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Jean Monnet Chair PROTECH "European Protection Law of Individuals in Relation to New Technologies"

> 3rd International Workshop A.Y. 2021-2022

ABSTRACTS BOOK FROM HUMAN BEING TO CYBORG

NATIONAL CASES ON HUMAN EMBRYOS AND THE EU COURT OF JUSTICE: FROM ARTIFICIAL PROCREATION TO HUMAN ENHANCEMENT IN THE ERA OF TRANSHUMANISM

> *Edited by* Lucilla Gatt Maria Cristina Gaeta

> > Livia Aulino

11. November 2022 Suor Orsola Benincasa University Webinar



With the support of the Erasmus+ Programme of the European Union







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ReCEPL ReCEPL SERIES

> 1. Gatt L., Montanari R., Caggiano I.A. (eds.) Privacy and Consent. A Legal and UX&HMI Approach University Suor Orsola Press, 2021, ISBN 978-88-96055-878

2. Gatt L. (ed.)

Social Networks and Multimedia Habitats. Jean Monnet Chair PROTECH. "European Protection Law of Individuals in Relation to New Technologies". 1st International Workshop A.Y. 2019-2020 University Suor Orsola Press, 2020, ISBN 979-12-80426-00-0

3. Grimaldi P. *Le fonti di energie rinnovabili nella circular economy* University Suor Orsola Press, 2021, ISBN 979-12-80426-05-5

4. Gatt L. (*ed.*) Legal design for transparency in consumer contracts operating in online and offline environments. A new chance for the interaction between academics and stakeholders. 2nd International Workshop A.Y. 2020-2021 University Suor Orsola Press, 2022, ISBN 979-12-80426-10-9

5. Gatt L., Gaeta M.C., Aulino L. (eds.) From human being to cyborg. National Cases on Human Embryos and the EU Court of Justice: from artificial procreation to human enhancement in the era of transhumanism. Jean Monnet Chair PROTECH. "European Protection Law of Individuals in Relation to New Technologies" 3rd International Workshop A.Y. 2021-2022 University Suor Orsola Press, 2023, ISBN 979-12-5511-003-3 The ReCEPL series is directed by Lucilla Gatt. The members of the scientific committee are available here: www.unisob.na.it/ateneo/c008.htm?vr=1 This International Workshop is dedicated to Prof. Cesare Massimo Bianca, my Mentor and among the most prominent scholars of the law of persons in Italy and Europe.

During his long activity as a university lecturer and researcher, Prof. Bianca has always worked to protect those who are in a position of weakness in legal relations.

His example is intangible.

This research has been anonymously refereed

Lucilla Gatt

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Editing Luciana Trama

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TABLE OF CONTENTS

11	<i>WORKSHOP INTRODUCTION</i> Lucilla Gatt From Human Being to Cyborg: the new era of legal research
17	Organizing Committee
19	Scientific Editorial Committee
29	Workshop Schedule
	WORKSHOP ABSTRACTS
	I PANEL — HUMAN BEING CREATION IN ARTIFICIAL ENVIRONMENT
37	Antonio D'Aloia
40	Luigi Montano Studies on the medium and long-term effects of medically assisted procreation
41	Geppino Falco <i>Diseases characterization and treatments finding through</i> in vivo and ex vivo models
42	Sergio Guida Golem v s. transhuman: the man of the future between biology, new technologies, ethics and sustainability
	Legal and Ethics Area Speakers
44	Sara Landini Ethical-legal aspects of organoids and their use in research. Manage risks and legal constraints for the development of ethical research

From Human Being to Cyborg Table of Contents

- 46 Laura Valle Surrogacy contract as an instrument of protection of individuals involved in the process
- 48 Francesca di Lella *Reproductive technologies and human embryo identity* in vitro: *perspectives*
- 50 Paola Grimaldi The protection of the human embryo in the new Gasparri proposed law
- 52 Marco Rizzuti Gene editing and private law
- 54 Francesca Ferretti Human enhancement and genetic identity of the embryo

II PANEL – HUMAN ENHANCEMENT TECHNOLOGIES – HUMAN-MACHINE INTERACTION AND HYBRIDIZATION

- 57 **Pasquale Arpaia** Brain Computer Interfaces (how not to lose the privacy of thoughts after that of data)
- 60 Andrea Emilio Rizzoli IDSIA project presentations
- 61 Roberto Montanari, Roberta Presta 'Scienza Nuova' projects and HMI technologies

Legal and Ethics Area Speakers

- 63 Maria Antonia Ciocia *The protection of intellectual creation and blockchain technology*
- 64 Erica Palmerini The market for human enhancement technologies
- 65 Andrea Bertolini Governing human enhancement through the principles of dignity and equality
- 67 Fiorella Battaglia, Giuseppe Di Vetta Sandbox for BCI devices and cyborg experimentation

KEYNOTE SPEECH

70 Pim Haselager Al and neurotechnology: mirroring human (im)perfections

Question by

- 71 Lucio Casalini The subject-object relationship between enhancement and fragmentation of the person
- 72 Fabrizio Cesareo The problem of the legal personality of artificial intelligence

From Human Being to Cyborg Table of Contents

III PANEL – HUMAN ENHANCEMENT TECHNOLOGIES IN VULNERABILITY SITUATIONS

Economics and Engineering Area Speakers

- 74 Anita Mollo, Domenico Napolitano, Luigi Maria Sicca *Technology* & Disability: Social and legal frameworks of assistance and protection
- **76** Martina Galli VRAILEIXA project, using AI and VR to support dyslexic students: what limits on vulnerability?
- **77** Francesco Flammini *REliable & eXplAinable Swarm Intelligence* for People with Reduced mObility

Legal and Ethics Area Speakers

- 79 Salvatore Orlando Data vs. Capta: not only a linguistic choice
- 80 Valentina Cuocci Supported Decision Making Agreement (SDM) and private 'support' mechanisms for informed choices
- 82 Giovanna Capilli Digital health: new challenges
- 86 Luigi Viola, Gianfranco D'Aietti Augmented justice and decision making

IV PANEL – FUTURE SCENARIOS IN THE ERA OF TRANSHUMANISM

- 90 Aldo lannotti della Valle Public policies for strategic investment in relation to new technologies
- 92 Roberto Paura Emerging megatrends toward a fully-disembodied future

Legal and Ethics Area Speakers

- 93 Lucilla Gatt, Ilaria Amelia Caggiano, Maria Cristina Gaeta, Anita Mollo BCI devices and their legal compliance: a prototype tool for its evaluation and measurement
- 95 Lucilla Gatt, Ilaria Amelia Caggiano, Emiliano Troisi, Livia Aulino, Luigi Izzo, Davide Silvio D'Aloia *BCI devices and their capacity to express human will having legal value: a model of risk-based classification*

KEYNOTE SPEECH

Question by

96 Andrea Del Forno Artificial intelligence in companny management processes

From Human Being to Cyborg Table of Contents

- 98 Francesco Ribezzo The new ways of legalising the body
- 99 Lavinia Vizzoni A Legal study of domotics: from the risks for the subjects involved to the goal of creating an integrated and effective protection system

WORKSHOP INTRODUCTION

LUCILLA GATT

Jean Monnet Chair Protech Full Professor of Private Law and New Technologies Law Director of the Research Centre of European Private Law (ReCEPL) Editor in Chief of European Journal of Privacy Law & Technologies (EJPLT)

From Human Being to Cyborg: the new era of law research

The Jean Monnet PROTECH – European Chair Protection Law of Individuals in Relation to New Technologies¹ of the Suor Orsola Benincasa University (Naples, Italy) will host the third PROTECH Workshop at the same University a.y. 2021/2022 entitled "From human being to cyborg. National Cases on Human Embryos and the EU Court of Justice. From artificial procreation to human enhancement in the era of transhumanism".

The European Union is founded on the values of human dignity, equality and respect for human rights. The European system promotes scientific and technological progress, focusing on ethical and social issues, in the context of the interactions between science and technological development. In this perspective, numerous *hard law* and *soft law* acts and multiple jurisprudential decisions have been published, at national and supranational level in order to guarantee the protection of the human being – including embryos or new forms of life created in the laboratory – in relation to the development of new technologies. Similarly, there are numerous proposals for legislative acts aimed at regulating the use of artificial intelligence, as well as the development of evaluation toolkits on the level of ethics compliance of the same.

The aim of the call is to create a qualified scientific debate between the Academy (University Professors, Researchers, PhDs and PhD students belonging to Italian or foreign research centers) Institutions (local and national) as well as private entities, on the issues indicated, in order to propose solutions to the multiple and delicate legal issues generated by the relationship between human beings and technologies in the indicated area or to broader questions concerning the same issues (e.g. relationship between ethics, economics and science). In particular, the workshop aims to indicate

¹ Erasmus + Jean Monnet Actions 611876-epp-1-2019-1-it-eppjmo-chair.

From Human Being to Cyborg Workshop Introduction

a possible solution to the problem of creating and disseminating reliable technologies that are not harmful to humans, artificially created or enhanced. The PROTECH workshop a.y. 2021/22, now in its third edition, places particular emphasis on:

1. Implementation of the protective approach in European law to the relationship between individuals and technologies, with particular regard to embryos and new forms of life created in the laboratory as well as to human enhancement through the use of artificial intelligence;

2. Increase scientific dissemination on the topics covered by the Workshop, through participation in a widely accessible call, whose selected contributions had been presented during the workshop and will published in the *European Journal of Privacy Law & Technologies* (EJPLT);

3. Strengthen international exchange and dialogue between Institutions and Academies on the themes of the Workshop.

The PROTECH workshop a.y. 2021/22 focuses on the protection of individuals in relation to the development of new technologies, with particular regard to artificially created life forms and human enhancement. In particular, the legal issues concerning human creation, hybridisation and enhancement through the use of artificial intelligence in all its various articulations and of technological tools in general will be studied in depth.

The aim of the Workshop is to highlight the need for a protective approach of European law regarding the relationship between individuals and technologies, with particular regard to the protection of human life created in the laboratory, or to the protection of the human being enhanced through the use of technology, and this because of the relationship of structural vulnerability of the human being (and not just human) in these situations.

The Workshop collected the responses to an international call, which requested adherence from those involved in a project context or belonging to research centres specializing in the relationship between law and technological innovation. The event was structured in 4 Panels and 2 Keynote Speeches.

The first Panel, entitled *Creation of the human being in an artificial environment*, is focused on the awareness that in the last decades the advances in biomedical knowledge have opened up new possibilities for manipulating the initial phase of human life from many points of view: early life, genetic editing, birth and development.

Today it is possible to produce embryos in vitro through medically assisted procreation with various techniques, just as it is possible to freeze the excess embryos, keep them or transfer them to the uterus of the biological or surrogate mother even after a long time. In recent years, both the gestation of the embryo in an animal uterus and the so-called ectogenesis, i.e. the gestation of the human embryo in an artificial uterus, are being planned. It is evident that the feasibility and concrete implementation of these practices has raised and continues to raise important issues of legal importance such as the qualification of the human embryo and of the so-called organoids. But even more pressing are the questions about the conditions of development and life of artificially procreated human beings. In this Panel experts, professors and researchers offer their contributions to understanding the different stages of individuals' artificial procreation processes in order to focus on the most critical legal aspects and find a meeting point between technological and scientific advances and the protection of fundamental human rights.

In the second Panel, entitled *Human enhancement technologies; human-machine interaction and hybridization*, the dialogue between different areas of knowledge opened a debate on a hybrid third dimension in which humans and machines are symbiotic.

Developments in artificial intelligence arouse attention and optimism, but also doubts and uncertainties; the goal is to realize the interaction between Artificial Intelligence and Law to achieve a balance between advantages and disadvantages. Legal and ethical mediation is needed to encourage and regularize technological innovation in the market by setting limits for human-machine hybridization, while also taking sustainability into account. Multidisciplinary collaboration is implemented to develop a greater awareness of the importance of innovation to improve the conditions of human life, but collaboration between lawyers teams and scientists teams to design Al technologies that are truly human-centered is essential. Experts, professors, and researchers offer their input to understand current human enhancement technologies and their impact on human life even and especially from a legal question perspective.

At the end of the second panel took place the first Keynote speech given by Prof. Pim Haselager, from Radboud University, entitled *AI and neurotechnology: mirroring human (im)perfections*, whereby the focus shifted to the conceptual connection between progress and happiness, emphasizing how technological evolution does not necessarily make humans happier and therefore is not identified with the progress of humanity.

In the third Panel, entitled *Technologies to support human beings in vulnerable situations*, the topic offered insights into the positive and/or negative consequences that can result from the use of technologies taking into account the specific condition of the person using them.

Seemingly different situations are examined but which have in common the exposure of the subject agent to a technology over which he or she does not or may not have control and with respect to which he or she

From Human Being to Cyborg Workshop Introduction

is therefore vulnerable. This happens to everyone who uses a technology to achieve a result more efficiently and quickly than their own capabilities, and this happens in many different contexts (disability, health issues, B2C relationships, decision-making process especially in the judiciary). Experts, professors and researchers offer their input on how, in all these contexts, it is appropriate to ask about the legal consequences of using such technologies.

With regard to the last Panel, the forth, entitled *Future scenarios in the era of transhumanism* the focus was on the massive and pervasive use of technologies to enhance physical and cognitive capabilities in order to improve those aspects of the human condition considered undesirable. All that paves the way for the progressive transformation of human beings into cyborgs and, more generally, for transhumanist perspectives.

It is crucial that a vision of "technologies legal and ethical compliance" accompanies technological evolution very closely in order to prevent it from becoming a slave to purely economic logic. Scenarios were imagined and possible directions were proposed from a perspective of *ex ante* measurement of the impact of technologies on the fundamental rights of human (and other living) beings. Representatives of public and private institutions expounded their forecast on the development of human beings in their increasingly symbiotic relationship with technologies.

At the end of the fourth panel took place the second Keynote speech given by Prof. Raffaella Sadun, Harvard University, entitled *The role of Fund of the Digital Republic*, in which the need to design training courses for the acquisition of digital area skills for a wide segment of the population was emphasized in order to prevent technological innovation from negatively affecting the labor market.

During the Workshop the European Journal of Privacy law and Technology was presented as an example of university open access review and this was done in order to support the idea of free and open scientific knowledge that underlies the Project PROTECH and its dissemination.

It is also worth noting the involvement during the event of young researchers who were able to display their research and dialogue with advanced researchers both with regard to content and the research methods adopted by them.

The WS was also sponsored by the Interdisciplinary Bioethics Research Center (CIRB), based in Naples at Federico II University. It generated interest from many research centres and other Italian universities and was accredited by the Council of the Order of Lawyers of Naples and by the National Council of Notaries. It was an intense meeting and allowed for a fruitful comparison between legal researchers and medical, computer science, and engineering

Lucilla Gatt From Human Being to Cyborg: the new era of law research

scientists with a specific focus on self-learning AI systems. This comparison highlighted the need for mixed research teams with lawyers present alongside scientists in order to achieve a truly human-centric development of AI, with specific regard to human-machine hybrid technologies.

The research domain on law&technology is initially seen as an investigation following two main streams:

a) the revision, in light of the penetration of technological realities into everyday life, of areas traditionally considered to be the subject of legal research, questioning the persistence of traditional categories with regard to emerging issues (e.g. robolaw, automotive liability, neurolaw);

b) the remodeling of the methods and objectives of legal research that places the research work in a *de jure condendo* perspective and impact analysis of new regulations.

Later, the last interaction between law and technology has developed on the research front into two other articulations:

c) the declination of the activity of lawyers as custodians of a set of shared values translated into general principles in supra- and international charters towards a by design (design-based) cooperation with scientists for the realization of a human-centered technology (AI). The law becomes a meeting point between secular ethics and religious ethics in the pluralistic world (s. Warren T. Reich).

d) the creation and application – by the lawyers – of evaluation (or, better, measurement) tools of the level of compliance and damage risk of technologies, with a consequent acquisition of fundamental role of lawyers in decision-making processes on the same development of technologies (e.g. development and market release).

In conclusion, the passage from the human being to the cyborg requires an increasingly close collaboration between jurists and scientists in the step-by-step conception and development phase of implantable technologies because only this cooperation can avoid abuses and violations of the fundamental rights of the human being as well as codified in documents such as the Nizza Charter of the European Union and the ECHR – European Charter of Human Rights.

ORGANIZING COMMITTEE

3rd INTERNATIONAL WORKSHOP ON "FROM HUMAN BEING TO CYBORG. NATIONAL CASES ON HUMAN EMBRYOS AND THE EU JUSTICE: FROM ARTIFICIAL PROCREATION TO HUMAN ENHANCEMENT IN THE ERA OF TRANSHUMANISM" - 11. NOVEMBER 2022 -SUOR ORSOLA BENINCASA UNIVERSITY

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Dedication This International Workshop is dedicated to Prof. Cenare Massimo Manea . My Mentor and among the most prominent scholars of the law of persons in Italy and scholars of the law of persons in Italy most person in Italy scholars of the law of persons in Italy scholars of the law of persons in Italy scholars of the law of persons in Italy most person in Italy most person in Italy most person in Italy scholars of the law of persons in Italy scholars o	Centro Exercise Bioetica Exercise UNIVERSITA DECLISTUDI Supromession Universitation Supromession Universitation <t< th=""></t<>
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MORNING SESSION 10.00 / 13.30 Online – Google Meet Platform

INSTITUTIONAL GREETINGS

Lucio d'Alessandro Rector of Università degli Studi Suor Orsola Benincasa

Tommaso Eduardo Frosini Director of the Department of Juridical Sciences, Università degli Studi Suor Orsola Benincasa

Antonio Patroni Griffi President of Centro Interuniversitario di Ricerca Bioetica (CIRB)

Maurizio Santise Deputy coordinator of the Ufficio del Massimario of Administrative Justice

Antonio Areniello President of Fondazione Italiana del Notariato and Vice-president of Consiglio Nazionale del Notariato

Antonio Tafuri Lawyer, President of Naples Bar Association

Introduction & Coordination Lucilla Gatt Jean Monnet Chair Holder PROTECH Director of Research Centre of European Private Law (ReCEPL)

I PANEL HUMAN BEING CREATION IN ARTIFICIAL ENVIRONMENT

Antonio d'Aloia Director of the University Center for Bioethics (UCB), Università di Parma Ilaria Amelia Caggiano

Jean Monnet Chair EUGREEEXT, Università degli Studi Suor Orsola Benincasa

From Human Being to Cyborg Workshop Schedule

Nicola Colacurci President of the Italian Society of Gynecology and Obstetrics, Università degli Studi della Campania Luigi Vanvitelli

Luigi Montano President of the Italian Society of Human Reproduction (SIRU) and Coordinator of the EcoFoodFertility Research Project

Geppino Falco Head of the laboratory of 'Staminalità e rigenerazione tissutale" of Biogem, Full Professor of applied biology Università degli Studi di Napoli Federico II

Sergio Guida Founder & Team Leader Sustaihuble Impact LAB

Legal and Ethics Area Speakers

Luisella Battaglia President of the Italian Institute of Bioethics and Member of the Italian Committee for Bioethics

Sara Landini PI of Goineu DGJ project, PI of GoinEuplus DGJ project, Module PI_IS Jean Monnet Chair, Università degli Studi di Firenze

Laura Valle Associate Professor, Free University of Bozen-Bolzano

Francesca di Lella Appointed Lecturer in BioLaw, Università degli Studi di Napoli Federico II

Paola Grimaldi Lecturer in Private Green Law, Università della Campania Luigi Vanvitelli

Marco Rizzuti Lecturer in Bio Law, Università degli Studi di Firenze

Francesca Ferretti Ph.D. (c) in Bio Law, Università degli studi di Camerino

II PANEL HUMAN ENHANCEMENT TECHNOLOGIES – HUMAN-MACHINE INTERACTION AND HYBRIDIZATION

Ugo Ruffolo Coordinator of the "Artificial Intelligence and Law" Cycle of Seminars, Alma Mater Studiorum Università di Bologna

Pasquale Arpaia Director of the Interdepartmental Center for Research in Health Management and Innovation in Healthcare (CIRMIS), Università degli Studi di Napoli Federico II II PANEL Human enhancement technologies - Human-machine interaction and hybridization

Andrea Emilio Rizzoli Director of the Dalle Molle Institute for Artificial Intelligence (IDSIA), Università della Svizzera Italiana – Scuola Universitaria Professionale della Svizzera italiana

Roberto Montanari Roberta Presta ReLAB Co-founder and Technical Director of the 'Scienza Nuova' integrated laboratory of innovative technologies for the social sciences, Università degli Studi Suor Orsola Benincasa

Legal and Ethics Area Speakers

Maria Antonia Ciocia Director of the Economics Department, Università degli Studi della Campania Luigi Vanvitelli

Erica Palmerini Coordinator of the RoboLAW Project, Scuola Superiore Sant'Anna di Pisa

Andrea Bertolini Director of EURA Jean Monnet Centre of Excellence, Scuola Superiore Sant'Anna di Pisa

Fiorella Battaglia Pl of AlnCP, Università del Salento

Giuseppe Di Vetta Post-Doc Research Fellow, CAIROS Research Project, Scuola Superiore Sant'Anna di Pisa

KEYNOTE SPEECH

Pim Haselager SIAC Principal Investigator, Department of Artificial Intelligence at the Donders Institute for Brain, Cognition and Behaviour, Radboud University

Lucio Casalini Postdoctoral Research Fellow, Università degli Studi di Camerino and JODI Member Fabrizio Cesareo

Postdoctoral Researcher Fellow, Università degli Studi di Milano Bicocca

III PANEL HUMAN ENHANCEMENT TECHNOLOGIES IN VULNERABILITY SITUATIONS

Giuseppe Corasaniti Former member of the Innovation Office of Italian Supreme Court Giovanna De Minico

Ermes Director, Università degli Studi di Napoli Federico II

From Human Being to Cyborg Workshop Schedule

Economics and Engineering Area Speakers

Luigi Maria Sicca Professor of Business and Public Administration Organization, Università degli Studi Suor Orsola Benincasa; Scientific Director PuntOorg International Network

Anita Mollo Senior Researcher of ReCEPL, Università degli Studi Suor Orsola Benincasa

Domenico Napolitano Lecturer in Theories and techniques of sound in media, Università degli Studi Suor Orsola Benincasa

Martina Galli Rector's Delegate to Inclusion and Equity, Università degli Studi della Tuscia

Amedeo Manzo President of Federazione BCC

Francesco Flammini Professor of Trustworthy Autonomous Systems, REXASI-PRO

Legal and Ethics Area Speakers

Salvatore Orlando Director of the Juridical Observatory on Digital Innovation-JODI, Sapienza Università di Roma

Valentina Cuocci Member of the Coordination Committee of the Summer School Governance in the digital age

Giovanna Capilli Director of the Advanced Course in Cybersecurity, Università San Raffaele di Roma

Luigi Viola Gianfranco D'Aietti JurAl Consortium Directive Members

IV PANEL FUTURE SCENARIOS IN THE ERA OF TRANSHUMANISM

Francesco Romeo Coordinator of CREA Project, Università degli studi di Napoli Federico II

Caterina Flick Manager in charge of the Legal Affairs Office, Agency for Digital Italy (AgID) Aldo lannotti della Valle

Ph.D., former Legal Expert in the Italian Prime Minister Mario Draghi's Office Emilio Tucci Ph.D., Legal adviser, Department for Digital Transformation of the Presidency of the Council of Ministers IV PANEL Future scenarios in the era of transhumanism

Roberto Paura President Italian Institute for the Future Caterina Flick Manager in charge

Legal and Ethics Area Speakers

Lucilla Gatt Ilaria Amelia Caggiano Maria Cristina Gaeta Anita Mollo ReCEPL Team Members

Lucilla Gatt Ilaria Amelia Caggiano Emiliano Troisi Livia Aulino Luigi Izzo Davide Silvio D'Aloia *ReCEPL Team Members*

KEYNOTE SPEECH

Raffaella Sadun Charles E. Wilson Professor of Business Administration, Harvard Business School, President of the Scientific Committee Fondo per la Repubblica Digitale (former Advisor of the Italian Prime Minister Mario Draghi)

Questions by

Lavinia Vizzoni Appointed Lecturer Department of Political Sciences, University of Pisa

Andrea Del Forno Ph.D. (c) Università degli Studi di Siena

Francesco Ribezzo Ph.D. (c) Università degli Studi di Bari Aldo Moro



I PANEL HUMAN BEING CREATION IN ARTIFICIAL ENVIRONMENT

Artificial intelligence, artificial procreation, cyborg, human enhancement, transhumanism: all these words show how the (always controversial) interplay among science, technologies, society and law has reached a turning point, whereby these new technological possibilities become transformative factors into our philosophical anthropology. These (e.g. Al, gene editing, synthetic biology) are called 'deep' technologies, innovations that reinvent ourselves, that mark a disruption in the world, because their aim is to better project the evolution, to reinvent the nature (J. Preston, 2019).

The divide between human and artificial is challenged. Michel Serres wrote about 'ominescence', emphasizing the phenomenon of a human being whose boundaries blur with things and other living beings (such as animals). The "image of the nature" moves away from the traditional representation of an objective, unique datum that has always and forever held true. According to Werner Heisenberg's famous expression, it is not simply the result of neutral, passive observation, but contains re-elaborated and 'constructed' elements.

On a different level, the unpredictable randomness of the nature is challenged by the modifying force of science and technology, which appear capable to intervene on its basic projections (life, birth, death, human body) and on the very boundaries between human and natural, so often – as M. Sandel wrote (2013) – a step ahead the ethical understanding and thus the attempt of legal reasoning.



This opens up a relevant and critical space between social sciences, humanities, realities and perspectives of technological development, and requires readiness for exchange, contamination between knowledge, and interdisciplinary discussion.

The technology produces cultural movements, desires, expectations, and claims that people demand to be recognized as rights; at the same time, it determines new attitudes and perceptions towards the human life and the nature. For example, the IVF has broken down the traditional concept of parenthood with the multiplication of the paternal and maternal figures. The parent can be biological, genetic, social, and some of these subjects can even take on different meanings (e.g., see the English case of mitochondrial donation to the figure of the biological mother).

Faced with these unprecedented facts, the law is experiencing the uncertainty and the difficulty of balancing scientific acquisitions, social claims, as well as ethical, religious, and cultural models. Nevertheless, even for the law, this uncertainty can have positive effects; it means dynamism, attention to and awareness of the plurality of ideas and values, and the ability to adapt to the novelties emerging on the scientific, social and cultural spheres.

Looking at the constitutional language, its open-ended and indeterminate clauses (life, dignity, personal identity, equality) are the most representative image of a normative framework able to follow the changes in the social structure, induced by new scientific and technological possibilities, but without giving up to guide these changes and to shape them into a constitutional perspective.

Scientific progress affects constitutional clauses, reshaping their meanings and applications (A. Ruggeri, 2020). New possibilities and unforeseen options come to the fore: in this context, emerging instances and concerns, linked to the meanings of dignity, of person's full development, and of equality, aspire to become (and often succeed in becoming) rights (R. Bin, 2015). These are no less fundamental than the values from which they find nourishment and justification: from the right to change sex to the right to procreate through 'medically and technologically assisted' techniques, to the rights produced by (or connected to) developments in genetic research, such as the right to not know, the right to not be discriminated because of one's genetic characteristics (M. Tomasi, 2019). Law is called upon to mark the boundaries of this transformative activity, to arbitrate a conflict within the very paradigm of nature redesigned by technology (N. Irti, 2013).

Likewise, the 'geology' of law is extremely complicated. The layering and the interplay of its resources (normative, jurisprudential, argumentative, enforceable, contractual) rests on a foundation that is absolutely 'inconstant'

I PANEL Human being creation in artificial environment

and permeable to a whole range of evaluative influences, 'pre-juridical' meanings and orientations (moral, philosophical, religious), experiences (the facts which change the way we perceive situations, relate to them, the existential dynamics, the technological possibilities...).

G. Zagrebelsky (2006) wrote «the law is still positive law [...] direct statement is one thing, the indirect one that operates referrals to something outside its specific positive determinations is another, [...]. Let us look at the arguments of our Constitutional Courts: when they deal with important issues (e.g., those relating to personal statuses, such as birth, life and death), they look more connected to 'natural law' than to 'positive law'. The reference to a principle written in the constitution is often the way to open a discussion elsewhere [...]»^{*}.

The elsewhere is clearly not a higher and distinct normative level from 'positive' law. Instead, it is a way of its being, its inalienable destiny and of listening to life, to its 'music' (as a sharp scholar wrote, see S. Prisco, 2015), while simultaneously it tries to regulate it.

The elsewhere is within the constitutional principles of protection of life and human dignity, in the commitment to realize the full development of the human person as a dynamic projection of his dignity, as well as in the link between rights and duties of solidarity. These principles do not have an unique meaning for everyone and in everytime; it depends on the human contexts of reference, cultural dynamics, and the course of time on all these things.

Translation by the author

LUIGI MONTANO

President of the Italian Society of Human Reproduction (SIRU) and Coordinator of the EcoFoodFertility Research Project

Studies on the medium and long-term effects of medically assisted procreation

GEPPINO FALCO

Head of the laboratory of 'Staminalità e rigenerazione tissutale" of Biogem, Full Professor of applied biology Università degli Studi di Napoli Federico II

Diseases characterization and treatments finding through *in vivo* and *ex vivo* models

Slide

Key-words

Medically assisted procreation, fertility, cancer, health issues.

Slide

Key-words

Diseases, Transhuman, Treatment Research & Innovation.





SERGIO GUIDA

Founder & Team Leader Sustaihuble Impact LAB

Golem vs. Transhuman: the man of the future between biology, new technologies, ethics and sustainability

The rise of modern science and technology has radically transformed the relationship between man and nature. Nature, which for millennia had seemed omnipotent and immutable, has suddenly become an object of control and manipulation, something that can be systematically shaped for human ends. In recent decades, radical advances in genetics and neuroscience, computer science and other new technologies have brought to the brink of another revolution, this time in our relationship with ourselves.

Genome editing, gene drives, big data, artificial intelligence, organoids and chimeras offer unprecedented possibilities but, contextually, unpredictable implications. Traditional fundamental concepts such as "humanity" and "natural" are at stake, while new challenges pose new questions that require new perspectives and approaches: emerging technologies not only revitalize the question "what is a human being?" but also ask the crucial question "What does it mean to be human?" and "what should we do to make it human?" Such questions require new and broader perspectives than those developed so far, starting with life sciences.

Foreshadowing the Future Man among different disciplines suggests how scientific discoveries and innovations, supported and enhanced by new technologies, pose important ethical implications and questions about the concrete advantages and well-being that human beings could derive from the conscious and responsible use of unprecedented and extraordi-



I PANEL Human being creation in artificial environment

nary tools, such as CRISPR Cas9, a genomic editing system Nobel Prize in Chemistry in 2020.

As highlighted by EGE and WHO, 'human recoding' does cross a border, so the broadest public consultations are essential to ensure that full scientific and technological sustainability is evaluated with the utmost awareness by global stakeholders. In a quintuple helix model, responsible research and innovation then generate a thoroughly positive "impact" and circulate as inputs and outputs on the natural environment, as the key to tackling sustainable development as inclusive and participatory as possible.

Thus sustainability-driven research and innovation will address properly societal challenges, being aligned by design with the values, needs and expectations of world citizens.

Slide

Key-words

Golem, Transhuman, Genome editing, Crispr/cas9, Life Design, Sustainability-Driven Research & Innovation.

LEGAL AREA SPEAKERS

SARA LANDINI

Pl of Goineu DGJ project, Pl of GoinEuplus DGJ project, Module Pl_IS Jean Monnet Chair, Università degli Studi di Firenze

Ethical-legal aspects of organoids and their use in research. Manage risks and legal constraints for the development of ethical research

The term organoids indicates three-dimensional (3D) cell structures that contain a multitude of organ-specific cells that are formed by organization and differentiation of stem cells.

The similarities that organoids share with organs make them a promising research tool for studying more complex biological functions. The use of organoids has already found application in areas such as developmental biology, regenerative medicine, disease modeling, drug discovery, and personalized medicine.

Moreover from the point of view of the "Do No Significant Harm (DNSH)" principle, according to which no measures financed by the notices must damage the objectives environmental, and according to ecological transformation PNRR mission, organoids represent an alternative to animal experimentation. Organoids also represent a key for advanced drug and personalized medicine therefore in line with the PNRR mission of innovation, competitiveness in fact as said they can be used for the development of new pharmacological products.

Some studies analyze the ethical issues raised by organoids and recommend measures that must be taken at various levels to ensure the ethical use and application of this technology. It lacks a more legal perspective connected to ethical and medical issues and a deep insight of boundaries between human and not human.



I PANEL Human being creation in artificial environment

This paper finds legal and ethical tools to support organoid research and ensure that we do not lose any of the potential benefits that organoids offer maintaining DNSH perspective.

To do that a multi-factor action is needed: the legal issues (the theory of goods, the body availability, industrial property issues in respect of product of the body) together with and not separate from the ethical perspective above mentioned, public engagement action, dialogue law-medicine.

Slide

Key-words

Organoids, stem cells, medicine, ethics, medical research.

LEGAL AREA SPEAKERS

LAURA VALLE Associate Professor, Free University of Bozen-Bolzano

Surrogacy contract as an instrument of protection of individuals involved in the process

In the Italian legal system surrogacy practice is forbidden and punished by criminal law by the article 12, par. 4 of the law n. 40/2004. Nonetheless, a certain number of Italian citizens go abroad and attend surrogacy practices. Coming back to Italy, they ask for the recognition under the national legal and citizenship system of the child born abroad.

They ask, as well, a full recognition of the intended mother as the mother of the child under any legal aspect. That means that the prohibition of surrogacy practices by the Italian legal system does not solve at its root the problem of surrogacy, but simply opens other legal issues that need to find a solution. That considered, the legal system should also concentrate on the very general question of what its ultimate goals are, and eventually decide to remain neutral in front of such kind of practices deciding to give them a regulation.

Being the surrogacy practices available in more countries around the world, it might be possible that fundamental personal rights end to be more protected in that perspective, of giving a law regulation to surrogacy, than in the situation in which the practices are completely forbidden and not recognized. Where the legal system allows the surrogacy practices, the relationships among the persons involved are regulated by contract.

These contracts – ad example in the English legal system – follows special rules, that leave for example broad possibility to the surrogate mother to keep the child with herself. Contracts dealing with a surrogacy practice



I PANEL Human being creation in artificial environment

should be in any case fully respectful of the fundamental rights (protected by the legal system) of the persons involved. The contract become that way an additional instrument of protection of the personal rights of the individual involved, first of all in the interest of the newborn by the surrogacy treatment. That is true in relation to the commitments of the intended parents towards the child and the surrogate mother, and to the commitments of this last one in behaving in the interest of the child during the pregnancy.

Slide

Key-words

Medically assisted procreation, surrogancy treatment, contract, fundamental rights.

LEGAL AREA SPEAKERS

FRANCESCA DI LELLA

Appointed Lecturer in BioLaw, Università degli Studi di Napoli Federico II

Reproductive technologies and human embryo identity *in vitro*: perspectives

I PANEL Human being creation in artificial environment

parenthood, the other hypothesis values a different interest of constitutional rank, such as that of promoting research aimed at protecting human health.

Slide

Key-words

Vulnerable subjects, reproductive technologies, human embryos, fundamental rights.

Advances in the field of reproductive medicine have brought a new entity to centre stage: the in vitro embryo. The reconstruction of its legal identity is preliminary to the search for solutions to one of the most sensitive issues currently animating the biojuridical debate, namely the fate of so-called supernumerary embryos. This is an issue that can no longer be avoided, given the large number of embryos in cryopreservation and the recognition, in many places, of the 'human dignity' of which they are carriers.

The contribution aimed to highlight, on the one hand, the current prohibition in Italian law on the killing of embryos, the violation of which constitutes a criminal offence; on the other hand, the heterogeneity of the category of cryopreserved embryos, since it includes both embryos that could still be destined for implantation and supernumerary embryos that, on the other hand, could not, because they are considered unsuitable for various reasons or rejected because they are affected by pathologies detected following a pre-implantation genetic diagnosis. With regard to the latter, a stalemate persists concerning their fate.

The two proposals under consideration for residual embryos – adoption for birth and destination for scientific research – appear to be inspired by different principles, but both require the intervention of the legislator to implement them. If the adoption hypothesis supports the natural destination of the embryo to a procreation project and the satisfaction of a couple's desire for



LEGAL AREA SPEAKERS

PAOLA GRIMALDI

Lecturer in Private Green Law, Università della Campania Luigi Vanvitelli

The protection of the human embryo in the new Gasparri proposed law

With the bill n. 165 Senator Gasparri returns to the art. 1 c.c. presenting a new proposal – new compared to those dating back to the 16th and 17th legislatures – entitled "Amendment to art. 1 of the civil code in the matter of recognition of the legal capacity of the conceived child"; precisely asking that the recognition of the legal capacity of the fetus already take place at the time of conception and not only after birth, as instead today enshrined in art. 1 of our civil code. A bill that gives the opportunity to reflect, once again, on the questions on the specific theme of the protection of the human embryo and therefore: What is the embryo? What rights should he be recognized? But above all since when should they be recognized?

It should be dutifully remembered that on this point Prof. Cesare Massimo Bianca already wrote that "our legal system recognizes the conceived as the bearer of interests worthy of current protection and that for this same reason it recognizes its provisional capacity which remains definitive if the conceived, according to the its natural cycle, comes at birth, and which is resolved retroactively if this event does not follow and that it can therefore be assumed that even for the conceived, the legal system recognizes a subjectivity considered outside the patrimonial perspective of legal capacity".

Over the years the issue has been addressed by the Constitutional Court with the sentence 27/1975 which had recognized the embryo as the holder of the inviolable human rights provided for, recognized and guaranteed



I PANEL Human being creation in artificial environment

by art. 2 of the Constitution, but had excluded the personality. Only with judgments 229/2015 and 84/2016, the same Council sanctioned the principle according to which <<embryos are not things>>, as there cannot exist in our legal system individuals belonging to the human species who are not recognized as persons. With the recent sentence of 20 June 2019, n. 27539 the IV criminal section of the Court of Cassation - which made history on this point - it was said that the fetus, even if still in the uterus during labor, must be considered a person; and if the fetus is a person, consequently so is the conceived as such, without distinction during the phases of its gradual and continuous development up to birth.

In recent years we have had the opportunity to learn from genetic engineering that today there are 15 ways to come into the world beyond the natural one; the positive side offered by the NTRs is known, but also all the problems they entail on an anthropological, ethical and juridical level. In the field of law, think, for example, of the repercussions that new reproductive technologies have on the family as a system of social relations. And keep in mind that we are dealing with a mostly submerged phenomenon. Precisely starting from the chaotic diffusion of the NTRs which we are now witnessing day by day, here we ask ourselves if this bill could not in some way represent an initial response, a point from which to start, to that need for regulation in this chaotic context now concerning the embryo and which we have repeatedly emphasized and invoked precisely during our meetings?

Key-words

Vulnerable subjects, reproductive technologies, human embryos, Gasparri law proposal.

LEGAL AREA SPEAKERS MARCO RIZZUTI Lecturer in Bio Law, Università degli Studi di Firenze Gene editing and private law

In 2018, after a very controversial experimentation, two Chinese babies are born from CRISPR-Cas9 edited embryos. In 2020 the Nobel Prize for Chemistry was awarded for the development of the CRISPR-Cas9 system. Gene editing is not just a mere hypothesis but a concrete reality, that will pose new problems also from a private law point of view.

If a human genome has been strongly modified through gene editing, or even artificially synthesized, genetic tests possibly will not show parental relations. Therefore, we could even say that such a child has no genetic parents at all. In such cases, legal or intentional parenthood will be not just an alternative option to be compared with genetic parenthood, but the only possible kind of available parenthood. The law will have to ensure that people born from gene editing can have a responsible parent to protect their best interests: probably he/she will be the person whose gametes were used to produce the embryo to be edited, or the one who commissioned the editing process.

Moreover, the law will have to rethink the limits and possibilities of the preemptive determination of a person's genome. With regard to preimplantation genetic diagnosis, that is already widespread, the issue is above all how to balance the right of the parents to select a healthy embryo with the right to life of the discarded embryos. On the other hand, gene editing would not discard any embryo but "just" modify the imperfect genome of the concerned embryo,



I PANEL Human being creation in artificial environment

so that the problem would turn out to be quite different. Therefore, maybe we will have to face wrongful life actions both for having been genetically edited or for not having been genetically edited. We will need to balance the use of such techniques of genetic health predetermination with the right of prospective children to an open future, or even to disability, as well as with the related risks of discrimination.

Key-words

Vulnerable subjects, reproductive technologies, gene editing, CRISPR-Cas9 LEGAL AREA SPEAKERS

FRANCESCA FERRETTI

Ph.D. (c) in Bio Law, Università degli studi di Camerino

Human enhancement and genetic identity of the embryo

The third edition of the World Crispr Day, celebrated last October 20, is a new opportunity to meditate on the impact of the "molecular scissors" (CRISPR-Cas9) on the human genome.

Genetic modification can occur both at somatic and germinal level, involving, in this second case, gametes (haploid cells) or embryo, generated by the fusion of egg and spermatozoon. The distinction between "somatic interventions" and "germline interventions" is recently included in a document by the STOA (Scientific and Technological Option Assessment) entitled "Genome editing in humans" published in June 2022. The same document underlines the vagueness and lability of expressions such as "somatic versus germline", "hereditable" genome editing; moreover, the text also says, "somatic as well as germline applications may carry associated dangers". This reflection is an opportunity to highlight the importance of definitions, in terms of clarity, absence of ambiguity and adherence to scientific findings. The STOA Report is also aware of this, emphasizes the importance of "uniform" and "harmonised definitions", which facilitate the comparison and adaptation among national regulations. Definitions should also be drafted in such a way as to "ensure sustained correspondence with scientific knowledge".

Another unclear distinction at the scientific – before than legal – level is that between "treatment" and "human enhancement": this second expression is qualified as "not useful, vague, value-charged and difficult to enforce". And



I PANEL Human being creation in artificial environment

this aspect is not insignificant, especially since art. 13 paragraph 3 letter. b) of L. 40/2004 on assisted fertilization, prohibits alterations to the genetic heritage, "with the exception of interventions for diagnostic and therapeutic purposes". If the legitimacy of genetic editing depends on the purpose of its use, the identification of a boundary between treatment and enhancement, health and disease, takes on a fundamental importance. This distinction, clear in theory, takes on in concrete nuanced contours, due to the progressive subjectification of health status, understood as a condition of overall well-being, which extends to the protection of psycho-physical integrity and to the right to self-realization of the individual and his personality. Also, Jurisprudence consistently held that the traditional idea of pathology is increasingly distant from that of health, now loaded with a strong subjective component; therapeutic acts, according to a broader vision of health, no longer refer to an organic conception of the disease, but take into account the physical and psychological aspects of the person, and his/her personal and unquestionable life expectancy.

On the other hand, the expression "human enhancement" assumes a residual character compared to the definition of treatment and care, activities aimed at removing a pathology. This term refers to any voluntary use of different biomedical knowledge and technologies of intervention on the body aimed at improving the normal physical-psychic-emotional functioning of the individual, to overcome some limitations of existing functions or to introduce new organic or mental abilities. The identification of the boundary between permitted and not permitted interventions can be achieved through different legal solutions. First, only manipulative interventions that correct a genetic malformation responsible for a disease contained in a special document could be considered legitimate, as suggested by recommendation 1047/1986 of the Council of Europe and, more recently, by the Italian Constitutional Court with judgment 96/2015, in the matter of access to the assisted reproductive technologies.

Similarly, the citated report suggests to determine types of editing that should be prohibited or restricted, practitioners' professional qualifications, safety and technical requirements, in order to ensure public health prevention. However, the European approach seems to be more flexible: in this field, a multi-level, risk-based approach should be adopted, that would allow specific rules to be defined for prohibited and high-risk genome-editing interventions. Possible criteria could include the objectives of the intervention, expected outcomes and levels of risk for individuals and society.

Key-words

Human enhancement, reproductive technologies, human embryos CRISPR-Cas9

PASQUALE ARPAIA

Director of the Interdepartmental Center for Research in Health Management and Innovation in Healthcare (CIRMIS), Università degli Studi di Napoli Federico II

Brain Computer Interfaces (how not to lose the privacy of thoughts after that of data)

HUMAN ENHANCEMENT TECHNOLOGIES HUMAN-MACHINE INTERACTION AND HYBRIDIZATION

II PANEL

A dream as old as Humanity: to transcend from the limits of the body and be able to freely implement thought into action. Imagination becomes action directly without the limits of the body. The Brain-Computer Interface makes it possible to achieve this goal. In fact, strictly speaking, the Brain-Computer Interface enables direct interaction between the mind and the digital world.

This serves two purposes. On the one hand, to interact with the virtual world directly by the thought, bypassing the limits of the body. Technically, this allows an integration of mind and virtual world unmediated by means of physical mediation, such as with a keyboard, touchscreen or mouse. Thus, being able to enter Virtual Reality directly with the mind, for example, into an archive, a book, or a game. On the other hand, to be able to use the computer directly with the mind to control a physical device, such as a prosthesis, a game, or unfortunately a weapon.

The next step is the integration of the Brain-Computer Interface with Augmented Reality, powered by the Internet of All Things. Direct access with the mind to a clever combination of digital/virtual information and measurement data immediately from the physical world.

At CIRMIS of Federico II, we focus on these concepts, dwelling mainly on wearable solutions for everyday use. We have seen that investments are becoming substantial and especially in the direction of treating neurovegeta-



tive diseases. There are various wearable solutions for everyday use and for various purposes. Within this use, we are beginning to "measure thoughts," in the purpose of determining some basic emotions: stress, attention and engagement in our daily activities, but also joy or sadness.

We are entering a new world, certainly exciting, if we look at the aspects in favor of Humanity.

But, perhaps also disturbing.

We realized and applied in two main clinical trials a Brain-Computer Interface: BrainGlasses.

Our first clinical trial was experimenting BrainGlasses in the operating room. On the operating table we are in the hands of the surgeon and his team of anesthesiology. It allows patients to be operated on not only without pain and anxiety, but more importantly by protecting the body from the trauma of the surgery itself. The anesthesiologist must monitor a great many vital parameters from the monitors in the operating room. But he also must remember the history, that is, the patient's medical history, and then keep an eye on the medical record. We experimented how BrainGlasses could help the anesthesiologist keep track of all this information in his hands-free augmented reality glasses. In fact, the anesthesiologist can navigate this sea of information simply by fixing his gaze on the menu or submenu he wants to access on his smart glasses.

The second venture concerns autism or, more generally, attention deficit disorders, which are growing dangerously in our society. In autism spectrum disorders, the abilities to relate to others, and to realize their needs, moods, expectations, are severely lacking. In the second case, it is a pathologically poor or short attention span and/or excessive vivacity and impulsivity, inappropriate for the child's age, that inhibit their functionality and development. The benefits of humanoid robot-assisted behavioral therapy in pediatric care for the above conditions are now scientifically and clinically recognized, and it is therefore commonly practiced in many care centers. It has been widely demonstrated by practice in many cases that the mediation of a child-sized humanoid robot is largely more effective.

The BrainGlasses were experimented with by children with attention deficit to pilot a humanoid robot with "thinking." The therapy involved young patients interacting with the robot in a series of sustained attention exercises. This helps them develop impaired cognitive and behavioral skills. It was seen that the young patients were remarkably fascinated by the idea of being able to control the robot by staring at arrows to the left or right in the smart glasses. Clinicians found significant increases in the yield of the therapy session. However, with an analogous device, we experimented how to measure emotions, attention, stress and engagement. This creates ethical problems of entering inside the personal and intimate sphere. As well as, we have found a legal vacuum. Research in law of Brain Computer Interface will help a lot.

Slide

Key-words

Wearable technologies, Brain-Computer Interfaces, privacy, data.

ANDREA EMILIO RIZZOLI

Director of the Dalle Molle Institute for Artificial Intelligence (IDSIA), Università della Svizzera Italiana – Scuola Universitaria Professionale della Svizzera italiana

IDSIA project presentations

The Swiss AI Lab IDSIA (Istituto Dalle Molle di Studi sull'Intelligenza Artificiale) is a joint research institute of both the Faculty of Informatics of the Università della Svizzera Italiana and the Department of Innovative Technologies of SUPSI, the University of Applied Sciences of Southern Switzerland.

IDSIA counts on 15 professors, more than 60 researchers and nearly 50 PhD students. We focus on various aspects of artificial intelligence: algorithms and theory of AI and computer science, machine learning (deep neural networks, graph neural networks, reinforcement learning), intelligent control of networked systems, geometric and visual computing, information retrieval and natural language processing, and autonomous robotics. A distinctive characteristic of the institute is its ability to provide a bridge between theory and applications, with many successful collaboration with industries. The institute has been researching on various aspects of Al for more than 30 years, and the dualism between the black box approach of neural networks and the transparency of rule based systems was evident even in th 90s, but the great power of deep neural networks and their ability to solve complex tasks with "superhuman" ability put this dilemma in the background. Now the wider application of Al algorithms to critical problems in the society, transparency has become "the" issue in Al research. We therefore commit to the coming research programmes on explainable Al in order to bring back transparency in Al-supported decision making.

Slide

Key-words

Al-based technologies, research&development, Al issues, transhumanism.



ROBERTO MONTANARI ROBERTA PRESTA

ReLAB Co-founder and Technical Director of the 'Scienza Nuova' integrated laboratory of innovative technologies for the social sciences, Università degli Studi Suor Orsola Benincasa

'Scienza Nuova' projects and HMI technologies

The intent of this speech is to present, in the context of today's meeting, the research activities that the *Scienza Nuova* interdepartmental design and research center of the Università Suor Orsola Benincasa carries out in the fields of intersection between the human sciences and the new technologies.

These can be classified in three main areas of reference within which Scienza Nuova's Laboratory carries out its activities, namely interaction and design thinking, cognition and user experience and virtual reality and body tracking. The laboratory environment of the center offers indeed the possibility of employing various technological tools for research purposes in the human factors and humanities fields. Within the laboratory, a space equipped with interactive walls lends itself to interaction design and design thinking activities; tools for testing and analyzing the quality of user experience such as eyetracking systems, EEG for monitoring brain functions, Emotional detection for behavioral research are mainly used in the area relating to cognition and user experience; finally, as regards the VR study area, the center is equipped with a room which, through immersive projections and suits for tracking the human body and its movements, it is possible to fully experience the immersive nature of virtual reality.

To provide an overview of the research activities carried out by the center, we therefore present here three projects differing in terms of theme,



area of affiliation and interactive strategies which provide, as a whole, an exhaustive representation of the possibilities of Scienza Nuova.

The first of the three projects pertain to the automotive and human machine interaction field and is entitled Next Perception – Sensing the experience. It is a European research project on the topic of DMS (Driver Monitoring Systems) which aims to develop interfaces for studying the best way to attract the driver's attention when the driver is in altered states (e.g., distraction). To achieve this goal, Next Perception therefore operates through immersive and interactive systems for simulating a driving environment and digital techniques for detecting the states of the driver.

The second project is part of the field of valorization of digital heritage through the potential offered by digital and new interactive technologies. Cappella Pignatelli takes the form of a digital installation for the enhancement of a historical and artistic place in the center of Naples, recently reopened, the Pignatelli Church from which the project takes its name. In fact, through the implementation and on-site installation of 3D spatialized audio for storytelling location based, cinematic virtual reality for 360° movies, app with augmented reality and gestural based interaction, the project manages to provide new ways of access and to give new life to one of the most beautiful jewels of Renaissance in Naples.

Finally, the third project, pertaining to the Web Humanities area, is a collection of projects: Mostre Digitali is in fact a series of 5 different exhibitions hosted on the online platform of the center and which can be visited directly from its website. Characterized by a great variety of contents and forms – ranging from the virtual representation of Piranesi's etchings in 13 extraordinary and 'browsable' views of Rome to the virtual exhibition of the restored works of the contemporary painter Pietro Scoppetta, from the virtual representation of the princess of Strongoli to the virtual representation of the historical heritage of the link between high fashion and Naples of the MO.DA project, up to the series of nineteenth-century engravings of the Napoleon Virtual Gallery – these web exhibitions represent a complex and evolving set of new strategies of interaction with historical and artistical contents in the context of the Web.

Key-words

HMI, research&development, behavioral research, interdisciplinarity.

LEGAL AREA SPEAKERS

MARIA ANTONIA CIOCIA

Director of the Economics Department, Università degli Studi della Campania Luigi Vanvitelli

The protection of intellectual creation and blockchain technology

Starting from the observation of the centrality of the data in all the evolutionary processes and projects of private law, the need for a rationalized use of artificial intelligence emerges. The primary requirement to be achieved is the authenticity of the data entered into the global network, which can be achieved through the application of the blockchain. Even artificial intelligence feeds on big data. Hence the importance of reaching a legal configuration of the blockchain that can be applied as an unquestionable tool of authenticity of every intellectual creation. The warning comes from the European Commission, with wide margins of discretion in the implementation within individual states, for the adoption of technical solutions that lead to augmented form of artificial intelligence for the best application of the Once only principle which consists in uniqueness of transmission of your data, limiting the multiplication of data requests that do not contribute to the optimization of each digitization process. The study intends to demonstrate how the construction of the blockchain on predetermined legal bases contributes to providing an effective solution to the many problems deriving from the relationship between the protection of fundamental rights and the protection of privacy.

Key-words

Blockchain, research&development, intellectual protection.



LEGAL AREA SPEAKERS

ERICA PALMERINI Coordinator of the RoboLAW Project, Scuola Superiore Sant'Anna di Pisa

The market for human enhancement technologies

LEGAL AREA SPEAKERS

ANDREA BERTOLINI

Director of EURA Jean Monnet Centre of Excellence, Scuola Superiore Sant'Anna di Pisa

Governing human enhancement through the principles of dignity and equality

The topic of human enhancement is slowly penetrating the legal discourse about innovative technologies. A conventional approach frames the problem of human enhancement in terms of fundamental rights and values – autonomy, freedom, dignity and equality – or assess its acceptability within a pure cost-benefit analysis.

However, we can observe attempts at transforming the human body and augmenting mental capabilities from a different angle. Various types of drugs and devices exist that can be used to monitor the neural activity in order to derive inferences on emotional states or mental conditions, to enhance focus or memory, to "train the brain"; digital contents and services, such as mental health apps, target the improvement of the general well-being.

The current availability of devices and substances that point to increase physical and cognitive abilities requires exploring the regulatory schemes that affect the relevant markets, pointing to potential criticalities and lack of effectiveness. In particular, the direct-to-consumer marketing of such products elicits an investigation on the safety legislation concerning general products, medical devices and pharmaceuticals, as well as an assessment of advertising and selling practices of said products and services against the backdrop of consumer law.

Key-words

Wearable technologies, research&development, BCI issues, transhumanism, human enhancement.



The desire for constant improvement is an intrinsic characteristic of human nature and determines the way human beings relate to their environment and seek to shape it. The goal of this aspiration is advancement, both as individuals and as an organised society. In this context, human enhancement through technology is a complex phenomenon that allows for different forms of bodily manipulation and raises the issue of distinguishing between what should be deemed licit and not in light of the existing legal framework.

Indeed, if the desire to improve oneself and perfect one's condition and quality of life is intrinsic to human nature, so much so that it has always influenced history and evolution, there are sufficient reasons to discern between different types of practices and attempts to manipulate the human body.

What is often presented as a continuum is, in contrast, a path consisting of a long series of separate stages, some of which are positive and desirable, others not. Mere technological development and the availability of specific technical expertise are not in themselves sufficient to consider lawful its use. The consequences must also be evaluated from an ethical and social point of view. To do this, philosophical and legal considerations must intertwine and benefit from their respective perspectives, which are in fact separate, both in terms of the scope of the issues addressed.

In this scenario, the study considers the existing philosophical debate: transhumanists v. bioconservatives. The anthropology of vulnerability forces



us to acknowledge that all improvements come at a cost to be assessed in light of the fundamental values that govern society. To this end it looks at the principles of human dignity – as elaborated in the existing bioethical debate – and equality – both in its formal and substantive specification – to conclude with the need to refine the former, and the insufficiency of the latter.

More in details, the first principle (human dignity), of great relevance for European law, is still insufficiently developed and refined. Scientific debate is, in fact, more advanced than jurisprudence, particularly at the European level, and there are no specific examples of its application to human enhancement contexts. The legislator, also through a dialogue with the doctrine, should be able to derive certain criteria from the existing legal system as it stands today, as well as from other fields of bioethical debate, including that relating to the manipulation of the body, however substantially different. This is, to a large extent, a technical issue, not inherently different from many others commonly addressed by legal doctrine.

The notion of equality (second principle) presents a duplicity that cannot be further reduced. A formal notion, applied to this scenario, gives rise to concerns about the right of access to enhancement techniques. Ensuring that all who wish to do so are able to modify their bodies, at least to a certain extent, would prevent the polarisation of society into two different classes: the enhanced and the unenhanced, as a consequence of different income levels.

From a legal point of view, the notion of equality and its consequences do not seem feasible, let alone enforceable, because they clash with the – often constitutional – rights not to be subject to compulsory medical treatment. This consideration, however, is largely limited by the empirical observation that the choice of the majority – or even of a well-organised minority – in such matters could radically limit the possibility of free determination.

In conclusion, the complexity of the phenomenon should lead us to understand, with sufficient clarity, what is really possible through technology, what interests and values are at stake, and to look into the legal system, as well as human history, to find analogies and guiding principles that, to a large extent, are already there and simply need to be adapted and perfected.

Slide

Key-words

Human Enhancement, transhumanism, bioconservative, human nature, vulnerability, human dignity, equality.

LEGAL AREA SPEAKERS

FIORELLA BATTAGLIA GIUSEPPE DI VETTA

PI of AInCP, Università del Salento Post-Doc Research Fellow, CAIROS Research Project, Scuola Superiore Sant'Anna di Pisa

Sandbox for BCI devices and cyborg experimentation

The benefits and harms of BCIs deserve further investigation. Not only the assessment of the fundamental conceptual, ethical and legal issues associated with BCI applications should be explored, but also the methods for conducting these explorations should be reconsidered. This comprehensive approach in the field of cyborg experimentation will ensure that the resulting insights will be fully exploited for the benefit of medicine and society.

We will characterize this approach with two focuses: the one zoomed in the epistemic and ethical impact of the peer-production of knowledge (citizen science) and the second zoomed in the legal criteria that should inform the introduction of novel form of regulation preparation such that envisioned by the sandbox approach (Truby *et al.* 2021).

With a view to complying with a translational research approach, it is required to foster co-creation of knowledge and therefore to include the active participation of patients, their families, clinicians, healthy users and the public in the process aiming at the regulation of the use of the BCI.

Citizen science is emerging as an important policy orientation but is still largely unknown (Biggeri and Tallacchini 2018). Acording to this approach, users are holders of some kind of practical knowledge, which should be emphasized in a translational approach There is a close connection between the emergence of a new model of governance of BCI, which takes into account the issues of epistemic injustice and the deep and profound implications on





science as a discipline, a profession, and as a practice, foreseen by the policy orientation of citizen science (Jasanoff 2005). Moreover, considering the user just a passive participant amounts to a wrong done to someone specifically in their capacity as a knower (Fricker 2007).

This talk of the special session is about providing a state-of-the-art account of what is going on in co-creation theory, which is the necessary premise for designing co-creation activities in the framework of the sandboxes. How is the co-creation of knowledge possible? Why does co-creation of knowledge bother? These questions are central in the epistemology of the co-creation and have significant effects on a number of dimensions (implementation, benchmarking, and regulation), which are the specific themes of this special session.

According to the European legal framework, it is required that all high-risk Al informed devices must be tested for legal conformity. This test can often be performed by the provider itself. The Proposal for a Regulation of the European Parliament and of the council encourages EU member states to create regulatory 'sandboxes', in which firms can try out novel services without fear of being hit by a penalty (European Parliament 2021).

During the temporary suspension of current regulations, that would prevent the use of the BCI, all interested stakeholders are requested to participate in the experiment aiming at testing the devices.

This test has two different kinds of requirements: the technical constraints responsible for the feasibility of the devices and the norms for the legal regulations. In between is the role of patients, users, families and the public.

Firstly, we will address the understanding of co-creation and provide the reasons for adopting a co-creation approach beyond the immediate evidence of benefit that is proceeding from the engagement in participatory practices in the production of goods, services, and knowledge. It is a theory that is capable of both explaining and formulating the epistemic and ethical reasons behind these processes, in order to enhance well-functioning practices and avoid possible shortcomings in their implementation especially during the last step, that of the regulation.

Secondly, we will discuss why 'sandbox' should be considered the most efficient regulatory environment to allow a real co-creation dynamic in BCI innovation, considering the strict liability regime foreseen by European Al regulation. As known, a regulatory sandbox should be a safe space for both discovery and application, or for both BCI innovation and regulation. In that sense, while sandbox approach can be conceived as a mean to improve proactive publicness in tech science, significant criticisms are raised. Discussing the legal implications of the sandbox regulatory approach, the paper will address many of these criticisms, especially regarding the consistency between strict liability regime and sandbox approach, as designed by EU regulators and the condition of legal-safe operating. This approach in terms of adaptive governance needs to be further detailed. What are the rules for experimentation? How should be these rules characterized? Are the envisioned rules tools of soft law? Lastly, we'll discuss the regulatory learning effect of sandbox approach: could it be real? Examples will be given from FinTech Regulation, where the sandbox approach has already been experimented; that regulatory experience has to be considered.

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Key-words

Wearable technologies, research&development, experimentation issues, transhumanism, sandbox.

KEY NOTE SPEECH

PIM HASELAGER

SIAC Principal Investigator, Department of Artificial Intelligence at the Donders Institute for Brain, Cognition and Behaviour, Radboud University

Al and neurotechnology: mirroring human (im)perfections

LUCIO CASALINI

Postdoctoral Research Fellow, Università degli Studi di Camerino and JODI Member The subject-object relationship between enhancement and fragmentation of the person

Slide

Key-words

Al-based technologies, research&development, Al issues, transhumanism, human enhancement



In recent years, the phenomenon of human enhancement has emerged overwhelmingly as a topic of interest – alongside the philosophical and ethical dimension - also in legal reflection. In contrast to the human as a closed and completed work in Humanism, today an investigation is required which contemplates a new (juridical) relationship between subject and object, in which the first represents an open and unfinished work, ready to hybridize with the second, that is with its own technological artifacts. In this dialectical perspective, the analysis develops according to a double track: that of the subject in relation to the object outside of itself (devices for therapeutic or enhancement purposes, which are incorporated into it) and, conversely, of the subject in relation to the object within himself (personal data, which he freely disposes of, even for speculative purposes). In the first case, a tension emerges between the principles of self-determination and the dignity of the person; in the second, there is a fragmentation of the identity of the person, according to the diversified interests of the market. Mutatis mutandis, the investigation appears to be necessary, given the relationship of structural vulnerability in which human beings find themselves, especially when they operate in a digital environment, under the illusory expectation of self-enhancement.

Key-words

Subject-Object Relationship, Human Enhancement, Fragmentation of the Person, Vulnerability



FABRIZIO CESAREO

Postdoctoral Researcher Fellow, Università degli Studi di Milano Bicocca

The problem of the legal personality of artificial intelligence

The new introduction of artificial intelligence in vitro fertilisation technologies is both medically promising and ethically perplexing. The new possibilities and complexities generated by the involvement of powerful and intelligent algorithms in human creation and reproduction raise a number of ethical-legal questions. To date, it appears that technologies based on artificial intelligence, leading to digital transformation and automation in the field of reproductive medicine, are designed to be applied in in vitro fertilisation as an essentially assistance tool, i.e. a decision-support tool for embryologists or fertility doctors. The European Parliament, for example, in a resolution of February 2017, called on the Commission to explore the implications of creating a specific legal status for robots and applying electronic personhood to cases where robots make intelligent, autonomous decisions or otherwise interact with third parties independently. This was countered by an opinion adopted in May-June 2017 by the European Economic and Social Committee, which considered that endowing robots or artificial intelligence with legal personality is an unacceptable risk.

This study reflects on one of the long-standing problems in civil law: the legal subjectivity. In this regard, considering the evolution on robotics and Al, it seems to be necessary to reject the idea that the criteria of legal subjectivity are sensitivity and reason, rereading Article 1 of the Civil Code and Law 40/2004 in a contemporary key.

Key-words

Al-based technologies, research&development, artificial reproduction, transhumanism, ethics.



AFTERNOON SESSION

III PANEL HUMAN ENHANCEMENT TECHNOLOGIES IN VULNERABILITY SITUATIONS

ECONOMICS AND ENGINEERING AREA SPEAKERS

ANNA ANITA MOLLO DOMENICO NAPOLITAO LUIGI MARIA SICCA

Postdoctoral Research Fellow in Private Law Scuola Superiore Meridionale Postdoctoral Research Fellow in Business Organitation Scuola Superiore Meridionale Professor of Business Organization and HR management, Università of Naples Federico II

Technology & Disability: Social and legal frameworks of assistance and protection

Assistive technologies, as most recently enhanced by artificial intelligence, are increasingly used by persons with disabilities to express their will. Among these, voice technologies deserve special attention, as they allow to artificially produce what is considered as one of the main human faculties: the faculty and speaking and communicate. At this regard, speech-synthesis technologies, besides various commercial uses, have interesting applications addressed to the assistance of speech-impaired people. In particular, they could allow those people to re-acquire the possibility to express their will orally, and in the specific to use a 'synthetic clone' of their original voice, that is a digital reconstruction of the characteristics of their voice before a disease or an accident caused its loss.

In this research we will start from the case of voice cloning technology to explore a series of issues risen by advanced technologies in the organizational and legal context.

Indeed, the current legal framework does not always allow the use of technological tools for the conclusion of valid legal transactions.

This leads us to reflect on the relationship between law and technology in order to assess how the latter can guarantee the protection of the fundamental rights of persons with disabilities also in the area of inheritance law. There is, in fact, no protection in relation to the possibility of validly expressing one's will for the time after death for people who have lost



III PANEL Human enhancement technologies in vulnerability situations

certain physical functions necessary to exercise their negotiating autonomy in a mortis causa perspective due to severely disabling pathologies.

More specifically, attention is focused on the analysis of the rules governing succession law in order to show how the rigid testamentary formalism that characterizes our legal system is an obstacle to the finalization of a valid will by those who can only express themselves by means of technological devices.

The aims of the research is to examine the repercussions, from the legal and organizational perspective, of the contradictions arising from the lack of coordination between technological development, the legal framework and the specific needs of people with disabilities.

Slide

Key-words

Disability, vulnerability, inheritance law, organizational studies.

ECONOMICS AND ENGINEERING AREA SPEAKERS

MARTINA GALLI

Rector's Delegate to Inclusion and Equity, Università degli Studi della Tuscia

VRAILEIXA project, using AI and VR to support dyslexic students: what limits on vulnerability?

III PANEL Human enhancement technologies in vulnerability situations

ECONOMICS AND ENGINEERING AREA SPEAKERS FRANCESCO FLAMMINI Professor of Trustworthy Autonomous Systems, REXASI-PRO REliable & eXplAinable Swarm Intelligence for people with reduced mobility

REXASI-PRO (REliable & eXplAinable Swarm Intelligence for People with Reduced mObility) is a project funded by the European Commission within the framework of the HORIZON Research and Innovation programme. Its aim is to support people with reduced mobility by means of autonomous and trustworthy social navigation systems based on Artificial Intelligence. More specifically, the project aims to release an engineering framework to support trustworthy autonomous wheelchairs for people with reduced mobility. Smart wheelchairs, provided with reliable on-board sensors, will be trained with swarm intelligence navigation algorithms in indoor and outdoor environments. Smart drones will be cooperating with smart wheelchairs to properly map unknown environments and accurately monitor any fixed or moving entities. Virtual Reality and Imitation Learning will be used to anticipate multiple operational scenarios and allow algorithms to be adapted, case by case, on the basis of previous experience. Bio-inspired navigation models, trained through implicit and explicit user communication, will be used with the aim of increasing users' confidence in the technologies employed.

The project can be framed in the context of research on trustworthy autonomous systems, and therefore it must tackle the main challenges related to robust, ethical, and legal Al. Aspects related to energy efficiency and sustainability will also be addressed in the project.

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Key-words

Disability, vulnerability, Al, VR, dyslexic.



The project, which started on October 1st 2022, is expected to be completed in three years, with end date set on September 30th 2025. The international project consortium is being coordinated by Spindox Labs and includes Consiglio Nazionale delle Ricerche (CNR) – Italy, German Research Center for Artificial Intelligence (DFKI) – Germany, Royal Halloway and Bedford New College –UK, Universidad de Sevilla – Spain, University of Applied Sciences and Arts of Southern Switzerland (SUPSI) through its Dalle Molle Institute for Artificial Intelligence (IDSIA USI-SUPSI), public policy development consulting group Euronet Consulting – Belgium, as well as leading automation and robotics companies such as AITEK Spa – Italy, and Autosystems Hovering Solutions – Spain, and V-research Srls – Italy.

Key-words

Disability, vulnerability, wearable technologies, Al.

III PANEL Human enhancement technologies in vulnerability situations

LEGAL AND ETHICS AREA SPEAKERS

SALVATORE ORLANDO

Director of the Juridical Observatory on Digital Innovation-JODI, Sapienza Università di Roma

Data vs Capta: not only a linguistic choice

It is not easy to identify the difference (if any) between the legal notions of data and information. An analysis of the legal definitions of data, as a matter of EU law, appears to show that a difference between the two exists. A number of definition issues are accordingly introduced with the aim of conceptualizing – through the opposition of the latin words data and capta – the nature of the relation between data and information with respect to data categories such as personal data, structured data, metadata, observed data, inferred data, biometric data, neural data, mental data etc. The analysis also leads to evidence that the legal problems arising from data and information processing, in the Artificial Intelligence environment (input data, training data, validation data, testing data, output of Al systems), largely exceed the traditional realm of privacy law and extend to virtually all fields of law, thus requiring lawyers to learn and put in practice a multi-layer approach when dealing with the legal problems relevant to the governance of the data economy.

Key-words

European Data Law, Data, Information, Artificial Intelligence.



LEGAL AND ETHICS AREA SPEAKERS

VALENTINA CUOCCI

Member of the Coordination Committee of the Summer School Governance in the digital age

Supported Decision Making Agreement (SDM) and private 'support' mechanisms for informed choices

In my presentation – Supported Decision Making Agreement (SDM). A Possible Solution for the Protection of Vulnerable Subjects in the Digital Dimension – I will talk about the mechanisms or rather possible mechanisms to protect vulnerable subjects in the digital dimension. Before discussing SDM Agreement, from a methodological perspective, I would like to point out that I have attempted, also thanks to contributions from the vulnerability literature, to identify which 'definition' of vulnerability best fits the field of data protection in the digital dimension. The vulnerable subject is not a well-defined category – such as creditor or debtor – but is always linked to the specificity of the human condition of weakness, fragility, exposure to risk. In my reserch I embrace the notion of 'positional vulnerability', to 'identify' and 'select' the vulnerable subjects in the digital dimension. According to the so called 'positional vulnerability', the subject's afference to the group does not depend on the individual's identity but on the subject's position in relation to the risk context (for example, the digital dimension) and the actions that are precluded or restricted and the lack of resilience (es: elderly; vulnerable adults, illiterate people: subjects who for certain reasons – age, incapacity, infirmity, illiteracy - are unable to perceive the risks of the digital dimension and to freely give consent and cannot exercise the related rights in which precisely privacy is articulated (opposition, data deletion, modification) triggering an imbalance between data controller and data subject). I suggest as a mechanism to protect



III PANEL Human enhancement technologies in vulnerability situations

vulnerable subjects in the digital dimension the so-called Supported Decision Making Agreement (SDM). Under the SDM Agreement the 'supported' person retains his or her capacity, which is therefore not limited: there is no substitute who performs the act in the interest of the incapacitated person but there is the promotion, precisely, of tools that can help the 'supported' person to make choices in an informed and conscious manner. In particular the 'supporter' does not have to perform acts in the interest of the 'supported' person, but must assist the person in making choices; assist the person in understanding options, responsibilities, and consequences of decisions; assist the person in accessing, gathering information relevant to a particular life decision, assist the person in understanding the information, the consequences of data processing, and the risks associated with the digital dimension.

Key-words

SDM, Data, Information, Artificial Intelligence, wearable technologies, BCI

LEGAL AND ETHICS AREA SPEAKERS

GIOVANNA CAPILLI Director of the Advanced Course in Cybersecurity, Università San Raffaele di Roma

Digital health: new challenges

Con l'introduzione in ambito sanitario dei sistemi digitali, oggetti intelligenti e intelligenza artificiale, si è avviata una vera e propria rivoluzione circa le modalità di cura ed anche nel rapporto medico-paziente, quest'ultimo, infatti, assume un ruolo attivo nella gestione e monitoraggio della propria salute. D'altra parte non si può non evidenziare che negli ultimi anni il lessico e il dibattito scientifico sono stati caratterizzati dall'uso frequente di espressioni come "sanità digitale", "medicina digitale", "telemedicina", "paziente virtuale", "App per la salute", "intelligenza artificiale per la medicina", "software come dispositivi medici" etc., tuttavia, si tratta di espressioni piuttosto generiche che rischiano di fuorviare l'interprete e creare fraintendimenti.

Ciò non deve sorprendere se si tiene in considerazione il fatto che la digitalizzazione sta notevolmente incidendo in molti ambiti della vita quotidiana e la pandemia Covid-19 ha sensibilmente amplificato e sollecitato queste trasformazioni.

Dopo tutto, in un contesto di emergenza sanitaria, le Autorità e il mondo scientifico hanno monitorato le opportunità offerte dalle soluzioni digitali per poterle attagliare al mondo della sanità e della salute, sviluppando per esempio la dematerializzazione delle ricette e dei referti medici, incentivando i controlli clinici da remoto, effettuando il tracciamento digitale dei contatti e tanti altri. L'integrazione di app e dispositivi mHealth nella pratica clinica costituisce, quindi, una sfida importante e complessa.



Nell'ambito della grande ed articolata categoria delle tecnologie digitali per la salute (Digital Health Technologies), infatti, si possono segnalare centinaia di migliaia di applicazioni e strumenti che hanno le più diverse finalità, tra cui per esempio la diagnosi, il monitoraggio delle condizioni cliniche, il supporto alle decisioni del medico, l'intervento nei confronti della malattia. Basti pensare al fatto che ogni casa potrebbe diventare un luogo in cui riuscire a ricevere le prestazioni mediche secondo modalità telematiche attraverso una rete di mHealth in grado di erogare servizi decentralizzati.

La mHealth (abbreviazione di mobile Health) si realizza attraverso smartphone, software, internet, applicazioni proprio dedicate al wellbeing e al lifestyle, digital assistant o altri dispositivi wireless che costituiscono i veri protagonisti di questa pratica medica e di salute pubblica.

L'Organizzazione Mondiale della Salute (OMS) ha dato la seguente definizione: "Una pratica di assistenza sanitaria pubblica e medica supportata dai dispositivi mobili, come smartphone, dispositivi per il monitoraggio del paziente, assistenza digitale personalizzata e altri dispositivi wireless".

Le applicazioni mHealth vengono utilizzate con più frequenza e si basano principalmente sulla raccolta di dati personali e comportamentali, il che richiede particolare attenzione alla privacy degli utenti.

È inevitabile, infatti, che attraverso tali applicazioni si possono acquisire molte informazioni essendo basati su servizi di messaggistica, geolocalizzazione e tecnologia bluetooth che richiedono al paziente l'inserimento di dati sanitari e comportamentali (si tiene traccia delle calorie consumate, dei segni vitali, sforzi fisici che vengono registrati in tempo reale) in un ambiente digitale dal quale gli operatori anche economici hanno la possibilità di attingere con la possibilità di attuare tecniche di profilazione al fine di effettuare pubblicità mirata.

Le loT rappresentano oggi strumenti che possono avere diverse applicazioni in ambito sanitario, per esempio per la somministrazione di farmaci oppure per monitorare costantemente la salute del paziente, dati che per avere una loro utilità devono comunque essere connessi con gli Electronich Health Records, come può essere appunto il FSE (fascicolo sanitario elettronico). Le tecnologie emergenti per la salute mobile, quindi, modificando le modalità con cui i pazienti raccolgono le informazioni relative alle loro condizioni di salute consentono ai medici di effettuare un costante monitoraggio che indubbiamente è di ausilio nella scelta della cura sempre più adeguata da prescrivere.

A tal proposito occorre segnalare che vi sono stati numerosi studi che hanno cercato di analizzare l'impatto delle tecnologie mHealth sui pazienti sia sotto il profilo sanitario che economico.

III PANEL Human enhancement technologies in vulnerability situations

Uno studio condotto da alcuni ricercatori ha verificato, per esempio, che i pazienti che utilizzavano le app conseguivano risultati di salute migliori ed erano in grado di regolare il proprio comportamento sanitario in maniera più efficace rispetto, invece, ai pazienti che non utilizzavano tali applicazioni. Altri studi hanno posto l'attenzione sulla necessità di far superare la riluttanza dei pazienti all'utilizzo delle tecnologie.

In America da un'indagine effettuato dal Rock Health e dallo Stanford Center for Digital Health è emerso un aumento della preferenza degli adulti statunitensi per la comunicazione di problemi di salute tramite app mobili; è stato rivelato che circa il 44% degli intervistati tiene traccia della propria salute e condivide le informazioni sanitarie con i propri professionisti medici, il 25% utilizza la telemedicina e uno su 25 possessori di dispositivi indossabili utilizza un'app per monitorare la propria salute.

In questo contesto si parla anche di Terapie Digitali (DTx) facendo riferimento a quelle tecnologie che "offrono interventi terapeutici che sono guidati da programmi *software* di alta qualità, basati su evidenza scientifica ottenuta attraverso sperimentazione clinica metodologicamente rigorosa e confermatoria, per prevenire, gestire o trattare un ampio spettro di condizioni fisiche, mentali e comportamentali".

Le DTx possono essere utilizzate in modalità indipendente o associate ad altri interventi terapeutici, come per esempio un farmaco, e devono essere differenziate dalle applicazioni digitali che riguardano il benessere e la salute, disponibili per cittadini e pazienti. Infatti, sebbene in Italia non vi siano terapie digitali prescrivibili o utilizzabili in ambito clinico e che siano riconosciute dal sistema sanitario nazionale, in altri Paesi, tra cui possiamo citare la Francia e la Germania, le DTx sono già autorizzate e disponibili su prescrizione medica e possono essere rimborsate dal servizio sanitario nazionale.

Le DTx vengono ricomprese nella categoria dei *Medical Devices*, cosicchè sono soggette alle disposizioni contenute nel Regolamento UE che riguarda i dispositivi medici 2017/745, entrato in vigore nel maggio 2021. Nell'ambito del Regolamento europeo, tuttavia, è assente una trattazione specifica delle terapie digitali e dal punto di vista regolatorio sono necessarie indicazioni specifiche tenuto conto delle loro peculiarità tra cui il modo con cui queste tecnologie si evolvono rapidamente oltre alle possibili vulnerabilità dal punto di vista della *privacy* e della *cybersecurity*.

È interessante approfondire il funzionamento delle terapie digitali; è proprio dall'interazione con il paziente che viene realizzato l'effetto terapeutico volto a correggere comportamenti disfunzionali che sono tipici di molteplici patologie croniche in prevalenza di tipo neuropsichiatrico, come la depressione, l'ansia, le dipendenze, l'insonnia, la schizofrenia, l'autismo, la sindrome da deficit di attenzione e iperattività nel bambino e tante altre, ma anche di tipo metabolico, si pensi all'obesità, all'ipertensione o al diabete.

Sostanzialmente da un lato il farmaco interagisce con la biologia del paziente, dall'altro le terapie digitali interagiscono con i pensieri e i comportamenti di chi le utilizza, in modo tale che il paziente e/o il *caregiver* finiscono per assumere necessariamente un comportamento attivo che diventa decisivo per gli esiti del percorso terapeutico.

L'impatto dei Big Data in ambito sanitario è determinante se si considera da un lato la possibilità di realizzare dispositivi medici che possano essere utili per i bisogni dei pazienti e dall'altro perché rappresentano una fonte inesauribile di informazioni utili per la ricerca.

Nel predisporre la terapia, infatti, le DTx consentono di raccogliere continuamente e in tempo reale dati e informazioni che alimentano banche dati utili per la ricerca al fine anche di adattare la stessa terapia; ciò significa che essendo notevole la quantità dei dati sensibili prodotti attraverso queste tecnologie occorre curare maggiormente la privacy e la cybersecurity e ciò è stato evidenziato da alcuni studi dai quali è emerso, per esempio che nel 23% dei casi le trasmissioni dei dati degli utenti è avvenuto su protocolli di comunicazione non sicuri, il 28% delle app non ha fornito politiche sulla *privacy*, mentre il 47% delle trasmissioni di dati degli utenti ha rispettato le regole sulla privacy. Conseguentemente, dal punto di vista della tutela dei dati personali, ancora occorre lavorare in questo campo per evitare, solo per fare qualche esempio, la condivisione dei dati personali senza il pieno consenso informato, il riutilizzo dei dati all'insaputa del paziente, violazioni dei dati che potrebbero esporre informazioni sensibili o personali.

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Key-words

Big Data, Information, cybersecurity, E-Health, DTx.

LEGAL AND ETHICS AREA SPEAKERS
LUIGI VIOLA GIANFRANCO D'AIETTI
Jural Consortium Directive Members

Augmented justice and decision making

The JurAl Consortium is an Italian working group (WG) born from the collaboration between academic professors (in the field of legal studies, computer science, design and UX&HMI), legal professionals and magistrates to study and offer solutions to tackle with the scenario and the already existing processing of judicial data by artificial intelligence (jurimatrics and predictive justice). The WG JurAl stands out for the development of a methodological approach that aims to enhance the ability of individuals (from students to legal professionals) to solve legal issues, making use of Al tools at the service of human capacity.

The JurAl group, scientifically, addresses the development of jurimetrics in light of Al, by analysing technological developments and their applications. Moreover, through an interdisciplinary work, in the past years, some of its members have developed operational tools, to facilitate the liquidation of damages and the prediction of legal solutions.

More recently, the Consortium has pointed out the necessity of classifying existing and forthcoming tools on predictive justice, promoting this task in various contexts (as a research subject itself and for the promotion of research networks) in order to develop a twofold objective:

 predictability of decisions by identifying the facts of the lawsuit and connecting them with the legal solution from the interpretation of releavant rules and the judges' main orientation and the relative 'ratio decidendi';



- identify criteria for measuring judicial discretion through algorithms based on data derived from judicial experience (eg: extension to other sectors of the tables from so-called biological damage).

The founders and coordinators of the JurAl group are: Prof. Lucilla Gatt and Prof. Ilaria Amelia Caggiano, Professors of Private Law and New Technology Law, with academic expertise in the evaluation of solutions to legal issues and ability to evaluate the results of solutions offered by Al tools; Dr. Gianfranco D'Aietti, former President of Court, appointed lecturer of Predictive justice and computational thinking, as well as e Avv. Luigi Viola who, amon the orther things, stands out in the forensic world for its scientific pubblications on computational sciences, and both have already developed jurimetric tools.

Under the guidance of the coordinators, the members of the JurAl Consortium support the activities of the WG thank to their multidisciplinary expertise (from Law to Computational Sciences).

By focusing on an interdisciplinary vision and making use of the tools of impact and scenario analysis, the WG JurAl has developed a noteworthy expertise in the fields indicated above, especially of a strategic nature, and supports the formula of "augmented justice" intended as the enhancement of traditional professional skills through the use of technologies.

The Working Group, in line with the objectives pursued by the European Union and the CEPEJ, pursues operational and verifiable results in the short-medium term. By focusing on an interdisciplinary approach, it intends to achieve the construction of decision support systems by creating/ using controlled, documented and transparent artificial intelligence systems (machine learning algorithms) in order to: speed up legal activities; measure and analyse the hermeneutic activities of the various interpreters; provide precise solutions to cases brought to the attention of the judicial bodies.

The innovative interventions proposed are divided as follows:

 implementation with operational tools of the model of structured formalization of appeals and the relative decision-making response (connection between party acts and decision-making acts);

 modeling of the structure of the law interpretation procedure (logical-deductive model), usable as a scientific method but also as a usable interface (transparency and explanation of the decision-making output, detector of interpretative contrasts, prediction of interpretative results/ judgment decisions);

 implementation of judgment prediction tools, thanks to the development of a system capable of identifying the jurisprudential orientation and the relative 'ratio decidendi' in a context of greater predictability of decisions;

- implementation of techniques for measuring judicial discretion ("weighted" and not "pure") through algorithms (different, sector by sector) which are based on the analysis of data obtained from concrete judicial experience (eg: extension to other sectors of the tables from the so-called biological damage).

> Slide 1 Slide 2

Key-words Justice, Artificial Intelligence, judicial discretion, decision-making

IV PANEL FUTURE SCENARIOS IN THE ERA OF TRANSHUMANISM

ALDO IANNOTTI DELLA VALLE

Ph.D., former Legal Expert in the Italian Prime Minister Mario Draghi's Office Public policies for strategic investment in relation to new technologies

In the digital era it is crucial to attract investment in strategic hightech sectors, as semiconductors. Semiconductors are currently at the centre of the global technology race and of strong geostrategic interests. Countries aims to secure supplies of the most advanced chips, considering that this will affect their ability to act economically and industrially, and drive the digital transition.

Semiconductors make digital products work: ICT, automation, energy, healthcare, and most other industries. Chips are also essential for artificial intelligence (AI) and 5G/6G communications.

The application of semiconductor technologies, and batteries, are also a powerful tool to facilitate the ecological transition: in this light is important to underline that electric and autonomous vehicles cannot work without them.

The European Commission proposal for a regulation in this field, so called Chips Act, aims to attract investments in next-generation technologies, providing a more investor-friendly framework for establishing manufacturing facilities in Europe, supporting research and innovative start-ups, building international partnerships and providing tools for anticipating and responding to semiconductors shortages and crises to ensure security of supply. The European Parliament and Member States will need to discuss the Commission's proposals on a European Chips Act according to the ordinary legislative procedure. If adopted, the Regulation will be directly applicable across the EU.

Meanwhile, a new Italian legislation is already in force and provides a legislative framework to attract large greenfield investment in strategic and highly technological sectors, by streamlining the entire process, from the decision to invest in Italy to the opening of the factory (Articles 32 and 33, Decree Law 9 August 2022, no. 115, converted into Law 21 September 2022, no. 142). These strategic sectors must be related to one of the 9

IV PANEL Future scenarios in the era of transhumanism

European strategic value chains: semiconductors; batteries; supercomputing; cybersecurity; Internet of Things; low-emission manufacturing; connected, autonomous and low-emission vehicles; smart health; hydrogen.

Several *ad hoc* tools are made available for investors, if needed, when some conditions are met: the ticket size of the investment in the abovementioned strategic sectors should be over 400 millions euro, the proponent should sign a Letter of Intent and should show proof of a sound business plan, which identifies a specific geographic area.

Once conditions are met, the Prime Minister identifies the chosen investment area as strategic by decree and no further steps are required: the area is automatically fit for public use.

A public vehicle that will plan and coordinate the activities is established or identified, if needed. Also, a Commissioner may be appointed for the area development, ensuring adherence to the investment plan's timeline. A backup option is provided: if the local authority is slow in the process, the government can intervene with ad hoc initiatives to unlock it.

Finally, a single accelerated permitting procedure (PAUAR), including the strategic environmental assessment (VAS), is provided if needed. The purpose of the procedure is to issue all authorisations, however named, that are necessary for the implementation and operation of the project. It applies to all the works necessary for the best realisation of the strategic investment.

Times are significantly shortened: for instance, permitting times are reduced by law from 9.5 to max 5.5 months.

The new procedure rationalises the different stages, where possible by reducing them or placing them in parallel, not merely reducing the time limits of existing stages. Such a significant reduction in time would not otherwise have been possible.

It will be very important to continue pursuing this path to ensure the effective realisation of the ecological and digital transition, also in the light of the environmental protection principle, as guaranteed by new Articles 9 and 41 of the Italian Constitution.

Slide

Key-words

Public policies, ecological and digital transition, semiconductors.

ROBERTO PAURA

President Italian Institute for the Future

Emerging megatrends toward a fully-disembodied future

LEGAL AND ETHICS AREA SPEAKERS

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BCI devices and their legal compliance: a prototype tool for its evaluation and measurement

In medical and educational fields, in workplaces, as well as more generally, in interpersonal relationships, the Brain Computer Interface (BCI) had an ever wider and faster development thanks to the implementation of the Al system. This occurred, for example, in the case of the neural interfaces that are able to monitor the stress conditions or other negative and positive human emotions, or the technologies used in the medical rehabilitation field (therapeutic BCI), also using wearable technologies. The neurotechnology used in verifying the level of involvement and understanding of the teaching contents by the learners, or those used by individuals to express their will in relationships between private individuals, are also very relevant.

The BCI can be very useful for assisting and protecting people in different environments, but an evaluation of BCI applications appears necessary to define the legal consequences of the individual's behaviours using BCI devices. This evaluation will help to verify the risk for individuals interacting with these technologies, to guarantee consequent adequate protection.

Indeed, the considerable potential of BCI is evident but, at the same time, the rapid spread of these neural technologies requires the analysis of multiple issues that can arise from the application of BCI devices or their software, to verify and measure the risks that can arise from these new technologies, and guarantee the legal compliance by design of the BCI application under an anthropocentric point of view.



Slide



In this regard, legals have the role to verify the functioning of BCI technologies and regulate them to protect human beings in the digital environment, alias artificial, since this environment places ontologically the former in a position of vulnerability. The category of "vulnerable individuals" includes, in fact, all natural persons, who, acting in a digital environment, are exposed to the risk of damages for various reasons (minor/old age, asymmetry of contractual power or information, patients with serious diseases). This vulnerability of individuals, strictly related to the development and application of new technologies can be defined as technological vulnerability.

Starting from a critical analysis of the legal issues related to BCI applications, the research work aims to provide the explanation of an evaluation and measurement tool prototype for legal compliance of BCI products, in order to ensure the compliance by design of the BCI products with the current legislation and the protection of human rights. Therefore, the research work briefly illustrates the main legal issues of interest and then the related sections of the tool prototype.

Slide

Key-words

BCI regulatory perspectives, security, privacy, cybersecurity.

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BCI devices and their capacity to express human will having legal value: a model of risk-based classification

One of the ultimate frontiers in biotechnology is Brain-computerinterface. BCI devices are currently developed for therapeutic purposes (e.g., as assistive tools) but also recreational ones. A BCI system detects brain activity, allowing a decoding of patterns of neural signals, then 'translatable' in commands a computer can understand and even carry out in the external reality. That's why BCI is now becoming more used (or experimented), considering the advantages that could derive from it. Nevertheless, it also raises some questions from a legal perspective. This Paper focuses on BCIbased devices used for assistive and augmented communication of users, and wonders what legal regime should be accorded to the personal will expressed through those tools. Once the risks have been identified, the parameters and requirements a BCI device must meet, for the human will expressed through it having legal value, are outlined. The Paper proposes, in conclusion, a self-assessment strategy to operationalize BCI technologies applicable to the context of legal relations, implementing methods of risk evaluation and management. A risk- based classification model is also suggested.

Slide

Key-words Wearable technologies, BCI, risk assessment, security



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Artificial intelligence in company management processes

The presentation – and the essay behind it – wants to provide a brief analysis of the state of the art in the field of artificial intelligence technologies in the management processes and in the business practices of the companies, with a specific focus on the relevance that algorithms could cover in the corporate governance.

Especially, starting from a general examination of artificial intelligence technologies in the legal literature, the aim of the study is to analyze what are – at the moment – the specific limits that do not allow an algorithm to directly cover – so in their own – the role of director within a board of directors.

Although the scientific literature is investigating in favor of openings on the topic, in the current context this possibility is held back both by:

1) technological limitations, concerning the methods of development of the algorithms. More specifically, currently the A.I. can replace the human contribution only in routine activities, regardless of whether of a cognitive or manual nature, because of the fact an algorithmic system thanks to technological development, is able to respond with optimal performance for routine tasks. On the contrary, for all those non-routine tasks that require adaptability to concrete circumstances, for which the contribution of human nature derives from elements that can hardly be translated into programming languages for the algorithm, current technologies are not suitable to the relevant replacement. The activity of a board of directors is a specific type of



IV PANEL Future scenarios in the era of transhumanism

this kind so the substitution of a director with an algorithm can be excluded for this technology limits;

2) subjective limitations, regarding the current impossibility of recognizing a legal status for A.I. technologies. In fact, the attribution of legal personality, or a minimum simple recognition of the status of subject of law, it is a primary thing to do to let the A.I. join the board of directors, especially for the practical requirements on liability for any damage caused.

Along these reflections – without any claim to exhaustiveness – considering these limitations, it is analyzed the VITAL (Validating Investment Tool for Advancing Life Sciences) case and the other suggestions and questions deriving from the business practices, with the hope of a future development for a generic inclusion of the A.I. in management contexts.

Slide

Key-words

Data, Artificial Intelligence, management, legal status

Ph.D. (c) Università degli Studi di Bari Aldo Moro The new ways of legalising the body

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A legal study of domotics: from the risks for the subjects involved to the goal of creating an integrated and effective protection system

This paper aims to analyse the relationship between the law and the body from a juridical and philosophical perspective.

The presupposition of the following remarks is that the technological development is the defining feature of the modern societies. This phenomenon has relevant implications on the languages describing the body and its disposability.

The enigma of the body, which has always concerned the philosophical thought, is nowadays of great importance, since it is a privileged position from which to look at the modernity.

The law, that has always taken the corporeity into account, is concerned with the emersion of the digital persona, which now more than ever calls for appropriate protection.

The investigated matter recalls the distinction between personality rights and property rights. The existential situations can be subject of agreements that entail a non-contractual nature. Yet, market-alienability and non-patrimonial interest get to be strictly entangled in the case of contracts regulating aspects of one's identity, in which case an existential components remain.

Key-words

Body, corporeity, digital persona, technological development, existential situations.



Domotics, the smart technology inside the domestic environments, is a complex issue since it includes a plurality of applications – from domestic systems (electrical, heating, alarm...), to smart objects such as household appliances and bulbs – that produce certain benefits, but also arise risks for the people involved.

On one side, domotics makes particularly clear how technology can be conceived from an instrumental perspective with respect to helping people, especially those with diminished physical abilities, as show, for instance, voice assistants, able to meet our needs and perform several tasks, or even smart floors that can sense the weight of the non-self-sufficient person who has fallen and needs intervention.

On the other side, in the domestic environment, those information asymmetries from which the massive advent of digital should have freed us, clearly re-emerge, because the individual shows a greater vulnerability to external intrusions and also because of the presence of vulnerable subjects, like minors or elderlies.

The "domotic phenomenon" offers stimulating food for thought in multiple areas. First of all, the issues related to the processing of personal data, which are often particular ones, are extremely crucial. Actually, the smart objects collect and process massive quantities of personal data, and they can indeed damage fundamental rights of the users.



The reflection can consequently shift to the contractual context: the user of the smart object is a party (buyer) to the contract concluded with the seller. This arises mainly two orders of issues: the intersection with the data protection, which becomes even more triggering when the user of the smart product is a party/consumer/data subject; and the definition of a contractual liability of a subject which is hardly identifiable for sure. Besides, a special attention deserves to be dedicated to the "particular third parties", that is to say people different from the buyer, but can be as well damaged by the functioning of domotics solutions.

Finally, the related implications on liability have to be considered as well. Technologically developed systems and objects can make very challenging to identify the person who is responsible for damages caused by malfunctioning and therefore required to pay.

What emerges is, in any case, the need to move toward an integrated and effective multi-level system of protection for the subjects involved.

Key-words

Al, Domotics, damage, liability, personal data.

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