I do very much believe that institutions, laws and review process are key and should be strengthened, I also think we should be mindful as to not allow that bio- and research ethics turn into a sterile, perceived as necessary, but ultimately bureaucratic exercise for researchers and medical professionals. Bioethics and research ethics are inherently linked to and safe-guard human rights principles, and the answers to many of the questions raised by the progress of the life-sciences touch

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one of the most important questions, as to 'how do we want to live?' - as individual and as societies, and this is not a question rational arguments alone - the emotions, cultural traditions and spiritual beliefs and world views have a role in determining this.

Looking at the controversies in the biomedical field we face today, I believe more than anything these controversies need to be spelled out in public debate, and engage the public. And here - whether it is the national ethics committees, research ethics committees, medical societies, research institutions, funding agencies and their scientific councils, but also medical doctors and individual researchers - all actors involved have a role to play.

I hope these thoughts and have provided a helpful starting point and I wish you an inspiring and productive conference! Thanks for your attention.

### Prof. Dr. Dr. h.c. Ludger Honnefelder (Germany)

**Professor emeritus of Philosophy, Friedrich-Wilhelms University, Bonn; former member of the Council of Europe Steering Committee on Bioethics (CDBI)**



*Ludger Honnefelder (1936) is Professor emeritus of Philosophy at the Rheinische Friedrich-Wilhelms-Universität in Bonn (Germany). He was Professor at the Universität Trier (1972-82), the Freie Universität Berlin (1982-88) and the Universität Bonn (1988-2001). He was Guardini Professor (2005-2007) and Otto Warburg Senior Research Professor of Philosophy (2009-2012) at the Humboldt Universität zu Berlin. Since 1989 he is member of the Nordrhein-Westfälische Akademie der Wissenschaften und Künste (Düsseldorf).*

*L.H. was director of the Institute of Science and Ethics and the German Reference Center for Ethics in Life Sciences at the Universität Bonn (1992-2005). He was member of the Steering Committee on Bioethics of the Council of Europe (CDBI: 1994-2011) and the Committee of the Deutscher Bundestag on Law and Ethics of Modern Medicine (2002-2004). Since 1998 he is member of the Permanent Working Group on Science and Ethics of All European Academies (ALLEA).*

#### ► “How to protect Human rights in the face of current biomedical developments? The significance of the Oviedo Convention”

What to do when the scientific progress in biology and medicine opens not only new ways of curing diseases, but at the same time allows applications which could endanger human rights and dignity? When the *Council of Europe* 20 years ago decided to draft a new convention, it was obviously necessary to depart from the *ECHR*, the basic document for the *Council's* central task to protect human rights and dignity. But the legal regulations which now were necessary could not be simply deduced from the general norms of the *ECHR*. In the *ECHR* the concept of human dignity is presupposed as the basic value, but is 'defined' only by prescribing requirements against its violation. For drafting a more detailed convention and additional protocols it was therefore necessary to go back to those ethical convictions which are lying 'behind' the legally defined norms of the *ECHR* and the fundamental rights that are part of the various national constitutions and some other international documents. However, it was important in addition to identify between the potential signatories an overlapping consensus of how human dignity should be protected actually, i.e. in face of the new practices. Of such a consensus the experience of real or potential misuse and suffering is an important source. The *Oviedo Convention* and the additional protocols can be considered as a paradigmatic procedure of updating the Human Rights Idea by a process of case and norm driven interpretation of the inviolability of human dignity.

## Prof. Sheila Jasanoff (USA)

Pforzheimer Professor of Science and Technology Studies, Harvard Kennedy School, Harvard University



*Sheila Jasanoff is Pforzheimer Professor of Science and Technology Studies at the Harvard Kennedy School. A pioneer in her field, she has authored more than 100 articles and chapters and is author or editor of a dozen books, including Controlling Chemicals, The Fifth Branch, Science at the Bar, and Designs on Nature. Her work explores the role of science and technology in the law, politics, and policy of modern democracies, with particular attention to the nature of public reason. She was founding chair of the STS Department at Cornell University and has held numerous distinguished visiting appointments in the US, Europe, and Japan. Jasanoff served on the Board of Directors of the American Association for the*

*Advancement of Science and as President of the Society for Social Studies of Science. Her grants and awards include a 2010 Guggenheim Fellowship and an Ehrenkreuz from the Government of Austria. She holds AB, JD, and PhD degrees from Harvard, and an honorary doctorate from the University of Twente.*

### ► An Ethic of Integration: Novel Biotechnologies and Human Dignity

A 20<sup>th</sup> anniversary is a good time to take stock of time's passage and its effects on experience and understanding. In the case of the Oviedo Convention these decades roughly coincide with a period that many have characterized as the era of convergent technologies. When the Convention was opened for signature, one could speak of the biomedical field as a domain of its own. Today that "field" is tightly interwoven with developments in computer science, artificial intelligence, materials science, and cutting-edge biotechnologies that have greatly complicated the questions of concern to the instrument's authors. In this talk, I will address the fragmentations, reductions, and recombinations of the human associated with today's technological developments and the role of transnational bioethical agreements, such as the Oviedo Convention, in safeguarding concepts such as dignity and integrity. How can human dignity be protected in the practices of biology and medicine when the boundaries of the human appear blurred and distributed as never before? How, moreover, can norms be implemented across legal and political cultures with divergent understandings of state responsibilities and the rule of law? Three approaches to accommodating diversity will be discussed and evaluated: coexistence, cosmopolitanism, and constitutionalism. Illustrations will be drawn from areas where old norms have been reopened for questioning, such as the 14-day rule for embryo research, and those where no internationally accepted norms are as yet in place, such as gene editing and the development of synthetic "organoids."

## Prof. Dr Zvonko Magić (Serbia)

### Chair of the Preparatory Group for the Conference



*Professor Zvonko Magić MD, PhD is Head of Institute for Medical Research at MMA, Belgrade since 2012. After graduation at the Medical School University of Belgrade he completed several courses in genetic engineering at home and abroad, specialization from clinical physiology and sub-specialization from oncology. His main occupation is research in the field of molecular oncology and bioethics. Leading researcher in many project financed by Ministry of Science and Education. Professor Zvonko Magić participated significantly in organization of UNESCO PPAGET and GENEDUNET (2005-2007) projects in Serbia and in two meetings with CoE (bilateral 2007 and regional 2010), DEBRA program.*

*Professor Zvonko Magić is teacher of Human Genetic, Oncology and Medical Ethics at Medical School. Lecturer on the PhD studies at Faculty of Science, University of Belgrade ; Medical Faculty in Kragujevac and Foča (B&H). Co-chairman of the National Committee for Bioethics of UNESCO-Commission of Serbia.*

*Membership: Medical Academy of Serbian Physicians Association ; Balkan Union of Oncology ; Serbian Genetic Society ; Member of the Ethics Committee of the MMA ; Member of UNESCO International Teachers Forum for bioethics ; Member of Center for the Study of Bioethics (Faculty of Philosophy, Belgrade) ; Member of DH-BIO of the Council of Europe.*

## Mr Hans-Jörg Behrens (Germany)

### Vice-Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe



*Born 22. October 1962, Braunschweig, Germany*

*Law studies in Marburg and Göttingen*

*LL.M. King's College London 1989*

*Legal doctorate (Dr. iur.), Göttingen 1991*

*Joined Federal Ministry of Justice August 1991*

*Member of German Team for the creation of the International Criminal Court, including Rome Conference (Member of Drafting Committee), 1996 - 1999*

*Head of Cabinet and Parliament Liaison Office, Federal Ministry of Justice, 2001 to 2005*

*Deputy Commissioner for Human Rights and Co-Agent before the ECHR, 2005*

*Head of Human Rights Office and Agent before the ECHR, 2010*

*Representing Germany in Council of Europe bodies*

*DH-PR, including working groups, since 2005*

*CDDH-UE (accession of EU); 47+1 (accession of EU)*

*CDDH since 2010*

*Bureau of the CDDH since 2013*

*Vice-Chair of the CDDH since 2016*

*Participation in Interlaken and Brighton Conferences*

#### ► Outcome of the high-level seminar organised on 5 December 2016 at the European Court of Human Rights

The main objective of the seminar was to assess the evolution of cases - both before the ECHR and on the national level – in the field of biomedicine and ethics.

The number of cases involving bioethical questions has grown substantially since the beginning of the 2000's. The following relevant topics were touched upon during the seminar:

- The concept and possible limits of **personal autonomy** (for example when a patient desires life-ending treatment)
- The **right to privacy**, together with the **principle of informed consent** **Data protection** and the **right to be informed** (including the right to know about one's genetic origins)
- The consequences **of increasing mobility between States** with different legal frameworks where specific treatments are prohibited in one country while being allowed in another ("medical tourism")
- **Surrogacy** is also relevant in this context: there exist many different scenarios, some of which have already been brought before the ECHR, others not yet
- The concept of the "**child's best interest**"

The seminar concluded that there was a need for clarification of terms and definitions as well as guidance on the content of certain legal notions. On the way forward, the importance of training for professionals both in the medical and the legal profession was highlighted. The CoE – especially DH-BIO – can provide very helpful information with regard to the legal situation in Member States on specific issues.

► **Full text**

We have heard this morning keynote speeches about the Oviedo Convention and the interaction between Human Rights and the continuing development of biotechnology and biomedicine.

I have now the honour to present the results of a high level seminar that took place just across the street in the European Court of Human Rights almost a year ago, bringing together judges from the ECHR and other eminent courts, academics and other experts. The seminar aimed to analyse the international case-law on bioethics. I will endeavour to summarize the discussions and convey to you the conclusions of the seminar.

At the outset, it is probably necessary to clarify the term “bioethics”. The most helpful definition given during the seminar was “the protection of the human being, his or her human rights and in particular human dignity in the context of the development of biomedical sciences”. With this broad definition as a starting point, the seminar went on to discuss a number of topics that have arisen in cases before national and international courts, in particular before the ECHR.

It is significant that in recent years the importance of this field of law has risen considerably. This is evident in the steadily rising number of “bioethics” cases before the ECHR. An impressive research report by the ECHR’s research division, done in October 2016<sup>2</sup>, lists 125 cases; all but one decided since 2000; that is, within the lifetime of the Oviedo Convention. Even more significantly, the number has doubled since the previous report, which was published in 2012. There is no doubt that science and technology will continue to provide new challenges for law and courts.

I will now turn to some of the topics that have been addressed at the seminar.

While the European Convention on Human Rights in its Article 2 states that everyone’s **right to life** shall be protected by law, the question of when life in this sense begins has not been determined by the Court. The Court has declared in 2004<sup>3</sup> (and repeated in 2015<sup>4</sup>) that the question whether an unborn child is a person cannot be answered in the abstract.

On other issues in this field, there have been decisions which have left a wide margin of appreciation to the Member States in their national regulations. This is the case with regard issues of medically assisted procreation, such as ovum donation.

With regard to the end of life, several cases have dealt with the difficult balancing of the right to life and the right to respect for private life and personal autonomy. The Member States are far from united in their approach towards the individual’s right to decide how and when their life should end. Taking this into account, the court has accorded the Member States a considerable margin of appreciation when legislating in this field. In the current state of the law in Member States, access to assisted suicide in specific circumstances, for example, is provided only in a few countries. Some systems accept “passive” assistance; others do not. Having regard to the moral and ethical nature of these questions, it is reasonable that the Court has accepted a wide spectrum of rules as compatible with the Convention. However, the Court has also made clear that the act of balancing the conflicting fundamental rights and obligations must be done diligently. Another aspect that I will touch upon in more detail later is the fact that increased mobility opens the road to circumvention of national legislation.

The **right to privacy** is protected in Article 8 of the European Convention on Human Rights. At the time of its drafting, it was probably not foreseen how this concept has expanded now to include genetic data. Article 8 also includes the **principle of informed consent** which is enshrined in Article 5 of the Oviedo Convention. Here, there is a close connection between the two Conventions, and this connection has found its way into several ECHR decisions which explicitly mention the Oviedo Convention in their reasoning. The protection of sensitive medical data was also mentioned as one of the areas where the specific right included in Article 10 of the Oviedo Convention has been taken into account in ECHR jurisprudence on the protection of private and family life.

Another part of the protection of private life is the **right to personal development** which may take on many different aspects. One aspect that has been dealt with by the ECHR is the right to know one’s

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<sup>2</sup> European Court of Human Rights: Research Report Bioethics and the case-law of the Court, updated 20 October 2016

<sup>3</sup> *Vo v. France* [GC], no. 53924/00

<sup>4</sup> *Parrillo v. Italy*, [GC] no. 46470/11



biological identity; that is, the right to know about one's biological parents. In many cases, this right needs to be balanced against another person's right to privacy. The different and often difficult choices can be traced in the court's jurisprudence<sup>5</sup>.

Another aspect of this right is the treatment of transsexuals. The landmark decision of *Goodwin vs. UK* (2002)<sup>6</sup> has highlighted the personal right to establish the details of his or her identity.

The topic of **surrogacy** was mentioned by several speakers in the seminar. This is not surprising since the factual and legal situations that have to be dealt with by national jurisdictions and often finally by the ECHR are manifold and new developments are sometimes not foreseen by legislators. However, the ECHR is in general less concerned with national regulation of surrogacy as such but with the consequent status of the children concerned. In particular, it is concerned with the status of children born abroad following surrogacy treatment which are then brought to a country where this specific surrogacy treatment is prohibited. In other words, what happens to the status of children brought into being in conscious contravention of the national law (which in itself is in conformity with the Convention)? The Court has in its judgments always considered the children's best interest to be of paramount importance.

This, however, leads to a more fundamental question: How does one enforce ethical rules established by law – again, rules established in accordance with Human Rights and international public law – when there are nowadays ways to circumvent them?

And there is also a social question involved here, that was touched upon quite rightly in the conclusions of the seminar: These possibilities exist – if you are rich enough to pay for them. What does that mean for our society and for the rule of law? We can see that bioethics may quickly lead to questions of ethics in a more general sense.

Coming to the **conclusions** from the seminar, it is difficult to state any "result". If one thing is clear in this area of law and ethics, it is that this is constantly evolving. Medical, scientific and technological progress are continuing to pose new and ever more difficult legal problems. It is therefore consequent that Professor Nußberger, the Vice President of the ECHR, has in her concluding speech of the seminar not given answers but rather formulated three questions as the essence of the discussions:

- First question: In the matters that were discussed and that I have attempted to outline, who should decide?

There are several levels of potential decision-makers, from the person concerned and his or her family via treating medical doctors, ethics committees, courts right up to the legislators, and ultimately to society as a whole. On each level, conflicting interests may intervene. The effort of balancing conflicting rights falls on all the actors within their respective competences.

- Second question: How should these matters be decided? Which aspects need to be taken into consideration?

Since legal and ethical concepts differ widely in an international context, it is important to take cultural, historical and social traditions and underlying approaches into consideration. Even quite fundamental concepts like human dignity may be viewed differently in different societies. International courts must be aware of these divergences.

- Third question: How much regulation do we need at all?

Here, too, the concept of "margin of appreciation" plays an important role. International oversight is necessary – but it should be careful to use the necessary judicial restraint.

Last year's seminar has indeed given us more questions than answers – but that was neither the fault of the participants nor that of the courts whose jurisprudence was analysed. It is the nature of the topic of "bioethics" to present a continuing challenge for law and ethics. We will have to come to terms with these challenges precisely by putting the right questions.

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<sup>5</sup> See e.g. *Odièvre v. France*, [GC] no. 42326/98; *Jäggi v. Switzerland*, no. 58757/00

<sup>6</sup> [GC] no. 28957/95

## RAPPORTEUR

Ms Isabelle Erny (France), Head of the Bioethics and Patients' Rights Division of the Division of Users' Rights and Legal and Ethical Affairs at the General Secretariat of the Directorate-General for Health, Ministry of Solidarities and Health; member of the DH-BIO



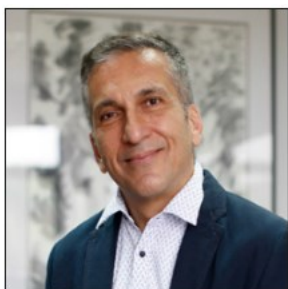
*Mrs Isabelle ERNY holds a Masters degree in civil law from the Law Faculty at the Robert Schumann University of Strasbourg (France) and is a graduate of the National School of Public Health (ENSP) in Rennes, where she began training in 1979 to be an Inspector of health and social affairs. On her graduation, she was appointed to the Directorate of Social Security in the Ministry of Social Affairs.*

*As a senior principal administrative officer since 1994 at the Directorate General of Health (DGS) in the Ministry of Social Affairs and Health, she is currently head of the department for bioethics, patients' rights and the rights of users of the health system within the Rights of Users, Ethics and Legal Support Division (DDUAJE), where she is in charge of cross-sectoral and ethical and legal monitoring of the activities and texts of the various ministries relating to bioethics, medical ethics, patients' rights and the rights of users of the health system.*

*Since 1994 she has been a member of the French interministerial delegation participating in the intergovernmental work of the Council of Europe in the field of bioethics carried out by the Steering Committee on Bioethics (CDBI) until 2011 and then by the Committee on Bioethics (DH-BIO) since 2012. She was a member of the Bureau of the CDBI from 2002 to 2008, being elected to serve as Vice-Chair of the Bureau from 2005 to 2006, and then as Chair from 2007 to 2008. In 2010, she was asked by the CDBI and then by the DH-BIO to co-ordinate the drafting of a "Guide on the decision-making process regarding medical treatment in end-of-life situations" as a follow-up to the symposium held in Strasbourg in November 2010.*

## RAPPORTEUR

Prof. Constantinos Phellas (Cyprus), Vice Rector for Faculty & Research University of Nicosia, Chairman of the Cyprus National Bioethics Committee; member of the Bureau of the DH-BIO



*Professor Constantinos Phellas is the Vice Rector for Faculty and Research at the University of Nicosia. Prof. Phellas received an MSc in Management Science and Operational Research from the University of Warwick, UK and an MSc in Advanced Social Research Methods and Statistics from City University London, UK. In 1998, Prof. Phellas obtained his PhD in Medical Sociology from the University of Essex, UK.*

*Prof. Phellas has nearly two decades of teaching experience both in the UK and Cyprus and has been involved in several research projects funded by the Cyprus Research Council, the United Nations Development Programme (UNDP), the Ministry of Health, as well as, the European Commission. Since 2004, he has served as the Executive Director of the Cyprus Medical Research Institute (NGO) which aims to improve understanding of the social and psychological processes and mechanism which influence the physical, psychological and mental health and well-being of the Cypriot population. He is also the Executive Director of the Cyprus Gerontological Research Center (NGO).*

*Between 2008 and 2011, he was Dean of the School of Humanities, Social Sciences & Law at the University of Nicosia. He has served as a consultant to various organizations including, among others, the World Health Organisation (WHO), Europa Donna Cyprus, the Cyprus Ministry of Health, the Council of Europe, the European Commission and the Bank of Cyprus Oncology Centre.*

*Prof. Phellas also serves as an Evaluator for European Funding Agencies and holds various official European and Governmental appointments; among others, he is the Chairperson of the Cyprus National Bioethics Committee. Prof. Phellas has published extensively and has attended several international conferences as an invited speaker.*

## CHAIR

### Ms Ina Verzivolli (Albania), Chair of the Ad hoc Committee for the Rights of the Child (CAHENF) of the Council of Europe



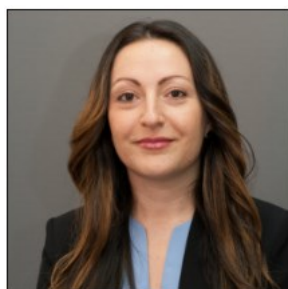
*Ina Verzivolli is the Chairperson of the Albanian State Agency for Child Rights and Child Protection, the agency mandated with monitoring the implementation of the rights of the child in Albania as well as the lead agency in child protection. She is dedicated to strengthening the protection of children's rights in Albania, with a particular focus on building an effective and integrated child protection system. Ms Verzivolli has led the process of drafting of new legislation on child rights protection, the national action plan for child rights and is currently involved in the coordination of the plan of action for the protection of children in street situation.*

*She is also involved with child rights at the international level and is currently the chairperson of the Ad Hoc Committee on the Rights of the Child of the Council of Europe, as well as member of the Lanzarote Committee for the Protection of Children from Sexual exploitation and abuse. Since 2014, she is the national focal point for the Council of European Network of Children's Rights Coordinators.*

*Ms Verzivolli has graduated in International Development Studies M.Sc. at the Geneva Graduate Institute (HEID). She has previously worked on the issues of child's right to health, food and nutrition, business and human rights, women's rights and sustainable livelihoods. She has a broad experience in international advocacy working closely with international organisations and human rights bodies, and in particular the Committee on the Rights of the Child.*

### Dr Kavot Zillen (Sweden)

#### LL.D and postdoctoral researcher, Faculty of Law, Stockholm University



*Kavot Zillén holds a doctoral degree (LL.D) in Medical Law from Uppsala University in Sweden and is currently a post-doc researcher at the faculty of law, Stockholm University Centre for the Rights of the Child (Barnrättscentrum). Her dissertation focuses on human rights in health care, specifically: the right to health, freedom of religion and the prohibition on discrimination. Her current research is on EU-migrant Children's Right to Healthcare in Sweden. Her position at the Faculty of Law involves research and teaching in the field of medical law, social rights law, administrative law, and human rights law. She has been the Course Director for a Medical Law course at the Faculty of Law and responsible for*

*a course on freedom of religion in secular and religious cultures at the Faculty of Theology in Uppsala. Since 2014 she has been teaching a summer course, together with a colleague, at the Summer Institute in Bioethics at Yale University on comparative human rights and health.*

#### ► Challenges raised by the evolution of practices for children rights

In June 2016, The Committee on Bioethics of the Council of Europe commissioned a study conducted by myself and two other medical lawyers at Uppsala University in Sweden, Dr. Jameson Garland and Dr. Santa Slokenberga, with the aim to mapping potential areas of heightened concern for the rights of children that may be adversely affected by scientific advances and uncertainties in biomedicine. Some of the areas identified in our report gave rise to questions with regards to children's right to autonomy – consent and privacy, which is the focus for this presentation. The presentation will start out by briefly describing the child's right to consent and private life in the Oviedo Convention (Article 5, 6 and 10). Thereafter examples from our report (Uppsala report) will be used to demonstrate how

scientific risks and uncertainties in the biomedical field may affect children's right to autonomy, in a variety of ways.

### Dr Santa Slokenberga (Sweden)



*Dr Santa Slokenberga represented Dr Kavot Zillen at the conference.*

### Prof. Dr. Ton Liefwaard (Netherlands)

Professor of Children's Rights/UNICEF Chair in Children's Rights, Law School, Leiden University



*Prof. Dr. Ton Liefwaard is a Professor of Children's Rights and holds the UNICEF Chair in Children's Rights at Leiden Law School, Leiden University, the Netherlands. He is the programme director of the Master's Programme (LL.M) Advanced Studies in International Children's Rights. He teaches and publishes widely on issues related to children's rights, juvenile justice, child friendly justice, child protection, alternative care and violence against children. He also coordinates the Leiden Summer School on International Children's Rights. Ton Liefwaard is a honorary juvenile judge at the District Court of Amsterdam, a member of the Council for the Administration of Criminal Justice and Protection of Juveniles, the Netherlands and a former member of Dutch Government Committee on the Reassessment of Parenthood. He regularly works as a consultant for international organizations, including UN agencies, the Council of Europe and the European Union. In 2015, he received the award for best lecturer of Leiden Law School in 2015. Ton Liefwaard holds a Master and a PhD in law from the VU University Amsterdam.*

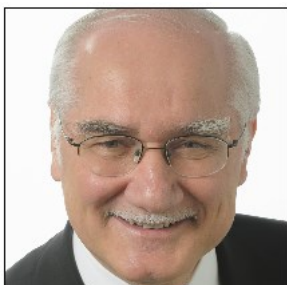
#### ► Action(s) to be undertaken at intergovernmental level to address the identified challenges

The presentation will begin with a brief review of the Leiden University report "From Law to Practice: Towards a Roadmap to Strengthen Children's Rights in the Era of Biomedicine" (Liefwaard, Hendriks & Zlotnik 2017), commissioned by the Council of Europe Committee on Bioethics. It will present the scope of the report and its analysis of children's rights and biomedicine from an international and European perspectives, particularly focusing on the Council of Europe Convention on Human Rights and Biomedicine ("Oviedo Convention") and its additional protocols.

The presentation will outline that developments in biomedical care and research have far-reaching implication for the rights and interests of children. This calls for further strengthening of the existing legal framework, as well as for additional guidance by the Council of Europe, to respond to the emerging challenges in relation to health care and research. To illustrate this, the presentation will highlight particular issues relating to child consent, participation and confidentiality in the context of biomedicine and offer observations for a future Council of Europe Strategic Action Plan.

## CHAIR

### Mr Miroslav Mikolášik, Member of the European Parliament and Chairman of the EPP Working Group on Bioethics and Human Dignity



*Miroslav Mikolášik (1952) holds a postgraduate certificate in general medicine, anaesthesiology and reanimation and studied at Medical Faculty of the Charles University in Prague. During his political career, in 1999 he was appointed Ambassador of the Slovak Republic to Canada. In 2004, he was elected Member of the European Parliament, re-elected in 2009 and 2014. As a member of the Christian Democratic Party in the Slovak Republic, which is part of the European People's Party, Miroslav Mikolášik sits on the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI), Committee on Regional Development (REGI) and the Subcommittee on Human Rights (DROI). He is the founder*

*and honorary president of the non-profit association Donum Vitae and he also lectured at the Institute of Medical Ethics in Bratislava. In 1978-1990, 1992-1994 and 2002-2004 he was practising medicine. Currently he serves as chairman of the EPP Working Group on Bioethics and Human Dignity in the European Parliament.*

### Prof. Ana Sofia Carvalho (Portugal)

#### Director of the Bioethics Institute, Universidade Católica Portuguesa (IB-UCP)



*Ana Sofia Carvalho, is Associate Professor with Aggregation in Bioethics and director of the Instituto de Bioética and the Chair holder of the Portuguese UNESCO Chair in Bioethics of Universidade Católica Portuguesa (UCP). She has been recently appointed as a member of the European Group on Ethics in Science and Technology (EGE).*

*She is the coordinator of the Doctoral Program in Bioethics and of the Office of Ethical Evaluation and Science Integrity in the Portuguese Foundation for Science and Technology. Member of the National Council on Ethics in the Life Sciences, elected by the Council of Rectors of Portuguese Universities (Parliament). Expert for ethics evaluation of the*

*European Commission since FP6 (Marie Curie Grants, European Research Council, European Commission DG Research & Innovation Directorate F - Health, European Commission DG Research & Innovation Directorate B - European Research Area B.6: Ethics and gender).*

#### ► Challenges raised by the evolution of practices for elderly persons

Our presentation will cover distinct aspects:

1. Decision making capacity assessment and informed consent taking into consideration different categories of vulnerabilities that can be found in different elderly persons;
2. Ethical issues and ageism:
  - 2.1 Equity and justice in using scarce resources and access to health care
  - 2.2 research and clinical trials inclusion criteria;
  - 2.3 Computerisation and digital skills

All these aspects should be subject to an ethical based analysis and practical conclusions drawn.

#### ► Full text

Ageing is a natural process, which presents a unique challenge for all sections of the society. With gradual improvement in health-care delivery services, life expectancy has increased and thus the percentage of the elderly population. These demographic transitions essentially require shifting the

global focus to cater to the preventive health-care and medical needs of the elderly population within a bioethical frame.

Therefore, the aim of this article is to present some, but not all, of the challenges raised by the evolution of practices for elderly persons; more specifically the ones related with decision making capacity assessment and informed consent and some reflection on age-based prejudice and discrimination related, mainly with equity.

## **1. DECISION MAKING CAPACITY ASSESSMENT AND INFORMED CONSENT TAKING INTO CONSIDERATION DIFFERENT CATEGORIES OF VULNERABILITIES THAT CAN BE FOUND IN DIFFERENT OLDER PERSONS**

Due to the dramatic increase in life expectancy over the last years, the number of older people needing medical and social care is growing. This represents a new challenge, particularly in ethics, due to frequent and potential age-related interfering factors. Medical information significantly impacts the decision-making process, especially for older patients, where the quality of communication is essential to obtain complete patient comprehension and compliance for the care plan to begin (Giampieri, 2012).

In fact, life demands that we make innumerable decisions on a daily basis. Some of these decisions have to be made quickly and unexpectedly, whereas others can be reflected on over time. Decisions must also be made about unfamiliar scenarios, without evaluation of the potential risks or benefits that might occur as a consequence of these decisions. Evidently, decision-making is crucial for everyday living. Decision-making capacity (hereafter only DMC) is an indispensable prerequisite for medical treatment choices, including consent to treatment, forgoing treatment, and refusal of treatment, and thus, the basis for patients' autonomy. Two moral requirements are entailed in DMC evaluations: respect for the autonomy of those who are able to make their own decisions and provision of protection for those with diminished decisional capacity and vulnerable. In view of these ethical implications, a careful assessment of DMC is essential and the design of adequate strategies to improve DMC is crucial.

In fact, the criteria for valid consent are, normally, based on three elements. The patient must (Sessums et al., 2011): (1) be given adequate information about the nature and purpose of proposed treatments, as well as the risks, benefits, and alternatives to the proposed therapy, including no treatment; (2) be free from coercion; and (3) have medical decision-making capacity.

The standards for whether a patient meets this last element also vary, but are generally based on evaluating abilities. The following cognitive criteria for medical DMC have been proposed and are widely used in research and practice (Appelbaum, 2007): (1) ability to understand relevant information, (2) ability to appreciate the nature of the disorder and the possibility that treatment could be beneficial, (3) ability to reason about the treatment choices, and (4) ability to communicate a choice.

For example, a person may have DMC for matters of everyday life (e.g., what to eat), but may not be sufficiently capable of making decisions about medical treatments. It follows that the assessment of DMC must be case specific, task specific, and, also time specific. Cognitive fluctuations, periods of behavioural confusion, inattention, and incoherent speech alternating with episodes of lucidity and capable task performance, significantly affect both clinical rating of dementia severity and neuropsychological performance. Therefore, they must be considered in the evaluation of decision making capacity. For instance, for older persons having cognitive fluctuations, it is important that the physician choose a day or a point in time in which the patient is in good shape compared to other days or moments. Information about different treatment options, risks, as well as informed consent should be best discussed at this point in time. (Trachsel et al., 2014).

Therefore, how informed someone becomes through "informed" consent depends on several issues, such as how well the information is presented, whether the recipient is hampered by mental or sensory impairments, the emotional tone of the situation, and the rapport with the examiner. Although the process can be modified to suit individual needs, there may still be some individuals for whom the information is unclear or unintelligible, and who lack the capacity to give an appropriate informed consent in certain situations.

## **Session II - Evolution of practices in the biomedical field**

### **Autonomy - Consent and Privacy**

In older persons, there is a particular concern about the process of informed consent and about decision-making capacity, which is the clinical equivalent of legal competence. The older population as a whole is a heterogeneous group, but includes a high proportion of subjects at risk for impairments in decision-making capacity. Also, the older population is also at a greater risk for physical illness, and consequently more often faces important decisions about medical treatment, long-term care, and life-sustaining measures. The challenge is to identify subjects at risk for impaired decision making and to ensure an adequate process of informed consent for them while not infringing upon their rights to autonomous decision making (Christensen et al., 1995).

#### **1.1 CATEGORIES OF VULNERABILITIES THAT CAN BE FOUND IN DIFFERENT OLDER PERSONS**

Vulnerability is the susceptibility of being wounded or hurt, a term of Latin origin, derived from *vulnus*, meaning "wound". The notion of "vulnerability" was introduced into the vocabulary of bioethics in the sphere of human experimentation, as a characteristic attributed to particular populations considered, for different reasons, as those most exposed to and poorly defended against the maltreatment and abuse of others.

Substantial debate has been conducted in terms of defining not only who vulnerable people are, but also targeting the minimization of their exploitation. However, in my opinion, if we want to guarantee the "protection of vulnerable" we cannot use vulnerability as a bioethics jargon; therefore in our opinion, is of utmost importance to identify vulnerability categories in order to design informed consent procedures adapted to each person and to design tools to improve vulnerable persons/groups' DMC .

Vulnerability is a touchstone in bioethics and a common denominator to both clinical and research ethics. This concept has been highlighted by Kipnis (2001), particularly in the case of medical/pharmaceutical research. In his commissioned paper "Vulnerability on Research Subjects: a Bioethical Taxonomy", Kipnis aims to highlight specific categories of vulnerability, as opposed to the institutionalized subpopulation focus (children, prisoners, pregnant women, etc.) which researchers/physicians mindfully should take into account.

Challenging this institutionalized paradigmatic profile, in line with the author we think that in order to guarantee an ethical robust informed consent procedure we must define and take into account the different categories of vulnerability. These categories correspond to ethically relevant features not only in older patients but that might be present in many other patients/persons. Kipnis classifies the following distinct characteristics of vulnerability and indicates how to identify each one of them through one question:

##### **a) COGNITIVE VULNERABILITY**

**DOES THE PERSON HAVE THE CAPACITY TO UNDERSTAND AND DECIDE TO BE TREATED OR NOT?**

This category includes, for instance, persons with early-stage dementia, with certain types of mental illness, intellectual disability, older adults who are institutionalised in nursing homes, older persons with educational deficits and/or unfamiliarity with the medical language.

##### **b) SITUACIONAL VULNERABILITY**

**IS THE PATIENT IN A SITUATION IN WHICH MEDICAL EXIGENCY PREVENTS THE EDUCATION AND DELIBERATION NEEDED TO DECIDE?**

This category includes patients who cannot be sufficiently informed and/or who cannot complete effective deliberation within the available timeframe (patients receiving a very serious diagnostic or closed prognostic; patients who are being submitted to an urgent surgery or who need to be sedated for a certain reversible reason).



c) MEDICAL VULNERABILITY

HAS THE PERSON A SERIOUS HEALTH-RELATED CONDITION FOR WHICH THERE IS NO SATISFACTORY SOLUTION?

Some patients could be more vulnerable due to a set of different circumstances. Therefore, a patient can have additional vulnerability when he/she has a serious health-related condition for which there are no satisfactory treatments; for instance, patients with palliative care needs, with metastatic cancers, Parkinson's disease, multiple sclerosis, Alzheimer's disease, and so on.

d) ALLOCATIONAL VULNERABILITY

IS THE PATIENT SERIOUSLY LACKING IN IMPORTANT SOCIAL GOODS THAT WILL INFLUENCE HIS/HER DECISION?

Very poor patients, and all the older patients who belong to a socially devaluated or disadvantaged group.

e) SOCIAL VULNERABILITY

DOES THE PATIENT BELONG TO A GROUP WHOSE RIGHTS AND INTERESTS HAVE BEEN SOCIALLY DISVALUED?

Addicted older patients, older migrants, homeless, prisoners and all the patients belonging to a socially disvalued or disadvantaged group.

f) DEFERENTIAL VULNERABILITY

IS THE PATIENT'S DEFERENTIAL BEHAVIOUR WHAT MASKS AN UNDERLYING UNWILLINGNESS TO DECIDE?

The powerful social and cultural pressures: the white coat and women or men who may find it hard to turn down requests from their spouses.

In fact, aging, in combination with other factors, puts one at risk for decision-making impairments and, hence, in an older person combined vulnerabilities may be more likely to have an impact on decision making than any individual vulnerability (Christensen et al., 1995). If the older person does not present any of these criteria or types of vulnerability, then decision-making capacity is intact. If only some of them are present, however, the issue becomes cloudier. Therefore, just where this threshold may fall is, still, often difficult to determine and is a future challenge to ethicist and clinicians. Overall, future research efforts should allow us to develop a more accurate understanding and identification of risk factors for impairment in decision-making capacity and the development of more effective instruments that will enable the participation of older vulnerable persons in the decision making process.

If we can more accurately recognize vulnerable older individuals, we will ultimately be better at protecting them from improper consent and, in other hand, in avoiding cases where too much protection results in lack of access to appropriate treatment or research opportunities (Cherubini, 2011). At the same time, we would not need to impose limitations on the larger number of older persons who are not at risk for impaired decision-making capacity, and therefore we could better maintain their rights to make free and voluntary decisions. In fact, the informed consent is only valid in terms of ethical legitimacy if we take this/these vulnerability(ies) into consideration when assessing decision making capacity in order to design adequate strategies that can empower the ones with vulnerabilities. This is a quite big challenge for researchers, physicians and ethicists.

## **2. ETHICAL ISSUES AND AGEISM**

Ageism has been a concern since 1969, when it was first introduced as a concept for social reform by the American psychiatrist Robert N. Butler. Butler's alarm was over the impact of "systematic stereotyping or discrimination against people because they are old" (Wilson et al., 2017). Therefore, in the second part of this article, we will address some ethical concerns related to ageism.

Research on age-based prejudice and discrimination demonstrates it to be surprisingly pervasive, potentially infecting numerous societal facets. For instance, ageism appears in medicine, where

## ***Session II - Evolution of practices in the biomedical field Autonomy - Consent and Privacy***

medical schools under-emphasize geriatrics and older people often face less adequate treatment for common ailments, which are dismissed as a natural part of aging. Many older people also face discrimination in the form of abuse and neglect in nursing homes and even within their own families. Still more disturbing, this form of ageism is likely under-reported, due to caseworkers and doctors being less familiar with elder abuse than other forms of domestic violence (North & Fiske, 2012). Ageism is also present in clinical trials and research protocols that contain unjustified upper age limits (Kolb et al., 2015) and in the differential access, use, and benefits derived from emerging health digital systems (Robinson et al., 2015).

Therefore, in this last part of my communication, I will try to underline some examples of ageism that, in my opinion, should foster the ethical analysis and the design of concrete public policy measures.

### **2.1 EQUITY AND JUSTICE IN USING SCARCE RESOURCES AND ACCESS TO HEALTH CARE**

Starting with ageism and equity and justice in using scarce resources and access to health care we should underline that the establishment of priorities in the planning and implementation of health care constitutes a legitimate and necessary procedure in any contemporary health policy; which, due to the scarcity of resources, must be implemented in order to reduce the health disparities gap (CNECV, 2012).

In fact, the underlying issues and individual needs of underserved and vulnerable populations, like older persons, must be effectively addressed. Rather than providing equal resources for all, health equity solutions examine and try to remove the underlying causes of health disparities and give to each person what he/she really needs and foster their dignity.

According to the WHO (World Health Organization), equity is "the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically." Therefore, as the WHO notes, health inequities involve more than lack of equal access to needed resources to maintain or improve health outcomes. As such, equity is a process and equality is the outcome; the route to achieving equity will not be accomplished through treating everyone equally. It will be achieved by treating everyone equitably, or justly according to their circumstances.

Inequity (or disparity) in the receipt of public health and healthcare interventions by age are rightly receiving attention. Given current trends towards ageing populations, it is unsurprising that a growing body of empirical studies, commentary pieces and policy documents call for action on 'age discrimination' within health services and unmet healthcare needs among older people (Salway et al., 2017). When such differences are labelled as 'inequitable' the implication is that they are unwarranted, unfair and avoidable; thus, ethically unacceptable. Older people may be less likely to receive potentially beneficial treatment or interventions than younger people due to a range of factors, resulting in poorer outcomes and that, of course could be acceptable. Clinical decision-making on the basis of patient sub-grouping, and the associated potential benefits and harms, does happen in practice. However, whether or not such resource allocation decisions are considered appropriate is an ethical, as well as a technical, judgment. Invasive treatments that will prolong the quantity of days without prolonging the quality of the days and that would not foster the dignity of the patient may be considered unacceptable. Nevertheless, the line between what constitutes ageism and what constitutes a decision that is equitable and just is blurry. Age cannot be a criteria "per se", but other factors related with age could, sometimes, constitute legitimate and ethical robust criteria of choice. This is, of course, quite challenging since the boundaries between medicine's focus on cure and its concern with life enhancement are increasingly blurred. The practices of the biomedical sciences continue to move beyond the confines of disease entities and whole individuals to investigate life itself rather than disease.

The impossibility of saying "No" to medical interventions is shaping the way we understand ageing; moreover, ageing itself is changing clinical practices. As patients go through the process of seeing specialists and subspecialist consultants, they get put on a "train" of aggressive interventions that is very difficult to stop. Diagnostic tests "confirm" the need for interventions. Procedures become "appropriate" by default in this organizational scheme (Kaufman et al., 2004). Reasoned choice about using specific interventions is obfuscated by the need to treat, the routinization of intervention, the specter of future risk, regardless of age, and the perceived opportunity to prevent future disease. These physicians' understandings of the shifting imperative to treat at older ages contribute,

pragmatically, to the elimination of any deliberation about treatment options for an individual case, and thus standard practice replaces choice. The idea that medicine can be expected to intervene, always, even in very late life, is therefore strengthened (Kaufman et al., 2004).

In fact, the evidence-based medicine model, grounded in the biases of dualism of medicine, has been the subject of critique as it may create a hostile environment for the good care of older and dying patients. Often, this curative model of care is perceived as “competing” with the one of person-centered care as if these two models of care would be completely separate and distinct realms (Rich, 2000). For example, (i) while the curative model of care is analytic and rationalist, the person-centered care model is humanistic and personal (Fox, 1999), (ii) while the curative model privileges scientific objectivity, the person-centered model values the patient’s subjective experience, and (iii) while the curative model perceives aging and death as an enemy, the person-centered care model considers aging and death as an inherent part of life and therefore embraces the human, clinical and ethical demand of providing end of life care. Development of the concept of patient-centredness is, in my opinion, intimately linked to perceived limitations in the conventional way of doing only medicine based on scientific evidence. More recent perspectives, specially the one that added patient-centered care as one of the seven domains on the evaluation of healthcare institutions, emphasize the need for integration. Patient-centered care is the right thing to do. In fact, it is hard to imagine how care that has not been patient-centered could ever have been justified (Greene et al., 2012).

In my opinion, reframing the WHO definition of equity for this specific context: we must underline that among groups of people (young groups and older groups) there are sometimes not avoidable and a lot of times not remediable differences and the route to achieving equity will not be accomplished through treating elderly persons equally; it will be achieved by treating everyone equitably, or justly, according to their circumstances and their needs in order to foster their best interests and their dignity; this should be common to all groups and, therefore, in my opinion, it cannot be considered ageism!

However, as stated by Antonio Cherubini, we must underline that there are cases about lack of equity towards older people in health that constitute AGEISM. The first one is when the appropriateness of the procedure is not even assessed because the person is old; in fact, these decisions need always to be individualized, but often are denied just because of age (this is ageism indeed!); The second one refers to scientific studies that have shown the appropriate way to care for older people in the hospital (e.g., admission to a geriatric ward), home care and nursing home. However, in many countries, older persons often do not have access to appropriate healthcare services because they are not available or not enough for all who need them (this is also ageism).

Before finishing this article, I would like to introduce two other forms of ageism that I think deserve to be mentioned and to be further explored in an ethical perspective.

## 2.2 RESEARCH AND CLINICAL TRIALS INCLUSION CRITERIA

The unjustified exclusion of older people from clinical trials (CT) has, for many years, been a matter of concern to geriatricians and others interested in the optimal care of older people. The aging process involves gradual and continuous changes of the human body. In older patients, metabolism is often prolonged, adverse drug reactions are more common, and due to patients being prescribed multiple medications, drug interactions are more likely to occur and require special attention in pharmacotherapy (Kolb et al., 2015). Even if older patients often represent the most significant group of consumers of drugs, strong evidence exists that older persons are often underrepresented and even excluded from clinical trials, especially in pharmaceutical studies and clinical data and evidence-based guidelines for prescriptions for older patients are rare (Cherubini et al., 2011). The inclusion of older people in clinical trials is imperative because they are different from young and younger adult participants due to the interplay between aging, chronic diseases, polypharmacy, and lifestyle. Compelling evidence exists. The results of clinical trials performed in younger participants cannot be automatically applied to older populations in terms of efficacy and safety (Cherubini et al., 2010).

Additionally, abolishing ageism practices is of foremost importance to develop further research on the ethical assessment procedures in order to tackle this exclusion criteria issue and to guarantee that the research and the trials are adapted to the real needs of the society.

### 2.3 COMPUTERISATION AND DIGITAL SKILLS

Last but not the least, Information and Communications Technology (ICT) is seen as a promising mean to solve the challenges of delivering care, improving health outcomes, and creating a more equitable health care system. However, as the information society has evolved, new forms of inequality have surfaced alongside these long-standing forms of inequality. Technologies are being used to improve access to clinical care, empower patients to monitor and self-manage their medical conditions, and control costs (Hale, 2014). Older groups, who experience the greatest burden of poor health, also are the most likely to lack the access, skills, and attitudes associated with making effective use of health digital systems. Therefore, further research is needed to evaluate how the introduction of these technologies in health care benefits all people or if inequalities will increase and, therefore, represent another form of ageism.

### CONCLUSION

Clearly, the tools and resources of ethics alone cannot solve the problem of ageism. An issue that evokes controversy on metaphysical, legal, and political fronts has deep cultural roots and will require the insights and tools of numerous disciplines and approaches. But ethics does have a role; ethics has a lot to teach about centering the care in the person; there is the need for practical ethics. This is a constructive approach to an ethics of older persons' care that is animated by a core philosophy of medicine as specific and focal to the uniqueness of each person, the older patient and the older patient clinician. This philosophy (i) defines the nature of the disease, (ii) recognizes the variability and subjectivity of its expression in each older patient, (iii) acknowledges the vulnerabilities rendered by the age of each person, (iv) adjusts the way to reduce inherent characteristics and asymmetries of the patient-clinician relationship, and (v) defines with the patient (and or family) the ends of the care. That these ends entail the provision of "good" care links the epistemic domains of medicine to its anthropologic focus and ethically sound conduct.

Integrative care approaches provide a perspective on re-integrating evidence-based care and person-centered care. The proposed paradigm of integrative elderly care (i) supports the basic deontic structure of the profession, (ii) allows for a more complete articulation of clinical and ethical responsibilities within the scope of general, specialty and sub-specialty practices, and (iii) upholds the value of care as an interpersonal interaction that seeks to execute good acts and ends as specifically defined by the needs of the patient and parameters of the clinical relationship.

A "whole patient-oriented" view of disease is more accurate than a disease-oriented view. This approach is more effective, more efficient, safer, more equitable and better aligned with the core principles and philosophy of medicine. To remedy inequity and the neglect and marginalization of older persons, health systems and medicine need to be redefined.

**ACKNOWLEDGEMENTS:** This paper is a tribute to the memory Daniel Serrão a major figure of Portuguese bioethics (1928-2017).

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## **Prof. Antonio Cherubini (Italy)**

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*Member of the Ethics committee of the Marche region. Author of more than 200 papers in peer reviewed journals and of five books. He is one of the Editors of the book "Clinical trials in older adults", Wiley, 2015. His main research interests are antioxidants in aging and age-related diseases, geriatric depression, comprehensive geriatric assessment, geriatric pharmacotherapy, including the exclusion of older subjects from clinical research. Editor of the section on clinical trial and aging, Journal of Nutrition Health and Aging. Editorial board member of the following journals: Aging, Clinical and Experimental Research; European Geriatric Medicine; Journal of Aging and Frailty.*

### **► Action(s) to be undertaken at intergovernmental level to address the identified challenges**

The European population is rapidly aging. In this time of increasingly rapid societal and scientific changes, it is particularly important that decision makers take in to consideration the peculiar characteristics and needs of the older population. The high heterogeneity of this age group represents a distinct issue. Concerning the challenges raised by the evolution of practices for older persons, it will be first necessary to undertake a thorough analysis of all these issues. The following actions might be relevant to be undertaken:

- Promote a comprehensive evaluation of current practices concerning the assessment of capacity and informed consent in the different countries and evaluate how to promote initiatives to increase homogeneity;
- Address the challenges posed by the widespread ageism at societal and health care level. In this respect it will be necessary to promote educational campaign in the school and in the workplace, including health care systems, concerning this phenomenon, its ethical and practical implications and how to change it;
- An urgent intervention is needed to promote a greater participation in research, particularly in clinical trials that evaluate new pharmacological and non pharmacological interventions, which too often exclude older subjects, particularly those who are older, frailer and disabled;
- Promote large scale education of older adults concerning information and communication technology use, i.e. digital literacy, to prevent the exclusion of too many subjects from the benefits of the IT revolution, which could support strategies to promote healthy and active aging.

### **► Challenges raised by the evolution of practices for elderly persons**

#### **Informed Consent**

My presentation will be complementary to that of Prof. Ana Sofia Carvalho and will further elaborate on ethical challenges posed by contemporary clinical practice and research in the older population. For each challenge identified, I will propose some actions that might be undertaken to address the challenges. Aging of the population is a worldwide phenomenon. It is characterized by two elements, the progressive increase of the percentage of older subjects within the population and the increase of individual life expectancy, leading to a much faster increase in the number of subjects aged 80 years and older. While many older subjects enjoy good health and autonomy, a large number of subjects,

particularly in the oldest old segment, develop multimorbidity, disability and frailty, becoming a truly vulnerable population, both from the clinical and the ethical point of view. Furthermore, increasing global mobility is leading to higher heterogeneity of older subjects from the ethnical and cultural perspective. The challenge posed by aging in the contemporary society is therefore related not only to the increasing number but also to the increasing heterogeneity, diversity and frailty of older subjects. From this perspective, it is clear that informed consent, which is an essential requisite for any clinical and research activity, becomes challenging when the person who has to provide it is an older vulnerable subject. During the past 50 years informed consent became more and more complex, highly regulated, while the difficulties and hurdles to obtain it remained unchanged or even increased. Recently it has been acknowledged that "Consent forms are increasingly long and complicated, obscuring important details, and are often designed to serve the interests of institutions and sponsors". (1) It is not surprising therefore that studies show that many subjects who sign the consent did not really understand its content and meaning. Physicians do not have sufficient training, education and in some instances adequate time to properly collect informed consent. This is particularly true when the person has a questionable capacity to provide consent. The assessment of decision capacity is complex, requires ability to evaluate cognitive function and to understand that capacity cannot be assessed in general but it is dependent on the task that is assessed, the time of assessment and the clinical conditions of the older person as well as the surrounding environment and social context. It is now accepted that, when an individual does not have the capacity to provide consent, then another person should be appointed to consent for her/him. However, the legislation of different countries within Europe is different with respect to whom and how this person can be identified and appointed. In Italy, for instance the person needs to be appointed by the Court. This is a long process which is often not compatible with the time available for obtaining consent during clinical activity or research. Therefore in many instances subjects unable to provide consent are prevented from participating in research that might be beneficial. A clear example is provided by the AdCare study, a non-profit, randomized, placebo-controlled, double-blind, multicenter, pragmatic trial coordinated by the Italian National Institute of Health. (2) The aim of the study was to evaluate the long-term safety and efficacy of three atypical antipsychotic drugs (risperidone, olanzapine and quetiapine) and one conventional antipsychotic drug (haloperidol) currently used off label for the treatment of behavioral disturbances in Alzheimer disease patients. The study was prematurely interrupted due to the difficulties encountered in obtaining a legally authorized person able to consent, when the participant was unable to provide it.

Considering all these challenges intergovernmental actions should be promoted both to agree uniform cross-national standards for the production and acquisition of the informed consent as well as to adopt similar cross-national criteria for the assessment of capacity to provide informed consent and for the appointment of the person able to provide a surrogate consent.

### **Ageism**

"Ageism can be seen as a process of systematic stereotyping of and discrimination against people because they are old" (3) The perception of older subjects as dependent, incapable and frail is widespread in European countries, as demonstrated by several studies, and represents an extraordinary obstacle hindering the development of good national and European policies on ageing and health. While sexism and racism are not commonly accepted, ageism is common, tolerated and even promoted in large sectors of European societies. In this respect, the expression "structural ageism" has been proposed to describe the situation whereby the society and its institutions act in a way that de facto maintains and promotes ageism (4) In this respect the phenomenon can be encountered in different areas, such as access to financial services, participation in social and civic activities, opportunity to have a job, access to social security benefits, health care as well as long term care. Ageism can take different forms, more overt such as upper age limits as well as more subtle, e.g. limitation of the possibility to access a service or to obtain a job that is justified with the need to optimise resource allocation or to promote intergenerational equity.

Ageism is a specific issue within the healthcare system, where older people might be denied adequate treatment: in Cyprus, older adults are excluded from innovative surgical procedures, while in Finland the rehabilitation reform of the 2016 excludes subject older than 65 years.

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### ***Autonomy - Consent and Privacy***

It has been found that health care professionals often tend to have more negative attitudes with older people respect to others age groups and might fail to prescribe appropriate diagnostic test and treatments. (5)

Furthermore, older people themselves might suffer from self-ageism, a condition which is fraught of negative consequences. Older subjects with intrinsic negative self-stereotyping have worse health condition, e.g. they exhibit a lower capacity to recover from disability and they live about 7.5 years less than people with positive attitudes towards aging.

Up to now, few European countries, e.g. France, Bulgaria, Italy, Sweden, United Kingdom, have a national legislation that protects older people from the discrimination based on age, although to a different extent. Many other countries do not have such a legal protection, besides the employment sector, which is covered by a European law. The lack of a specific and wide ranging European law against ageism that is integrated with similar national laws represents a condition that favours the persistence of age discriminative practices within the society. A brilliant example of a well conceived legislation to defeat ageism is the Equality Act implemented in the UK, that protects people from discrimination in several areas including ageism. The Equality act has a wide range of application, including consumer services, health care services, employment sector and public services. The Equality Act protects people from the direct discrimination (i.e. the exclusion of a person because of her/his age), indirect discrimination (i.e. when a service is characterized by features that can become discriminatory), harassment (i.e. when a person is humiliated and intimidated, and when the behaviour creates a hostile environment), victimisation (i.e. when a person is treated badly because he has denounced a discrimination).

With respect to ageism it is important to promote a common European legislation to combat ageism as well as information campaigns to promote a greater awareness of ageism at all society levels

#### **Ageism in research**

Another clear example of ageism is present in clinical research. Randomized clinical trials investigating new drugs as well as non pharmacological treatments for conditions that are highly prevalent in older subjects, e.g. heart failure, hypertension, Alzheimer disease, colorectal cancer and depression, commonly exclude older subjects (6-8). Participants enrolled are typically much younger than patients who are seen in clinical practice and their general health is much better, due to the selection based on explicit upper age limit and other indirect exclusion criteria. This practice is justified using practical reasons: the heterogeneity of the older subjects might prevent the possibility to investigate a specific condition if comorbidities and related drug therapies are not limited; the difficulty to obtain the informed consent, to recruit and maintain older subjects in a study. The inclusion and continuing participation of older people in research is often associated with higher costs. Geriatricians as well as other physicians advocate for the inclusion of older persons in clinical trials because the results of studies including in younger populations are not necessarily applicable to older people because of differences related to aging, multimorbidity and polypharmacy. In the end, the exclusion of older subjects prevents health care professionals from having the necessary information on the efficacy and safety of treatments. This lack of appropriate evidence on which clinical decisions can be made might lead to inappropriate treatments, both in terms of overtreatment or undertreatment, waste of resources and higher risk of adverse clinical outcomes. This situation is no longer acceptable not only from a scientific and professional but also from an ethical point of view. In this respect, it is important to mention that a "Charter for the rights of older people in clinical trials" has been elaborated in the context of an EU funded project, named Predict, whose specific aim was to investigate the causes of the exclusion of older subjects in research projects and to identify possible solutions (9). The Charter has been endorsed by different professional and non-governmental organizations and widely disseminated.

A similar situation to that just described was also present in children, who were often excluded from clinical trials. Therefore, physicians treating these subjects were often lacking the appropriate evidence when prescribing treatments and had to rely on studies performed in adult subjects. To address this issue, the European Commission approved in 2006 the Paediatric Regulation on Medicinal Products for Pediatric Use. This legislation aimed at improving the quality of research for drug that are used in this specific population. After ten years from its implementation, it has been



reported that there are more drugs for children and clinicians have more information on their use in pediatric subjects (10).

My suggestion is that specific actions should be undertaken to guarantee a better inclusion of older subjects in health research, e.g. the implementation of a specific legislation requiring the inclusion of older subjects in clinical research, analogously to the pediatric one.

### **Digital inclusion of older adults**

The use of information and communication technology (ICT) can produce relevant benefits for the health and well-being of older subjects reducing the social isolation and loneliness. However, older subjects, who suffer the greatest burden of multimorbidity, frailty and disability, belong to a group that is often reported to have a lower access to ICT. This might be related to the low digital literacy, lack of perception of usefulness, low usability of ICT solutions, physical and mental problems as well as to high cost of technology (11). Considering the rapidly increasing role of ICT in our daily lives, older subjects who do not use it can become more and more disadvantaged.

In this respect it is important that European member states take actions to increase digital inclusion of older adults.

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## CHAIR/MODERATOR

### Ms Brigitte Konz (Luxembourg), Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe



*Brigitte KONZ studied law at the Universities of Strasbourg and Paris I Pantheon-Sorbonne.*

*She has a Master in fiscal law with post graduate specialisation in economical law. She completed her legal training in Luxembourgish law and in succeeding the Luxembourgish bar examination.*

*Her initial career was as a barrister, which was followed as a lawyer in the Luxembourgish Administration of Indirect Taxes.*

*Since 1985 she has occupied various posts in the judiciary, initially as an attorney at the public prosecutor's office in Luxembourg, and as a judge in the District Court in Luxembourg, for which she has been vice-president for*

*many years, and as president of a criminal court specialised in economic and financial cases.*

*She has occupied various posts at the court of appeal (labour, civil and cases involving young children).*

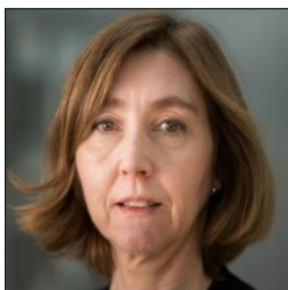
*She is currently the director of the Justice of Peace of Luxembourg.*

*She is active as the Luxembourg expert for the Minister of Justice for various committees at the Council of Europe, and since 2016 she is the Chair of the steering Committee for Human Rights of the Council of Europe.*

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### Ms Marit Frogner (Norway)

### Member of the European Committee of Social Rights (ECSR) of the Council of Europe (Rapporteur for Article 11 of the European Social Charter)



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*She has previously worked as a lawyer, and from 2011, as a judge in the Labour Court of Norway. She was elected member of the European Committee of Social Rights from 2015. Frogner is currently also an adjunct lecturer at the Department of Law and Governance at BI Norwegian Business School. She is the co-author of books in Norwegian labour law.*

#### ► Effectively exercising a right to protection of health: common or individual challenges?

This is a good occasion to speak about the relationship between the European Social Charter and the Oviedo Convention. The two are complimentary – Article 11 of the Charter guarantees the right to protection of health (in a more comprehensive way – access to health care, including equitable access to health care, prevention, health education), while Article 3 of the Oviedo Convention lays down the principle of equity of access to health care. The European Committee of Social Rights (ECSR) assesses whether the State Parties comply with their obligations under the European Social Charter. The presentation will focus on the practice of the ECSR in regard to the rights laid down in Article 11, and with a view to address whether the rights and principles are particularly challenged for specific groups.

► **Full text**

Ladies and Gentlemen, I am honoured and grateful for this opportunity to talk about the European Social Charter.

The European Social Charter and the Oviedo Convention are complimentary. Article 11 of the Charter guarantees the right to protection of health in a more comprehensive way – access to health care, including equitable access to health care, prevention, health education – while Article 3 of the Oviedo Convention lays down the principle of equity of access to health care.

Article 3 of the Convention reads:

“Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.”

The topic of this discussion is equity of *access* to health care. A right is not a right if it exists only in theory – it must also be ensured in practice. The question is how as many as possible can be covered, being aware of the fact that the right to health care is challenged to a larger extent for certain groups – those considered more vulnerable.

Time does not allow me to give an in depth presentation. I will thus highlight this topic by presenting a few relevant examples based on the practice of the European Committee of Social Rights. Hopefully, this may be a basis for further discussions and we may also share experiences and discuss common challenges.

Firstly, let me give a brief introduction to the European Social Charter:<sup>7</sup>

- The European Social Charter is a Council of Europe treaty that guarantees fundamental social and economic rights as a counterpart to the European Convention on Human Rights, which refers to civil and political rights. It guarantees a broad range of everyday human rights related to employment, housing, health, education, social protection and welfare.
- **The Charter lays specific emphasis on the protection of vulnerable persons such as elderly people, children, people with disabilities and migrants. It requires that enjoyment of the abovementioned rights be guaranteed without discrimination.**<sup>8</sup>

Of the 43 States that have ratified the Charter – either the 1961 or the Revised Charter, almost all have accepted Article 11. Armenia is the only exception.

The rights of the Charter must take a practical and effective, rather than a theoretical form. The European Committee of Social Rights monitors compliance with the Charter under two complementary mechanisms;

- through collective complaints that are lodged by either social partners and other non-governmental organisations, and
- through conclusions based on national reports drawn up by the contracting states.

My focus will, as mentioned, be on Article 11. However, it must be emphasized that the Charter has several articles that address the situation of vulnerable persons.

Article 11 of the Revised European Social Charter (1996) reads:

**“Article 11 – The right to protection of health**

Part I: Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable.

Part II: With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organisations, to take appropriate measures designed *inter alia*:

- 1 to remove as far as possible the causes of ill-health;

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<sup>7</sup> 43 out of the 47 member States of the Council of Europe are parties to either the 1961 Charter or the Revised Charter (1996).

<sup>8</sup> <https://www.coe.int/en/web/turin-european-social-charter>

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2 to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;

3 to prevent as far as possible epidemic, endemic and other diseases, as well as accidents.”<sup>9</sup>

As the wording clearly indicates – the scope of the Article is wide. It imposes a range of positive obligations on the States. This includes, inter alia, that the healthcare system must be accessible to everyone.

When assessing whether the right to protection of health can be effectively excised, the Committee pays particular attention to the situation of disadvantaged and vulnerable groups. In this regard, it is important to bear in mind that health risks may be disproportionate.

According to Article 11 § 1, the healthcare system must as mentioned be accessible to everyone. This is an issue that has been mentioned by several of the previous speakers as well. There are many factors that are addressed under this heading – including, and of particular relevance to our topic the following may be mentioned:

Firstly, the cost should be borne, at least in part, by the community as a whole. It should not impose an excessively heavy burden for the individual.

Secondly, healthcare should be free of charge for those without the necessary resources.

And thirdly, it should be accessible. This may clearly relate to disadvantaged groups, including differences based on geography – typically urban vs. rural areas, but also on socio-economic differences.

I have chosen to focus on three specific groups – i.e. Roma, elderly and children. These groups clearly face different challenges, but they are also overlapping. The particular situation of children and elderly, and the challenges they may encounter in regard to health services, have also been addressed earlier today.

I will start with two collective complaints that involved Roma.

Collective complaint no. 67/2011, Médecins du Monde – International v. France, concerned migrant Roma living in France in great poverty. The complaint related to several Articles of the Charter, including Article 11. In regard to the breach of Article 11 § 3 – that states parties have to take appropriate measures to prevent, as far as possible, epidemic, endemic and other diseases as well as accidents – the Committee stated:

“The Committee takes note of the high proportion of infectious diseases, in particular tuberculosis, among migrant Roma. On this point, it stresses the main explanations given by the health observatory authority of the Ile-de-France region on the difficulties encountered by the actors working in the health sector, such as a lack of health education provided to Roma, their distrust towards institutions, their limited use of health devices and the fact that repeated evictions contribute to weaken access to care and support ....”<sup>10</sup>

The particular situation with “repeated evictions” was taken into consideration. Further, the Committee noted that:

“Infectious diseases and risk of domestic accidents largely results from the poor living conditions in the migrant Roma camps. The Committee further notes the very low vaccination coverage among the migrant Roma. The Government provides no information on preventive measures taken for migrant Roma to address these problems but only refers to the emergency care fund. The Committee finds that this is not sufficient. The particular situation of migrant Roma requires the Government to take specific measures in order to address their particular problems. Treating the migrant Roma in the same manner as the rest of the population when they are in a different situation constitutes discrimination.”<sup>11</sup>

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<sup>9</sup> Article 11 § 3 of the 1961 Charter does not cover accidents.

<sup>10</sup> Paragraph 161

<sup>11</sup> Paragraph 163

The Committee found that there was a violation of Article E<sup>12</sup> (non-discrimination) in conjunction with Article 11§ 3. The vaccination coverage was very low, and the particular situation of Roma required the Government to take specific measures. I would like to emphasize what Committee said – that treating the migrant Roma in the same matter as the rest of the population when they are in fact in a different situation, constitutes discrimination. This is an important aspect and consideration to bear in mind when considering the situation of vulnerable groups.

In another Collective Complaint, Complaint no. 104/2014, European Roma and Travellers Forum (ERTF) v. the Czech Republic, the Committee found:

“The Committee considers there is sufficient evidence, which shows that Roma communities in many cases do not live in healthy environments. This situation can in part be attributed to the failure of the relevant policies by the State, for instance lack of protective measures to guarantee clean water in Romani neighbourhoods, as well as inadequacy of measures to ensure public health standards in housing in such neighbourhoods.”<sup>13</sup>

The right to clean water should be a given – and the importance is obvious. However this right is not always ensured. And once again, we see that the particular situation of Roma have lead to a situation where Roma communities in many cases did not leave in healthy environments.

The second group I would like to address is the elderly. Elderly are often faced with negative stereotypes and age discrimination, and they face various barriers to access to good quality health care. There are several articles of the Charter that may be invoked when considering the situation of the elderly. In addition, the Charter contains a specific provision in this respect. Article 23 of the Revised Charter, or Article 4 of the 1988 Additional Protocol to the 1961 Charter, was the first provision to protect the elderly in an international treaty. Now, Article 25 of the EU Charter on Fundamental Rights also protects the elderly.

In regard to our topic, equity of access to health care, Article 23 of the Charter states:

**“Article 23 – The right of elderly persons to social protection**

With a view to ensuring the effective exercise of the right of elderly persons to social protection, the Parties undertake to adopt or encourage, either directly or in co-operation with public or private organisations, appropriate measures designed in particular:

...

– to enable elderly persons to choose their life-style freely and to lead independent lives in their familiar surroundings for as long as they wish and are able, by means of:

...

b the health care and the services necessitated by their state; ...”

Again, the Charter implies positive obligations on the States.

The last group that I would like to address is children. The Committee has dealt with the situation of children in several collective complaints. The complaint I would like to refer to relates to the situation of both accompanied and unaccompanied foreign minor. In collective complaint 69/2011, Defence for Children International (DCI) v. Belgium, the Committee held:

“With regard to the right of access to health care (article 11§1), the Committee notes that the total lack – since 2009 – of reception facilities for accompanied foreign minors and the partial lack of such facilities for unaccompanied foreign minors, leading some of them to live in the street, makes it difficult for foreign minors unlawfully in the country to access the health system. This is because the FEDASIL reception and assistance network has reached saturation point and because it is hard for the persons concerned to prove that they have fixed addresses or de facto addresses.”<sup>14</sup>

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<sup>12</sup> Article E – non-discrimination – reads: “The enjoyment of the rights set forth in this Charter shall be secured without discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national extraction or social origin, health, association with a national minority, birth or other status.”

<sup>13</sup> Paragraph 124

<sup>14</sup> Paragraph 116

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The situation of these children is, unfortunately, an increasing and pressing challenge in many European countries.

Finally, I would like to mention two collective complaints that are pending, but that raise topics and questions relevant to our discussions:

The first also concerns unaccompanied minors – collective complaint 114/2015 European Committee for Home-Based Priority Action for the Child and the Family (EUROCEF) v. France.

The complaint registered on 27 February 2015, relates to Articles 7 (right of children and young persons to protection), 11 (right to health), 13 (right to social and medical assistance), 14 (right to benefit from social welfare services), 17 (right of children and young persons to appropriate social, legal and economic protection), 30 (right to protection against poverty and social exclusion) and 31 (right to housing), taken alone or in conjunction with the non-discrimination clause set forth in Article E of the Revised European Social Charter.<sup>15</sup>

As you may see, this collective complaint involves several articles. The complaint also includes the legitimacy of the practice on determining the age based on analyses of bone density. In this respect, the complainant organisation also questions the use of consent in order to perform such tests. The notion of “consent” is also an issue that has been addressed earlier today.

The last case that I would like to mention, and that is still pending, is complaint no. 117/2015, Transgender-Europe and ILGA-Europe v. Czech Republic.

The complaint registered on 30 March 2015, relates to Article 11 (the right to protection of health), alone or in conjunction with the non-discrimination principle stated in the Preamble of the 1961 Charter. The complainant organisations, Transgender Europe and ILGA-Europe, allege that, in the Czech Republic, the legal requirement of sterilization imposed on trans people wishing to change their personal documents so that they reflect their gender identity, is in breach of the above mentioned provisions of the 1961 Charter.<sup>16</sup>

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Hopefully, the above cases and the practice of the European Committee of Social Rights may give insights into how the Charter serves to address both long-term challenges in Europe as well as emerging and complex issues reflecting a continent with diverse societies. I look forward to the discussion and hope that the practise and the background I have provided will inspire further reflections.

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<sup>15</sup> [https://www.coe.int/en/web/turin-european-social-charter/pending-complaints/-/asset\\_publisher/lf8ufoBY2Thr/content/no-114-2015-european-committee-for-home-based-priority-action-for-the-child-and-the-family-eurocef-v-france?inheritRedirect=false&redirect=https%3A%2F%2Fwww.coe.int%2Fen%2Fweb%2Fturin-european-social-charter%2Fpending-complaints%3Fp\\_p\\_id%3D101\\_INSTANCE\\_lf8ufoBY2Thr%26p\\_p\\_lifecycle%3D0%26p\\_p\\_state%3Dnormal%26p\\_p\\_mode%3Dview%26p\\_p\\_col\\_id%3Dcolumn-4%26p\\_p\\_col\\_count%3D1](https://www.coe.int/en/web/turin-european-social-charter/pending-complaints/-/asset_publisher/lf8ufoBY2Thr/content/no-114-2015-european-committee-for-home-based-priority-action-for-the-child-and-the-family-eurocef-v-france?inheritRedirect=false&redirect=https%3A%2F%2Fwww.coe.int%2Fen%2Fweb%2Fturin-european-social-charter%2Fpending-complaints%3Fp_p_id%3D101_INSTANCE_lf8ufoBY2Thr%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-4%26p_p_col_count%3D1)

<sup>16</sup> [https://www.coe.int/en/web/turin-european-social-charter/pending-complaints/-/asset\\_publisher/lf8ufoBY2Thr/content/no-117-2015-transgender-europe-and-ilga-europe-v-czech-republic?inheritRedirect=false&redirect=https%3A%2F%2Fwww.coe.int%2Fen%2Fweb%2Fturin-european-social-charter%2Fpending-complaints%3Fp\\_p\\_id%3D101\\_INSTANCE\\_lf8ufoBY2Thr%26p\\_p\\_lifecycle%3D0%26p\\_p\\_state%3Dnormal%26p\\_p\\_mode%3Dview%26p\\_p\\_col\\_id%3Dcolumn-4%26p\\_p\\_col\\_count%3D1](https://www.coe.int/en/web/turin-european-social-charter/pending-complaints/-/asset_publisher/lf8ufoBY2Thr/content/no-117-2015-transgender-europe-and-ilga-europe-v-czech-republic?inheritRedirect=false&redirect=https%3A%2F%2Fwww.coe.int%2Fen%2Fweb%2Fturin-european-social-charter%2Fpending-complaints%3Fp_p_id%3D101_INSTANCE_lf8ufoBY2Thr%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-4%26p_p_col_count%3D1)

## Dr Rogelio Altisent (Spain)

Director of academic projects on the Clinical Ethics and Professionalism Chair,  
University of Zaragoza, Spain



### Current Work Position

General Practitioner in Actur-Sur Health Center in Zaragoza (Spain)

Professor at the University of Zaragoza (Spain)

### Academic details

Degree in Medicine 1978

Doctorate in Medicine 1986

Specialist in Family and Community Medicine (1984)

Graduated in Bioethics in the University of Monash, Melbourne, Australia (1999)

### Bioethical experience

Associate professor in the Faculty of Medicine since 1991. In charge of the teaching of Bioethics since 2003.

Director of academic projects on the Clinical Ethics and Professionalism Chair in the University of Zaragoza since 2012.

President of the Deontology Commission of the Spanish Medical Colleges Organisation (2006-2009).

Spanish representative on the Standing Committee of European Doctors (Ethics subcommittee) (2005-2008).

Member of the Spanish delegation in the World Medical Association and member of the Ethics Committee (2006-2008)

Co-ordinator of the Bioethics Group in the Spanish Society of Family and Community Medicine (1997-2013).

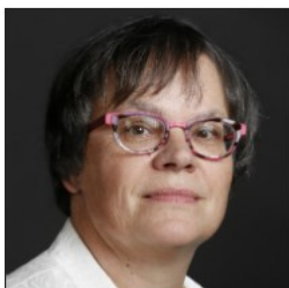
President of the Aragonese Bioethics Committee since 2013.

### ► **Equity and palliative medicine in Europe**

1. Equity in the provision of palliative care for those people suffering from an incurable disease in the final stages of life is an indication of the moral quality of a society and a right of European citizens reinforced by the Oviedo Convention.
2. Despite noticeable improvements in recent years, there are significant inequalities in the provision of palliative medicine in Europe. We will present a map showing a comparative study of the healthcare resources dedicated to those patients in a terminal situation where we can see the differences between healthcare services, especially between Western European and Central and Eastern European countries.
3. We will present information related to the teaching of palliative medicine in European universities where there are also important differences which should be taken into account when proposing actions to promote equity in the provision of palliative medicine in Europe.
4. We propose that the Council of Europe appeal to member countries requesting their health authorities commitment in the undertaking of corrective measures for these care inequalities and that the educative authorities adopt measures for all future doctors, nurses and other health professionals to learn basic palliative care during their university training.

## Ms Liliane Maury Pasquier (Switzerland)

### Chair of the Committee on Rules of Procedure of the Parliamentary Assembly of the Council of Europe



#### Professional experience

2009-2013 **President of the Swiss Federation of Midwives, Bern**  
Since 1989 **Independent midwife, Arcade Sages-femmes, Geneva**  
1988-1993 **Midwife in private clinics, in university hospitals and assistant teaching midwife, Geneva**

#### Political experience

- Since 2007 **Member of the Council of States** (for the canton of Geneva) Bern, Strasbourg
- Member and former Chairperson (2011-2013) of the Swiss delegation to the Parliamentary Assembly of the Council of Europe (PACE)
  - Chairperson of the PACE Committee on Rules of Procedure, Immunities and Institutional Affairs since 2015
  - Former Chairperson of the PACE Sub-Committee on Public Health of the Committee on Social Affairs, Health and Sustainable Development
  - Member and former Chairperson (2013-2015) of the Committee for Social Security and Public Health of the Council of States
  - Member of the Foreign Affairs Committee of the Council of States
- 1995-2007 **Member of the National Council** (Social Democratic Party), Bern
- President of the National Council and the Federal Assembly in 2002
  - Member of the Committee for Social Security and Public Health and of the Foreign Policy Committee
- 1993-1995 **Member of the Cantonal Parliament** (Social Democratic Party), Geneva
- Member of the Committees for Spatial Planning, Health and the Environment
- 1983-1991 **Municipal Councillor** (Social Democratic Party), Veyrier (Geneva)
- President of the Council in 1989-1990
  - Member of the Committee for Town Planning, the Youth Committee and the Finance Committee

#### ► Preliminary reflexions on the application of the principle of equity of access to health care

Article 3 of the Oviedo Convention reads :

#### **Article 3 – Equitable access to health care**

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

According to the Explanatory Report, "equitable", in this context, means on the one hand **the absence of unjustified discrimination** and implies, on the other hand, **effectively obtaining a satisfactory degree of care.**

Furthermore the Explanatory Report specifies that it is for the States an obligation of means, being aware that access to health largely depends on the volume of available resources.



- ▶ In recent years, the Parliamentary Assembly of the Council of Europe has adopted several resolutions and recommendations on the issue of access to health care. In its resolution 1946 (2013) « Equal access to health care », which specifically deals with that issue, recalling that the right to health is a fundamental right and that access to health care is a key aspect of it, the Assembly observed that inequalities in access to health care were growing in the Council of Europe member States.
- ▶ The Assembly noted that these inequalities particularly affect **vulnerable groups**, including people experiencing financial problems (*because of the increase of charges payable by patients*), single-parent families, pregnant women, children and the elderly, as well as Roma, migrants, refugees, transgender persons, persons in detention and homeless people.<sup>17</sup>
- ▶ Other resolutions specifically dealing with the groups mentioned above report :
  - Discrimination against **Roma**, including **lack of adequate prenatal and infant health care**<sup>18</sup> ;
  - Different factors that are deterring **migrants** from accessing **prevention and treatment services (for HIV)** because of a range of factors, including their status of irregular migrants (*for fear of being denounced to immigration authorities if they approach the health authorities*)<sup>19</sup> ;
  - Concerns about the fact that the prison health-care system does not always provide for timely access to **vital medical treatment**, particularly for **critically ill detainees**<sup>20</sup> ;
  - The lack of **end-of-life** or **palliative care** plans in many detention centres, or their misuse or poor implementation where they do exist<sup>21</sup> ;
  - Forms of discrimination against **transgender people**, including difficulties in access to health services<sup>22</sup> ;
  - Significant deficiencies in the provision of **health care to children** (difficulties in access to health care for children, particularly for those living in insecure conditions or belonging to vulnerable groups)<sup>23</sup> ;
  - Problems in accessing good-quality health care and **long-term care** still for many **older persons** in Europe<sup>24</sup> ;
- ▶ On the basis of these findings, the Assembly recommended :
  - (for Roma children) to expand access to integrated early childhood services, particularly by sending mobile health care units to visit Roma neighbourhoods and communities for screening on dental care, childcare and reproductive health<sup>25</sup> ;
  - To set up geriatric, palliative and end-of-life care plans that address the specific needs of an elderly detainee population and terminally and seriously ill detainees<sup>26</sup> ;
  - To make gender reassignment procedures, such as hormone treatment, surgery and psychological support, accessible for transgender people, and ensure that they are reimbursed by public health insurance schemes;
  - To ensure adequate funding to develop health care systems of the highest standard possible to be available to all children in an equitable manner across every country, which are comprehensive (including prevention, diagnosis, treatment, rehabilitation and palliative care), address health emergencies and chronic diseases affecting physical and mental health<sup>27</sup>;

<sup>17</sup> Groups that combine several vulnerability factors (e. g. Roma children and women, refugee children) often experience additional difficulties in terms of access to health care.

<sup>18</sup> Resolution 1927 (2013) « Ending discrimination against Roma children»

<sup>19</sup> Resolution 1997 (2014) « Migrants and refugees and the fight against Aids»

<sup>20</sup> Resolution 2082 (2015) « The fate of critically ill detainees in Europe»

<sup>21</sup> Ibidem.

<sup>22</sup> Resolution 2048 (2015) « Discrimination against transgender people in Europe »

<sup>23</sup> Resolution 2139 (2016) « Ensuring access to health care for all children in Europe»

<sup>24</sup> Resolution 2168 (2017) « Human rights of older persons and their comprehensive care»

<sup>25</sup> Resolution 1927 (2013) « Ending discrimination against Roma children»

<sup>26</sup> Resolution 2082 (2015) « The fate of critically ill detainees in Europe»

<sup>27</sup> Resolution 2139 (2016) « Ensuring access to health care for all children in Europe»

## Session II - Evolution of practices in the biomedical field

### Equity of access to health care

#### ROUNDTABLE

- To ensure the availability, accessibility and affordability of health care and long-term care for older persons; ensure adequate training of health-care professionals in geriatrics and establish geriatric centres throughout the territory where possible; foster a person-centred approach in the provision of care, by organising it around the needs and preferences of older persons, and involving them in its planning;
- ▶ Furthermore, four other reports – on palliative care<sup>28</sup>, maternal health care<sup>29</sup>, adolescents<sup>30</sup> and detainees with severe disabilities<sup>31</sup> - are under preparation and will raise new issues in terms of equity of access to health care.

## Ambassador Santiago Oñate Laborde (Mexico)

### Permanent Observer to the Council of Europe, Mission of Mexico to the Council of Europe



*Santiago Oñate Laborde, Mexican diplomat, jurist and politician, currently Permanent Observer of Mexico to the Council of Europe.*

*He has also served his country as Permanent Representative to the Organisation of American States (1991-1992); Ambassador to the United Kingdom of Great Britain and Northern Ireland (1997-2001); Ambassador to The Kingdom of The Netherlands (2001-2003) and as Agent before the International Court of Justice in the case Avena et autres ressortissants Mexicains (Mexique c. Etats-Unis d'Amérique).*

*Deeply involved in the OPCW and in the development of the Chemical Weapons Convention as Permanent Representative of Mexico from 2001 to 2003, as Legal Adviser from 2004 to 2012, and as Special Adviser to the Director-General in the preparation of the 3th Review Conference (2013).*

*He has written articles and books on Human Rights, Civil Procedure, Sociology of Justice, Environmental Protection and Disarmament.*

## Dr Ucha Vakhania (Georgia)

### Executive Director of the “Coalition Homecare in Georgia”



*Ucha Vakhania, MD is the chairman of Taoba – CSO working in the field of elderly, and the executive director of Coalition Homecare in Georgia – the union of homecare provider institutions. He graduated from Tbilisi State University (Georgia). He had a medical practice in emergency service and hospital, worked as a head doctor for a private medical institution, and later, as a general director. From the 2000s he has been working in a civic sector and directed innovative projects which contributed in Georgia to the development of new services such as homecare, nursing home, elderly day care center, assisted living, palliative care, etc. Since recently, he has been directing the Eastern Partnership countries regional project on*

<sup>28</sup> The provision of elderly and palliative care in Europe, Doc. 14039

<sup>29</sup> Universal access to maternal healthcare, Doc. 14051

<sup>30</sup> Addressing the health needs of adolescents in Europe, Doc. 14182

<sup>31</sup> Detainees with severe disabilities in Europe, Doc. 14107

*advocacy for elderly rights. He regularly collaborates with the Parliament of Georgia, the Ministry of Health, municipalities, CSOs, and media to promote the development of healthcare and social policy reforms and new services, and to advocate elderly rights.*

► **Healthcare rights for elderly in the Eastern Partnership countries**

Human rights for elderly are recognized and practiced in developed countries what is considered as one of the indicators of society development. Elderly from the less developed societies represent one of the vulnerable groups, and economic and demographic changes significantly jeopardize elderly rights. The rapid aging of the population in Georgia and other Eastern Partnership countries coincided with the collapse of the Soviet system and old age became associated with poverty and deteriorated health. A new demographic reality and elderly rights have not been properly reflected in the strategic documents of the countries in transition. The biomedical model of health care from the Soviet period is not adequate to various needs of elderly. The system lacking bio-psycho-social approach is expensive and ineffective. Healthcare systems do not provide for preventive approaches (healthy aging, active aging); rehabilitation and care are not developed; there are no geriatric institutions; the system is totally incapable of dealing with the dramatically growing number of dementia cases, as well as chronic diseases, and long-term care needs. The weakness of primary health care adds to the problem, which leads to inadequate pressure on emergency service and hospitals. On top of it, medical institutions mass privatization and commercialization of the sector have been taking place over the years. In parallel, the number of those involved in informal care significantly decreased because of a disintegration of traditional families, mass migration of youth and increased female employment. Thus, there is a distinct asymmetry regarding elderly rights among the member states of the Council of Europe. However, highly developed EU states still have challenges e.g. isolation of elderly still remains as a problem in the models of these countries. That's why Eastern European countries should have a close look at the positive and negative sides of elderly care, and with their small budget, they should ensure the basic health rights of elderly through developing of family and community-based services, establishing of age-friendly environment and developing of integrated care principles.

## RAPPORTEUR

Dr Anne Forus (Norway), Senior Adviser, Department of Biotechnology and Health Legislation, The Norwegian Directorate of Health, member of the DH-BIO



*Anne Forus is a Senior Adviser at the Norwegian Directorate of Health. She works mainly on ethical, legal and scientific /medical issues related to biomedicine and the application of biotechnology in health care and biomedical research. Her field of knowledge cover issues related to the use of genetic analyses, assisted reproduction technologies, prenatal diagnosis, pre-implantation genetic diagnosis, biobanks in research, and the use of tissues, cells and organs.*

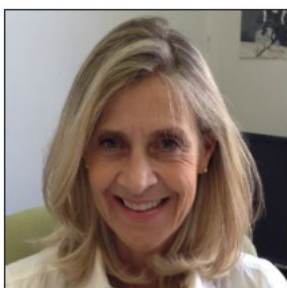
*Anne has been a delegate to DH-BIO/CDBI since 2003. She was Vice Chair in 2012 and Chair in 2013 and 2014. Anne was appointed as member of the UNESCO International Committee on Bioethics (IBC) from 2016-2019.*

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*Anne has a PhD in molecular biology and background in cancer research. She has published a number of scientific papers in peer-review journals and a book on ethical issues related to assisted reproduction technologies.*

## RAPPORTEUR

Dr Tina Garani-Papadatos (Greece), Lawyer, National School of Public Health, member of the DH-BIO



*Dr Tina (Stamatia) Garani-Papadatos is a Senior Lecturer in the National School of Public Health in Athens, Dept of Public Health since 1990. Law Degree (University of Athens), Master of Arts in Medical Law and Ethics (Centre of Medical Law and Ethics -King's College (London) and a PhD from the Dept of Forensic Medicine of the Faculty of Medicine (University of Athens). Her continuing education includes short trainings (Imperial College-London (Health Centre and Centre for Humanities), Harvard School of Public Health (The François-Xavier Bagnoud Center for Health and Human Rights) and Association of Schools of Public Health of the European Region (ASPHER).*

*Member of the Athens Barristers Association (1989-1999). Visiting lecturer in higher education institutions in Greece (National School of Administration, Faculty of Medicine of the University of Athens, Technological Educational Institute of Athens-TEI, Military School of Nursing). Participation in various EU funded research projects. Member of various legislative and Ethics committees in Greece. Member of ad hoc Expert Committees of the Council of Europe. National representative of Greece at DH-BIO, Chair of the DH-BIO (then CDBI, 2009-11). Independent expert of the EU DG Research and Innovation and of the European Research Council (Ethics Sector). Deputy member (2005-2010) of the National Authority of Medically Assisted Reproduction. Chair of the Bioethics Committee of the NSPH.*

## RAPPORTEUR

Prof. Stefano Semplici (Italy), Professor of Social Ethics, Department of Literature, Philosophy and History of Art Studies, University of Rome Tor Vergata; Chair of the Bioethics Committee of the Italian Society of Pediatrics; former Chair of the International Bioethics Committee of UNESCO



*Stefano Semplici is professor of Social Ethics at Rome Tor Vergata University, where he teaches also Moral Philosophy and is a member of the teaching board of the PhD in Philosophy (jointly organized with The University of "Roma Tre"). He is the chair (since 2014) of the Committee for Bioethics of the Italian Society of Pediatrics and an Associate Editor of the journal «Medicine, Health Care and Philosophy» (since 2010). He was the Chair of the International Bioethics Committee of UNESCO from 2011 to 2015, Editor and later Co-editor (from 2015 to 2017) of the journal «Archivio di filosofia/Archives of Philosophy», and Scientific Director of the University College «Lamaro-Pozzani».*

*Among his most recent books: The subject of irony (Il soggetto dell'ironia, Padova, Cedam, 2002); Bioethics. Questions, conflicts, laws (Bioetica. Le domande, i conflitti, le leggi, Brescia, Morcelliana, 2007); Eleven thesis on bioethics (Undici tesi di bioetica, Brescia, Morcelliana, 2009); An invitation to bioethics (Un invito alla bioetica, Brescia, la Scuola, 2011); Inclusive Constitution. A Challenge for Democracy (Costituzione inclusiva. Una sfida per la democrazia, Rubbettino, Soveria Mannelli, 2015).*

## CHAIR

**Prof. Milan Macek (Czech Republic), Head of Department of Biology and Medical Genetics, Charles University, Prague**



*Professor Milan Macek Jr. MD, DSc is the chairman of the largest academic medical / molecular genetics institution in the Czech Republic and co-chair of the National Cystic Fibrosis Centre. He is also the past President of the European Society of Human Genetics ([www.eshg.org](http://www.eshg.org)) and past-board member of the European Cystic Fibrosis Society ([ECFS.eu](http://ECFS.eu)). He also serves as the Commission Expert Group on Rare Diseases (formerly [www.eucerd.eu](http://www.eucerd.eu)). His institute was designated by the Czech Ministry of Health as a National Coordination centre for rare diseases and serves as a "clearing centre" for dissemination of knowledge in rare disease-related genetics gathered within various international European projects related to cystic fibrosis, such as CF Thematic Network, EuroGentest, EuroCareCF, Norway Grants to Central / Eastern Europe and the Middle East. Prof. Macek did his postdoctoral studies at the McKusick-Nathans Centre for Genetic Medicine, Johns Hopkins University in Baltimore and during that time he was also a fellow at Harvard School of Medicine in Boston. His main research and clinical interest is molecular genetics of cystic fibrosis and rare diseases, and how to bring genetics knowledge to the bedside. Prof. Macek is also the Czech National coordinator of Orphanet and member of the Diagnostic Committee of the International Rare Disease Consortium ([www.irdirc.org](http://www.irdirc.org)). He has been the chief advisor of the Czech EU Council Presidency ([www.eu2009.cz](http://www.eu2009.cz)) under which the EU Council Recommendation on an action in the field of rare diseases was adopted in June 2009. His citation index is over 3200x with H-index of 35.*

**Prof. Anne Cambon Thomsen (France)**

**Emeritus Research Director, Paul Sabatier University, Toulouse; member of the European Group on Ethics in Science and New Technologies, European Commission**



*Anne Cambon-Thomsen, MD and immunogeneticist, with degrees in biology, medical statistics and health ethics, is Emeritus Research Director in CNRS (French national centre for scientific research) in Toulouse, France. She works presently in a joint research Unit on epidemiology and public health at Inserm (National Institute for Health and Medical Research) and University Toulouse III Paul Sabatier where she previously created a societal platform on "genetics and society" in Toulouse. Her most recent researches address the societal aspects of biotechnology, the implications of genomics for public health, especially issues pertaining to biobanks, genetic testing, especially in complex disease genetics and data sharing. She has experience in national and European ethics bodies and expert groups. She has been co-director and coordinator of BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure) Common Service ELSI (Ethical, Legal and Societal issues). Her work with and on biobanks and bioresources and afferent research policies led her to launch the BRIF (Bioresource research impact factor) international initiative since 2010 with focus on data and sample sharing. She has recently been appointed as a member of the EGE (European Group on Ethics in Science and New Technologies) of the European Commission and is Chair of the Deontology and ethics committee of the French National Cancer Institute (INCa) and co-leads the "Ethical, regulatory and societal dimensions" working group of the French National Plan of Genomic Medicine 2025. She is the Champion of the EuroScience Open Forum (ESOF) for its 8<sup>th</sup> edition, 9-14 July 2018 in Toulouse.*

► **Sequencing and analysis: Human rights challenges raised by scientific and technological developments**

The Oviedo Convention addresses both research and clinical practice challenges related to biology and biomedicine. This is particularly relevant in the present time of technological developments in large scale genomics and application of genome sequencing. Through the massive use of new technological tools, such as the sequencing of the genome we have indeed a reading frame much more massive but at the same time much more accurate than before. How does the development of the sequence in clinical and research practice re-question the values and the practice of genetics and the relations between the persons involved? What are the rights at stake?

As a matter of fact one of the elements that affects all the domains concerned by such technologies is the blurring of established boundaries between research and clinical practice, rendering inoperative classical frameworks well established and re-stimulating the collective reflection.

We shall address the following contrasted aspects:

- Specific clinical question *versus* genome exploration
- Clinical care *versus* research
- Protocol of research *versus* database driven discovery
- Health information *versus* non health information
- Body elements *versus* information
- Clinical utility *versus* personal utility.

Such large scale characteristics, with various levels of predictive values as well as complex and evolving interpretation brings a new dimension to the meaning of "predictive test" and poses the challenges of return of results. How to maintain the right to know or not to know in this context? What is a relevant informed consent in this domain? How are rights of children affected? What is the meaning of anonymity or is this still a relevant notion?

**Prof. Bartha Knoppers (Canada)**

**Director of the Centre of Genomics and Policy, Faculty of Medicine, McGill University, Montreal**



*Bartha Maria Knoppers, PhD (Comparative Medical Law), is Full Professor, Canada Research Chair in Law and Medicine and Director of the Centre of Genomics and Policy, Faculty of Medicine, Human Genetics, McGill University. She is a Member of the Scientific Steering Committee of the International Cancer Genome Consortium (2009- ), and Co-Chair of the Regulatory and Ethics Working Group of the Global Alliance for Genomics and Health. She holds four Doctorates Honoris Causa and she is Fellow of the American Association for the Advancement of Science (AAAS), the Hastings Center (bioethics), the Canadian Academy Health Sciences (CAHS), and of the Royal Society of Canada. She is also an Officer of the*

*Order of Canada and of Quebec.*

► **Principle at stake - Action(s) to be undertaken at intergovernmental level to address the identified challenges**

The sharing of health data (research/clinic) brings with it increased statistical power and significance, to say nothing of precision. Will insurers meet their obligation to "...take account of new scientific knowledge" (CoE, Prin. 5 CM/Rec(2016)8) and achieve actuarial fairness regarding the estimation of health risks by increasingly including genetic data (Oviedo, art. 12)? If so, will this be seen as "discrimination" (Oviedo, art. 11), even if more equitable?

Moreover, many of the original fears surrounding breaches of genetic privacy have not materialized. Perhaps this argues for greater emphasis on sharing data so as to sustain and improve public health and the common good. Should we therefore turn our attention to realizing the right of everyone “to share in scientific advancement and its benefits” (Universal Declaration of Human Rights, art. 27)?

► **Full text**  
**Genetics, Genomics, and Human Rights**

Since 1997, have both article 11 and article 12 of the Council of Europe’s Convention on Human Rights and Biomedicine (“Oviedo Convention”)<sup>32</sup> been effective in preventing the use of predictive genetic testing results for discriminatory purposes? To answer that question, we begin with revisiting articles 11 and 12 before turning to an analysis of the issue of “genetic discrimination” itself (I), then questioning whether recourse to big data may mitigate this alleged phenomenon (II) and finally, postulating that activating a different human rights approach may be a more effective tool, or, at a minimum be used in parallel with genetic anti-discrimination approaches.

I. Oviedo Revisited

Oviedo’s article 11 states that: “Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited”, while article 12 maintains that: “Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling”.

These articles are further buttressed by article 21.1 of the 2012 Charter of Fundamental Rights of the European Union that posits: “Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited” (emphasis added).

In the absence of legal instruments, non-discrimination is also advocated under professional, self-regulatory guidance. While not the subject of this article, such “soft law” provides both researchers and clinicians with additional specific policy for their work since Oviedo’s adoption in 1997, especially in countries that have not signed or ratified Oviedo. Overall, the last 20 years of legislation and guidance has warned against the use of genetic information for non-medical purposes. What then is the outcome in 2017 of this position as concerns genetic testing and insurance?

2016 witnessed the adoption by the Committee of Ministers of the Council of Europe of a specific Recommendation on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests.<sup>33</sup> The preamble of this Recommendation accurately reflects the socio-ethical and legal issues in the context of insurance. Indeed, even countries with universal, health care share these concerns since the availability of life and disability insurance are necessary for access to mortgages, loans and other economic “goods” in modern society:

“Bearing in mind the significant expansion of private insurance contracts covering risks related to an individual’s health, physical integrity, age or death;  
Considering the sensitive nature of the personal health-related data processed in these contracts;  
Taking into account developments in the field of genetics, in particular the prospects of obtaining data more and more easily on the genetic characteristics of individuals, the analysis of which may be particularly complex;  
Bearing in mind the risks of an incorrect or excessive interpretation of these data regarding the state of health of the persons concerned in the – sometimes very distant – future;

<sup>32</sup> Council of Europe (1997) Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. (Oviedo) <https://www.coe.int> › Conventions

<sup>33</sup> Recommendation CM/Rec(2016)8 of the Committee of Ministers to the member States on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests.



Convinced of the social importance in each country of appropriate coverage for certain risks related to health, physical integrity, age or death;  
Recognizing at the same time the insurer's legitimate interest in assessing the level of risk presented by the insured person;”

Hence, the Recommendation's Principle 4 states that: “Insurers should not require genetic tests for insurance purposes”, but the Principle is tempered by the fact that the processing of the data resulting from such tests may be “specifically authorised by law”. The same holds as concerns genetic test results from family members.

Moreover, often forgotten is the fact that in order to be allowed to “legitimately” discriminate in pooling risks amongst applicants and in setting premiums, insurers must base their actuarial calculations on scientific knowledge. “[I]nsurers should take account of new scientific knowledge” (Principle 5). This professional duty involves regular updates of their actuarial tables and baselines. Medical information including genetic, environmental and socio-economic and demographic data are a part of this exercise. Indeed,

“[i]n the insurance contract, rational, scientifically sound and empirically supported discrimination is possible. Discrimination among risks is considered ethically problematic only where there is no sound actuarial basis for the manner in which the risks are classified, or individuals of the same risk class are treated differently. Hence, the more information available to the insurers the better, the more precise the discrimination, the greater the actuarial fairness of the system.”<sup>34</sup>

So how has the issue of genetic discrimination been addressed in the last twenty years since Oviedo?

In an international study published in 2017, we identified 8 approaches:<sup>35</sup>

- Human Rights
- Genetic Exceptionalism
- Sectoral Prohibition
- Ethical Guidance
- Self-Regulatory
- Moratoria
- Status Quo and,
- Hybrid

These approaches were defined as follows:

- (i) Human Rights: This approach aims to provide a broad, human rights based protection against GD by including it as an illicit ground of discrimination in a country's human rights legislation. *Highlights*: Broadly formulated prohibition vulnerable to judicial interpretation and statutory exceptions. Offers a degree of flexibility of interpretation.
- (ii) Genetic Exceptionalism: This approach consists of creating a specific law differentiating genetic information from other types of health or personal information to provide specific, more stringent, protection. *Highlights*: Approach assumes that genetic information is more sensitive than other types of medical information. Purports a rather pessimistic and deterministic view of genetics.
- (iii) Sectoral Prohibition: This approach aims to prevent the processing of genetic information by specific stakeholders through the use of prohibitive clauses in sectoral legislation such as employment, immigration, or insurance laws. *Highlights*: Application limited to specific types of stakeholders or limited instances of GD. Often formulated too narrowly to protect against GDS based on new types of OMICS data and on family history of diseases.
- (iv) Ethical Guidance: Guidelines may be fairly broad in nature and are not legally binding. They may have a different normative strength depending on the specific context. *Highlights*: Difficult to enforce. Useful to stimulate debate as well as to promote the development of more stringent laws and policies.

<sup>34</sup> Joly Y, Bartha BM and Godard B. (2003) Genetic information and life insurance: a 'real' risk? *European Journal of Human Genetics*: EJHG 11.8: 561 citing Anderlik MR and Rothstein MA. (2001) Privacy and confidentiality of genetic information: what rules for the new science? *Annual review of genomics and human genetics* 2.1: 401-433.

<sup>35</sup> Joly J, Ngueng Feze I and Knoppers BM. (2017) Comparative Approaches to Genetic Discrimination: Chasing Shadows?" *Trends in Genetics* 33.5:299-302.

- (v) **Self-Regulatory:** Under this approach, professional organizations have proposed guidance (ex. policies and codes) to address the challenges raised by GD in their field. *Highlights:* Relies on the goodwill of specific actors and on nonbinding guidelines to address GD. Model is flexible and can serve as a source of professional obligations. It can also be easily modified for new types of predictive data or emerging contexts of GD.
- (vi) **Moratoria:** This approach consists of an agreement between a representative professional association and the government, that its members will not make use of genetic information. *Highlights:* Temporary approach that could be abandoned to adopt a different model depending on future scientific developments and incidence of GD. Flexible approach, can be easily modified to account for new types of predictive data or emerging contexts of GD.
- (vii) **Status Quo:** Stakeholders have not taken any specific action to address GD. There may still be national debates and studies undertaken within the country to determine potential future options. *Highlights:* Does not differentiate genetic information from other types of medical data or offer specific protection against GD. Some default protection may be available through existing human rights law including privacy laws.
- (viii) **Hybrid:** Some countries have integrated elements from one or more of the other identified approaches to develop their own, multilayered, personalized format. *Highlights:* Custom fit governance model that includes aspects of different approaches to provide robust degree of protection.

Most importantly, in spite of this array of approaches to genetic discrimination, our earlier study in 2013 had concluded that while there were individual cases of discrimination,

“[[t]he significance of this initial finding is, however, greatly diminished by four observations. First, the methodology used in most of the studies is not sufficiently robust to clearly establish either the prevalence or the impact of discriminatory practices. Second, the current body of evidence was mostly developed around a small number of ‘classic’ genetic conditions. Third, the heterogeneity and small scope of most of the studies prevents formal statistical analysis of the aggregate results. Fourth, the small number of reported genetic discrimination cases in some studies could indicate that these incidents took place due to occasional errors, rather than the voluntary or planned choice, of the insurers.”<sup>36</sup>

In short, this 2013 study which examined 33 articles of alleged genetic discrimination in the literature between 1991-2012 found that, outside of selected rare adult onset monogenic conditions such as Huntington, “there [was] no conclusive data demonstrating a systemic discriminatory practice on the part of life insurers”.<sup>37</sup> Is then public perception or fear sufficient to fuel these current approaches and tools against genetic discrimination? What are possible future avenues?

## II. Big Data to the Rescue?

A decade ago, the creation of population cohorts for longitudinal studies was necessary in order to provide reference maps for the understanding of the genetic heterogeneity of modern diverse populations. Socio-demographic, environmental, personal, genetic and medical data were to be collected and stored in searchable biobanks and databases for future unspecified research by clinical, disease studies.<sup>38</sup> Organizations such as the Population Project in Population Genomics (P3G) attempted to prospectively harmonize the policies and standards used on an international scale so as to ensure future interoperability and thereby achieve statistical significance.<sup>39</sup> Today, large scale biobanking involving population cohorts (e.g. UK Biobank), if not whole countries (e.g. Estonia) are accepted epidemiological resources for clinical studies, that is, scientific infrastructures used for discovery science.

This new infrastructure science has been boosted by the tools of Big Data and cloud computing. Will such databases finally provide the quantity and diversity of data needed to build actuarially fair

<sup>36</sup> Joly J, Ngueng Feze I and Simard J. (2013) Genetic discrimination and life insurance: a systematic review of the evidence. BMC medicine 11.1: 25.

<sup>37</sup> Id.

<sup>38</sup> [www.p3g.org/biobank-lexicon](http://www.p3g.org/biobank-lexicon)

<sup>39</sup> Burton PR, Hansell AL, Fortier I, Manolio TA, Khoury MJ, Little J, Elliot P. (2009) Size matters: just how big is BIG?: Quantifying realistic sample size requirements for human genome epidemiology. International Journal of Epidemiology. 38.1: 263-273.

insurance tables for the classification of applications and the pricing of premiums? Perhaps, another roadblock remains however to insurance companies having the statistically significant data to be able to legitimately “discriminate” in today’s multicultural societies – the ability to transfer health data between countries so that their tables are representative of modern diversity. This data sharing problem is severe enough to have drawn the attention of the Organisation for Economic Co-operation and Development (OECD) whose Council adopted a Recommendation on Health Data Governance in January, 2017.<sup>40</sup> The OECD noted that progress in human health requires data on pathways, treatments, outcomes and costs as well as the ability to link datasets and electronic medical records during the cycle of care. Thus, the OECD’s Recommendation IV asks:

“that governments support transborder cooperation in the processing of personal health data for health system management, research, statistics and other health-related purposes that serve the public interest subject to safeguards consistent with this Recommendation and

- i. Identify and remove barriers to effective cross-border cooperation ...
- ii. Facilitate the compatibility and interoperability of health data governance frameworks.

In May 2018, the EU’s General Data Protection Regulation (GDPR) comes into force. This has legal force and the potential to both limit or facilitate data sharing. While the GDPR only applies to identifiable data and not the anonymized aggregate data needed for the creation of actuarial tables, it does not solve the issue of insurers asking for individual applicants “to consent” to access to their medical record where genetic data will be increasingly present as part of health care.

So we could argue that perhaps the “genetics leads to insurance discrimination” presumed equation could be mitigated by more data sharing and access by the insurance industry so that the process is fairer and science-based. We do so however from the vantage point of a country such as Canada and those European countries with universal health care and social security programmes where access to life or disability insurance is via a private contract.

Under the eight approaches we described in PART I, even countries with universal health care coverage and social security systems have still adopted legislation or policies to safeguard at least the possibility of access by their citizens to a limited amount of life insurance coverage. A “no genetic questions”, a moratorium on genetic questions except for certain severe diseases, or, an amount of insurance coverage without questions but commensurate with one’s actual income, are the most widely used approaches. Today, a minimum of life and disability insurance is seen as a necessary “socio-economic good” in modern society.

Thus, under a social and structural approach, access to a minimum of life and disability insurance should be provided to all citizens even via such a private contract and with a low premium irrespective of genetic “history” or future. Would such a systemic approach make the fears of discrimination disappear? Under such an approach, insurers should then be given access to more data so as to be able to set actuarially fair premiums and risk pooling for applicants that wish additional insurance above the minimum. Would this approach make citizens less fearful of participating in genetic research and genetic testing and so, genetic information be “normalized” as part of medical data? Consented access to one’s medical record for this “above-minimum policy” would thereby be possible as genetic data would be integrated as medical data.

This question is more than a rhetorical one as such structural change could gain impetus if founded on the human right of everyone to benefit from advances in science and their applications.

### III. A Human Rights Approach?

Article 27(1) of the Universal Declaration of Human Rights (1948) states: “Everyone has the right ... to share in scientific advancement and its benefits”. This right was rendered legally binding by Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966). 165 States have signed and ratified the ICESCR and are bound to implement the treaty in their national laws. Moreover, contrary to bioethics declarations, this human right of citizens to benefit from science, is legally actionable and imposes positive duties on governments and private actors. “Until now there have been limited efforts to develop the content of this right to science, but it likely includes a

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<sup>40</sup> Recommendation on Health Data Governance. [www.oecd.org](http://www.oecd.org)

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continuum of access rights including the right of researchers to access data. In the context of data intensive health research, it can also build on the jurisprudence of other human rights such as those to health, to procedural fairness, anti-discrimination, equitable access, and privacy”.<sup>41</sup>

Until now, an examination of the responses of the individual national reports to the UN’s Committee on Economic, Social and Cultural Rights established under the ICESCR reveals that while initially, in the ’70-s up to the late 90’s, very few States reported under Article 15(1)(c) and mostly focused in their reports on cultural rights and the rights of authors, there is a definite shift of emphasis in the 2000’s with an increasing number of States reporting on their measures to give effects to the right to benefit from science and a number of these measures involving giving more access to scientific information.

Moreover, UNESCO’s Venice Statement of 2009 began to develop the contours of this right as including the:

- Creation of a legal and policy framework promoting the conservation, development and diffusion of science and technology;
- Promotion of access to the benefits of scientific progress and its applications, including technology transfer and capacity-building; and,
- Protection from abuse and the adverse effects of science and its applications.<sup>42</sup>

This was followed in 2012 by more detail on the specific contents of this right by the Special Rapporteur for Cultural Rights:

- Access to the benefits of science by everyone, without discrimination;
- Opportunities for all to contribute to the scientific enterprise and freedom indispensable for scientific research;
- Participation of individuals and communities in decision-making; and,
- An enabling environment fostering the conservation, development and diffusion of science and technology.<sup>43</sup>

This Report while largely addressing the cultural rights also found in Article 15 did recognize the right to access “big data” freely and without discrimination and the right to equitable access to scientific applications and technologies.

Finally, two further international initiatives merit mention. The first is the 2014 Framework for Responsible Sharing of Genomic and Health-Related Data of the Global Alliance for Genomics and Health<sup>44</sup> and the second, OECD’s 2017 Recommendation on Health Data Governance.<sup>45</sup> The former explicitly aims to activate the right to the benefits of science by promoting responsible data sharing while guided by the human rights of privacy, non-discrimination and procedural fairness. The latter as we have already mentioned: “Recommends that governments support transborder cooperation in the processing of personal health data”.

#### Conclusion:

Our study of international policy developments in human genetics and discrimination since the adoption of the Oviedo Convention in 1997, has revealed a panoply of national approaches to prohibit, or, at a minimum, limit perceived or actual possible genetic discrimination in insurance. We also raised the possibility that “normalizing” genetic data as medical data and including it in big data could foster more not less data sharing and so be a route to mitigate or prevent such discrimination. Irrespective, the findings of a recent systematic literature review not only further complicates the viability and validity of prohibiting the inclusion of data in insurance but also call for a revisiting of approaches that focus on monogenic diseases: “Legislation prohibiting genetic discrimination does

<sup>41</sup> Knoppers BM, Thorogood A. (2017) Ethics and Big Data in Health. *Current Opinion in Systems Biology*. 4:53-57.

<sup>42</sup> UNESCO, *The Right to Enjoy the Benefits of Scientific Progress and its Applications*.  
<http://unesdoc.unesco.org/images/0018/001855/185558e.pdf>

<sup>43</sup> UN General Assembly. HRC/20/26 (2012) Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed.  
[www.ohchr.org/](http://www.ohchr.org/)

<sup>44</sup> Knoppers BM. (2014) Framework for responsible sharing of genomic and health-related data. *The HUGO Journal*. 8(1): 3-8.

<sup>45</sup> Supra, reference 9.

not seem to (completely) alleviate fears of genetics discrimination”. Such “fears seem to arise from pre-existing experiences of living with the social consequences of disease in the family”.<sup>46</sup>

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<sup>46</sup> Wauters A and Hoyweghen I. (2016) Global trends on fears and concerns of genetic discrimination: a systematic literature review. *J Hum Genet* 61.4:275.

## CHAIR

### Dr Petra de Sutter (Belgium), member of the Council of Europe Parliamentary Assembly



*Petra de Sutter is a medical doctor specialising in obstetrics and gynaecology and holding a PhD in biomedical sciences; areas in which she has produced numerous publications and lectures. She has been Professor in Reproductive Medicine at Gent University since 2000 and Head of the Department for Reproductive Medicine of Gent University Hospital since 2006.*

*Next to her medical practice and scientific activities, Petra has been a member of the Belgian Senate and the Parliamentary Assembly of the Council of Europe since 2014, where she is particularly interested in the legal regimes of parenthood and new health applications.*

*Petra regularly follows the activity of the Committee on Bioethics (DH-BIO) on behalf of the Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly and its Sub-Committee on Public Health and Sustainable Development. She was rapporteur on children's rights related to surrogacy in 2016, and will present her report on the use of new technologies in human beings to the Assembly in October 2017.*

### Prof. Jonathan Montgomery (United Kingdom)

#### Professor of Health Care Law, University College, London; former Chair of the Nuffield Council on Bioethics; member of the European Group on Ethics in Science and New Technologies, European Commission



*Jonathan Montgomery is Professor of Health Care Law at University College London, Chair of the Health Research Authority (which oversees research ethics committees for England), and a member of the European Group on Ethics in Science and New Technologies. He chaired the UK's Human Genetics Commission from 2009-2012 and the Nuffield Council on Bioethics (the UK's national bioethics committee) from 2012-17. He was a panel member on the Morecambe Bay Investigation into maternal and neonatal deaths (2013-5) and of the expert advisory group on the establishment of the Healthcare Safety Investigation Branch (which becomes operational in 2017). Between 1998 and 2013 he served as chair*

*of a number of National Health Service organisations in Hampshire and the Isle of Wight, in the South of England; including providers, commissioners and a Strategic Health Authority. He has been involved in the preparation of ethical guidance in a several of areas of health practice and chaired a task and finish group for the General Medical Council overseeing the revision of its guidance on confidentiality published in 2017. He is an Honorary Fellow of the Royal College of Paediatrics and Child Health. His current programme of work includes examining bioethics as a governance practice.*

#### ► **Modification of the human genome: Human rights challenges raised by scientific and technological developments**

The genesis of Human Rights Conventions brings together the messy world of politics and the reflective activities of academia to co-create a new normative order. In their operation they can play a conservative role, using the textual formulations of the past to judge the present and limit imagined futures. They may also operate as living documents, supported by institutional activity and nurturing a methodology for scrutiny and deliberation in the face of new challenges. Such an approach aims to preserve the spirit of the value tradition against those who would dilute it, while avoiding its

fossilisation into the letter of past formulations in ways that undermine social justice by blocking the application of science and philosophy for the common good. The question of human genome modification that is now before us invites consideration of how Article 13 of the Oviedo Convention should be understood, taking into account the preamble and with regard to Articles 15 and 28. As we do this, we need also to ask whether Oviedo hopes to enshrine a universal vision of humanity or is better understood as the expression of distinctive European values. Intertwined with this question is whether it belongs primarily to the family of bioethics documents, the older sister of the UNESCO Declaration, or is related more closely to the wider human rights movement and especially its European expression.

► **Full text**

*Abstract: The genesis of Human Rights Conventions brings together the messy world of politics and the reflective activities of academia to co-create a new normative order. In their operation they can play a conservative role, using the textual formulations of the past to judge the present and limit imagined futures. They may also operate as living documents, supported by institutional activity and nurturing a methodology for scrutiny and deliberation in the face of new challenges. Such an approach aims to preserve the spirit of the value tradition against those who would dilute it, while avoiding its fossilisation into the letter of past formulations in ways that undermine social justice by blocking the application of science and philosophy for the common good. The question of human genome modification that is now before us invites consideration of how the ban in Article 13 of the Oviedo Convention should be understood, taking into account the preamble and with regard to Articles 15 and 28. It is argued that the genealogy of Article 13 shows that its apparent simplicity obscures the fact that the Convention's creators were acutely aware of the contingencies that made their drafting task difficult. Further, developments in human rights law suggest the need for a clearer exposition of the meaning and basis of the prohibition of germline modifications. To revisit the terms of Article 13 would be true to the values underpinning the Convention, and there should be a broad an informed public debate about the best way to articulate them in the face of current scientific developments.*

**Introduction**

In its recommendation of 12 October 2017, the Parliamentary Assembly of the Council of Europe has asserted that 'Deliberate germline editing in human beings would cross a line viewed as ethically inviolable.'<sup>47</sup> The Recommendation cites in support of this position the text of Article 13 of the Oviedo Convention, whose twentieth anniversary we are privileged to be celebrating at this conference. Article 13 states that

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

As was noted by Rogers and de Bousingen in their book *Bioethics in Europe* this opposition to germline interventions 'echoes a wide international consensus'.<sup>48</sup> They summarised the concerns in the following terms

Somatic cell therapy – say, administering a spray of genetic material into the respiratory system of a patient with an inherited lung disorder – would benefit that patient alone. However, modifications to germ cells would be inherited by the patient's descendants. Doctors would be interfering with future, unconsenting generations.<sup>49</sup>

**Scientific and technical developments**

At the time that the Convention was drafted, the future of gene therapies was uncertain.<sup>50</sup> Twenty years later, somatic modification of the human genome has already occurred, for example to save the

<sup>47</sup> Recommendation 2115 (2017) Provisional version 'The use of new genetic technologies in human beings' <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-EN.asp?fileid=24228&lang=en>

<sup>48</sup> A. Rogers & D.D. de Bousingen, *Bioethics in Europe* (Council of Europe Press 1995) p 93.

<sup>49</sup> Ibid pp 92-3.

<sup>50</sup> For a review of the current scientific position, ethical and regulatory challenges, see G. Cossu, M. Birchall, T. Brown, P. De Coppi, E. Culme-Seymour, S. Gibbon, J. Hitchcock, C. Mason, J. Montgomery, S. Morris, F. Muntoni, D. Napier, N. Owji, A.

lives of children at Great Ormond Street Hospital in London.<sup>51</sup> The gene-edited cells were used to target cancer and were subsequently killed off by the patients' immune systems. Thus, no edited cells were inherited. This clearly acceptable within the scope of the Oviedo Convention.

Imagine, though that a patient seeks a gene therapy that will operate to modify their genome to correct a code malfunction that would otherwise end their life. In this case, the alteration will be transmitted to their children. This is, broadly the case of mitochondrial replacement therapies. This is best understood as a germ-line intervention, as we concluded at the Nuffield Council on Bioethics.<sup>52</sup> Some argue it is not a modification of the human genome because no human genes are changed, just transplanted. Or perhaps the human genome means only the nuclear genome? In the UK Parliament, the responsible health minister, Jane Ellison addressed the issue in the following terms when introducing the legislative provisions that have permitted the licensing of case-by-case use of mitochondrial replacement therapies:

... the removal of the faulty mitochondria will be passed on to the next generation. That is exactly what we have been describing, but I do not accept my hon. Friend's description of it as genetic modification. It has to be said that there is no universally agreed definition of genetic modification, but for the purposes of these regulations, we have used a working definition and it involves not altering the nuclear DNA.<sup>53</sup>

As well as raising important ethical issues, these scientific developments show how the concept of 'the human genome' is not easy to define. How should we apply the terms of the Oviedo Convention to interventions where the modification is to RNA rather than DNA, as in a study published during this celebratory conference?<sup>54</sup> Given the knowledge that is emerging of epigenetics, there are many things that impact on the expression of genes. Is such external manipulation a 'modification'? Resolution of these ambiguities may be required if legal action is brought around the use of Article 13 to deny patients access to therapies. While the Oviedo Convention does not provide for rights of individual petition, it is already being used in European human rights jurisprudence.<sup>55</sup> A consideration of the human rights challenges raised by scientific and technical developments related to the modification of the human genome therefore needs to consider the precise meaning and impact of the prohibition of germ-line interventions.

### The need for an 'affirmative genealogy'

In this paper, I want to outline an 'affirmative genealogy' of Article 13, building on the model that Hans Joas has developed in his book on human rights, *The Sacredness of the Person*.<sup>56</sup> An affirmative genealogy aims to provide an account of the genesis of ideals that reminds us of its historical contingency, but does so without 'negating our commitment' to the values that it enshrines, and in a way that 'opens our minds to the way in which historically embodied meaning calls upon us'.<sup>57</sup> It is not therefore about denying or resisting the process of 'value generalization'<sup>58</sup> that led to the drafting of the Oviedo Convention, but 'affirming the way in which historically formed ideals call upon us... with a sense of subjective self-evidence and with affective intensity'.<sup>59</sup> We need to understand the genealogy of the Convention precisely because it matter to us that we remain true to its spirit.

This is fully in accordance with the European tradition of understanding human rights conventions as 'living documents'. It will help us avoid the agonies that Ronald Dworkin has documented in relation to

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Prasad, J. Round, P. Saprai, J. Stilgoe, A. Thrasher, J. Wilson *Lancet Commission: Stem cells and regenerative medicine* (Online 4 October 2017) [https://doi.org/10.1016/S0140-6736\(17\)31366-1](https://doi.org/10.1016/S0140-6736(17)31366-1).

<sup>51</sup> M. Le Page, 'Gene editing has saved the lives of two children with leukaemia' *New Scientist* 15 January 2017, <https://www.newscientist.com/article/2119252-gene-editing-has-saved-the-lives-of-two-children-with-leukaemia/>. Q. Qasim et al, 'Molecular remission of infant B-ALL after infusion of universal TALEN gene-edited CAR T cells' *Sci. Transl. Med.* 9, eaaj2013 (2017), <http://stm.sciencemag.org/content/9/374/eaaj2013.full>.

<sup>52</sup> Nuffield Council on Bioethics, *Novel techniques for the prevention of mitochondrial DNA disorders* (2012) paras 3.24-3.31.

<sup>53</sup> House of Commons debate 3 February 2015, <https://hansard.parliament.uk/Commons/2015-02-03/debates/1502034800001/HumanFertilisationAndEmbryology>

<sup>54</sup> D. B. T. Cox, J. S. Gootenberg, O. O. Abudayyeh, B. Franklin, M. J. Kellner, J. Joung, F. Zhang 'RNA editing with CRISPR-Cas13' *Science* Published Online 25 Oct 2017, DOI: 10.1126/science.aag0180.

<sup>55</sup> European Court of Human Rights, Research Report, *Bioethics and the case-law of the Court* (2016) available at [http://www.echr.coe.int/Documents/Research\\_report\\_bioethics\\_ENG.pdf](http://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf).

<sup>56</sup> H. Joas, *The Sacredness of the Person: A new genealogy of human rights* (2013 Georgetown UP) chapter 4.

<sup>57</sup> Joas p 127.

<sup>58</sup> Joas Chapter 6.

<sup>59</sup> Joas p 127.



the USA in his book *Life's Dominion*; showing how the sterility of originalist fundamentalism around the meaning of constitutional documents has horribly distorted the bioethical debates on abortion.<sup>60</sup> In the European tradition, the interpretation of human rights conventions is sensitive to the evolution of norms, the degree of consensus across states (recognising that a margin of appreciation that is appropriate where such a consensus does not exist), and also to the development of scientific knowledge. The Recommendation of 12 October recognised this, in that it recommends a process of debate and notes that there is an explicit mechanism for amendment of the Convention (should such debate conclude that it is appropriate). Of course, this is implicitly to accept that the line related to genome-editing that can be inherited may not in fact be 'inviolable' at all.

I shall show in the next section how the particular genealogy of Article 13 demonstrates reasons to be concerned about inappropriate absolutism and unintended side effects. Before turning to that, however, it is important to make some general points about the genealogies of human rights norms. The first is that all conventions have specific histories in which we see coming together strands of expert reflection, political deliberation, and (at least in recent years) debates amongst interested publics (which may engage quite distinct constituencies, hence the plural noun).

Mary Ann Glendon's account of the genesis of the Universal Declaration of Human Rights draws out the twin strands of its origins.<sup>61</sup> The primary strand concerns the deeply political processes of drafting and negotiation of the texts, through many months of discussion and through many layers of the United Nations machinery. Alongside this, she stresses a second strand of philosophical reflection, co-ordinated by UNESCO through its Committee on the Theoretical Bases of Human Rights.<sup>62</sup> This involved serious philosophical reflection by the members of the Committee, but also canvassed the views of leading scholars and political leaders through a questionnaire.<sup>63</sup> While the text of the Declaration is the most obvious legacy, Glendon suggests that its achievement lay less in the precise terms of its wording than in the ability of 'a group of men and women who learned to cooperate effectively despite political differences, cultural barriers, and personal rivalries.... To bring forth from the ashes of unspeakable wrongs a new era in the history of rights.'<sup>64</sup> It was not that the text was perfect, as was widely acknowledged in the General Assembly debate on its adoption,<sup>65</sup> but that it was 'an important milestone on a long and difficult journey... to deeper understanding in the future.'<sup>66</sup>

We do not possess such a detailed and richly personal account of the genesis of the Oviedo Convention, but we can see that it shares some of these features. The French title of the book commissioned by the Council of Europe from Arthur Rogers and Denis Durand de Bousingen better captures the flavour of the project that came to fruition in Oviedo on April 4<sup>th</sup> 1997 than the English version. In English it sounds as though there is some alien enterprise of bioethics that arrived on the continent as part of its travels. *Bioethics in Europe* could be part of a series, in which the heroic protagonist 'Bioethics' travels the world in search of adventures. There would be other volumes covering Bioethics in the USA, Asia, Australia and wherever else she went. In French, however, the volume is entitled *Une Bioéthique pour L'Europe* – making the work a chronicle of the search for a ('une') distinctively European expression of bioethical principles that would embody its moral values and serve its peoples ('pour' – 'for' Europe, not merely 'of' or 'in').

The book shows how various European states developed national committees to engage with bioethical issues, beginning with France in 1983. The European Commission established its first advisory group in 1991. At the Council of Europe, both the Parliamentary Assembly (PACE) and Council of Ministers have long been active in bioethics and in 1992 the Ad hoc Committee of Experts on Bioethics became the Council of Europe Steering Committee on Bioethics (CDBI) and was charged with developing the Convention on Human Rights and Biomedicine.<sup>67</sup> Thus, the drafting of the convention was partly a matter for the experts. Nevertheless, the PACE maintained a degree of democratic scrutiny and issued an opinion on the Draft Convention that recommended a significantly

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<sup>60</sup> R. Dworkin, *Life's Dominion* (Random House 1993).

<sup>61</sup> Mary Ann Glendon, *A World Made New: Eleanor Roosevelt and the Universal Declaration of Human Rights* (Random House, New York, 2001).

<sup>62</sup> *Ibid* ch 5.

<sup>63</sup> Jacques Maritain, *Human Rights: Comments and Interpretations* (London, Wingate, 1949).

<sup>64</sup> Glendon, p xxi.

<sup>65</sup> *Ibid* pp 163-171.

<sup>66</sup> *Ibid* p 231.

<sup>67</sup> Recommendation 1160 (1991).

different wording for what became Article 13 (which was at that stage Article 16 of the Draft Convention, see further below).<sup>68</sup> Finally, the Convention took legal effect as a formal treaty between the member states. Thus, its authority is not merely legal. It has democratic and expert roots and draws its legitimacy from those foundations.

This is an example of what Joas describes as a process of 'value generalisation'.<sup>69</sup> Through social and political interactions a 'single legitimizing value pattern'<sup>70</sup> can be crystallised in which specific and separate 'value traditions may develop a more general, and mostly more abstract understanding of their content, without being entirely uprooted from the specific traditions and experiences that are the source of affective binding force for the actors involved.'<sup>71</sup> The problem facing us in interpreting Article 13 is precisely concerned with understanding the foundations of the 'affective binding force' of the values that lay behind its production.

One of the pathologies of bioethics, particularly apparent in its US manifestations, is its displacement of 'thick' discussion of deep values with 'thin' explorations of 'public reason'.<sup>72</sup> This draws on the insights of John Rawls into how principles of justice (as fairness) can delineate the common principles of public ethics, which he argues can be justified without reference to the 'thick' theories of morality that are adopted from within value traditions but require some degree of commitment to those traditions. 'Public reason' in this sense latches onto the formulations (whether in documents such as Oviedo or in quasi-canonical writings, such as the Beauchamp and Childress formulations of the 'four principles' of autonomy, non-maleficence, beneficence and justice). This invites technocrats, skilled in extracting the meanings of value statements to drive public bioethics.

In the context of germ cell science, John H Evans discusses this type of 'thin' argument in terms of the working out of the supposed shared principle of non-maleficence in terms of risks of harm or loss of control and their management. This became dominant through the early framing effects of enthusiastic scientist-entrepreneurs and especially the institutions in which they work. He suggests that both professional bioethics and this framing effect serves to privilege the avoidance of suffering and the value of knowledge discovery.<sup>73</sup> Further, it crowds out 'thick' debates about value. He argues that such arguments tend to be dismissed (citing 'religious' or 'intrinsic objections' such as violations of nature, commoditisation of life, 'playing God') as 'vague, simplistic or ill-conceived' as he quotes from an MIT Press book.<sup>74</sup> Alan Petersen has made similar points about the way in which the globalisation of bioethics has 'establish[ed] ways of marginalizing competitors such as the Catholic Church'.<sup>75</sup> An affirmative genealogy seeks to recover rather than to exclude the affective power of the values that are generalized into human rights documents and 'thin' theories offer too anaemic reasons to commit to their implementation.

We might think about the tasks of bioethics governance, of which the Oviedo Convention is part, in terms of three challenges: pluralism, relativism, and nihilism.<sup>76</sup> These distinctions can clearly be related to the models of co-existence, cosmopolitanism and constitutionalism that Sheila Jasanoff introduced in her presentation, although their function and the perspective from which they are drawn is slightly different. My purpose in drawing attention to them is to delineate the nature of the legitimation challenges that we need to address when constructing our 'affirmative genealogy'.

The context is clearly determined by the existence of moral pluralism. We are faced by respected, well-articulated, and enduring value traditions that find themselves grappling with difficult boundary issues. In the account that Joas provides of the emergence of human rights, the process of value generalisation secures the crystallization of fundamental values in a way that enables societies to

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<sup>68</sup> Opinion No 184 (1995).

<sup>69</sup> Joas chapter 6.

<sup>70</sup> T. Parsons, *Social Systems and the Evolution of Action Theory* (1977) p 308, quoted by Joas at p 179.

<sup>71</sup> Joas pp 180-1.

<sup>72</sup> J. H. Evans *The History and Future of Bioethics: A sociological view* (Oxford, OUP 2012).

<sup>73</sup> J. H. Evans "'Teaching Humanness' Claims in Synthetic Biology and Public Policy Bioethics" In: *Synthetic Biology and Morality: Artificial Life and the Bounds of Nature*, G.E. Kaebnick & T.H. Murray (eds) (Cambridge Mass, MIT Press 2013), 177-204, see especially 179-80.

<sup>74</sup> M. A. Bedau and Triant 'Social and ethical implications of creating artificial cells' in *The Ethics of Protocells: Moral and Social Implications of Creating Life in the Laboratory* M.A. Bedau and E.C. Parke (eds) Cambridge Mass, MIT Press 2009:31-48 at 35.

<sup>75</sup> A. Petersen, *The Politics of Bioethics* (Routledge 2011) 81.

<sup>76</sup> The first two of these were discussed briefly in J. Montgomery, 'Bioethics and a Governance Practice' *Health Care Anal* (2016) 24:3-23. <https://doi.org/10.1007/s10728-015-0310-2>

hold together conflicting views in order to adapt to social change without compromising their foundational moral solidarity.

However, the fact of moral pluralism is not a reason for regarding all the asserted positions as equal. We need to guard against the challenge of relativism, which would deny us the basis for critique of different value traditions and suggest that there are no limits than can be justifiably set. Perhaps on the basis that they are objectively required of us, or at least command such widespread consensus that they can be treated as objective. Article 13 of the Oviedo Convention engages this issue. Does it serve to establish the boundary of acceptable moral pluralism? If so, to abandon it would be a betrayal of the values that were generalized and would constitute a collapse into a relativism that cannot hold developing science properly to account. Or is it better understood as a jurisdictional device that was used in 1997 to establish a boundary that could not be crossed without careful deliberation about its merits when the scientific prospects could be more clearly considered? I consider that it is better understood in the latter terms, as I have also suggested in relation to the UK's limitation of human embryo research to the emergence of the primitive streak.<sup>77</sup>

The reason for this relates to the third challenge that must be met, that of nihilism. The problem here is that if the establishment of bioethical principles is nothing more than mere 'fiat', an exercise of will that creates values out of nothing, then there is little to oblige those who were not part of their creation to regard them as binding. Ronald Dworkin argues that the fact that *Roe v Wade* changed abortion law through such an exercise of will, by a majority vote from an unelected Supreme Court, is one of the reasons why its legitimacy has never been universally accepted in the USA.<sup>78</sup> Sheila Jasanoff noted judicial anxiety about this from the US Supreme Court in the case of *Diamond v. Chakrabarty* (1980), quoting Burger CJ: "... legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides"<sup>79</sup> To counteract the challenge of nihilism, we need to be able to articulate the connection between the wording of the Convention and the values to that demand our commitment. It is not sufficient to point only to the fact that they were agreed.

A genealogical approach guards against the problem of nihilism by excavating the historical processes by which formulations were reached, so as to expose their contingency and alert us to the risk of giving undue authority to socio-politically constructed compromises. The 'affirmative' approach focuses the genealogical analysis on its roots in values. It demands that we take seriously the need for commitment to those values, so that pluralism is respected rather than marginalised. The attention to the process of generalisation, through which such affective commitments become shared helps us with the problem of relativism, because it recognises that there must be mutual recognition of common ground and a communal judgement that the values are sound.

### **A genealogy of Art 13**

The genealogy of Article 13 undermines the claim that there is anything 'inviolable' about this particular line. The absolutist interpretation of the ethical position adopted in the Convention does not sit well with the discussion from which the text emerged. It obscures an expectation that it would quickly be reconsidered, which was manifest throughout the deliberations. Further, considerable effort was put into trying to find a way to craft exceptions in order to avoid excluding therapeutic uses that were regarded as acceptable and even desirable. The final version was a result of the political processes rather than the expert deliberation. It was characterised more by a desire to achieve simplicity and to express the Convention's provisions as deep principles than by carefully reasoned argument on the supposed inviolability of the line. In short, the drafters of Article 13 had persistent concerns over the risks of absolutism, unintended consequences, and the challenges of suitable terminology. We can reasonably infer that they would be surprised at the suggestion that there was a simple and inviolable moral rule against all germ-line interventions.

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<sup>77</sup> See J. Montgomery, 'Introduction' to *Human Embryo Culture* "Discussions concerning the statutory time limit for maintaining human embryos in culture in the light of some recent scientific developments" (Nuffield Council on Bioethics, August 2017, <http://nuffieldbioethics.org/wp-content/uploads/Human-Embryo-Culture-web-FINAL.pdf>) especially 4-7.

<sup>78</sup> R. Dworkin, *Life's Dominion* (Random House 1993).

<sup>79</sup> *Diamond v. Chakrabarty* (1980) 447 U.S. 303, at 318, emphasis added.

### ***The worry about absolutism***

Consideration of how to avoid an absolute prohibition of germ-line interventions is apparent from the travaux préparatoires. In its meeting of December 1992, the Working Party considered two alternative proposals. One supported an absolute prohibition on 'interference with the germ cell line'. The other would have recognized some 'exceptional cases (where there is no conceivable alternative) in order to correct recognised abnormalities provided that it is carried out for the purpose of ending or alleviating severe human suffering and that strict standards of reliability and safety are observed.' If this alternative had been adopted, reliability and safety concerns were to have led to a requirement of prior approval from 'an independent body, preferably a national ethics committee'. It was proposed that developments 'should be closely monitored by the CDBI and the relevant national bodies' and the possibility of revising the article was to have been specifically mentioned in the Explanatory Report. Although the alternative version was not accepted, it was unanimously agreed at that meeting to state that there should be a review of the provision within a specified time (giving as an example five years after the entry into force of the Convention).<sup>80</sup>

The Steering Committee recognized the importance of periodic review generally, and in particular of Article 13. However, it resisted the suggestion of one delegation that 'given the current state of scientific knowledge' should be inserted because it would create too much uncertainty and it would be unclear who would make the judgment that science has 'made sufficient progress to render the provision no longer applicable.'<sup>81</sup> Both these concerns address problems of regulation, the need for clarity and accountability, rather than reflect a substantive certainty on the moral question.

These concerns persisted right up to the final stages of the Convention's birth. In Paragraph 112 of the draft explanatory report from the Steering Committee, referring to what was then Article 16, it was noted that the advisability of exceptions had been examined in the light of recent or expected scientific developments:

'However, it was felt that, at the present stage of scientific knowledge, it was impossible to know all the effects that these interventions might have on following generations. Owing to this uncertainty, it was decided to adopt the rule as it appears....'<sup>82</sup>

It was not the unacceptability of impact on future generations that was the issue, but its unpredictability (and therefore the impossibility of assessing the risks and potential benefits). The final version of the explanatory report does not contain this material. It thus obscures the genealogy of the germ-line prohibition, which was intrinsically connected to uncertainty and the limitations of contemporary scientific knowledge rather than to a moral principle about intergenerational effects.

### ***The worry about unintended consequences***

Also in the genesis of Article 13 we can see nervousness about the potential inflexibility of a hard rule against modification and the possibility that its rigidity might outlaw important therapeutic options. The original rejection of 'any therapy on the human germinal line' in 1989 was replaced by an attempt to distinguish licit therapies which impacted on genes from those who raised fundamental concerns.<sup>83</sup> At the Steering Committee on Bioethics meeting in July 1993, concerns were raised by several delegations that the drafting might exclude some cancer treatments that had a side effect of interfering with the germ cell line. Their proposal to deal with this by addressing the intentions of the 'interferors' rather than the objective fact of interference was taken forward by the Working Party in January 1994. Their acceptance of the focus on the 'purpose' of the intervention was partly supported by the argument that 'for the time being' there would be oversight from ethics committees because the techniques were 'still at an experimental stage' and that the Article would also fall to be reviewed after a certain period of time.<sup>84</sup> Thus, the issues were assumed to be appropriate for governance rather than prohibition.

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<sup>80</sup> CORED 14-16/12/92 (summarised in CDBI/INF (2000) 1 Provisional at pp 63-4)

<sup>81</sup> CDBI 6-9/07/93 (p 64)

<sup>82</sup> A. Rogers & D.D. de Bousingen, *Bioethics in Europe* (Council of Europe Press 1995) reproduces the draft explanatory report on pp 261-90, the quotation is found at p 285.

<sup>83</sup> See Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, Appendix para 18, reproduced in A. Rogers & D.D. de Bousingen, *Bioethics in Europe* 311-19, the specific reference is at 318.

<sup>84</sup> CORED 24-27/01/94 (p 65)

There was a persistent tension between a subjective approach based on intentions and the search for objective tests, based on categorising the activities involved or the proper scope of applications of techniques. Thus, the Parliamentary Assembly's Recommendation 934 (1982) on genetic engineering proposed a European agreement on what constituted 'legitimate application to human beings (including future generations)' based on 'a list of serious diseases which may properly, with the consent of the person concerned, be treated by gene therapy'.<sup>85</sup> Such a position assumes the acceptability of some applications that impact on offspring, but searches for clear and objective lines that can be established by regulators to constrain the enthusiasm of researchers. There is a balance to be maintained and the Recommendation notes that due recognition of rights at stake must 'not impede development of the therapeutic applications of genetic engineering (gene therapy), which holds great promise'.<sup>86</sup> When the Assembly came to issue its opinion on the draft bioethics convention in 1995, it proposed an amendment that focussed on the actual impact of the techniques, so that the good intentions would be insufficient and permissible only 'without any intervention in the germ-line'.<sup>87</sup> The search for a clear and objective distinction thus continued.

Concerns were also raised in the Parliamentary debates about the possibility that drafting would exclude well-established therapies. In 1995, the Danish delegation raised concerns that proposals to amend (what was then) Article 16, coming from the Committee on Science and Technology, would prohibit chemotherapy treatment for cancer.<sup>88</sup> The Rapporteur of the Committee on Legal Affairs and Human Rights proposed an amendment to Art 13 (as it had become by September 1996) that sought to permit radiotherapy for curative purposes, despite effects on defendants, by adopting the language of intention. It would have amended the text so that 'intervention in the human germ cell line shall be neither an aim nor an accepted secondary effect'. However, this was rejected on the advice of the steering committee because it failed to reflect the values on which the Convention was based.

If we say that life-saving interventions that have the additional accepted medical side effect of impairing the ability to father or mother healthy children must not be carried out, we are doing something that the committee believes is unethical. It is also against the Hippocratic oath: we cannot forbid a doctor to heal a patient if he is aware of the method of achieving that end.... the wording is not useful. It is too restrictive and the amendment should be rejected.<sup>89</sup>

It is therefore clear, that concerns about excluding therapeutic interventions merely because they had an effect on the germline were apparent throughout the genesis of Article 13. Revisiting its impact in order to assess whether its consequences have unintentionally compromised patient care would be consistent with the values that lay behind the drafting.

### ***Conceptual instabilities***

A third reason for being cautious about interpreting the text narrowly and inflexibly becomes apparent when the terminological challenges that the drafters struggled with are considered. There are significant shifts in the language used through the drafting process that shed some light on what was understood to be at stake in the deliberations. These movements should not be given anachronistic significance, as if they somehow knew how scientific understanding would develop in the future. We should also recognise that the language of human rights conventions does not always use precise legal terms of art so much as metaphors, although given the legal status of the Oviedo Convention a proper understanding of the terms used is important.

The drafting process settled on the term 'human genome', a term that we have already seen is now recognised to be ambiguous. However, these ambiguities were not at the forefront of the drafters' minds and the term was not used initially. There has also been an interesting transition of metaphors that illustrates some important underlying questions. The initial draft of Article 13 referred to outlawed aims as relating to 'interference with the germ cell line'. The agreed version refers to the 'genome' but not germ cells and adopts 'intervention' in its title and 'modification' in its text. We are now discussing the 'editing' of the human genome. As Sheila Jasanoff's presentation showed, there is also the metaphor of 'engineering' that has been used in this area and was the term used by the Parliamentary Assembly in Recommendation 934 in 1982. These metaphors have subtly different meanings.

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<sup>85</sup> Para 7(a) & (c).

<sup>86</sup> Para 4(iii).

<sup>87</sup> Opinion 184 (1995) para 8(x).

<sup>88</sup> Mrs Arnold, 2 February 1995, reproduced in CBI-INF(2000) p 8.

<sup>89</sup> Mr Plattner, 26 September 1996, reproduced in CBI-INF(2000) p 38.

Interference is a form of obstruction, it prevents a pre-existing purpose being fulfilled.<sup>90</sup> In interventions and modifications the actor supplies the purpose (although perhaps with less control than in engineering). An editor does something in between, they improve or perfect the material on which they are working in order to enhance its meaning. These linguistic turns indicate different underlying attitudes to what is at stake.

In a parallel shift, the atomistic and mechanical component germ cell line has become the integrated entity of 'the human genome' with an ontological ring to it.<sup>91</sup> The 'human genome' is an obscure concept.<sup>92</sup> It is unclear whether it suggests that the drafters had in mind a sort of species genome, which was thought to be shared by all humans, Alternatively, it might refer to a category of human genomes; recognising that we all have a unique genome but asserting that it belongs in the category of human genomes that can be distinguished from those of other species. Thus, should we understand the drafting to direct the prohibition to the modification of a human person's genome? Or to the introduction into humans of non-human DNA?

In the 1982 position of the Parliamentary Assembly, the issue at stake was understood to concern 'Right to inherit a genetic inheritance that has not been artificially interfered with' (although this was not absolute and exceptions were recognised 'for example in the field of therapeutic applications').<sup>93</sup> The Assembly thought this right was implicit in Articles 2 (right to life) and 3 (right to human dignity (sic)) of the European Convention on Human Rights.<sup>94</sup> This seems to adopt an individualistic approach, protecting specific human beings from indignity. Yet, Committee discussions also examined the idea that 'human genes are the common heritage of mankind' but rejected that wording, although they 'accepted the inherent principle to the extent of its implication that in genetic manipulations performed on human beings it is imperative to preserve the human species and refrain from combinations with other species.'<sup>95</sup>

The tensions between these interpretations are likely to become significant if individual patients come to perceive the provisions of the Convention as denying them access to therapies that they would like to use. This may require us to consider whether the way in which the limitations on germ-line interventions were phrased in 1997 is consistent with the individual rights to benefit from scientific advance and to respect for personal privacy and autonomy. We need, therefore to consider how to interpret the Convention in the light of developments in European human rights law. As we have seen, the Parliamentary Assembly believed that the Oviedo Convention drew from the fundamental values enshrined in the European Convention on Human Rights and envisaged that the two documents should be read together.

### **Human Rights challenges to denial of access to germ-line therapies**

We can now envisage that a human rights challenge might be brought to clarify the possible tension between the articles of the Convention and also with wider human rights law. This is not the place to make that argument fully, but I shall outline its shape to show why I think it is a serious matter. My main purpose in doing so is to use it as a springboard for assessing how we might re-examine the terms of the Oviedo Convention in the light of such human rights concerns, and in the light of the resolution of the European Parliament.

There is no right of individual petition under the Oviedo Convention, but there is value in considering how Article 13 might be considered in cases where an individual claims that they have been wrongly denied access gene therapies in breach of their human rights. This possibility is not fanciful. We know that the Convention has been cited in cases before the European Court of Human Rights.<sup>96</sup> Working within the Oviedo Convention, a petitioner might claim that their Article 3 rights of equitable access to health care are breached in a way that discriminates against them because their genetic

<sup>90</sup> On this, see the approach taken by Pope Benedict XVI in *Dignitas Personae*, discussed below.

<sup>91</sup> CDBI-INFO(2000)1 Provisional pp 63-68 records the committee debates. ADDENDUM I CDBI/INF (2000)1 has the various draft texts. ADDENDUM II CDBI/INF (2000) 1 contains extracts from the parliamentary assembly debates. All are available from <https://www.coe.int/en/web/bioethics/oviedo-convention>.

<sup>92</sup> See Nuffield Council on Bioethics, *Genome Editing: an ethical review* (NCoB 2016) paras 1.4-1.8.

<sup>93</sup> R934(82) *Genetic Engineering* Art 7(b).

<sup>94</sup> R934(82) at Art 4(i). It should be noted that the summary of Article 3 as a right to human dignity is problematic, as that article is concerned with protection from 'inhuman and degrading treatment'

<sup>95</sup> CORED 14-16/12/92. See CDBI-INFO(2000)1 Provisional p 7.

<sup>96</sup> *Bioethics and the case-law of the Court* (2016) available at [http://www.echr.coe.int/Documents/Research\\_report\\_bioethics\\_ENG.pdf](http://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf).

heritage is different to those who can be treated through somatic therapies (thus breaching Article 11 – Non-Discrimination). They would note also that the Universal Declaration on the Human Genome and Human Rights (1997) explicitly states in its Article 12 that the ‘benefits from advances in biology, genetics and medicine, concerning the human genome shall be made available to all’ that ‘the applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals’. This is echoed in the Preamble to the Oviedo Convention.

Coming before the European Court of Human Rights, and therefore drawing on the European Convention on Human Rights, the claimant would argue that their rights to respect for private and family life under Article 8 entitle them to access gene therapies that modify the germline because it is arbitrary and discriminatory to deny them when other gene therapies are permitted. The Court has held that access to assisted reproductive technologies engages Article 8 rights to private life,<sup>97</sup> and that states must be consistent in their restrictions.<sup>98</sup> The UK experience of litigation against the fertility clinics and against the regulator, the Human Fertilisation and Embryology Authority, also suggests that human rights arguments can be raised against restrictions on access to services. In *Evans v Amicus Healthcare Ltd* the English Court of Appeal accepted that ‘the refusal of treatment is an interference with, and therefore a failure to respect, Ms Evans’ private life’, and that ‘by regulating the circumstances in which Ms Evans can have an embryo transferred to her, the state has interfered with Ms Evans’ private life for the purposes of Article 8’.<sup>99</sup> There must be legitimate reasons for such interference, and the interference must be proportionate. Blanket bans are inherently problematic, although not always impermissible, because they cannot easily balance competing considerations.<sup>100</sup>

Faced with the counter-argument that there is a European wide consensus against germ-line modification, the applicant might assert that freedom of scientific research (Oviedo, Article 15) is being improperly constrained because, although that freedom is explicitly subordinated to other principles, there has been no public debate or consultation as required by Article 28. The failure to introduce appropriate review or amendment could be argued to make the continuation of the ban arbitrary, as scientific advances have been ignored. The failure to explore the prohibition of potentially life-saving treatment means that the ban disproportionately interferes not only with their Article 8 rights but also their right to life (Art 2 ECHR) and further that this is discriminatory under Article 14 because the ban is based on their genetic status.

I am not claiming that these arguments would succeed, merely that there are human rights arguments that suggest that we need to consider very carefully the proper status of the ban on germ-line modification. What is at stake here can be characterised, in part, as the suppression of individual human interests to the demands of society, using a line drawn in the sand that is of dubious ethical validity and even could be characterised as arbitrary. When Ms De Sutter spoke as rapporteur of the report to the Parliamentary Assembly, she asked of the scientific enthusiasm for human genome editing:

Is this to the greater benefit of society, of humankind, of all patients? Is there justice involved? Or are we going into a world where genetic modification of embryos will enhance babies to create designer babies that will only be affordable for the happy few? Is the future that we want? It is definitely not the future that I want. Are we really all going to be cyborgs in a century, with bionic limbs and increased brain content? Of course, we will then edit our own genome and help human evolution. Is this the future of mankind? It is definitely not the one that I would want to see.<sup>101</sup>

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<sup>97</sup> *SH v Austria* (Application no. 57813/00, Judgment 3 November 2011).

<sup>98</sup> *Costa and Pavan v. Italy* (Application no. 54270/10, Judgment 28 August 2012).

<sup>99</sup> [2004] EWCA Civ 727 [60] and [108]. NB the European Court of Human Rights agreed that Article 8 was engaged, although the UK’s regulations fell within the margin of appreciation, see *Evans v. the United Kingdom* [GC], Application no. 6339/05, Judgment of 10 April.

2007. See also *Warren v Care Fertility (Northampton) Ltd & Anor* [2014] EWHC 60Para 119-20 ‘Mrs Warren relies on Article 8 in that she has the right to decide to become a parent by her deceased husband, which would accord with his wishes, and the written consent he gave.... I accept the proposition that she has this right and that this right should be respected by the state.’ This is not to say that the English Courts have not always found it necessary to resolve such Art 8 claims, see e.g. *R (M) v Human Fertilisation and Embryology Authority* [2016] EWCA Civ 611, [34].

<sup>100</sup> *Costa & Pavan v Italy, Pretty v UK* Application no. 2346/02, ECHR 2002-III, judgment of 29 April 2002.

<sup>101</sup> Ms de Sutter, p 28 of 48 in the English transcript of the debate of 12 October.

The human rights challenge that I anticipate will be cast differently. It will ask why the resistance to all humans becoming cyborgs should mean that an individual who could benefit from genome editing must continue to be confined to a wheelchair, or be prohibited from overcoming a memory problem? From the perspective of an individual bearer of human rights, the aspiration to protect an abstract concept of human dignity will look like an example of the 'interest of society' prevailing over the welfare of the human being. They might suggest is therefore in direct conflict with Article 2 of the Oviedo Convention. The assumption set out in the Explanatory Report on the text of the Convention in paragraph 14 that individuals 'had to be shielded from any threat resulting from the improper use of scientific developments' would appear to such a human rights claimant to be a patronising and paternalistic prejudice. On this view, the enthusiasm is not from scientists but from patients and they are entitled to be shown why the ban on germline interventions is a legitimate and proportionate restriction on their right to choose the therapies that they want.<sup>102</sup> The human rights challenge requires us to articulate an answer and satisfy ourselves that it is true to the values that drove the creation of the Conventions (both Oviedo and the European Convention on Human Rights).

#### **Time for 'broad and informed public debate'**

The Oviedo Convention itself recognises that it was not to be understood as an inflexible and eternally fixed document. If that had been the intention, then there would have been no need for public debate and consultation (Article 28), nor for protocols to elaborate the principles in particular contexts (Article 31), nor for a process to enable amendments (Article 32), nor the specific commitment for the Convention to be monitored against scientific developments within five years of agreement and then at intervals determined by the Committee charged with oversight (Article 32(4)).

Nor would engagement in further reflection on the ethics of germ-line interventions bring the institutional machinery of bioethics in the Council of Europe into conflict with religious traditions. The Roman Catholic position, in the Instruction *Dignitas Personae* approved by Pope Benedict XVI in 2008, does not propose an absolute ban on germ-line intervention as a matter of principle.<sup>103</sup> Rather, it concludes that on the state of science at that time there were no licit forms of germ line cell therapy. The Instruction recognizes the general moral appropriateness of gene therapy. In such therapy, 'actions seek to restore the normal genetic configuration of the patient or to counter damage caused by genetic anomalies or those related to other pathologies'. It concludes that it follows that 'procedures used on somatic cells for strictly therapeutic purposes are in principle morally licit.' Two problems were identified with germ-line modifications. First, it was anticipated that therapies then proposed to be performed on embryos would have been done in the context of in vitro fertilization 'and thus runs up against all the ethical objections to such procedures'. Second, and more generally, the Roman Catholic objection to germ-line modification was expressed to be based on safety concerns. Thus, there was no fundamental concern that there was something intrinsically different about germ-line interventions.

Further, the conclusion was specifically noted to be contingent on the contemporary scientific understanding:

Because the risks connected to any genetic manipulation are considerable and as yet not fully controllable, in the present state of research, it is not morally permissible to act in a way that may cause possible harm to the resulting progeny.<sup>104</sup>

Importantly, the Instruction also explains linking restrictions to their moral basis: 'the legitimacy of every prohibition is based on the need to protect an authentic moral good.'<sup>105</sup> It is therefore entirely consistent with this Roman Catholic teaching to revisit the conclusion reached in 2008 that 'in its current state, germ line cell therapy in all its forms is morally illicit' to see whether scientific knowledge and possibilities suggest a more nuanced position based on distinctions that were not available for consideration in 2008.

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<sup>102</sup> This is not to say that access to experimental therapies cannot be carefully regulated; see *Gard v UK* Application no. 39793/17, Admissibility decision 27 June 2017, *Hristozov v. Bulgaria* Applications nos. 47039/11 and 358/12, ECHR 2012, judgment of 13 November 2012.

<sup>103</sup> Unless otherwise indicated, the extracts are taken from Para 26.

<sup>104</sup> *Ibid.* para 26.

<sup>105</sup> *Ibid.* para 36.



Other denominations are also supportive of such reflection. Earlier in 2017 the Council of the Community of Protestant Churches in Europe published a guide to the Ethics of Reproductive medicine, *“Before I formed you in the womb...”* that concludes

that an ethic of love, freedom, justice and responsibility could in principle support the use of germline therapy as a way for parents to take responsibility for the identity and well-being of their children.<sup>106</sup>

It raises concerns about the use of the technologies for enhancement, and in particular about ‘a grandiose “transhumanist” agenda for the transformation of humankind into a new (and supposedly better) species.’<sup>107</sup> However, even here, it suggests that ‘enhancement projects with more modest aims, theological suspicion might stop short of blanket rejection’.

The section of this report dealing specifically with human genome modification argues that two distinctions are key to the ethical discussion, First, that between somatic and germline modifications and, second, that between therapy and enhancement. It suggests that the assumption that germ line modification would not be a reality for a long time ‘has at times lent a rather speculative character and an air of unreality to ethical discussions’, but as this has changed with the development of CRISP/Cas9 ‘it is timely, therefore, for Christian churches to take these developments seriously as areas of current concern that call for careful deliberation and response.’<sup>108</sup> For the Council, ‘the most obvious ethical issues are concerned with safety, efficacy, and the balance of intended benefits against the risks of harmful consequences.’<sup>109</sup> They note that views are split on whether these concerns justify a moratorium.

The conclusion that I draw from this analysis of two contributions from the Christian faith tradition is that to treat the ban on germline interventions as an inviolable sacred line would be to abandon our responsibility to take seriously the ethics of medical advances. As the creators of the Convention anticipated, there is a need to re-examine the provisions of Article 13 to see whether the terms that were agreed in 1997, based on contemporary scientific possibilities and understanding, continue to reflect the values that it was intended to promote.

## **Conclusions**

The reasons why we need to refresh our understanding of Art 13 are captured in the observation from Hans Joas that the preciousness, in his terminology the ‘sacrality’, of human rights is built on subjective self-evidence and affective intensity.<sup>110</sup> I have shown that it was not self-evident in the preparation of the Convention that modification of the human genome could never be compatible with human rights. It was a matter of recognising multiple values in a specific scientific context. The regulatory solution was not obvious but complex. The obviousness of the ban on genome editing seems even less now. We should be wary of conflating ‘affective intensity’ with strong feelings. If nothing else, the violence of anti-abortion activism should remind us that passion can eclipse reasoned debate. Indeed, I am doubtful that we should ever respect an affective response to a prohibition itself, rather than to values on which it is based.

In the case of Article 13, the reference to aim encourages us to reflect on the purpose of the prohibition not merely its letter. Joas ends his discussion by noting that if values are to be effectively codified into rights that all can invoke, then we need ‘an argumentational justification of the universal validity claim’. He suggests earlier that such a case can only be built on a narrative that explains how the values are ‘appropriate articulations of the experiences that we or others have been through; we embrace new ones not through a decision but because we have encountered an articulation experienced as even more appropriate.’<sup>111</sup>

What we need, recognising this affirmative genealogy, is to recreate the deliberative process from which Article 13 emerged. We need to see whether experience now suggests a new articulation of the way in which the relationship between the advance of science and respect for human dignity calls for a response. This might be no more than an elaboration of the meaning of the words, in the manner of

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<sup>106</sup> Council of the Community of Protestant Churches in Europe, *“Before I formed you in the womb...”* (2017) p 17.

<sup>107</sup> Ibid.

<sup>108</sup> Ibid. p 150.

<sup>109</sup> Ibid p 150.

<sup>110</sup> Joas p 5.

<sup>111</sup> Joas p 137

a revised explanatory report. It might lead to an elaboration of the Conventions' values in the context of germ-line therapies, perhaps as a protocol. It could mean a revision of the text itself. The human rights challenge is to reassure ourselves that we have not lost sight of the primacy of the rights of the individual by creating an idol of the words that were adopted in 1997.

### **Prof. Ewa Bartnik (Poland)**

**Professor of Genetics, Faculty of Biology, University of Warsaw; member of the International Bioethics Committee of UNESCO**



*Professor of Genetics at the University of Warsaw and the Institute of Biochemistry and Biophysics, Polish Academy of Sciences. Current research interests: role of mitochondria in human diseases and aging; previous – biochemical genetics of *Aspergillus nidulans*, DNA methylation, regulation of gene expression in mitochondria, mitochondrial DNA mutations in cancer. She coordinated the program of reforming the science curriculum in Polish schools in 2008 and is active in popularizing science. Member of the PISA Science Expert Group 2006-2009. Member of the Bioethics Committee of the Praesidium of the Polish Academy of Sciences since 2015.*

*Member of the Identification Committee for selection of new members of The European Group on Ethics of Science and New Technologies (2016).*

*Member of the International Bioethics Committee of UNESCO 2010-2017, rapporteur since 2015.*

► **Principles at stake - Action(s) to be undertaken at the intergovernmental level to address the identified challenges**

Many important papers and at least one book have been published since the Baltimore et al. letter appeared in the spring of 2015. To mention just a few, The Committee on Human Genome Editing has specified 7 principles that should be used in setting up an oversight system for germline editing, namely promoting well-being, transparency, due care, responsible science, respect for persons, fairness and transnational cooperation. The European Academies Science Advisory Council Report has underlined public engagement and enhancing global justice, whereas a paper co-authored by the Hugo Committee on Ethics Law and Society stresses the concept of genomic solidarity and the priority on public good.

The regulatory situation in Europe is complicated, and for countries that have ratified the Oviedo Convention there is - among others - a problem with art. 18.2, which forbids creation of embryos for research purposes, as the most successful way of germline genome editing published so far combines in vitro fertilization with injection of editing tools so embryos are created for research purposes.

Two actions appear to be of fundamental importance, first of all a situation should be avoided which resembles what has happened with mitochondrial replacement, as while legal mechanisms were implemented in the UK, babies were born in Mexico and the Ukraine without appropriate oversight, thus transnational agreements are required. Second, countries that allow modification of the human genome in embryos must have appropriate regulatory mechanisms in place with competent bodies responsible for oversight. The main problem is when there is a grey zone - something is not forbidden, but there are no proper mechanisms to ensure that if it is done, it will be done with appropriate oversight.

Perhaps one of the most important aspects is public engagement. There is no good prescription for this, as the attitudes in Europe of many people to GMOs and (fortunately to a lesser extent) vaccines are examples showing how difficult it is to explain science.

► **Full text**

People who were already active in science in the 1970s may have had a feeling of déjà vu when a letter by Baltimore, Berg et al. (2015) appeared in *Science* in the spring of 2015. The letter called for reflection and discussions on the possibility of using a new method of gene editing, CRISPR-Cas9, to modify human embryos. The most important phrase (for me) was "Strongly discourage...any attempts at germline modification for clinical application in humans while societal, environmental, and ethical implications of such activity are discussed among scientific and governmental organizations.... This will enable pathways to responsible uses of this technology, if any, to be identified".

The déjà vu was due to the Berg, Baltimore et al. (1974) letter concerning genetic engineering. For genetic engineering, essentially all problems were resolved within a year, even though the technology was completely new, and people were afraid of things which we currently know could not happen such as obtaining aggressive bacteria bearing oncogenes.

The current discussions will not go away so quickly, as the genetic engineering concerns of the 1970s were more about fear of the unknown than about ethics. Now although the discussions also concern other matters than modifying the human germline, it is this particular idea which is in the center of most of them.

Thus, there have been many discussions, many position papers have appeared from very serious organizations, and two books - one from the National Academy of Sciences, Engineering and Medicine (NAS/NAM) and one from the Nuffield Bioethics Council, a second book from the Nuffield council is expected soon.

The NAS/NAM book listed under what conditions human germline genome editing might be tried; the list contained: the absence of reasonable alternatives; restriction to editing genes that have been convincingly demonstrated to cause or strongly predispose to a serious disease or condition; credible pre-clinical and/or clinical data on risks and potential health benefits; ongoing, rigorous oversight during clinical trials; comprehensive plans for long-term multigenerational follow-up; and continued reassessment of both health and societal benefits and risks, with wide-ranging, ongoing input from the public.

This had been taken as a "yellow light" for germline genetic engineering, and a recent document by the Deutscher Ethikrat commented on the fact that the book has shifted the emphasis from "do not allow till the risks are better understood" to "allow when the risk can be better evaluated". The European Group on Ethics in Science and New Technologies has called for an inclusive debate on "acceptability and desirability" extending to civil society not limited to safety issues, potential health risks and health benefits, and taking into consideration such fundamental ideas as dignity, justice, equity, proportionality and autonomy.

On October 12, 2017 the European Council adapted Document 2115(2017) which sets forth 5 steps that should be undertaken by member countries in regard to human germline modification regulation. In contrast to other documents which are more ethical and general, this one is addressed directly to states.

- 1) Member states should be urged to ratify the Oviedo Convention or at least implement ban on pregnancy with a modified embryo
- 2) A broad and informed public debate should be fostered
- 3) The Council of Europe Committee on Bioethics should assess the ethical and legal challenges
- 4) A common regulatory and legal framework should be developed
- 5) Member states should develop a clear national position on use of new genetic technologies "setting the limits and promoting good practices".

A paper has appeared recently, suggesting that the 20th anniversary celebration of the Oviedo Convention could be an opportunity for introducing changes into the document conducive to modern research (Sykora and Caplan, 2017). This is unlikely to happen, due to the current situation - many countries have signed and ratified the Oviedo Convention, some have only signed, but not ratified, and others have done neither.

### **Session III - New Scientific and Technological Developments**

#### **Genetics - Genomics**

It is important to remember two facts, the first one is that Europe (including the United Kingdom, in spite of Brexit) is very diverse in respect to regulation of what is allowed in research concerning human embryos, and also in the field of in vitro fertilization (Araki and Ishii, 2014). The latter is pertinent, as it is embryos from in vitro fertilization that can be used - if the law permits it - used for experiments with genome editing. The second is that the Declaration of Oviedo has two important paragraphs affecting this type of research. Article 13 – Interventions on the human genome - states that "An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants". Thus, in countries which allow in vitro fertilization and whose legislation allows for the use of supernumerary embryos for research purposes CRISPR could be used in experiments but only if the embryos are not subsequently implanted.

The second paragraph is Article 18.2, Article 18 is on Research on embryos in vitro and 18.2 states that "The creation of human embryos for research purposes is prohibited".

A number of papers on CRISPR technology applied to human embryos have appeared, starting from a paper using non-viable triploid embryos obtained from in vitro fertilization (Liang et al., 2015) to a very recent paper by Ma et al. (2017) where the CRISPR system was co-injected with sperm, thus in fact creating embryos for research. Doubts have been raised as to whether results of the Ma et al. paper, which obtained an unusually high percentage of correctly modified embryos without off-target effects, were indeed properly documented (Egli et al., 2017), the matter has still not been resolved.

Papers with both ethical deliberations (e.g. Church, 2017; Cwik, 2017) and with new techniques modifying the CRISPR method (e.g. Liang et al., 2017) are appearing at a frequency which makes them difficult to follow. What is of paramount importance is that germline editing must not follow in the footsteps of mitochondrial replacement technology, which has to some extent been hijacked. On the one hand, even though the United Kingdom did not sign the Oviedo convention, it went through a fairly long process involving thorough examination by the Nuffield council, the introduction of changes to the law (which previously did not permit implantation of a human embryo modified in any way). Scientists in Newcastle spent over 15 years doing careful preparatory experiments and only obtained permission to perform 5 mitochondrial transfers per year for 5 consecutive years in the spring of 2017. No pregnancies have been - at the moment - achieved. However, two babies were born in 2016 and 2017 - in Mexico to a woman with a mitochondrial disease and in the Ukraine to a couple where the mother had problems getting pregnant but there was no mitochondrial disease. Plans for more babies were announced for 2017, but seem to have not worked/or not been announced. Thus the above-mentioned points 4 and 5 (4) A common regulatory and legal framework should be developed and 5) Member states should develop a clear national position on use of new genetic technologies "setting the limits and promoting good practices".) are very important.

The importance of public engagement also cannot be underestimated. There is unfortunately no perfect method to ensure this, as the attitudes in Europe of many people to GMOs and (fortunately to a lesser extent) vaccines are examples showing how difficult it is to explain science, and how easy it is for people to have opinions which are not based on scientific facts. These opinions may be even stronger, and not necessarily more evidence-based, when the health of future children is considered.

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## CHAIR

### Mr Jean-Yves Le Déaut (France), former member of the Council of Europe Parliamentary Assembly



*Jean-Yves Le Déaut was a Socialist member of the French National Assembly representing the sixth constituency in the département of Meurthe-et-Moselle from 1986 to 2017 and Chair of the French Parliamentary Office for the Assessment of Scientific and Technological Choices (OPECST) from 1989 to 1992, 1997 to 1998, 2001 to 2002 and 2014 to 2017.*

*Between 2004 and 2013 he was Vice-President of the Council of the département of Meurthe-et-Moselle and First Vice-President of the Region of Lorraine, with responsibility for higher education, research, innovation and economic development. He is a member of the Parliamentary Assembly of the Council of Europe, which elected him in 2014 as General Rapporteur on Science and Technology.*

*Mr Le Déaut has a Doctorate in Sciences from the Louis Pasteur University in Strasbourg (1976), where he was a faculty assistant (1968-1971) then an assistant in fundamental sciences (1973-1976) in the Faculty of Medicine. After serving as a professor on a co-operation agreement with the University of Antananarivo (Madagascar), he was appointed, on his return to France, as a professor of biochemistry (1983-1998) at the Faculty of Sciences in Nancy. During this time, he was the director of the Food Biosciences Laboratory (1983-1998) and the Biological Sciences Department of the University of Nancy 1 (1984-1986).*

*In January 2013, having completed the parliamentary assignment entrusted to him by the Prime Minister of translating the conclusions of a General Meeting on Higher Education and Research into law, he submitted his report entitled "Reforging university education – revitalising research and enhancing success through co-operation", much of which was incorporated into the new law on higher education. He argued in particular for the establishment of groupings of universities and establishments, regretting that the French university system was so fragmented, comprising 86 state-run or private universities and another 1 509 higher colleges of various types.*

*At the OPECST, he conducted over twenty studies relating not only to bioethics and biotechnologies but also to renewable energies, the information society and Internet governance, as well as issues at the heart of debates between the scientific community and society such as those surrounding nuclear waste, asbestos, GMOs and pesticides.*

*In January 2012, he published a report on innovation and the constraints placed on it by fears and risks. For several years he lectured at the Institute of Political Sciences in Paris on the major issues of the 21<sup>st</sup> century.*

*In July 2014, with his colleague, the Senator Marcel Deneux, he presented a report on the regulatory constraints on innovation in the field of energy savings in buildings. In November 2014, as the advocate of a principle of innovation which is not at variance with the precautionary principle enshrined in the Constitution but a complement to it, he held a public hearing with his colleague, Senator Bruno Sido, on the innovation principle, with the assistance of the Forum on Innovation Policies. The discussions during this hearing enabled OPECST to draw up conclusions in which it proposed to amend the Research Code and the Public Procurement Code to stimulate innovation and innovative activities. Since 2014 he has been the Chair of the Commission for Investment and Economic Mobilisation through Innovation of the Region of Lorraine – now the Grand Est Region.*

*In March 2017, he and the Senator, Catherine Procaccia, published the first ever report in Europe on genome editing. In April 2017, his report on technological convergence, artificial intelligence and human rights was adopted by the Parliamentary Assembly of the Council of Europe.*

Since 1995, he has dealt with issues of research and innovation within the Socialist Party. He was a member of the party's national secretariat for six years and was in charge of research questions in François Hollande's campaign team for the 2012 presidential elections.

## Prof. Nikola Biller-Andorno (Switzerland)

Director of the Institute of Biomedical Ethics and history of medicine, Center for Medical Humanities, University of Zürich



*Prof. Dr. med. Dr. phil. Nikola Biller-Andorno is Director of the Institute of Biomedical Ethics and History of Medicine, University of Zurich (UZH), Switzerland, which serves as WHO Collaborating Centre for Bioethics and hosts the PhD program "Biomedical Ethics and Law" (medical track) as well the Center for Medical Humanities. She acts as Vice-President of the Clinical Ethics Committee of the University Hospital Zurich and as member of the Research Ethics Committee of the Federal Institute of Technology Zurich and has served as ethics expert for the Human Brain Project. Nikola Biller-Andorno is Past-President of the International Association of Bioethics and a member of the Swiss Academy of Medical Sciences. She has been a Commonwealth Fund Harkness Fellow (2012-13), a Safra Network Fellow (2013-14) and a Visiting Professor of Biomedical Ethics (2012-14) at Harvard University. Most recently, she has been elected as Fellow to the Collegium Helveticum, an Institute of Advanced Study sponsored by the University of Zurich, the Federal Institute of Technology Zurich, and the Zurich University of the Arts.*

### ► Human rights challenges raised by scientific and technological developments

Brain science has developed fast over the past decade. Emerging technologies to read, simulate, alter and create new interfaces with the human brain carry revolutionary potential. Whereas developing clinical applications, such as brain testing for diagnostic and predictive purposes or therapeutic neuromodulation seem to primarily raise ethical concerns regarding respect for patient autonomy, the ratio of harms/risks and benefits and justice issues such as fair access, brain-computer interfaces also touch on more fundamental matters regarding personhood, agency and human dignity. The use of brain technologies for human enhancement purposes and the development of intelligent devices raises questions about societal norms and values, as do other non-clinical applications, e.g. the use of information on an individual's neural activities or neurotype for legal prosecutions. Algorithm-based decision-making, particularly in closed loop systems, lead to challenges regarding accountability. Abuse such as mind hacking or hacking devices linked to brain-computer interfaces (e.g. a robotic arm) point to the urgency of addressing concerns regarding privacy, safety and security, possibly even by formulating a new set of human rights. The presentation will provide a brief overview of emerging brain technologies and will highlight ensuing ethical and human rights challenges.

### ► Full text

Dear ladies and gentlemen

Let me start with a personal note: When I was a medical student I remember taking the train to Strasbourg, full of excitement and enthusiasm, to witness some of the discussions in preparation of the Convention on Human Rights and Biomedicine. It was fascinating to see ethical considerations getting translated into a political and legal context. A few years later I came back from a postdoctoral fellowship in the US and learned that the Convention had been opened for signature. I have followed the reception with interest ever since, and am honored to take part today in the Convention's 20th anniversary celebration.

### **Session III - New Scientific and Technological Developments**

#### **Brain technologies**

Brain science – the subject of my talk today - has developed fast over the past decade. Emerging technologies to read, simulate, alter and create new interfaces with the human brain carry revolutionary potential. Whereas clinical applications, such as brain testing for diagnostic and predictive purposes or therapeutic neuromodulation seem to primarily raise ethical concerns regarding respect for patient autonomy, the ratio of harms/risks and benefits and justice issues such as fair access, brain-computer interfaces also touch on more fundamental matters regarding personhood, agency and human dignity. The use of brain technologies for human enhancement purposes and the development of intelligent devices raise questions about societal norms and values, as do other non-clinical applications, such as the use of information on an individual's neural activities or neurotype for legal prosecutions. Algorithm-based decision-making, particularly in closed loop systems, lead to challenges regarding accountability. Abuse such as mind hacking or hacking devices linked to brain-computer interfaces (e.g. a robotic arm) point to the urgency of addressing concerns regarding privacy, safety and security, possibly even by formulating a new set of human rights. The presentation will provide a brief overview of emerging brain technologies and will highlight ensuing ethical and human rights challenges.

When looking at the convention it seems fair to say that topics other than brain technology have been treated more prominently; the terms “brain” or “neuro” are not even mentioned in Convention text. There are some general provisions that can be brought to bear on the subject, among them the “dignity and identity of all human beings”, respect of integrity and fundamental freedoms, the principle of non-discrimination, and the right to respect for private life. However, this does not compare to the attention that other domains received, particularly genetics, reproductive medicine, organ transplantation and biomedical research, which have also been the subject of Additional Protocols.

This lack of explicit engagement with neurosciences and brain technologies may seem somewhat surprising given that the 1990s had been declared the “decade of brain”. Possibly this has to do with the somewhat theoretical, abstract nature of findings back then, although many important foundations were laid at the time. Today, brain technologies – including easy-to-grasp applications for a broad circle of potential users – appear to grow exponentially, to the point that the field has become hard to summarize in a single talk.

Current efforts are characterized by an interdisciplinary collaboration of neuroscience, medicine, information technology, psychology, mathematics, engineering and further disciplines. Goals are not limited to the prediction, prevention, diagnosis and treatment of disease or understanding and modeling the human brain. Research and development efforts frequently include an enhancement component, or can at least be used towards this purpose.

There are several big projects with very significant funding underway, including the Human Brain Project, a flagship project of the European Commission, or the Brain Initiative, sponsored by the US Department of Health and Human Services and other partners. Among these is the Defense Advanced Research Projects Agency (DARPA) whose Neural Engineering System Design program aims to develop a human brain port that can translate the electrochemical language of the brain into the binary language of information technology. The device is supposed to be no larger than one cubic centimeter while being able to selectively stimulate up to 100'000 neurons. Possible applications might include functions such as powering prostheses or exoskeletons, restoring or modulating memory. Some researchers hesitate to collaborate with the military as they are worried about dual use issues, the fuzzy border between restoration and augmentation and the concern that early volitional stages might be translated into (military) action before the user has made a definite commitment.

Private investors have also started to engage in the area. Elon Musk, CEO of Tesla, has founded a start-up company called Neuralink that aims to build “ultra high bandwidth brain-machine interfaces to connect humans and computers.” Beyond economic motives Musk has argued for a need to enhance our intelligence with machines lest we be overtaken by some form of non-human Artificial Intelligence.

Another, much more profane application is neuromarketing. Using rather traditional methods such as electroencephalogram (EEG), skin conductance and heart rate, facial expression, eye tracking, and consumer self-reports, proponents claim to use neuroscience tools to predict consumer behavior.

The consumer market itself offers various brain technology-based gadgets, ranging from a brain wave powered headband with cat ears that rise with concentration to wearables using brain signals



as input for gaming, communication or wellness devices.

Of course, there are also medical applications. One example is an implantable neurostimulator for epilepsy patients that can detect unusual brain activity patterns that may lead to a seizure. By sending brief pulses the device normalizes brainwaves. A remote monitor allows the patient to collect information from the neurostimulator. This information can be transferred to a Patient Data Management System that is accessible to the treating physician. Such a device, which detects a signal, compares it to normal activity and notes deviations, and acts to normalize relevant parameters, is called a closed loop system.

Another clinical application that has received quite a bit of attention is the mind-controlled arm. A neural interface system enables paralyzed patients to move a robotic arm by thinking about moving their own arm. The topic has inspired television productions such as “Arm-aggodon”, in which an ex-soldier claims his prosthetic arm was hacked and used to murder his wife.

Brain technologies – some already existing, some still hypothetical - are developed to serve different purposes, which can be grouped in the following way:

- Reading: Brain activity can be read through electroencephalograms, fMRIs or other methods, some of which are invasive (e.g. electrocorticography). The ability to detect or monitor brain activity is, for example, of clinical relevance in the case of patients in a minimally conscious state but has also been exploited more broadly for commercial purposes (e.g. for insights about consumers). Another potential application is to “de-code” the recorded data, e.g. by translating it into language. This function is of interest for people with aphasia or for patient with a locked-in syndrome, who are paralyzed and unable to speak but conscious. Brain activity data can also be saved on an external device (“mind uploading”). If the device learns to simulate brain functions it has been speculated that it might gain virtual consciousness. Brain activity data can also be used to identify a person (“brain fingerprint”) or to determine if an information is stored in a person’s brain or not, which has controversially been claimed to be of useful for legal proceedings.
- Simulating: Brain activity can be studied to simulate it in silico. Artificial neural networks are, for instance, inspired by biological neural networks, allowing computers to perform a variety of tasks, including computer vision, speech recognition, translation or playing games.
- Altering: EEG data have been used for some time for neurofeedback, which allows individuals to better self-regulate their brain activities, e.g. in the case of ADHS. Brain data can also be used to trigger a neurostimulator, which can be implantable (“deep brain stimulation”) or work through the skull (e.g. transcranial magnetic stimulation). This technology has been used for some time with Parkinson and epilepsy patients, and the range of applications is broadening or include conditions such as compulsive-obsessive disorder or depression.
- Controlling devices: Brain activities can also be used to control devices, such as neuroprotheses, which is relevant to patients with paralyses. The range of potential application is broad, including devices such as remote controls, mobile phones etc. In closed loop systems devices act automatically, in open loop or patient-controllable systems further input is needed to trigger or modulate activity.

Brain computer interfaces (BCIs), i.e. direct communication pathways between the brain and an external device, play a key role in the burgeoning field of brain technologies. There is a great variety of BCIs, ranging from EEG based wearables to invasive BCIs. Annual awards are given for innovative projects. Applications are not limited to scientific or clinical purposes but extend to consumer markets, offering tools for entertainment or wellness.

A major issue of the emerging interfaces between the brain, monitoring and executive devices is that they can be hacked. This is of particular concern given the huge amount of highly personal data that can be accumulated with the help of brain technologies. Data can be other purposes than the ones the user had consented to or devices can perform functions that differ from what the user had intended. It is questionable to what extent consumers are actually fully aware of the risks when purchasing a product.

Another feature of brain technologies concerns the potential for dual use, both in the sense of being used both for civil and military ends and in the sense of being used for medical and enhancement purposes. The potential applicability of BCIs is very broad: brain powered remote controls can be

### ***Session III - New Scientific and Technological Developments*** ***Brain technologies***

connected to very different devices such as mobile phones, wheelchairs, cars or drones. When decisions are taken automatically (such as in self-driving cars) in closed loop systems, questions about accountability arise – who is responsible in the case of damage, the user, the company, the individual or group who developed the algorithms? Convergence with artificial intelligence systems will broaden the range of possible applications still more.

Ethical issues of brain technologies will need to be discussed with a view to their purpose - e.g. diagnostic, therapeutic/restorative, predictive/preventive, for enhancement or transhumanism -, the area of application - e.g. clinical, military, legal (e.g. lie detection; prediction of criminal behavior), market research, entertainment, transport (driver alarm for fatigue or distraction) or personal identification (brain fingerprint) -, the method and set up – e.g. invasive or non-invasive, closed loop – open loop.

These dimensions, and likely more, will need to be distinguished when discussing ethical issues arising from brain technologies. There is, however, a set of considerations that is likely to play a role no matter what application is considered: Respect for persons – with concepts such as dignity, autonomy, authenticity, integrity, fundamental freedoms and privacy -, risk for harm – with considerations regarding safety, security and dual use issues -, justice – e.g. equitable access, non-discrimination -, benefits – which are mostly area specific and are partly hypothetical, such as virtual immortality -, and social values – particularly solidarity and liberalism.

Some have claimed that the challenges brought forward by brain technologies are so formidable that they need indeed be addressed by a new set of human rights, including a right to cognitive liberty, a right to mental privacy, a right to mental integrity and a right to psychological continuity. It can be debated, however, if there is a need for new human rights or if the task does not rather consist in the specification and concretization of existing human rights as they are also present in the European Convention of Human Rights, such as the right to liberty, the right to respect for private life and freedom of thought.

It is certainly true, though, that brain technologies put a fundamental tenet of our societies at risk that has been a comfort to those under duress for the past centuries and which has been quite aptly expressed in the title of the old German folk song “The thoughts are free”. It cannot be expected that data protection regulation alone can take care of the issue. Rather, it might be time for the Council of Europe to consider an Additional Protocol on Brain Technologies to complement the Oviedo Convention.

With this humble suggestion I would like to close and congratulate the Council of Europe to this remarkable anniversary.

**Prof. David Winickoff (OECD)**

**Senior Policy Analyst, Secretary of the Working Party on Bio-, Nano- and Converging Technologies (BNCT)**



*David E. Winickoff, JD, MA, is Senior Policy Analyst and Secretary of the Working Party on Bio-, Nano- and Converging Technology at the Organization for Economic Cooperation and Development (OECD) in Paris. He came to the OECD from a tenured professorship in bioethics and biotechnology policy at University of California, Berkeley, where he directed the Program in Science and Technology Studies for four years and wrote widely in the areas of genomics policy, technology transfer, science advice, risk, science and law, and international trade law. At the OECD, he leads international work advancing the responsible development of emerging technologies in areas such as synthetic biology, neurotechnology, gene editing, the bioeconomy, and convergent production technologies such as robotics and cyber-physical systems. He has over fifty publications in academic journals and other outlets. His articles have appeared in Science, New England Journal of Medicine, Nature Climate Change, and the Yale Journal of International Law, among others. Winickoff has served as a working group member and co-author at the U.K. Royal Academy, the U.S. National Academies of Science, and the Bipartisan Policy Center. He was a Greenwall Scholar in Bioethics from 2010-2013. He holds degrees from Yale University, Cambridge University, and Harvard Law School and was a fellow for two years at the Harvard Kennedy School in Science and Technology Studies.*

► **Principles at stake – Action(s) to be undertaken at intergovernmental level to address the identified challenges**

Neuroscience, Neurotechnology and Society: The International Governance Challenge

Like other emerging technologies, neuroscience and neurotechnology present major challenges for governance: uncertainties make appraisal of risk and benefit difficult, hype is prevalent, precautionary and innovation logics compete, and dual use resents hard choices. But there are of course unique issues raised with technologies of the brain, those that call into question our very notions of human capacity and identity. Any governance choices around controversial topics like, e.g., cognitive enhancement and dual use are likely to be difficult, but international governance choices even more so. Differences across communities on regulatory approach, let alone issues like enhancement, are assured. And what if neurosciences are destabilising the very conception of freedom and autonomy on which universal human rights are predicated? International governance is certainly possible and must be explored. But at a time when the international community may be finding it difficult to execute new legal agreements, more flexible forms of governance might be useful. In particular, international standards may constitute a good mechanism for building agreement so long as the right spaces for collaboration are created. The international governance challenge will be discussed in the context of recent activities at the OECD towards international recommendations on the responsible development of neurotechnology.

► **Full text**

I am currently at the Organisation for Economic Cooperation and Development, the OECD, and I come from an academic background at the intersection of bioethics, law and science and technology studies (STS). I help lead the Working Party on Bio-, Nano-, and Converging Technologies at the OECD, whose task is to foster policies for the responsible development of key emerging technologies. Our group has embarked on a project to consider developing soft law in the area of neurotechnology to help balance different social goals in the course of innovation. At the OECD, as here at the Council of Europe, one can see the challenge of building good governance around innovation, especially

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areas of emerging technology where science and technology are quickly evolving, where norms and practices are changing quickly, and where effects move across jurisdictions and levels.

But here at the Council of Europe, celebrating the 20<sup>th</sup> Anniversary of the Oviedo Convention, the focus is *not* on soft law. My central task is to consider whether new human rights are necessary to address issues raised by new neurotechnologies. The question of human rights and the implication of neuro technologies have been raised in various contexts. The French National Bioethics committee weighed in almost 20 years ago. More recently, the U.S. Presidential Commission for the Study of Bioethical Issues, the Nuffield Council in the U.K., and the Rathenau Institute in the Netherlands have considered the issue of neurotechnology and rights. And more recently, scholars, especially Ienca and Adorno (2017), have argued that legal innovation, if not in fact new human rights, are required in this area given the new and important interests raised by new technologies.

Let me lay out my two main points now, and come back around to them in the end. The first point is that we should probably *develop* these rights and *not invent* new ones. But, although we shouldn't rush to invent new rights, human rights discourse allows us to aspire to the highest of values and goals of society, and it should be one of many mutually reinforcing pathways of governance. Second, at this point in time with neurotechnologies, we should be thinking in terms of *process* rather than substance: how can we foster broad societal conversations among multiple stake holders as we develop norms over time. Given that multi-stakeholder discussions are necessary to reach the relevant actors, including business consumers, governments and clinicians, the development of standards will be necessary. But they may not be sufficient.

As Professor Biller Andorno made clear in the last presentation, developments in brain science and neurotechnologies deserve close consideration. This is true in part because of the major investments that countries are making in the field in the form of national brain projects. Nearly across the board of these national brain projects. Two things stand out about this landscape. First, the emphasis is technology rather than basic science. Second, it is focused on application, especially for health for in some cases for military. The US brain initiative in 2017 alone is spending about \$500 million dollars in this area, and this doesn't count what is by all accounts a substantial investment by the military. Many other countries have major brain initiatives. The Japanese brain project, called Japan Brain/Minds, will be spending hundreds of millions of dollars over the next few years, and you probably well know about the European Brain Project. China has just embarked on a major new initiative. The point is that there is a lot of interest and money going into this area of innovation.

At the same time, we have to be aware that this area is full of hype, perhaps because of linkages to robotics and artificial intelligence. It is difficult sometimes to disentangle the hype from reality, when these are highly technical areas and when AI is such a buzzword right now. We have to be careful to collect multiple perspectives on what is occurring and be judicious in how we consume prediction.

Some major categories in new neurotechnologies have been covered in the previous talk. I agree with Professor Biller Adorno that, from a human rights perspective, *reading the brain* is one of most important. New forms of lie detection and emerging mechanisms to read thought patterns raise concerns from the perspective of criminal law and civil liberties. With new neurosciences, we are seeing the redefinition of the normal and abnormal brains. New classifications of cognitive function have implications for education, criminal justice and health care, social systems that rely on definitions of normal to assign benefits, liabilities, rights and obligations. With these technologies of reading come exciting possibilities for understanding our brain states and health, but there are also dangers if we return to ideas of biological determinism that have underwritten the history of phrenology and eugenics. There are affinities between the issue raised by genetics and neurotechnology, in part because of potential slippages into biological determinism. This also means that the ethical and rights discourses that have emerged around the new genetics may be useful for thinking about the brain.

Intervening in brain, both invasive and non-invasive techniques, introduces another set of difficult issues. Certain invasive techniques have been shown effective for treating mental disorders, although there has been debate on the issue for decades. Non-invasive devices have shown promising results in the treatment of epilepsy in children. In fact, there's a clinical trial going on in children's hospitals. It involves nearly the same kinds of devices that are being used in gaming communities and other do-it-yourself communities. This raises questions of therapy versus enhancement that are common in the field of bioethics, as well as "dual use", which is notoriously difficult to govern.

In sum, there are important interests here around privacy, freedoms, risk and safety, health benefit and well-being. Furthermore, some of these interests have not really emerged before, since they are only arising along with these (i) scanning/reading and (ii) intervening/manipulating neurotechnologies. How do you govern these different uses? Let me just briefly cover, a few of the human rights proposals on the table. I'm not capturing everything but just to put a little slightly finer point on it.

One is the interest in so-called *cognitive liberty*. Following Isaiah Berlin's classic taxonomy of liberty, this would entail both positive and negative freedoms. On the negative side – freedom *from* – this might protect us from unconsented intrusions into our mental activities. Here the concern might be mind reading, lying detection, criminal context, and the manipulation of mental states by employers, police, or military personnel. In the related context of robot intelligences and AI, the Rathenau Institute in the Netherlands recently proposed the right not to be analyzed, measured or coached.

On the positive side – the freedom *to* – this might entail the freedom to use neurotechnologies on oneself without interference. This is the other sign of the coin, the freedom to use or refuse to use brain stimulation or other techniques. So, this is used as a defensive mechanism, as if to say, “government, get off my back This is my brain, this is my body”. So that's the flip side and maybe there's a tension between recognizing both.

However, is what we already have on the human rights landscape adequate for protecting cognitive liberty? The most important or most relevant existing rights have to do with privacy, although I would argue there are things about equitable access and other kinds of things that are clearly relevant, such as non-discrimination principles. The regard to the human right to privacy, the most important provisions would probably be: The Universal Declaration of Human Rights (Article 12) on privacy, the European Convention on Human Rights (Article 8), and then one could consider the Oviedo Convention (Article 10). The first two are fairly broad rights of privacy, where the Oviedo pertains only to biomedicine.

Let me go to another potential right, which is that of “psychological continuity”. Here the aim is to protect people from actions that may result in unintended alternations to personality and could harm the sense of identity. So, as you heard in the last talk there could be brain interventions for therapy or other reasons, that disorient the user or the patient, such that memory is changed, personality and behavior altered. And do we want to raise the level of protection against activities that we predict could have this effect? And there are rights to identity, under the European Court of Human Rights, as recognized by that court, and also a right to have and develop a personality, under the Universal Declaration. Are these existing formulations adequate, or do we need to specify new norms to address novel neurotechnologies? So that's the question. Recently, in addition to recommending that we convene this meeting today, the Rathenau Institute argued for the creation of two new human rights, especially in the context of robots and AI. These included a right “not to be measure, analyzed or coached” – as mentioned before – and a right to “meaningful human contact”. These are related respectively to a right of privacy and right for family life.

So, one of the things you will see and I will touch on coming up is are we going to create sets of rights for each new emerging technological field? That's a basic question that is important and that might be a especially complicated when those fields are conceived of in different ways and can be overlapping. So, rights in the robot age might concern aspect in the neurotechnological age. So, you would have instruments doing both things with overlaps that could at best raise confusion and at worst conflict. We do have examples to assess *ex post*. Indeed, we might in considering the efficacy or advisability of a specified instrument by looking of the case of genetics, how's that worked out, how successfully genomic instruments have negotiated the potential problems of proliferation, overlap, and the like.

A few more general considerations for this inquiry. One is the well-known discussion about the cost of rights inflation, the expansion on the numbers of rights, which could potentially spread skepticism about fundamental rights. For this reason, of course, some human rights scholars have tried to create criteria for new rights, key characteristics such as novelty, non-overlap, fundamentality, right to be implemented, these kinds of things. So, we would need to look at those.

Second, there are puzzles of scope with the construction of human rights to address concerns with emerging technology. In particular, specialised instruments might be underbroad to address the range of uses of new technologies. With neuro, we already heard how there are multiple fields of use for technology, clinical medical occupational, military and also the public consumer use. Governance of

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neurotechnology, therefore, would be difficult using sector specific human rights instruments such as the Oviedo Convention, which applies only to the field of biomedicine. This would not address the occupational, military and public uses of the technologies. Similarly, many of our more specified protocols deal with only one area. So that's really important to keep in mind and a real challenge with regulating particular technologies, because by their nature they can be used in many fields of use.

Third, another problem of scope is the choice of technological frame, mentioned a little bit previously. Robots raise human rights issues that are also informational. These might be concerned with artificial intelligence and other elements that engage the realm of neurotechnology. Perhaps to avoid arbitrary definitions of technologies, the Bergen study commissioned by the Council of Europe talked about a convention on emerging technologies. This is an interesting idea, as it would avoid the problem of exclusion and overlap and also identify common issues for humanity in technology.

The question might boil down to whether you believe more specific rights are necessary to these interests, perhaps because broad rights are too open ended. On the other hand, we might be concerned about proliferating rights instruments, and favor broad rights that can and should speak to new situations as they arise. Perhaps "protocols" and specification of various kinds present a third way.

Should there be one common instrument on emerging technologies? We've thought about it in the Working Party on Bio-, Nano-, and Converging Technologies. This OECD Working Group is predicated on the idea that emerging technologies are a coherent policy field. Across a range of new and emerging technologies, one finds common policy concerns such as scientific uncertainty, difficulties in assessing risk, responsible innovation, and public engagement. One could imagine a human rights instrument that looks at the broader issue of ensuring human rights as these technologies come to fruition.

A potential concern with this approach is that, without specific technologies and their concerns in mind, the common normative elements might only consist of high level nostrums that may not even be useful from one field to the next. Furthermore, we soon get into definitional problems as to what exactly constitutes an emerging technology and therefore worthy of special human rights concern.

So, with privacy and neuro technologies, I would argue that we might seek to understand these issues under the umbrella of privacy, with some specification within certain policy fields. The countervailing viewpoint might say that the law of privacy is lagging behind the science and technology, and needs to be explicitly addressed. The idea that these general notions of privacy are out of date if there not specified to the latest technology. This is especially evoked for emerging technologies.

I think the concern I would have is that privacy is, in this view, always catching up. Alternatively there is the open-ended approach to high-level norms like privacy. They become real and engaged by being applied in new areas. Do you do violence to the concept of privacy by cabining off these different areas? I think one point of scholarship in STS is that there's a coevolution occurring with norms and technology and so the question then is not how you control various uses but how you shape the co-evolution of technology and norms.

If not more human rights now, wherein lies the path to good governance?

One answer lies in tracing the shape of global governance today. It is complex, it is multi-scalar, and it is cross-sectoral as described well by political scientists like Elinor Ostrom. How can and should governance of emerging technologies engage this? The study by Roger Strand and Matthias Kaiser at the University of Bergen commissioned by DH-BIO articulates a plethora of institutions that should be engaged in the process of norm formation and deliberation. The recommendations of the Nuffield Council as well illustrate a complex governance approach, featuring the engagement of regulatory authorities, institutional ethics committees, clinical work, and professional organizations.

At the OECD we have had a series of meetings on the idea of developing soft law for the governance of neurotechnology, especially highlighting potential risks to privacy and safety, dual use, innovation in accordance with societal values and needs, open science, equity in access, and public deliberation. The work of the OECD is rooted in this bottom up process to develop the right forms of governance.

I would like to close with 5 recommendations that occur under the heading, *Good governance of emerging technology: disparate streams, mutually deepening.*

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1. Human rights bodies and legal/ethics scholars should continue to develop work on unique aspects of neurotechnology (e.g. Council of Europe) with particular work on the concept of privacy, personhood, and discrimination;
2. Bioethics experts and stakeholders should continue to develop principles for clinicians and researchers working with human participants. Issues are coming up right now in these contexts, and good ideas are being developed in the new field of neuroethics;
3. Both public and private funders of brain science and neurotechnology should support social science scholarship *parallel to* and *integrated with* neurosciences examining the co-constitution of new knowledges and new kinds of rights;
4. Open science and transparency should be promoted by scientists, engineers, and funders both to enable discovery and to support good governance;
5. Stakeholder and publics should promote processes to help develop codes of responsible innovation (science, government, industry, publics) to steer the innovation process.

Thank you very much.

## CHAIR

### **Ms Tesi Aschan (Sweden), Vice-Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe**



*Tesi Aschan (jur.kand.) works as a senior legal adviser for the National Board of Health and Welfare in Sweden. Her main areas include the legislation on organs, tissues and cells, medical devices, assisted reproduction technology, genetic tests and end of life treatment.*

*Tesi Aschan has been on the Committee on Bioethics (DH-BIO) since 2012 and a member of the Bureau since 2015, currently in the position of Vice Chair.*

### **Ms Antoinette Rouvroy (Belgium)**

#### **The Research Centre in Information, Law and Society (CRIDS), Namur University; member of the Ethics Advisory Group of European Data Protection Supervisor**



*Antoinette Rouvroy holds a Ph.D. in Law from the European University Institute (Florence, 2006) and is a FNRS (Fund for Scientific Research) Research Associate at the Information, Law and Society Research Centre (CRIDS, University of Namur, Belgium). Since 2000 she has been interested in relations between, on one hand, the law, risk-construction processes, science and technology, and on the other hand, neo-liberal governmentality. From 2000 to 2005 her work at the European University Institute in Florence, the Department of Science and Technology Studies at the University of York (UK) and the Centre for Intellectual Property Policy at McGill University (Canada) mainly focused on the co-production*

*relationships that exist between the over-emphasis on predictive genetics and the neo-liberal approach to government (A. Rouvroy, "Human Genes and Neoliberal Governance. A Foucauldian Critique", Routledge-Cavendish, 2007). Her participation in European research contracts at the Information, Law and Society Research Centre since 2007, and her subsequent appointment as a FNRS Research Associate, since 2008, together with her role as an expert for the Foresight Committee of the CNIL (Commission Nationale Informatique et Libertés – the French data protection authority), have led her to focus her research on the challenges of polycentric governance (which recognises that the law does not have a monopoly on standard-setting, and that normative phenomena transcend the traditional boundaries of state territories), of normative technologies (both the metabolism specific to the "legal system" and non-legal technologies which engender governance effects), and the links between legal, technological and social rule-making. In addition to addressing the challenges brought about by digital technology and its applications (autonomic computing, ambient intelligence and data mining) for legal systems concerned with the protection of private life and personal data, in recent years she has developed a new line of research around what she terms "algorithmic governmentality". The type of "knowledge" which feeds it and which is shaped by it, the ways in which it affects individual and collective behaviour, the modes of individuation which can influence it or resist it are examined under an approach combining three types of closely linked challenges: semiotic and epistemological challenges, power interests and individuation issues.*



## Ms Alessandra Pierucci (Italy)

### Chair of the Council of Europe Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)



*Alessandra Pierucci is a lawyer and has been working for several years at the Italian Data Protection Authority. She has been actively involved in data protection at EU, OECD, and Council of Europe level. She has long been a member of Consultative Committee of Convention 108, of which she became Chair in 2016. She worked for the Council of Europe dealing with human rights in the Information Society. As part of her research activity, she has published several papers concerning fundamental rights and data protection issues on juridical journals and books. She has taught data protection in post graduate courses in some European universities.*

#### ► Principles at stake – Action(s) to be undertaken at intergovernmental level to address the identified challenges

Privacy and protection of personal data in the health sector has been always particularly relevant, for the discriminatory potentiality coming from the disclosure of information on the present or future health of a person, and for the need to preserve her dignity. The current landscape – with constantly emerging technologies enabling unprecedented results for individuals' health and health care – raises new challenges for data protection to which the Council of Europe has been reacting. The modernised Convention 108 reaffirms the need to give a strengthened protection to health data, and to biometric and genetic data; it now includes new rights that reinforce self-determination such as the right of the person not to be subject to automated decisions without having her views taken into consideration, or to obtain knowledge of the reasoning underlying data processing where the results of processing are applied to her. The new Convention also stresses the need for a privacy by design approach according to which specific measures should be designed to implement data protection principles in the technologies in use at the earliest stage of the processing. The Consultative Committee of Convention 108 is playing a role in this context. At the beginning of this year it adopted guidelines on big data, with the aim of promoting an ethical and socially aware use of data, and is now finalising the revision of Recommendation (97)5 on health data to reply to manifold difficult tasks raised by the digitalisation of health.

However, constantly new challenges oblige us to carry out new reflections on the necessary tools to preserve fundamental rights. With artificial intelligence - which is gaining a crucial role in the health and research sectors - technology gets more and more 'autonomous' to the point that it "escapes" human prediction; the exercise of the right to know the logic of the processing becomes more complex once the results of automated decisions are unpredictable even for the designer of the device. The dialogue with the data controller gets problematic once the decision power is more and more gained by machines replacing human being.

The Council of Europe is an ideal forum to explore such new frontiers.

The idea that should accompany the process is that privacy and data protection enable a sustainable and dynamic digital environment, are not at all an obstacle, but on the contrary a necessary requirement to ensure a fair and transparent processing of data and to guarantee to all individuals the control of their personal information, and therefore their self-determination, in particular when health and ethical choices are at stake.

► **Full text**

Let me first of all thank you very much for giving me the possibility to participate in this outstanding event. I hope that I will bring some relevant information and reflections on the current data protection landscape, in particular in respect of Big data and the action(s) to be undertaken to address the identified challenges.

I am here in my quality of Chair of the Consultative Committee of Convention 108, the Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Convention 108, which was adopted in 1981, is currently undergoing a modernisation process aimed at ensuring a high level of data protection in a scenario which in more than 30 years has considerably changed for the immense impact of technologies and globalisation on the collection and processing of data.

I would like to start my presentation with a general consideration regarding the Oviedo Convention and its relation with Council of Europe data protection principles which are included in Convention 108 and the related recommendations deriving from it.

The Oviedo Convention and Convention 108 speak the same language:

‘Dignity’, ‘identity’, ‘non-discrimination’, ‘integrity’ of the individual, which are mentioned in the first Article of the Oviedo Convention, are recurring words in the data protection scenario, especially in the text of the modernised Convention. I will focus on in a few minutes.

‘Free’, ‘informed’, ‘withdrawable’ consent of Article 5 provided for by the Oviedo Convention is also among the main data protection legal requirements set forth by Article 5 of the modernised Convention.

The attention to the information to be given to the patient/data subject is another common feature of the two Conventions. We are of course speaking about two different expressions of ‘informed consent’, the one to medical treatment, the one related to data processing, but they both respond to the same philosophy, namely to ensure the individual’s awareness and self-determination.

Before introducing the topic of Big data and the relative data protection tools as requested by the title of my presentation, let me first give you some additional information on Convention 108 which is the fundamental legal framework of the work of the Council of Europe in data protection and legal basis and source of inspiration for a large number of domestic laws.

Convention 108 – composed of 51 Parties (47 member states of the CoE together with Mauritius, Senegal, Tunisia, Uruguay, and with 5 new countries - Argentina, Burkina Faso, Cabo Verde, Morocco and Mexico - in the process of acceding) is an extremely valuable instrument for a number of reasons: it is the only legally binding tool for data protection at international level; it is open to any country, as it can be acceded also by non-members of the Council of Europe; it sets forth a high level of protection for fundamental rights by means of flexible standards and in a technologically neutral language.

As mentioned before, Convention 108 entered a modernization process (in parallel and in consistency with the reform package that at EU level brought to the adoption of the ‘General Data Protection Regulation’ in 2016) which we all hope will be promptly finalized.

Let me now highlight the main novelties of the modernised Convention, in particular in respect of the new elements having a significant impact on the health sector and research.

The modernised Convention reaffirms the need to give a strengthened protection to health data, as well as to biometric and genetic data which are now explicitly included in the realm of the “special categories of data” (so called “sensitive” data) which, for the potential risk of discrimination deriving from their processing, can only be processed where appropriate safeguards are enshrined in law, complementing those of the Convention; it now includes new data subjects’ rights which reinforce self-determination, such as the right of the person not to be subject to automated decisions without having her views taken into consideration, or to obtain knowledge of the reasoning underlying data processing where the results of processing are applied to her. Moreover, the Convention introduces additional obligations for data controllers and, where applicable, processors, who are therefore obliged to: a) take all appropriate measures to comply with the obligations of the Convention and be

able to demonstrate such compliance, in particular to the competent supervisory authority; b) examine the likely impact of the intended data processing on the rights and fundamental rights of data subjects prior to the commencement of the processing, c) design the processing to prevent or minimise the risk of interference with such rights and freedoms; d) implement technical and organisational measures which take into account the implications of the right to the protection of personal data at all stages of the data processing.

You can perceive how important these obligations are in the sector of health and scientific research where the need for data controllers' accountability and for a preventive approach to minimise the risks of data processing is extremely relevant, in particular considering the increasing use of new technologies in healthcare and its digitisation.

Against this background, I now go to the specific topic of my presentation, Big data, to which the Consultative Committee, whose main task is to facilitate and improve the application of Convention 108 also by means of its opinions and proposals for sectoral recommendations, dedicated special attention.

At the beginning of 2017 the Consultative Committee adopted "Guidelines on the protection of individuals with regard to the processing of personal data in a world of Big data", with the aim of promoting an ethical and socially aware use of data in such field.

The work carried out by the Committee started from some relevant preliminary considerations: that Big data is a new paradigm in the way in which information is collected, combined and analysed; it can be a source of significant value and innovation for society, including in the health sector, enhancing productivity, public sector performance, and social participation; it can have a direct impact on individuals and their rights, in particular when it is aimed at identifying attitude patterns and predict behaviours of groups and communities. The Committee - while therefore acknowledging the potential benefits of Big data – focused on the risks deriving from an unregulated use of data, in particular the potential bias of data analysis, the underestimation of the legal, social and ethical implications of the use of Big data for decision-making processes, and the marginalisation of an effective and informed involvement by individuals in these processes.

The Guidelines - which are intended to be complemented in sector-specific applications - focuses on the need of:

- adopting a broader idea of control over the use of data, not limited to individual control but evolved in a more complex process of multiple-impact assessment of the risks related to the use of data. Consent is not the only requirement which renders the processing legitimate, but must be combined with further elements, in particular the preliminary evaluation of the impact of Big data on fundamental rights. Moreover, when referring to consent as legal basis for the processing, it should be clear that consent is not freely given if there is a clear imbalance of power between the data subject and the controller, which affects the data subject's decisions with regard to the processing and that therefore it is up to the controller to demonstrate that this imbalance does not exist or does not affect the consent given by the data subject;
- adapting traditional principles of data protection to the new technological scenario by ensuring, for example, that personal data must be processed for specified and legitimate purposes and not used for incompatible purposes or in a way that would appear unexpected or objectionable by the data subject (purpose limitation), that such processing must be as transparent as possible, including on the results of the assessment described above and the potential impact of the processing (transparency and fairness of processing);
- promoting an ethical and socially aware use of data, in particular by requesting data controllers a preliminary consideration of the likely impact of the intended Big data processing and its broader ethical and social implications to safeguard fundamental rights. Such assessment could be also carried out by establishing ethical committees whose members must guarantee independence, competence, experience and impartiality;
- providing for preventive policies and assessment of the specific risks for the protection of personal data including with regard to equal treatment and non-discrimination. According to such principle data controllers are required to identify the risks of each processing activity involving Big data and its potential negative outcome on individuals' rights and freedoms and

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to ensure appropriate safeguards such as privacy by design and by default mechanisms (as I will say in a moment). Such assessment is not *una tantum*, but implies the monitoring of the effectiveness of the solutions provided, and should be based on the involvement of the different stakeholders potentially affected by Big data;

- ensuring by-design solutions at the different stages of the processing of Big data in order to minimise the presence of redundant or marginal data, avoid spurious correlations, potential hidden data biases and the risk of discrimination or negative impact on the rights and fundamental freedoms of data subjects, in both the collection and analysis stages. By-design solutions are particularly relevant in respect of sensitive data, such as health related data, also to avoid as much as possible non-sensitive data being used to infer sensitive information and in such case to extend the same safeguards to these data as adopted for sensitive data;
- using anonymisation where possible, being aware that a relevant part of controllers' accountability is also to assess the risk of re-identification, which increasingly grows with the development of new technologies;
- stressing the role of the human intervention in Big data-supported decisions, avoiding that decisions based on the results provided by Big data analytics are based on merely de-contextualised information or data processing results. Where decisions based on Big data might affect individual rights significantly or produce legal effects, the data subject should be entitled to request a human decision-maker to provide her or him with the reasoning underlying the processing, including the consequences for the data subject of this reasoning, and to challenge this decision before a competent authority.

After having considered the main elements of the work of the Consultative Committee with regard to Big data (which I repeat, is not an exhaustive work, being a general framework to be completed in the future by sectoral guidelines such as in health sector), let me now spend some words regarding another topic – I believe of your interest - the Consultative Committee is currently working on, namely the revision of the Recommendation on the protection of medical data.

Such Recommendation was adopted in 1997, exactly as the Oviedo Convention, and, as it was the case for Convention 108, its modernisation started to respond to the several challenges raised by the continuous development of new technologies over the last 20 years, which considerably altered the scenario we have to deal with.

Big data, data digitization of the health sector, development of medical devices and connected objects, geographical mobility accompanied by growing exchanges of data are just some of the relevant changings which made the re-thinking of existing tools necessary.

Although the revised recommendation will be discussed within the next Consultative Committee's Plenary that will take place here in Strasbourg on the 22-24 November for possible adoption, I can already summarise some elements which appear to be consolidated: an expanded notion of 'health-related data', no longer limited to medical data; the inclusion of privacy by design, by default and accountability obligations for data controllers; specific safeguards for genetic data, in consistency with Recommendation CM/Rec(2016)8 on the processing of personal health-related data for insurance purposes; the explicit extension to mobile health applications of relevant data protection principles; the need to ensure that interoperability, a condition for data portability, is carried out in due respect for strong security measures.

Before concluding, I would like to draw your attention to a last topic, definitively connected with what I have described so far, and which is susceptible to have a very relevant impact on human rights and data protection, namely Artificial Intelligence.

Artificial Intelligence – which is gaining a crucial role in the health and research sectors – is raising unprecedented challenges for human rights and data protection as the recent work of different institutional actors show. The PACE Recommendation 2102(2017) on Technological convergence and Artificial Intelligence, the EU Parliament Resolution of 16 February 2017 on Civil Law rules on Robotics, the Paper of the European Data Protection Supervisor on Artificial Intelligence, Robotics and Data Protection of 2016 are just a few relevant examples of the increasing attention devoted to artificial intelligence.

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From a data protection point of view, there are extremely relevant questions we are called upon to answer to: In a scenario where technology gets more and more 'autonomous' to the point that it escapes human prediction, we should explore, for example, how to exercise data subjects' rights towards machines, in particular how to exercise the right to know the logic of the processing once the results of automated decisions may be unpredictable even for the designer of the device. Moreover, it may be problematic even to determine who is the data controller once the decision power is more and more gained by machines replacing human beings.

The Council of Europe is an ideal forum to explore such new frontiers and their impact on fundamental rights and this is why the Consultative Committee agreed to include such topic in its work program.

To conclude, I believe that the idea that should accompany the consideration of the new challenges I have tried to identify so far is that privacy and data protection enable a sustainable and dynamic digital environment, are not at all an obstacle, but on the contrary a necessary requirement to ensure a fair and transparent processing of data and to guarantee to all individuals the control of their personal information, and therefore their self-determination, in particular when health and ethical choices are at stake.

Thank you very much for your attention.

## **MODERATOR**

**Prof. Dr. med. Christiane Woopen (Germany), Professor of Ethics and Theory of Medicine, University of Cologne; member of the International Bioethics Committee of UNESCO; Chairperson of the European Group on Ethics in Science and New Technologies, European Commission**



*Christiane Woopen is Professor for Ethics and Theory of Medicine at the University of Cologne. There she is Executive Director of the Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health (ceres). She is as well Head of Research Unit Ethics and vice dean for academic development and gender at the University Hospital Cologne. She is coordinator and leader of several international and national research projects concerning ethical aspects of reproductive medicine, neuroethics, quality of life, aging, genome editing as well as health and society in the digital age. She is former chair of the German Ethics Council, President of the 11th Global Summit of National Ethics/Bioethics*

*Committees 2016 and amongst others member of the International Bioethics Committee of UNESCO. In April 2017 she has been appointed as chair of the European Group on Ethics of Science and New Technologies (EGE). Prof. Woopen received her medical degree from the University of Bonn and worked in gynecology and obstetrics before focusing on bioethics.*

## **Prof. Nikola Biller-Andorno (Switzerland)**

**On behalf of WHO, Director of the Institute of Biomedical Ethics and History of Medicine, WHO Collaborating Center in Bioethics, University of Zurich**



*Prof. Dr. med. Dr. phil. Nikola Biller-Andorno is Director of the Institute of Biomedical Ethics and History of Medicine, University of Zurich (UZH), Switzerland, which serves as WHO Collaborating Centre for Bioethics and hosts the PhD program "Biomedical Ethics and Law" (medical track) as well the Center for Medical Humanities. She acts as Vice-President of the Clinical Ethics Committee of the University Hospital Zurich and as member of the Research Ethics Committee of the Federal Institute of Technology Zurich and has served as ethics expert for the Human Brain Project. Nikola Biller-Andorno is Past-President of the International Association of Bioethics and a member of the Swiss Academy of Medical Sciences. She*

*has been a Commonwealth Fund Harkness Fellow (2012-13), a Safra Network Fellow (2013-14) and a Visiting Professor of Biomedical Ethics (2012-14) at Harvard University. Most recently, she has been elected as Fellow to the Collegium Helveticum, an Institute of Advanced Study sponsored by the University of Zurich, the Federal Institute of Technology Zurich, and the Zurich University of the Arts.*

## Prof. Jean-François Delfraissy (France)

### President of the National Ethics Committee

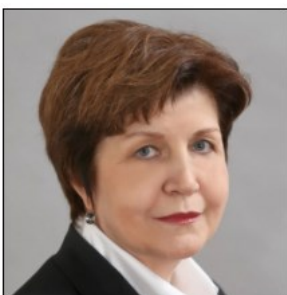


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From 2005 to the end of 2016, Professor Jean-François Delfraissy was the director of the French national research centre on HIV/AIDS and viral hepatitis (ANRS). Between 2008 and 2017, he ran the Institute of Immunology, Inflammation, Infectious Diseases and Immunology of INSERM-AVIESAN (National Institute for Health and Medical Research - National Alliance for Life Sciences and Health). He is the Chair of the local board for biomedical research in the public health at the Bicêtre Paris-Sud public hospital and professor emeritus at Paris-Sud University's Faculty of Medicine. Since 4 January 2017, he has been the Chair of the National Ethics Advisory Committee (CCNE).

## Dr Lyalya Gabbasova (Russian Federation)

### Adviser to the Health Minister



#### Education & Qualifications

Chelyabinsk State Medical University, Medical doctor. Ural State Medical Academy of Postgraduate Education, residency in Therapy.

Ph.D., Professor (in 1997 defended the thesis in Cardiology, in 2006 – the doctoral thesis in Pharmacology, Clinical Pharmacology; has more than 60 scientific publications).

#### Current position

Advisor to the Minister of Health of Russian Federation, for Biotechnology-related issues (Organ, Tissue and Cells Transplantation), AMR-related issues, Tuberculosis, HIV/AIDS and other Infectious diseases.

Previously worked in: Ural State Medical Academy of Postgraduate Education, Ministry of Health of the Chelyabinsk region, Ministry of Health and Social Development of the Russian Federation.

In the Russian Ministry of Health Dr Gabbasova is working on health policy development and implementation in the field of Biomedicine and of Infectious diseases, including coordination of national and international programs. She also very involved in the Ministry's international cooperation activities.

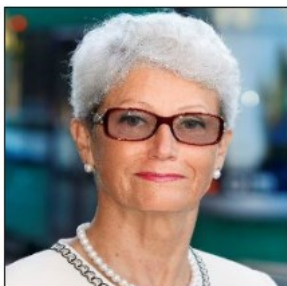
Lyalya Gabbasova is representative of the Russian Federation in the European Committee on Organ Transplantation (CD-P-TO) and coordinator for cooperation with the Council of Europe Committee on Bioethics (DH-BIO).

Dr Gabbasova is co-author of the National strategy to combat the spread of HIV/AIDS in Russia, and participated in developing of WHO documents on AMR, HIV/AIDS, hepatitis, sexually transmitted infections, and of the United Nations political declarations on AMR, HIV/AIDS.

She is representative of the Russian Federation in the Executive Board of UNAIDS, and was also Chairman of the Joint High-Level Working Group on tuberculosis (WHO and Ministry of Health (2012-2016)).

## **Ms Paula Kokkonen (Finland)**

**Former emeritus Chairperson of the National Advisory Board on Health Care Ethics, former Chair of the Council of Europe Steering Committee on Bioethics (CDBI)**



*Mrs Paula Kokkonen, RTD, born in 1946, has occupied leading positions within health care and social services, e.g. As Director-General in the Finnish National Board of Health periodically during 1984-1990, Director General in the Finnish National Agency for Welfare and Health during 1991-1992 and in the Finnish National Authority for Medicolegal Affairs during 1992-2004, Deputy Mayor responsible for Social Affairs and Public Health in Helsinki City during 2004-2011.*

*Mrs Kokkonen was a Member of the Finnish Parliament with the mandate of the National Coalition party during 1992-2003. She was the chairperson of the Committee of Constitutional Affairs during 2000-2003.*

*Mrs Kokkonen has served as an Extraordinary Justice of the Supreme Administrative Court of Finland in 1986. In her early career she worked in administrative positions at Helsinki University Central Hospital and at the Faculty of Medicine of the University of Helsinki. Among her numerous and diverse positions of trust, a list amounting to over 70 titles, Mrs Kokkonen has played an active role in Finnish national and municipal politics and served in various advisory roles on boards of national and international organizations i.a. WHO, OSCE, Council of Europe. Her many recognitions include the highest honours and decorations in Finland. Mrs Kokkonen earned a Master of Laws degree in 1971 and was raised to the Bench in 1974.*

## **Ms Brigitte Konz (Luxembourg)**

**Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe**



*Brigitte Konz studied law at the Universities of Strasbourg and Paris I Pantheon-Sorbonne.*

*She has a Master in fiscal law with post graduate specialisation in economical law. She completed her legal training in Luxembourgish law and in succeeding the Luxembourgish bar examination.*

*Her initial career was as a barrister, which was followed as a lawyer in the Luxembourgish Administration of Indirect Taxes.*

*Since 1985 she has occupied various posts in the judiciary, initially as an attorney at the public prosecutor's office in Luxembourg, and as a judge in the District Court in Luxembourg, for which she has been vice-president for*

*many years, and as president of a criminal court specialised in economic and financial cases.*

*She has occupied various posts at the court of appeal (labour, civil and cases involving young children).*

*She is currently the director of the Justice of Peace of Luxembourg.*

*She is active as the Luxembourg expert for the Minister of Justice for various committees at the Council of Europe, and since 2016 she is the Chair of the steering Committee for Human Rights of the Council of Europe.*

*She is member of the National Commission of Ethics and Life Sciences and of the Luxembourgish Commission of Sport's Arbitration.*



**Dr Petra de Sutter (Belgium)**

**Member of the Council of Europe Parliamentary Assembly**



*Petra de Sutter is a medical doctor specialising in obstetrics and gynaecology and holding a PhD in biomedical sciences; areas in which she has produced numerous publications and lectures. She has been Professor in Reproductive Medicine at Gent University since 2000 and Head of the Department for Reproductive Medicine of Gent University Hospital since 2006.*

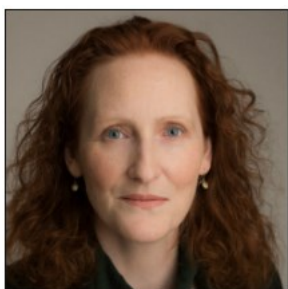
*Next to her medical practice and scientific activities, Petra has been a member of the Belgian Senate and the Parliamentary Assembly of the Council of Europe since 2014, where she is particularly interested in the legal regimes of parenthood and new health applications.*

*Petra regularly follows the activity of the Committee on Bioethics (DH-BIO) on behalf of the Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly and its Sub-Committee on Public Health and Sustainable Development. She was rapporteur on children's rights related to surrogacy in 2016, and will present her report on the use of new technologies in human beings to the Assembly in October 2017.*

## GENERAL RAPPORTEUR

Dr Siobhan O’Sullivan (Ireland)

Lecturer in Healthcare Ethics and Law, Royal College of Surgeons; Vice Chair of the European Group on Ethics in Science and New Technologies, European Commission



*Siobhán is a lecturer in Medical Ethics and Law at the Royal College of Surgeons in Ireland. She was the Chief Bioethics Officer at the Department of Health from 2010 until Sept 2016 and was responsible for drafting policy advice and legislative instruments on bioethics related issues. From 2002-2010, Siobhán was Director of the Irish Council for Bioethics an independent, autonomous body to consider the ethical issues raised by developments in science and medicine. She is Vice-Chair of the European Group on Ethics in Science & New Technologies, an independent, multidisciplinary body advising the European Commission. She received her Doctorate of Medicine from Karolinska Institutet, Stockholm in 1998.*

*She holds a Masters in HealthCare Ethics and Law and an LLM in Human Rights Law.*

## Dr Beatrice Ioan (Romania)

### Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe



*Beatrice Gabriela Ioan is Professor of Legal Medicine and Bioethics at “Grigore T. Popa” University of Medicine and Pharmacy of Iasi, Romania, as well as its Vice-Rector of institutional strategy. She is senior physician at the Institute of Legal Medicine of Iași, Romania. She graduated from the Faculty of Medicine in 1993 and received her PhD degree in 2003 at the University of Medicine and Pharmacy of Iasi, Romania. She also graduated from the Faculty of Psychology in 2002 and from the Law Faculty in 2012. In 2004 she completed the Master of Art Program in Bioethics at Case Western Reserve University, USA, and in 2013 the Master du Droit et Gestion de la Santé at Institut Catholique de Rennes/Université Montpellier, France. She joined the DH-BIO as a member in 2007 and is presently its Chair. She also joined the International Bioethics Committee (IBC) of UNESCO in 2016. Moreover, she is the Chair of the Bioethics Commission of the Romanian College of Physicians, member of the Discipline Commission of the Romanian College of Physicians, and member of several research ethics committees in Romania. Her research interests in Bioethics are: death and end of life issues, organ transplantation and research ethics. She participated in European and national research projects, she is the author and co-author of several scientific papers, books and book chapters on Bioethics and Legal Medicine.*