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CELAB

Center For Ethics And Law In Biomedicine

2009–2010

ANNUAL REPORT

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1. FOREWORD

This is the Fifth Annual Report of the CEU Center for Ethics and Law in Biomedicine (CELAB). With this Annual Report we wish to present a summary of our main achievements during the 2009-2010 Academic Year, as well as to look back to our research and policy activities we have completed since 2005.

Our first year of operation was dedicated to setting priorities, developing networks and creating a biomedical legal database. In the second year we submitted numerous applications to various agencies to receive research grants, and within a short time we started two new research projects. During our third year of research activities, the network of CELAB partners, associates and collaborators became truly international, which was accentuated by our participation in five European research projects. The fourth year of our Center witnessed the publication of numerous books, book chapters, journal articles, research reports, policy papers, and brochures as a result of the previous projects we had participated in. In the fifth year, while still focusing on the ethical and legal implications of new biotechnologies, we have also started to explore a classical subject within the field of health and human rights: the legal issues of living organ donation, organ trade and trafficking within the framework of the *EULOD* Project.

Our small research team has been gradually expanding and, with our new colleagues and research associates, we are working on a wide range of academic and administrative tasks. Regardless of this necessary institutional expansion, our staff has been able to preserve its original enthusiasm to work in the exciting cross-disciplinary domain of biomedical ethics and law. In January 2010, a historian joined CELAB: Ohad Parnes, who teaches at the CEU Departments of History and Gender Studies, was involved in submitting an application for an FP7 project. In order to strengthen our research team in the *EULOD* Project, we hired a part-time research assistant, George Tudor Florea to help two CELAB fellows: Violeta Beširević and Enikő Demény. And due to the high number of projects to be completed, we also hired a part-time coordinator, Krisztina Zsukotinszky, who joined our team in February 2010.

Entering the age of the human genome project and biobanks, stem cell research and nanotechnology, the role of biomedical science has shifted toward the purposeful transformation of various human capacities. For instance, while the new reproductive technologies managed to overcome some problems of infertility, they also pose new questions of what sexuality, gender, and kinship mean in our contemporary societies. We also have to realize that the technologies of genetic testing and preimplantation diagnosis allow for enhancement beyond therapy. And all these changes force the various social sciences and the practice of governance to rethink decision-making in science policy, reexamine the way resources are allocated, and reconsider the ethical and legal concerns related to the various uses of genetic data. Our Center has focused on these issues in the framework of different European research projects funded by the European Union and UNESCO.

CELAB works on the national, regional, and international levels. In European research consortia, knowledge about the Hungarian and Central European legal system is often required while it is also essential to be familiar with other European legal and ethical approaches. Nevertheless, as international research projects have become increasingly global in their scope, we have also developed a wider comparative perspective in our work

> *"The technology industry is at the cutting edge of scientific research and innovations. As a scientific art and commercial process it is problematic not merely for scientists and economists but also for lawyers and the general public. Problems for research scientists include how to discover and examine the workings of nature."*
>
> *Oliver Mills,* Biotechnological Inventions: Moral Restraints and Patent Law *(Farnham and Burlington: Ashgate, 2010), 1.*

that includes studies of North American and East Asian legal and ethical discourses.

In 2009–2010 one of our major projects was *RemediE,* which we are to complete in 2011. Among the CELAB fellows, Judit Sándor participates in this project as a work package leader and two legal experts, György Kovács and Márton Varju, have assisted her as hired researchers. CELAB fellow Enikő Demény has also contributed to certain research aspects of the project. The concept of *RemediE* is based on the realization that as the number of transnational research projects increases, differences between the available natural resources, the characteristic traditional knowledge, the local scientific practices and discourses, and the capacity to do research become more and more salient among the various countries participating in such projects. In the different social contexts, legal and customary norms may involve very diverse cultural perspectives on who owns biological materials or genes, who may benefit from this ownership, and who traditional knowledge belongs to (individual, inventor, community, society, and so on).

Patents in the field of human biotechnology (especially in the field of regenerative medicine) raise some fundamental moral and policy questions. The consequences of biotechnological advances are felt in many societies. But in the context of increasing political, economic and cultural globalization, there is also a need for examining variations in the intellectual property regimes. Europe adopted its main related norm after long years of deliberation. The *European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions* seeks to confirm that the human body at the various stages of its formation and development, and the processes of cloning human beings and of modifying the germ-line genetic identity of human beings may not be regarded as patentable inventions.

During the first two years of the project our aim was to map the legal framework of regenerative medicine and its broader implications in the field of intellectual property and to write a comparative assessment of our already existing and continuously developed Biomedical Legal Database. In the next phase of our research we conducted in-depth surveys of the legal sources and conducted interviews with different experts and stakeholders in order to clarify our findings and refine the cross-cultural and cross-continental comparison.

New ethical, legal and social concerns are raised not only by biotechnology in general, but also by a widening range of specialized disciplines. *Regenerative medicine* offers the potential to replace a diseased organ with a new one, grown from an embryonic or other forms of stem cells. *Pharmacogenomics* promises access to a far wider variety of drugs than we have today: moreover drugs that are safer and more effective because they are tailored to our own genetic makeup. *Genetic testing* would allow us to know with certainty our individual disposition toward various genetic diseases rather than relying on the medical history of the family. *Gene therapy* promises to cure genetic diseases by "switching off" the function of "bad" genes in the body. And *genetic engineering* has the potential to improve the genetic makeup of our children, ridding them of genetic diseases and disabilities, and perhaps even giving them better capacities. All the above listed social expectations and the technologies themselves have wide social, ethical and legal implications that require careful assessment and long-term monitoring in different phases of the technological development.

In 2009–2010 we continued to participate in the *Francophone network of biomedical lawyers*. After the successful workshop held in Kyoto in January 2009 on “Adolescents and Medical Treatment”, the next meeting was held in Rennes in May 2010 with the topic of “Dying Patients and Their Relatives.” The first book of this project came out in French in January 2009 with the title *Procréation médicalement assistée et anonymat: Panorama international*, the second book was published at the end of 2010 as a result of the Kyoto workshop, entitled *Adolescent et acte médical, regards croisés*. The third book has been prepared as an English version of the first one, with the title *Who Is My Genetic Parent? Donor Anonymity and Assisted Reproduction: A Cross-Cultural Perspective*.

This book is the fruit of rich debate and reflection among lawyers, doctors, psychoanalysts and sociologists during the first Workshop of the International Academic Network on Bioethics (IANB). Through a comparative approach, the chapters examine how the question of anonymity in sixteen different countries is dealt with – anonymity which may be absolute, relative or even non-existent. Despite the diversity of legal systems, one thing is certain: the question of abolishing anonymity is of immediate importance. The answer strongly unites or divides. But could it be any other way on a subject which goes to the heart of our social perceptions on individual identity, parentage and parenthood?

Besides these relatively more limited-scope research activities, our Center’s main task was to participate in five extensive projects financed by the European Commission. Perhaps our strongest research field at the moment is the one that analyzes the ethical, social and legal implications of biobanks. This is reflected by our involvement in three projects dealing with privacy and genetic data.

We have completed the *PRIVILEGED* (Privacy in Law, Ethics and Genetic Data) Project, in which representatives of no less than thirty-two universities took part, among them not only European experts but also lawyers from Japan, Taiwan, and Israel. This project has aimed to make recommendations for research practice and public policy-making, including regulatory options at the national, regional, and European levels. *PRIVILEGED* has sought to identify, analyze and compare plural ethical, cultural, and social concepts of legitimate privacy interest engaged by research using genetic databases and biobanks.

In 2009 we also completed the *GenebanC* Project that focused on the governance of genebanks and the European legal and ethical framework to regulate their activities. The participants in this project were Judit Sándor, Petra Bárd and Enikő Demény. One of the major outcomes of the work was the publications of CELAB Series on Biobanks, which involves 13 country reports on the analysis of regulating biobanks.

In 2008 we started our third research project in this field, *TISS.EU,* which mobilizes the resources of ten European universities. The major aim of this project is to carry out a high-quality interdisciplinary comparative analysis of European health policies in order to assess the impact of EU legislation in this field and to explore the relevant ethical and legal situation across the European Union. The first *TISS.EU* project meeting was held in Göttingen, Germany and focused on the ethical and legal challenges to conducting research on human tissues. Our Center organized a workshop in Budapest in 2009, and we have attended workshops in Paris, Padova, Leiden, Stockholm, and Vilnius. The participants in this project are Petra Bárd and Judit Sándor.

The third EU funded project that we have completed is *Nanoplat* (Framing the Deliberative Process on the Responsible Development of Nanoscieneces and Nanotechnologies), which also started in 2008. It focuses on 'deliberative processes' in nanotechnology because these may be seen as useful, although possibly highly problematic regulatory forms supplementing democratic mechanisms. On the other hand, the conceptual shift from 'government' to 'governance' might allow for more participatory forms of shaping public policy. Four workshops had been held (in Bergen, Manchester, Istanbul, and Brussels) before the project was successfully completed in 2009. The papers are expected to be published at the end of 2010. The participants in this project were Enikő Demény, Péter Kakuk and Judit Sándor.

We seek to integrate the results of these research projects into our academic teaching curricula. Therefore, we have organized workshops and seminars, film screenings and policy debates open to the CEU community and beyond. We also participate in legal policy development activities and provide research tools for the international scientific community.

As in the previous years of our activities, our Center's research staff has continued to develop new methods of teaching human rights and bioethics. For example, the CELAB Bioethics Film Sessions, co-organized with the Human Rights Students Initiative of CEU, included several film screenings, each time followed by lively debates. Topics included organ trafficking, assisted suicide, abortion, and research on the terminally ill. The seminars and film sessions were a big success and it has become clear that more and more scholars within and outside of the CEU community express their interest in the ethics of science and technology. Therefore, in the near future, we also envision the development of specific teaching curricula in this field, once we have the necessary resources available.

For more information about CELAB, please consult our website at
www.ceu.hu/celab or check our Facebook page at
www.facebook.com/pages/CELAB/321473511079

Judit Sándor

Director of the Center for Ethics and Law in Biomedicine
Central European University

2. ACTIVITIES

2.1. RESEARCH

2.1.1. EULOD: Living Organ Donation in Europe

Partners

Erasmus Universitair Medisch Centrum, Rotterdam (EMC), The Netherlands
European Society for Organ Transplantation (ESOT), The Netherlands
Goeteborgs Universitet (UGOT), Sweden
Westfaelische Wilhelms-Universitaet, (WWUM), Germany
Katholieke Universiteit Leuven, (KU), Belgium
Bulgarian Center for Bioethics, (BCB), Bulgaria
Kozep-Europai Egyetem, (CEU), Hungary
Fundatia Renala (FR), Moldova
Sihtasutus Tartu Uelikooli Klinikum (TUH), Estonia
Societatea Academica de Cercetare a Religiilor si Ideologiilor (SACRI) Romania
Polish Transplant Coordinating Center (Poltransplant), Poland

Duration of the project: 2010-2012
Webpage: www.eulod.eu

The project on living organ donation in Europe is a coordination action that aims to establish an inventory of living donation practices in Europe; to explore and promote living donation as a way to increase organ availability and to develop tools that improve the quality and safety of living organ donations in Europe. This action aims to achieve broad European coverage with a specific focus on new EU Member States. It draws upon the support, knowledge and network of the European Platform on Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT) and the European Society for Organ Transplantation (ESOT).

The project contains two scientific research packages. The first focuses on living unrelated donation practices in Europe. The second focuses on legal restrictions and safeguards for living donations in Europe. The remaining three work packages ensure the coordination of this work, dissemination of the project results and the organization of meetings. The major goal of the project is to exchange best practice and effective organizational models in order to pro-

mote and safeguard living donation in Europe.

The CELAB team contributes to WP3 part II, which focuses on legal restrictions and safeguards for living donations in Europe, paying attention to issues related to organ trafficking and tourism by analyzing the effectiveness of existing legal provisions (and their maintenance) against organ trafficking and tourism and the ethical, social and legal context of living organ and tissue donation.

The project kickoff meeting took place in April 2010 along with the conference *Ethical, Legal and Psychosocial Aspects of Organ Transplantation: Expanding the European Platform.* CELAB was represented at this event by the principal investigator Judit Sándor who gave a presentation on "The Ethical, Legal and Psychosocial Aspects of Organ Transplantation."

CELAB researchers started to work on the project in May 2010. They have mapped the regulatory framework of organ trafficking, tourism and paid donation in Romania, Hungary and Serbia. In parallel, they have done literature review and started to identify cases of organ trafficking in the region. Research Assistant Teddy Florea has conducted stakeholder interviews in Romania. Each member of CELAB team prepared presentations for the 3rd ELPAT conference and project meeting.

As a result of their implication in the EULOD project, Violeta Beširević and George Tudor Florea have joined the ELPAT network, Judit Sándor and Enikő Demény being already members of the network.

Participants:

Judit Sándor (Principal Investigator); Enikő Demény (Researcher); Violeta Beširević (Researcher); George Tudor Florea (Research Assistant)

2.1.2. REMEDiE: Regenerative Medicine in Europe: Emerging Needs and Challenges in a Global Context

Partners:
SATSU, University of York, United Kingdom
University of the Basque Country, Spain
University of Hanover, Germany
Life Science Governance Institute, Austria
CELAB, Central European University, Budapest, Hungary
University of East Anglia, United Kingdom

Duration of the project: 2008-2011
Webpage: www.york.ac.uk/res/remedie/index.htm.

REMEDiE is a European Union financed collaborative research project focusing on the current and emerging socio-economic, political and bioethical issues in

regenerative medicine in Europe and in the world. The work packages are organized around the three interrelated streams of research (socio-economic, political and bioethical).

In the RemediE Project the CELAB team is responsible for Workpackage No 6. on *"EU and global bioethics: Intellectual property and cultural difference"*. CELAB's main task within this project is to explore the relevance of bioethical soft laws in different intellectual property regimes. Special attention is paid to the status of the human body in the field of regenerative medicine, benefit-sharing and morality clauses, especially in cases of transnational research. It was also CELAB's responsibility to develop an international database of the legal sources of regenerative medicine.

In the framework of this project in 2009–2010, CELAB researchers attended two conferences, one organized in Madison, USA and one in Vienna, Austria.

The Second RemediE Workshop was held in Madison, Wisconsin on June 9–10, 2010. Major issues in the field of Regenerative Medicine (RM) were discussed in the light of recent legislative changes in the US via the Obama government and recent EU reviews of the RM field, notably that in May 2010 the European Science Foundation identified ongoing ethical, regulatory and clinical concerns.

The participants were discussing such issues as the distinctive aspects of Regenerative Medicine (RM) within biotechnology (1), lessons related to global governance, investments and policy (2), new challenges ahead regarding stabilizing and governing RM (3), and questions related to governance and ethics in the field of RM and reproductive bodies (4).

The Third RemediE Workshop was organized in Vienna, Austria on October 8–9, 2009. CELAB was represented by Prof. Judit Sándor and Researcher Márton Varju. The participants agreed that the final REMEDIE conference will be held on April 18–19, 2011 in Bilbao, Spain.

CELAB participants in this project: Judit Sándor (Principal Investigator) Enikő Demény, György Kovács and Márton Varju (Researchers)

2.1.3. Tiss.EU: Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union – an Evidence-Based Impact Analysis

tisseu
Assessing Legal and Ethical Aspects of Research Using Human Tissue and Cells

Partners:
Department for Ethics and History of Medicine, University of Göttingen, Germany – Coordinator
Medical Law and Bioethics Group, Institute for German and European Private and Commercial Law, University of Hanover, Germany
Center for the Study of Global Ethics, University of Birmingham, United Kingdom
Stockholm Bioethics Center, Stockholm University, Sweden
Fondazione Lanza, Padova, Italy
Forensic & Legal Medicine, School of Medicine and Medical Science, National University of Ireland, Dublin
Center de Recherche Droit, Sciences et Techniques, Université Paris 1, France
Institute of Bio-Law „Legal Pathways", Aerdenhout, Netherlands
Department of Medical History and Ethics, Vilnius University, Lithuania
CELAB, Central European University, Budapest, Hungary

Webpage: www.tisseu.uni-hannover.de/

The acronym Tiss.EU stands for "Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union - an Evidence-Based Impact Analysis." The project, funded by the European Commission as part of the 7th Framework Programme, runs from March 2008 to early 2011 and addresses questions of ethical and legal regulation in relation to research using human tissue. Tiss.EU is made up of four parts, the ethical and legal aspects of which are going to be looked at by the project partners: first, procurement, storage and transfer of tissue and cells for research; second, rights and entitlements to tissue and cells; third, anonymization and pseudonymization to protect privacy rights; and, finally, research using biobanks.

Within the Tiss.Eu Project, the CELAB team focuses on anonymization and pseudonymization for privacy protection in the following countries: Bulgaria, Czech Republic, Hungary, Slovakia, and Romania. CELAB organized a conference in the spring of 2009 and reported on the impact of EU legislation and documents in this country group. As a culmination of the project, recommendations are to be drafted for possible ethical and legal guidelines in the interests of European-wide convergence and harmonization.

During the second part of the project, several workshops were organized in Leiden (2009), Stockholm (2010), Dublin (2010), Birmingham (2010) and Vilnius (2010). The Final Conference will be held in 2011. One of the major outputs of the work will be an edited book including chapters from each research partner. The tentative title of the book is: "Biobanks and Tissue Research: The Public, the Patient and the Regulation" and it is edited by Christian Lenk, Judit Sándor and Bert Gordijn. A book chapter is written by Judit Sándor and Petra Bárd.

2.1.4. PRIVILEGED: Privacy in Law, Ethics and Genetic Data

privileged
privacy in law, ethics and genetic data

Main Partners:
University of Sheffield, United Kingdom
Biomedical Law Center, University of Coimbra, Portugal
University of Vilnius, Lithuania
CELAB, Central European University, Budapest, Hungary

Webpage: www.privileged.group.shef.ac.uk/

The full title of the PRIVILEGED Project is "Determining the Ethical and Legal Interests in Privacy and Data Protection for Research Involving the Use of Genetic Databases and Biobanks." The aim of the project is to make recommendations for research practice and public policy, including regulatory options at the national and European level and to promote the optimal relationship between research using genetic data and bio-banks and ethical interests in privacy. Ethical interests in privacy are being explicated through surveys, descriptions and comparisons of the alternative conceptions of privacy currently operating throughout Europe, Israel, Japan and Taiwan, paying particular attention to the relative interests accorded an individual as a member of a group.

The Project started in 2007 and lasts for 36 months. It is one of the largest research networks in which CELAB participates, including 49 Research

Partners in various European countries and in Israel, Taiwan and Japan. The project was completed in the 2009/2010 Academic Year. The last year of the project was dedicated to Stage Three, which involved working in sub-groups in Coimbra and in Vilnius to develop five articles on key problem areas in privacy and data protection in relation to genetic information and biobanking (the "key issues" articles). This stage of the work aimed to produce creative papers addressing some of the most difficult questions in the area of privacy and data protection in relation to research using genetic information and biobanks. The Stage Three articles will form the major part of a special edition of the journal *Medical Law International*. This special edition is scheduled for publication in 2010. Steering groups also met in Brussels in December 2009. Judit Sándor participated in Coimbra and Vilnius workshops, as well as attended the Steering Committee Meeting in Brussels.

CELAB Participant in this project: Judit Sándor

2.1.5. Equal Opportunities for Health: Action for Development

Partners include:

Doctors with Africa Cuamm, Padova, Italy
University of Bologna, Italy
Transylvania University of Brasov, Romania
Poznan University of Medical Sciences, Poland
Medical University of Pleven, Bulgaria

In 2010, CELAB was part of a successful grant application for a project entitled *Equal opportunities for health: action for development*. The aim of the project is to establish a network of institutions involved in health-related higher education, including relevant health development NGOs, health science schools, medical students associations, research organizations from Italy, Poland, Romania, Latvia, Bulgaria, Hungary and Malta, who will regularly meet, discuss and exchange experiences on global health education and, in turn, advocate the up-dating of formal European health science education systems to better integrate development and global health issues.

Main issues to be dealt with will include: health and its determinants; the origin and development of health systems; health as a human right; globalization and health; inequalities in health and in healthcare assistance; immigration and health; international health cooperation.

The project will start its activities in 2011.

CELAB participant: Ohad Parnes

2.2. POLICY ACTIVITY IN CELAB

2.2.1. Participation in the Global Ethics Observatory (GEObs) established by UNESCO

This observatory is a system of databases with worldwide coverage in bioethics and other areas of applied ethics in science and technology, such as environmental ethics, science ethics, and technology ethics. The GEObs Database 4 deals with the Ethics Related Legislation and Guidelines. Information for this database of the Global Ethics Observatory (GEObs) is collected and analyzed by legal experts identified from various Member States, and subsequently reviewed and validated by the Review Committee consisting of legal experts from various regions and legal traditions. The International Review Committee includes the following experts from different continents and from different organizations. Thomas Faunce, Australia; Monica Serra, Brazil; Mr Herman Nys, Belgium (Coordinator); Ms Maria Bartha Knoppers, Canada; Mr Dirk Lanzerath; Germany; Ms Judit Sándor, Hungary; Ms Cinzia Carporale, Italy; Mr Ryuichi Ida, Japan; Mr Carter Snead, USA; Ms Geneviève Pinet, WHO.

The Review Committee met in December 2005 and in September 2006 in Paris in order to develop a common methodology of obtaining and presenting data. Experts are provided with a standardized methodological schedule designed to ensure comparability in their collection and analyses of legislation and guidelines stemming from different legal systems around the world. Experts are required to collect and analyze the types of legal instruments mentioned above for provisions that are relevant to specific bioethical themes and articles of the Universal Declaration on Bioethics and Human Rights and the International Declaration on Human Genetic Data. Once validated, these provisions are then entered into the data-

2.3. TEACHING

CELAB's staff and fellows are involved in teaching both at CEU and at other universities in Hungary and in other countries in the region. They offer courses that are in close connection with CELAB's main fields of inquiry. One of CELAB's goals is to develop a teaching network for bioethics and biolaw in the region.

2.3.1. Teaching at CEU

Judit Sándor

Department of Political Science and Gender Studies
Reproduction and Gender
Human Rights and Biopolitics

Department of Legal Studies
Privacy Rights and Data Protection
Patients' Rights in the Twenty-First Century

NICLAS Summer School on the Rights of Future Generations 2010
Hosted by CELAB-CEU
Keynote lecture: "Delineation Problems in Contemporary Bioethics and Law"
July 5–17, 2010

Petra Bárd

Department of Legal Studies
EU Constitutional Law
EU Fundamental Rights

Total Law™ course
Lecture on "Genetic databases in the forensic context – An EU perspective"
July 5, 2010

NICLAS Summer School on the Rights of Future Generations 2010
Hosted by CELAB-CEU
Lecture on "The Charter of Fundamental Rights"
July 5–17, 2010

Ohad Parnes

History Department
Age and Aging in History
History of Public Health and Health Policy

2.3.2. Teaching and Lecturing at Other Institutions

Judit Sándor

"Ethics and Law in Modern Health Care"
Lecture held at the post-graduate training for medical doctors entitled "Ethics and law in the contemporary health care"
October 2, 2009, Kaposvár, Hungary

"Challenges of the Politics of Life in the Twenty First Century: Clones, Chimeras, Supermen, and the World of the Human DNA"
Guest lecture at Radnóti Miklós Secondary School, Teaching School of the Eötvös Loránd University
April 23, 2010, Budapest, Hungary

"Teaching Law and Health: Courses on Law, Human Rights and Patient Care"
Guest lecture at Sts. Cyril and Methodius Faculty of Law and Faculty of Medicine/Center for Public Health; based on the OSI Initiative
May 18–21, 2010, Skopje, Macedonia

Petra Bárd

European Union Law
European Business Law
Courses at ESSCA, Budapest, Hungary

How to Become Homo Europeus?
ELSA Summer Law School 2010
Lectures and workshops held by Petra Bárd on EU Fundamental Rights with a Special Focus on Disability Rights and Data Protection in Criminal Cooperation
July 19–24, 2010, Tatranská Lomnica, Slovakia

Violeta Beširević

Medical Law Courses
Specialized Studies in Medical Law/Law and Ethics in Biomedicine
Specialized Studies in Medical Law/Patients' Rights
BA/Medical Law at Union University Law School, Belgrade, Serbia

Enikő Demény

Family and Identity in the Age of Genetics
Foundation of Gender Studies
MA Courses at the Faculty of Political, Administrative and Communication Sciences, Babeş-Bolyai University, Cluj, Romania

Péter Kakuk

Bioethics courses
Bioethics on Films course
Ethics of Science: Responsible Conduct of Research course
University of Debrecen, Debrecen, Hungary

József Kovács

"Ethical Questions of Psychotherapy"
Lecture held as an invited speaker for clinical psychologists in postgraduate training. Organized by the Department of Clinical Psychology of the Semmelweis University
September 24, 2009, Budapest, Hungary

"Ethical Questions in Health Insurance"
Lecture held as an invited speaker in the course *Postgraduate Training Course in Health Insurance*, organized by Dr. Éva Keller, Institute of Forensic- and Insurance Medicine
September 25, 2009, Budapest, Hungary

"Some Ethical Questions in Psychology II."
Lecture held as an invited speaker on the PhD course *The Methodology of Health Sciences*.
Organized by the Institute of Behavioral Sciences of the Semmelweis University
October 7, 2009, Budapest, Hungary

"Bioethical Questions in the 21st Century"
Lecture held as an invited speaker at the teacher section of the Hungarian Philosophical Society
November 7, 2009, Budapest, Hungary

"Bioethical Aspects of the Relationship with Aggressive Patients"
Lecture held as an invited speaker at the CME course "Possibilities of prevention and management of aggression in clinical practice. Organized by Dr. János Pilling
March 27, 2010, Budapest, Hungary

"Ethical Questions in Clinical Psychology and Psychotherapy"
Lecture held as an invited speaker at the postgraduate training course. Organized by the Department of Clinical Psychology of the Semmelweis University
April 21, 2010, Budapest, Hungary

2.4. PARTICIPATION IN KEY EVENTS AND NETWORKS IN THE FIELD OF BIOETHICS AND BIOLAW

2.4.1. Making Perfect Life. Bio-Engineering in the 21st century

On November 10, 2010 Prof. Judit Sándor participated in the conference on "Making Perfect Life: Bioengineering in the 21st Century" at the European Parliament. In her intervention, she spoke about the relevance of dignity and privacy in the shaping policies of bioengineering. The panel addressed the issues of the political and policy implications of bio-engineering in the 21st century and was chaired by Vittorio Prodi (STOA Panel Member). Discussion was moderated by Bernd Beckert (Frauenhofer ISI), followed by discussion with Members of European Parliament. STOA (Science and Technology Options Assessment) is an official organ of the European Parliament, but its work is carried out in partnership with external experts, namely research institutes, universities, laboratories, consultancies or individual researchers contracted to help prepare specific projects. At these events Members of Parliament and invited experts from EU institutions, international institutions, universities, specialist institutes, academies and other sources of expertise worldwide can jointly participate in the analysis of current issues.

During two round table sessions, two trends at the crossroads of biology and technology were discussed with experts and Members of the European Parliament. Chaired by MEP and STOA Vice Chairman Malcolm Harbour, both the state of the art in distinctive research fields and their societal impact were presented. What does it mean when parts of the human body or brain can be engineered and modified outside of the body? When tissues, cells and neurons become products? Or synthetic substances create a life of their own?

2.4.2. Meeting of the Inter-University Francophone Network of Lawyers in the Field of Biomedicine. Third Topic: "Dying Patients and Their Relatives"

In 2007 based on Prof. Brigitte Feuillet-Liger's idea, an inter-university network was created in the field of bioethics. After a preparatory meeting in Paris, the first workshop was organized in 2007 in Rennes. The third meeting, organized in collaboration with the Faculty of Law, took place on January 5–6, 2009 in Kyoto, Japan. And then in 2010 the next meeting was held in Rennes again. This Francophone network includes mainly lawyers but also social scientists who work in the interdisciplinary field of studies of biomedicine, family law, and ethics. Since 2007 it has been significantly enlarged and several new scholars have entered the framework of this cooperation; thematic sessions and publications aim to explore legal and cultural differences in bioethics. The Kyoto workshop focused on the topic of "Adolescents and Medical Treatment".

Members of the network are: Brigitte Feuillet-Liger, Pénélope Agallopoulou, Amel Aouij-Mrad, Marco Ventura, Thérése Callus, Maria-Claudia Crespo-Brauner, Françoise Furkel, Ryuichi Ida, Dominique Manai, Kristina Orfali, Véronica San Julian, Geneviève Schamps, and Judit Sándor. The major output of this international network is a Collection on Law, Bioethics and Society published in Belgium by Bruylant. By the end of 2010, three books have been completed; two edited books in French and one in English. The first book was published with the title *Procréation médicalement assistée et anonymat*, the second is *Adolescent et acte médicale* and the third published book is in English with the title *Who Is My Genetic Parent? Donor Anonymity and Assisted Reproduction: A Cross-Cultural Perspective*. Professor Judit Sándor has been a member of the Advisory Board and the network since the beginnings. She delivered three papers: two in 2007 and 2010 in Rennes, and one in 2009 in Kyoto. The title of the paper presented in 2010 was: “Les règles de la dignité. Débats juridiques et éthiques sur l’interruption digne de la vie et de l’euthanasie en Hongrie.”

2.4.3. The 18th World Congress on Medical Law

The **W**orld **A**ssociation for **M**edical **L**aw (WAML) was formally established in 1970. Since its creation the WAML has had 17 World Congresses, and used its *International Journal Medicine and Law* for the publication of more than 1500 articles of authors from more than 100 countries. The purpose of the WAML is to encourage the study and discussion of problems concerning health law, legal medicine and ethics, and their possible solution in ways that are beneficial to humanity and the advancement of human rights. The aim of the WAML is to promote the study of the consequences in jurisprudence, legislation and ethics of developments in medicine, health care and related sciences. Biannual World Congresses are organized in all continents. In 2010 the Congress was held in Zagreb, Croatia, on August 8–12, 2010. Prof. Judit Sándor attended and delivered a presentation with the title “Lost in Translation? – Relevance of Scientific Terms in Shaping Contemporary Medical Law.” Prof. Violeta Beširevič and Judit Zeller also submitted abstracts to the conference.

2.4.4. ELPAT: European Platform for Ethical, Legal, and Psychosocial Aspects of Organ Transplantation

Webpage: www.elpat.org

The working group on organ trafficking, tourism and paid donation aims to address questions such as: Is the current legislation of European countries efficient in preventing and prohibiting human organ trafficking and tourism? If not, what are the loopholes and what improvements can be proposed? What outreach can be given to actual vendors / victims? What actions can be taken to diminish vulnerable populations / groups’ risk of being targeted as donors / vendors? The working group also aims to study how providing medical, legal and psychosocial support to actual organ vendors / victims can improve their condition and the negative outcomes of their selling an organ; to study how information, education and awareness campaigns can prevent vulnerable populations from being targeted as vendors. Regarding the use of the internet for soliciting of paid donation and advertising the need of transplantation, the working group will explore if legal measures can be proposed and adopted for prohibiting internet solicitation and advertising.

CELAB Researcher Enikő Demény took part in the *Second ELPAT Working Groups Invitational Conference* on “Organ Trafficking, Tourism and Paid Donation”, organized in Juan les Pines, 13-15 November, 2009 and presented a paper on “Internet practices related to organ solicitation and advertising and the law in Hungary and Romania.”

2.5. PARTICIPATION IN CONFERENCES

During the 2009–2010 Academic Year, CELAB staff and fellows took part in the following academic and scientific events:

RemediE Project: Third Wokshop
Participants: Judit Sándor and Márton Varju
October 8–9, 2009, Vienna, Austria

The Perfect Body: Between Normativity and Consumerism
Conference organized by the European Science Foundation
Presentation by Judit Sándor on "Human Enhancement? Tools for Ethical and Legal Assessment"
October 9–13, 2009, Linköping, Sweden

Conference at the Hungarian Supreme Court
Organized by the National Institute of Criminology at the Public Prosecutor's Office
Presentation by Petra Bárd on "Forensic Genetic Databanks"
October 26, 2009, Budapest, Hungary

Sixth Bioethics Forum of the South-Eastern European Countries: Bioethics, Medicine and Politics
Presentation by Violeta Beširević on "Bioethics in Democracy: Transforming the Clash of Absolutes into Human Rights Issues"
November 5–6, 2010, Belgrade, Serbia

ELPAT working groups: Second meeting
Presentation by Enikő Demény on "Internet Practices Related to Organ Solicitation and Advertising and the Law in Hungary and Romania"
November 13–15, 2009, Juan-les-Pins, France

Universal Application of the Universal Declaration of Human Rights: Towards Poverty Eradication
Conference organized by Institute for International Education
Presentation by Violeta Beširević on "Is Reducing Poverty a Task of Constitutional Courts?"
November 24–25, 2009, New York, USA

Tiss.EU Workshop Focal Theme B: "Rights and Entitlements in Human Tissue and Cells"
Participants: Judit Sándor and Petra Bárd
December 9–11, 2009, Leiden, The Netherlands

Theoretical and Practical Questions of Organ Transplantation
Scientific meeting organized by the Scientific Committee of the Budapest Saint John's Hospital and its Ethical Commission
Participant: József Kovács
December 10, 2009, Budapest, Hungary

Are Patients Rights Realized in Hungary?
Lecture held at Lege Artis Medicinæ (LAM) Club by József Kovács
December 10, 2009

PRIVILEGED Project: Steering Committee Meeting
Participant: Judit Sándor
December 15, 2009, Brussels, Belgium

International conference: "Dying with Dignity"
Patron: Dr. András Baka, President of the Hungarian Supreme Court
Organizing president: Dr. Mihály Filó
Participants from CELAB: Judit Sándor and József Kovács
Presentation by József Kovács on "Is Withholding Cardio-pulmonary Resuscitation Euthanasia?"
Presentation by Judit Sándor on "Euthanasia as a Political Issue"
January 22–23, 2010, Budapest, Hungary

Health and DNA: My Life, My Genes
Workshop organized by the International School for Advanced Studies of Trieste (SISSA)
Presentation by Judit Sándor on "Destiny Lost Ethical and Legal Implications of Genetic Testing for Neurodegenerative Diseases"
January 28–29, 2010, Trieste, Italy

Day of Rare Diseases – Conference
Presentation by Judit Sándor on "Physician-Patient Relations in the Postgenomic Age"
February 28, 2010, Budapest, Hungary

6th International Tiss.Eu Workshop: Anonymisation and Pseudonymisation as a Means of Privacy Protection
Participant: Judit Sándor
March 24–26, 2010, Stockholm, Sweden

Ethical, Legal and Psychosocial Aspects of Organ Transplantation: Expanding the European Platform
Presentation by Judit Sándor on "Ethical, Legal and Psychosocial Aspects of Organ Transplantation"
April 17–20, 2010, Rotterdam, The Netherlands

OSI's Law and Health Initiative: Developing Post-Graduate Education in Law, Human Rights, and Patient Care in Armenia, Georgia, Kazakhstan, Kyrgyzstan, Macedonia, Russia, and Ukraine
Presentation by Judit Sándor on "Human Rights and Biotechnology"
May 18–21, 2010, Skopje, Macedonia

X.th Day of Behavioral Sciences
Presentation by Péter Kakuk on "Autonomy and Trust in Medical Decision-making"
May 25–26, 2010, Pécs, Hungary

Fourth Meeting of the Francophone Network of Lawyers in the field of Biomedicine: "Dying Patients and Their Relatives"
Presentation by Judit Sándor on "Les règles de la dignité »Débats juridiques et éthiques sur l'interruption digne de la vie et de l'euthanasie en Hongrie"
May 27–28, 2010, Rennes, France

The Bioethical Aspects of Psychiatry and Psychotherapy
Public defense of Dr. József Kovács. Thesis submitted to the Hungarian Academy of Sciences
Participants: Judit Sándor and Enikő Demény
June 1, 2010, Budapest, Hungary

Religion in the Public Sphere
18th Annual Conference: The Individual vs. the State
Judit Sándor chaired the session on "Fundamental Concepts and Tensions II"
Petra Bárd chaired the session on "Religious Teachings on Politics and Law"
June 4–5, 2010, Budapest, Hungary

Second International Conference of the RemediE Project
Presentation by György Kovács on "Legal Uncertainties in Regenerative Medicine"
June 9–10, 2010, Madison, Wisconsin, USA

18th World Congress on Medical Law
CELAB participants: Violeta Besirevic, Judit Sándor and Judit Zeller
Presentation by Judit Sándor on "Lost in Translation? –Relevance of Scientific Terms in Shaping Contemporary Medical Law"
August 8–12, 2010, Zagreb, Croatia

Biopolitics, Biosociality and the Body
ESF/COST Workshop
Presentation by Judit Sándor on "Human Rights and Biopolitics: Parens Patriae: Politics of Birth in Hungary"
August 30, 2010, St. Gallen, Switzerland

Ninth International Workshop of the Tiss.EU Project: Procurement, Storage and Transfer of Tissues and Cells For Non-Clinical Research Purposes
Organized by the Department for Medical History and Ethics, Vilnius University and Lithuanian Bioethics Committee
Participant: Judit Sándor
September 9–10, 2010, Vilnius, Lithuania

PartnErS Project Workshop: 'Comparative embryonic stem cell research in mammalians'
Member of the Advisory Group: Judit Sándor
Presentation by Judit Sándor on "Ethics of Animal and Human Stem Cell Research"
September 14–15, 2010, Eger, Hungary

2.6. SCIENCE COMMUNICATION AND MEDIA EVENTS

The Director and Fellows of CELAB have taken part in many media events and science communication activities in which they contributed to the awareness-raising on current ethical dilemmas in the field of biomedicine and newly emerging technologies and have had the opportunity to make CELAB more widely known in the media.

“Anonymity and Gamete Donation”
Interview with Judit Sándor, Reporter Eszter Barna
MR1 Kossuth Rádió: “Napközben”
October 9, 2009.

“Ageism in Medical Treatment”
[Az idősebbekkel szembeni diszkrimináció orvosi kezelés során]
Interview with József Kovács, Reporter: György Bolgár
Klub Rádió
October 16, 2009.

“One Hour with Judit Sándor”
[Záróra beszélgetés Sándor Judittal]
Reporter Alinda Weiszer
Hungarian Public TV, MTV1 and MTV2: “Záróra”
October 27–28, 2009.

“On the Questions of Psychiatric Ethics”
[A pszichiátriai etika kérdéseiről]
Interview with József Kovács, Reporters: Judit Takács and Henrik Havas
Klub Rádió
November 2, 2009.

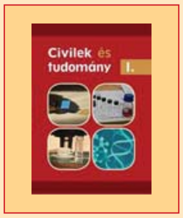
“Ethical Questions of the Hungarian Health Care System”
[A magyar egészségügy etikai problémái]
Interview with József Kovács, Reporter: Anikó Köbli
In: Köbli, Anikó (2009) *Aszklépiosztól a betegjogokig* [*From Asclepios to Patients Rights*]
Budapest: Szépíró Műhely.

“Ethical and Legal Issues on H1N1 Vaccines”
[A H1N1 oltás etikai és jogi kérdései]
Interview with Judit Sándor and Zsombor Kovácsi, Reporter: József Orosz
Klub Rádió
December 3, 2009.

“How Much is a Life Worth? And How Much Can We Pay for It?”
[Mennyit ér egy élet? És mennyit tudunk adni érte?]
Interview with József Kovács, Reporter: László B. Papp
In *Rákgyógyítás*, vol. 2, no. 4 (Winter 2009), 4–7.

“Porcupine or Shark? Ethical Problems Raised by Profit Oriented Medical Research”
[Tarajos sül vagy cápa? A profitorientált orvostudományi kutatás által felvetett etikai problémák]
In: *2000*, vol. 21, no. 10 (December 2009), pp. 49–61. (Republished excerpt from the book József Kovács (2007): *Bioetikai kérdések a pszichiátriában és a pszichoterápiában. [Bioethical Questions in Psychiatry and Psychotherapy*] Budapest: Medicina, 523–556.)

“Ethical and Social Aspects of Nano-Biotechnology”
[A nano-biotechnológia társadalmi megítélése és alkalmazásának etikai kérdései]
Interview with Enikő Demény, Reporter: Ágnes Ferbert-Vadász
In György Fábri (ed.) *Civilek és tudomány I. Nanotechnológia, humángenomika [Civil Society and Science I.: Nanotechnology, Human Genomics*], Budapest: Tudástársadalom Közhasznú Alapítvány, 2009, 115–125.



“International and National Regulations in Bioethics”
[A bioetika jogi szabályozottsága a hazai és a nemzetközi színtéren]
Interview with Judit Sándor, Reporter: Ágnes Ferbert-Vadász
In György Fábri (ed.) *Civilek és tudomány I.: Nanotechnológia, humángenomika* [*Civil Society and Science I.: Nanotechnology, Human Genomics*], Budapest: Tudástársadalom Közhasznú Alapítvány, 2009, 177–191.

“Health and DNA: My Life, My Genes”
Round table discussion in Italian with simultaneous translation
Participant: Judit Sándor
January 29, 2010, Trieste, Italy

“The Gravest Choice: Who Should Receive Treatment?”
[A legsúlyosabb választás: ki kapjon ellátást?]
Interview with József Kovács, Reporter: Anna Danó
In *Népszabadság*
February 3, 2010, pp. 1–4.

“We Still Cannot Trust the Personal Genetic Tests”
[Még nem bízhatjuk magunkat a személyes géntesztekre]
Article and interview with Judit Sándor by András Illyés
In *Origo Tudomány*
February 11, 2010.

“Ethical and Legal Aspects of Home Child Birth”
Reflections by Judit Sándor on the book written by Marsden Wagner: Born in the USA: How a Broken Maternity System Must Be Fixed to Put Women and Children First at the Book Launch and Discussion on the Maternity System
Chair: Miklós Hadas
April 7, 2010, Budapest, Hungary

“Embryo with Three Genetic Parents?”
[Embrió három szülővel?]
Interview with Judit Sándor, Reporter: Júlia Gimes
MR1 Kossuth Rádió: “Challenge” program
April 21, 2010.

“Genes and Patents: the Myriad Case”
[Gének és szabványok: A Myriad-eset]
Interview with Judit Sándor, Reporter: Júlia Gimes
MR1 Kossuth Rádió: “Challenge” program
May 3, 2010.

“The Future Medical Science through the Lens of Ethics”
[Az orvostudomány jövője etikai szemmel]
Interview with Judit Sándor
In: *eLit.Med.hu*
July 13, 2010.

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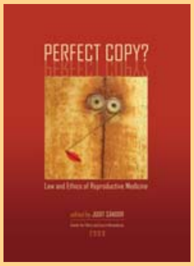

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3. BUDGET

3.1 REVENUES IN AY 2009–2010

Approved Budget from CEU for AY 2009/2010 (code C-5036):	42,002 €
External Funding:	
RemediE	49,818 €
Nanoplat	13,331 €
Tiss.EU	11,634 €
EULOD	11,791 €
TOTAL	86,574 €

3.2 SPENDING IN AY 2009–2010

C-5036 CELAB main budget code

Budget category	Amount in Euro
Personnel cost	41,282
Web-page design	720
Total Total	42,002

C-8341 Tiss.EU project

Budget category	Amount in Euro
Personnel	4,303
Other costs	2,846
Total	7,149

C-8340 RemediE project

Budget category	Amount in Euro
Personnel	48,144
Other costs	1,435
Total	49,579

C-8336 EULOD project

Budget category	Amount in Euro
Personnel	8,356
Other costs	100
Total	8,456

C-8336 Nanoplat project

Budget category	Amount in Euro
Personnel	4,741
Other costs	0
Total	4,741