

# Overcoming The Challenges of International Legal Regulation in The Field of Biomedicine and Human Rights Proposal for the establishment of Humankind Organization and a Committee on Bioethics and Biomedicine

**Aleksandar Slavkov Milanov,**

*Associate Professor in Jindal Global Law School, Jindal Global University, Sonipat, Haryana, India.*

## Abstract

This article explores the challenges of achieving a comprehensive global legal regulation in the field of biomedicine and human rights. The analysis is focused on the different reasons for states not to ratify the Convention on Human Rights and Biomedicine and the overall reasons of most states to not support the adoption of common legally binding international standards of bioethics and biomedicine. The author provides a proposal for the establishment of a sui generis global institution which functions in the interest of humankind. In the article are stipulated arguments for the need of new type of institutions to regulate bioethical issues in the interest of humankind. The proposal is focused on institutionalizing a Humankind Organization and in its structure to be established a Committee on Bioethics and Biomedicine.

## Introduction

The Convention on Human Rights and Biomedicine, often referred as the Oviedo Convention continues to be the most comprehensive legally binding instrument on the protection of human rights in the biomedical field, including bio-medical engineering. Even though it is a regional European treaty, adopted in the framework of the Council of Europe, the convention was opened for signature on April 4<sup>th</sup> 1997 to all countries in the world. However, the convention is ratified by a total of 29 countries, many of which has made reservations or interpretative declarations to articles of the convention to which they have different ethical views or state practices and not a single non-European country ratified it. What are the reasons for states not to adopt or adjoin legally binding agreements in this field?

### 1. Types of Limitations of the Legal Regulatory Effect of the Convention

Below are analyzed the core motivations of states not to ratify the Convention

#### 1.1. Regional character of the instrument

As a regional international organization on the European continent, the Council of Europe is seen by many legal scholars and representatives of states, as an organization which represents the core values of Europe, not of the whole world. The role of the organization of defining, developing and promoting the modern understanding of human rights cannot be overstated.<sup>1</sup> However, the view of European countries as colonial powers, which are trying to exercise soft postcolonial power over developing countries through imposing “liberal values” that are going to “weaken” their citizens and their regimes, is expressed publicly by many representatives of states and legal scholars.<sup>2</sup> The other leading non-European countries will also not ratify the Oviedo Convention or a UN treaty on biomedicine and human rights for different reasons. For

<sup>1</sup> Kicker, Renate, and Markus Möstl. Standard-setting Through Monitoring? The Role of Council of Europe Expert Bodies in the Development of Human Rights. Council of Europe, 2012.

<sup>2</sup> Swadener, Beth Blue, and Kagendo Mutua. "Deconstructing the global postcolonial." Handbook of critical and indigenous methodologies (2008): 31-43.

example USA is not willing to follow international standards, adopted by other states, and are often opposing the international legally binding commitments as a whole, pursuing a national policy of exceptionalism.<sup>3</sup> Consequently, countries like China and Russia would not take the initiative to ratify the Oviedo Convention or another similar treaty that is related with bioethical and biomedical standards. One of the reasons is because violation of those standards and conducting of scientific experiments could lead to scientific innovations that have national security applications.<sup>4</sup>

The global practice in relation to the adoption of global human rights legal treaties is not to extend the regional character of a convention, but to use the UN treaty-based system and adopt a treaty and a human rights body (Committee) that is monitoring the implementation of the treaty.<sup>5</sup> Instead of adopting such a convention and establishing such a body, the issue of bioethics in the interest of humankind is addressed in three separate international bodies, International Bioethics Committee (IBC) and World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) and Intergovernmental Bioethics Committee (IGBC). The first two international organs have been established in the system of UNESCO and IGBC is a Committee that reflects the interests of states in the field of bioethics.<sup>6</sup> Under the leadership of UNESCO in 2005 was organized a General Conference which adopted the legally non-binding document Universal Declaration on Bioethics and Human Rights.<sup>7</sup>

The above-mentioned three international organs are succeeding in identifying the relevant contemporary issues that present a bioethical concern, which requires appropriate regulation. However, their expert work is not authorized to adopt a comprehensive legally-binding regulation, as this would not be accepted by states. For this reason working legal mechanism to regulate bioethical issues on a global level is missing.

## **1.2. Difficulties of drafting and enforcement the norms in the Oviedo Convention**

The drafting of every convention becomes a compromise, build between nations, instead a legal instrument, based on scientific needs for optimal protection of interests of those nations and humankind. As Vera Raposo concludes, the Council of Europe had to be careful, in the process of adopting the Oviedo Convention, so that it could gather the required number of ratifications to enter into force.<sup>8</sup> This regard of the national interests reflects to the quality of the norms of the final document.

The monitoring of the implementation of the Oviedo Convention by the ratifying states is due to the Council of Europe's governing bodies and not to the ECtHR.<sup>9</sup> The result is that there are no effective sanctions provided for the violation of its norms, which weakens the legal strength of the document. It has to be restated that the national governmental agencies and national

---

<sup>3</sup> Koh, Harold Hongju. "On American Exceptionalism." *Stanford Law Review* (2003): 1479-1527.

<sup>4</sup> See examples: Armstrong, Robert E., and Mark D. Drapeau, eds. *Bio-inspired innovation and national security*. NDU Press, 2010.

<sup>5</sup> Goodman, Ryan, and Derek Jinks. "Measuring the effects of human rights treaties." *European Journal of International Law* 14, no. 1 (2003): 171-183

<sup>6</sup> Rules of procedure of the Intergovernmental Bioethics Committee (IGBC), SHS/EST/IGBC-5/07/CONF.204/7 REV

<sup>7</sup> Records of the General Conference, 33rd session, Paris, 3-21 October 2005, v. 1: Resolutions

<sup>8</sup> Vera Lúcia Raposo (2016) The convention of human rights and biomedicine revisited: Critical assessment, *The International Journal of Human Rights*, 20:8, 1278, DOI: 10.1080/13642987.2016.1207628

<sup>9</sup> *Ibid.*

courts remain the most important institutions to implement the norms of the convention.<sup>10</sup> The issue of bioethics and specifically, bioethics in medicine requires legal regulative efforts beyond the national and even classical international legal instruments, because it effects the interest of humankind on a very deep level.

### **1.3. Religious-based differences in bioethics**

Major scientific researches analyze the role of different religious, atheistic and nontheistic beliefs on adopting bioethical standards in medicine<sup>11</sup> and legal norms and point out the need for changes in the field of medicine<sup>12</sup> and encouraged further the development of alternative medical practices.<sup>13</sup>

What steps should be made to achieve common bioethical standards in medicine and ideally global legally binding regulation on all relevant bioethical issues? The fundamental role of religious beliefs to influence, shape and hinder bioethical standards cannot be overstated.<sup>14</sup> The transformation of the national and international legal norms and the society as a whole is prudent to be directed politically to achieve simultaneously three long-term goals:

1. The first one is the modernization of major religious doctrines to interpret their religious norms and beliefs with respect to the interest of humankind and in correspondence with international human rights law.
2. The second goal is to increase the cooperation efforts among major religions and to facilitate a dialogue between them in a permanent forum on bioethical issues of different character.
3. The first two long-term goals require persistence and commitment for decades on behalf of religious and political leaders and for this reason it is necessary to mitigate the non-constructive influence of religions on matters of bioethical concerns. The third goal is to guarantee that states maintain or adopt secularism in order to guarantee legal protection of the human rights of their citizens on all issues that cause biomedical concern.

### **1.4. Encouraging scientific progress in medicine without regards the interest of humankind**

Human rights very often are seen by multinational corporations as an obstacle for their growth and economic prosperity. This statement is valid also for the field of medical and pharmaceutical industries and biomedicine and for this reason the work of the UN Special Rapporteur on the Right to Health developed guidelines for the pharmaceutical industry.<sup>15</sup> The

---

<sup>10</sup> R.ANDORNO, "The Oviedo Convention: a European framework at the intersection of human rights and health law", *Journal of International Biotechnology Law*, 2005, p. 136

<sup>11</sup> Metzler, Ingrid, and Anna Pichelstorfer. "Embryonic Silences: Human Life Between Biomedicine, Religion, and State Authorities in Austria." In *Religion and Biopolitics*, pp. 73-96. Springer, Cham, 2020

<sup>12</sup> Engel, George L. "The need for a new medical model: a challenge for biomedicine." *Psychodynamic psychiatry* 40, no. 3 (2012): 377-396.

<sup>13</sup> Barrett, Bruce, Lucille Marchand, Jo Scheder, Mary Beth Plane, Rob Maberry, Diane Appelbaum, David Rakel, and David Rabago. "Themes of holism, empowerment, access, and legitimacy define complementary, alternative, and integrative medicine in relation to conventional biomedicine." *The Journal of Alternative & Complementary Medicine* 9, no. 6 (2003): 937-947

<sup>14</sup> See more Feder, Ellen K. *Making sense of intersex: Changing ethical perspectives in biomedicine*. Indiana University Press, 2014. pp. 118-131

<sup>15</sup> UN Special Rapporteur on the right to health, "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines", submitted to GA of UN in 2008

purpose of these guidelines is to avoid practices in which the multinational pharmaceutical companies are disregarding the high biomedical standards in order to increase their profit.<sup>16</sup> The desire of states and private organizations of more rapid scientific progress without taking into consideration the interest of humankind has led to increasing the social inequality in the world in the time of long-lasting pandemic.<sup>17</sup> The private sector, which is willing to sacrifice the higher bioethical and biomedical standards to pursue bigger profits, will continue its activities in countries that have not ratified the Oviedo Convention or any future international treaty in this field. At the same time this option for the private companies, becomes a strong motivator for many leading countries not to ratify the Oviedo Convention.

## **2. Above-national approach towards achieving the goals of higher biomedical standards**

The need for establishing an organization, which represents humankind, promotes and defends its interests, is greater than ever. Such an organization should also adopt bioethical and biomedical standards which are developed to pursue the interest of humankind.

Humankind is facing above-national challenges but all existing global institutions are based entirely on nation-states membership and participation. Even when international committees are established with independent experts, acting in individual capacity, the will of the sovereign states is primary in relation to the implementation of the international treaty. This is the reason that humankind should emerge as a sui generis legal subject outside of United Nations system and any inter-national legal framework.

Presently, in the face of unprecedented challenges, which are a concern for every state, private organization and for every human being, there should be adequate institutions to address them.<sup>18</sup> These challenges are of above national character and require above national response. Example of such above-national challenge we have experienced with Covid-19 pandemic. Beside pandemics and rapid climate crisis, there are also the issues of integrating technology with biology<sup>19</sup>, human cloning<sup>20</sup>, genetic experiments with different biological organisms, introducing artificial intelligence and developing of robotics<sup>21</sup>, cyber-attacks of critical infrastructures<sup>22</sup> and others. The resolution of these challenges requires rapid transformation of our socio-economic relations as a whole, and the creation of above national humanistic paradigm, which is capable to inspire highly ethical policies in the interest of humankind. As stewards of Earth and its resources, human beings have certain environmental legal obligations,

---

<sup>16</sup> Rajan, Kaushik Sunder. *Pharmocracy: Value, politics, and knowledge in global biomedicine*. Duke University Press, 2017.

<sup>17</sup> Ohlbrecht, Heike, and Josephine Jellen. "Unequal tensions: the effects of the coronavirus pandemic in light of subjective health and social inequality dimensions in Germany." *European Societies* (2021): 1-18.

<sup>18</sup> Galaz, V., *Global Challenges, Governance, and Complexity: Applications and Frontiers*, Elgar, 2019, p.2

<sup>19</sup> MacFarlane, J.M., *Transhumanism as a New Social Movement: The Techno-Centred Imagination*, Spinger, 2020, pp.91-99

<sup>20</sup> Vöneky, S., Wolfrum, R., *Human Dignity and Human Cloning*, Springer, 2013, p.141

<sup>21</sup> "which will substitute at least 47 % of the working force globally", Frey and Osborne, Report "The future of employment", University of Oxford, 2013 <https://www.oxfordmartin.ox.ac.uk/downloads/academic/future-of-employment.pdf>

<sup>22</sup> Johnson, T., *Cybersecurity: Protecting Critical Infrastructures from Cyber Attack and Cyber Warfare*, CRC Press, 2015, pp.287-305

which have been described to include at least two aspects: inter-generational equity and precaution.<sup>23</sup>

## **2.1. The Humankind Organization and the Committee on Bioethics and Biomedicine**

The Humankind Organization is envisioned to be a sui generis global organization, which represents humankind as a whole and expresses the common will and positions of humanity. It is a general type of organization, which should consist of many domains of interests. One of these domains is the field of bioethics and biomedicine. The Humankind Organization should consist of Committees, established on different criteria. One of these committees has to be the Committee on Bioethics and Biomedicine. It should consist of independent experts, acting in individual capacity, without the influence of national or corporate interests to affect its work and legal acts. Its main purpose should be to research and adopt the optimal standards for bioethical and biomedical protection of the interest of humankind.

The good work of UNESCO and in particular the functioning of the International Bioethics Committee (IBC) and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) should be preserved and further developed in the new Committee. The difference would be that in the Committee will participate independent experts, thinking from the perspective of humankind with authority to adopt legally binding standards for all human-beings, private organizations and states, which are recognizing the Humankind Organization as the legal subject that represents humankind.

The detailed structure and function of the Humankind Organization deserves a separate publication. In this article is explored the need for the establishment a Committee on Bioethics and Biomedicine in the internal structure of the Humankind Organization.

## **Conclusion**

The international legal regulation through international treaties cannot address adequately the global challenges of above-national character. The risk of our civilization to degrade by lowering the humane character of its standards in bioethics and biomedicine is greater than ever, due to rapid technological and scientific development which is guided mainly to protect nations from each other, instead to improve the quality of life of everyone and satisfy the interests of humankind in a better way.

---

<sup>23</sup> Weiss, E. In fairness to future generations, International law, common patrimony and intergenerational equity, MN, 1989