

## Speech by Ivana Roagna

Ladies and Gentlemen, distinguished speakers,

today I have been asked to present you the **Key human rights principles in Biomedicine**, as covered by the CoE's HELP Course. The theme is a very actual one. And in fact, last night, after I reviewed the notes I had prepared for this event, I learned that the Constitutional Court of my country, Italy, had just issued a historical decision on the topic of end of life and assisted suicide, in a landmark case that has divided public opinion.

The case concerned the lives of these two men, who at a certain point of their existence met. The one you see on the left is Fabiano Antoniani, aka DJ Fabo, a music producer, left tetraplegic and blind by a traffic accident five years ago. The man on the right is Marco Cappato, a member of Italy's Radical Party. In February 2017 the politician drove DJ Fabo to Switzerland. There the man, aged 40, was helped to die. Before travelling to Switzerland, DJ Fabo had written a letter to the Italian President Mattarella: "I feel like I'm in a cage. I would like to choose to die without suffering". Upon return to Italy, Cappato turned himself in to the authorities after his "act of civil disobedience" to highlight what he saw as an unjust law. He claimed that assisted suicide could not be a privilege reserved for those with the physical and financial means to travel to Switzerland by themselves and this is why had chosen to help DJ Fabo fulfill his desire. This led to a wide public debate that will certainly continue after the yesterday's decision.

The politician faced up to 12 years in prison for "instigating or assisting suicide". Last year, the District Court tasked with the criminal case, asked the Italian Constitutional Court to clarify whether the norm that equate instigation and assistance to suicide was constitutional, thus making the conduct of the politician punishable. This, having in mind that DJ Fabo, who was affected by an irreversible condition, who was enduring physical and psychological sufferance he considered unbearable, who was artificially kept alive, had freely and autonomously manifested his intention, more than oncel, to end his life. Invested with the case, the Constitutional Court postponed the examination of the matter of one year, asking the Parliament to fill the existing vacuum on the topic. This did not happen. Last night, then the Court decided that given the circumstances, the conduct of the politician could not be considered punishable, as he helped someone to execute an act that the person had voluntarily decided to pursue, as he did no longer consider his life worth of living.

The story I told you is a typical example of a situation where human rights and biomedicine encounter. Under human rights laws, States have a duty to protect the life of the individuals within their jurisdiction. Can we say that in this case, with this decision, the State has failed to fulfil this obligation? Can we say that the right to life also encompasses the right to dispose of one's life? The European Court of human rights, which is the enforcement mechanism of the European Convention on Human Right and at the heart of human rights protection in Europe was asked several times to rule on such as well as other similar questions.

In the case of [Pretty v. UK](#), which bore a number of similarities to that of DJ Fabo, the Court established the right to life (article 2 ECHR) does not encompass the right to die. In *Lambert v. France*, a case I am sure all of you know quite well, which concerned the decision to discontinue nutrition and hydration allowing a patient in state of total dependence to be kept alive artificially, the Grand Chamber of the European Court found both the legislative framework laid down by domestic law, as interpreted by the *Conseil d'État*, and the decision-making process, which had been conducted in meticulous fashion were, to be compatible with the requirements of Article 2 ECHR. As to the judicial remedies that had been available to the applicants, the Court reached the conclusion that the case had been the subject of an in-depth examination in the course of which all points of view could be expressed and all aspects had been carefully considered, in the light of both a detailed expert medical report and general observations from the highest-ranking medical and ethical bodies. Consequently, the domestic authorities had complied with their positive obligations flowing from Article 2 ECHR, in view of the margin of appreciation left to them in the present case.

Over the last 20 years, the European Court of Human Rights was called upon to decide upon an ever increasing number of cases touching on various issues from the bioethical field, such as consent to medical treatment, examinations, or to the removal of organs and tissues; reproductive rights (prenatal diagnosis, medically assisted procreation and the right to a legal abortion); decisions taken in end-of-life situations; retention of biological data by the authorities and the right to know one's biological identity.

I am sure that when confronted with these judgements, one of the first questions many people will ask is the following "Is this right or wrong, good or bad? Is this acceptable or not? Can we, as a society, make it happen?". Ethics, one of the themes touched by the Course, is a word that brings to mind the never ending struggle of humankind to determine what is right and wrong. But what does ethics entail in the area of medicine? Before the 1950s or so, medical ethics was a matter relevant for physicians only. Ethics was deeply connected with the ancient Hippocratic tradition and focused almost exclusively on the welfare of patients and medical professionalism. By the 1960s, however, a wide range of new ethical issues came along, all of them driven by incredible advances in medicine and biology. The old model of medical ethics was no longer sufficient to cover their scope and variety ranging from contraception to abortion, from gene therapy and stem cell research to new and sophisticated ways to keep people alive. At the same time, people became more educated and were less willing to accept that "doctors know best", demanding instead to have the possibility to know, to be consulted, and have their say in issues concerning their bodies and lives. The word bioethics well captures the rich complexity of issues that the developments in medicine and technology have and will raise.

For Aristotle, ethics was a branch of politics, and politics needs to be rooted in some notion of the common good and to develop the relevant laws and policies regulating the society. What is ethical in a given circumstance at a given time, however, can be rather subjective, influenced by religious, moral or ideological

beliefs. At the same time, advances in science and their application to medicine and biology, fields where individuals are directly involved, can have a bright or dark side, according to how they are used, as the possibility that they are distorted from their original objectives is a constant threat. It is therefore necessary to ensure that the beneficial side prevails by constantly investigating what is at stake and constantly reviewing and regulating all the possible consequences. Bioethics is the study of the implications of the developments in biomedicine for human beings. Every time a medical or biomedical action is implemented the question of its human rights compliance arises. Bioethics aims to set as clearly as possible the boundaries of any medical intervention on the human body by identifying common, minimum standards and values. These can only be rooted in human rights.

The question that comes next is then: What are the human rights relevant in the context of biomedical activities and research? And which are the instruments in which they are enshrined? At regional level, as we already mentioned, the ECHR occupies an important place. Even though the ECHR does not specifically target biomedical activities, it contains a number of provisions that traditionally, offer protection to the individual's physical and mental integrity. Think about  
the right to life (article 2);  
the prohibition of torture (article 3);  
the right to respect to private life (article 8).

But others, less obvious provisions, can also come into play. Think about freedom of expression and the possibility to impart and receive information on issues such as abortion or end of life.

Of course a compression of the human rights of the individuals is often possible. But for it to be acceptable under the European Convention and the Oviedo Convention (the other treaty we will soon talk about), the restriction will have to meet the requirements of legality (referring to the existence of legal basis), it will have to be considered necessary in a democratic society and must be in pursue of a legitimate aim, namely public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others. The compression will also have to be proportionate to the aim pursued.

At the level of the EU, the provisions of the ECHR are mirrored by those of the Charter of Fundamental Rights of the EU, whose scope of applicability, however, is more limited, as it is confined only to the implementation of EU legislation. Its relevance is actual, for example, in relation to the application of the Human Tissue Directive, the Organ Safety Directive or the Regulation on Clinical Trials.

Both the ECHR and the Charter, however, are human rights treaty of general nature. The only specific treaty on Human Rights and Biomedicine is the Oviedo Convention (short for The [Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine](#)), which was opened for signature on 4 April 1997 and entered into force on 1<sup>st</sup> December 1999. This treaty, which is open also to non-Council of Europe States, is the first and only legally-binding international text of its

kind. In legal terms, the Oviedo Convention is defined as a framework convention "setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences". In essence, it serves as an umbrella document which lays down the principles, objectives and the rules of governance of the treaty regime. Over the years, it has been supplemented by four protocols, dealing with Prohibition of Cloning Human Beings (CETS 168), on Transplantation of Organs and Tissues of Human Origin (CETS 186), on Biomedical Research (CETS 195) and on Genetic Testing for Health Purposes (CETS 203). These protocols take full account of the potential implications for the human being of scientific actions.

By ratifying the Oviedo Convention States also undertake an obligation to:

- make available an appropriate, rapid judicial procedure able to prevent or put a stop to an unlawful infringement or threats of the principles (article 23 Oviedo);
- set up a system whereby those who have suffered undue damage, not inherent in the therapeutic intervention, are able to seek for fair compensation (article 24 Oviedo).

The reference to "Human Rights", included in the title of the Oviedo Convention alludes to the principles laid down in the ECHR. The ECHR and the Oviedo Convention, thus, share not only the same underlying approach but also many ethical principles and legal concepts. When it comes to human rights, the key principles are recalled at the beginning of the preamble to the Oviedo Convention, of which they are the cornerstone.

Two principles can be identified as being at the core of the system – the primacy of the human being and human dignity. These constitute the essential values guiding the interpretation of the norms.

**Primacy of the individual** is protected by the Oviedo Convention at three levels:

The first level is that of the individual, who has to be shielded from any threat resulting from the improper use of scientific developments. Several articles of the Convention underline this point: protection against unlawful interference with the human body, prohibition of the use of all or part of the body for financial gain, restriction of the use of genetic testing are just a few examples.

The second level relates to society. Indeed, in this particular field, to a greater extent than in many others, the individual must be considered to constitute part of a social corpus sharing a number of ethical principles and governed by legal standards. Whenever choices are involved in regard to the application of certain developments, the latter must be recognised and endorsed by the community. This is why public debate is so important and is given a place in the Oviedo Convention. Only in very precise situations, and subject to the respect of strict conditions, however, social interest would take priority over the individual's.

The third and final level relates to the human species. Many of the current

achievements and forthcoming advances of science are based on genetics. Progress in knowledge of the genome is producing more ways of influencing and acting on it. This knowledge already enables considerable progress to take place in the diagnosis and, sometimes, in the prevention of an increasing number of diseases. This puts at risk not the individual or society as such, but the human species itself. The Oviedo Convention responds to this threat by setting up safeguards, to protect the identity of the human being.

### **Dignity of the human being**

The dignity of the human person is the second core human rights principle of the Oviedo Convention. Dignity is not only a fundamental right in itself but also lies at the foundation of most of the rights enshrined in the ECHR. It is also explicitly mentioned in article 1 of the Oviedo Convention. Placing the dignity of the human being at the center, means that human beings cannot be treated solely as means to external, collective or individual ends. Human beings and their bodies, therefore, cannot be merely considered as therapeutic resources.

In terms of key human rights principles we must not forget the prohibition of discrimination, which is cross-cutting. According to Article 14 of the ECHR, the enjoyment of the rights and freedoms set forth in the Convention must be secured without unjustified distinction on the basis of sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status. Article 11 of the Oviedo Convention adds to this list a person's genetic heritage and bans all forms of discrimination based on the grounds of a person's genetic heritage.

### **The right to protection of private life**

The notion of private life (Article 8 ECHR and article 10 Oviedo Convention, which also covers the right to information) encompasses the physical and moral integrity of a person. On this basis, the ECtHR has been able to develop a particularly rich body of case-law in relation to biomedicine, in fields as diverse as assisted-reproductive technologies, organ removal and the use of tests to identify genetic characteristics.

In addition to those explicitly mentioned in the Oviedo Convention, the following are additional principles that must inform bioethical actions

### **Individual autonomy** which entails, amongst others:

- The obligation to obtain the free and informed consent of a person before any medical intervention, including treatment;
- The possibility of the person to withdraw the consent;
- The right to be informed about one's health, including the results of predictive genetic tests;
- The "right not to know";
- The protection of persons not able to consent.

**Beneficence and non-maleficence** refer to the moral obligation in the field of health care and research involving human beings, to maximise potential benefit and minimize potential harm.

Last but not least is the **principle of justice**, that shows the need of fairness and equity in health care and research involving human beings.

Medical research and technology are changing our lives in dramatic ways. We live longer and in better health, and there is more we can do to raise healthy children and improve medical care. But few of these advances come with problem-free or inexpensive outcomes. Someone has defined these as the dilemmas of success. Bioethics is not the panacea that can solve all those problems by itself. But because of the unique way it brings ethical and policy issues together it has some special contributions to make.

Thank you very much for your attention.