The Universal Declaration on Bioethics and Human Rights – contributions to the Brazilian State

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Resumo Este artigo registra a contribuição histórica para a reflexão bioética trazida pela Declaração Universal sobre Bioética e Direitos Humanos (DUBDH), aprovada em 2005 pela Unesco. Concentrando-se nos aspectos relativos à vulnerabilidade e à responsabilidade social, são destacados e interpretados fatores orientadores para o Brasil. Em primeira mão é apresentado um histórico dos encontros que precederam a consolidação da Declaração e sua promulgação. O artigo conclui mostrando que a DUBDH trouxe valiosa contribuição ao âmbito das pesquisas científicas e tecnológicas, reafirmando que embora devam gozar de liberdade criativa, sejam orientadas por princípios éticos que respeitem claramente a dignidade humana, os direitos humanos e as liberdades fundamentais, dispensando especial atenção aos vulneráveis.

Palavras-chave: Vulnerabilidade. Responsabilidade social. Estado. Organização das Nações Unidas para a Educação, Ciência e Cultura.

Scientific and technological development progresses achieved in the last 30 years, particularly in biotechnology and human health fields, enabled undertakings that were unimaginable before. Diseases that then were incurable, today have treatment, organisms taken as enigmatic, currently have their genomes sequenced, situations taken as impossible, such as living organism genetic engineering and cloning are currently reproduced by routine methodologies in many places around the world and in Brazil.

At the same time, that humanity gets knowledge and power to improve substantially its quality of life; paradoxally it also acquires knowledge and power to cause large scale or irreversible damage. Deforestation of huge areas (due to extensive agriculture or logging activities), liberation of gases that affect the ozone layer (by using non-renewable fossil fuel)

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and construction of mass destruction weapons are examples evidencing moral frailness of human kind.

The great ethical issues set due to scientific and technological progress do not refer to human being potentialities, but to its *responsibilities*. Theoretically, researches may follow in many directions, but, in practice, not all paths lead to benefits for humanity or yield them immediately, creating, however, possibility for costly long-term consequences. Thus, the problem does not lie in rejection of new technologies that are not morally acceptable by society, but rather in enforced ethical control that should exist.

At about 30 years ago, an American physician, Van Rensselaer Potter, realized that humanity survival could be under threat. He created, then, the neologism *bioethics* to designate the need of a scientific area that would dedicate to searching knowledge and wisdom. According to him, wisdom would represent knowledge needed to manage knowledge itself aimed at the social well being[1]. Since then, bioethics revealed to be one of the reflection areas that grew most. Currently, when biotechnology acquired enormous strength and not only economic, but transformer of human life and nature, bioethics analysis on technoscientific progress became an unadjournable initiative.

In this present-day scenario, the Universal Declaration on Bioethics and Human Rights by the United Nations Educational, Scientific, and Cultural Organization – UNESCO is like a milestone for bioethics. Therefore, this reflection proposes not only to record relevant historical events for the construction process of the declaration (even if without pretension to turn into an exhaustive and complete historical narrative; but assuming the tangibility of such endeavor), as well as to emphasize and to interpret two specific topics – namely, vulnerability and social responsibility – that express general agreement concerning its relevance to Brazilian society.

Vulnerability and social responsibility

Vulnerability, according to Lorenzo, *carries a sense of susceptibility, that is, characteristics that leave us capable of been harmed by an external event of any sort, which reports to the possibility that this event trajectory finds us in its path*[2]. It is consensus that vulnerability is an universal human condition. This conclusion may be found in arguments from different scholars in all ages. These understand, completely, as necessary an equal State protection to all due to this condition[3].

This universality, according to Hurst, expands too much the borderline of the concept, bringing on hardships for the consequent need of special protection. The reductionist standpoint of vulnerability, parallel, when referred only to condition in which the subject, definitively or temporarily, finds himself without conditions to defend his own interests, may cause that a few, who effectively should be taken as vulnerable, to not receive suitable protection. The dilemma of an encompassing construction of the concept or of its restrictive view which currently pervades discussion on vulnerability[4].

However, it is an agreement point that *vulnerability* is not necessarily the same among all human being, existing indivíduals, groups of people or even countries that are more exposed because they present certain additional frailness set by historical factors or temporary circumstances, who find themselves in greater susceptibility condition[2,3,5]. Under these conditions, not only equal State protection should be requested, but specific additional measures need implementation[2,3,4,5]. State action as promoting human rights and basic freedom recognizing human being dignity may be seen as the foundation for developing needed protection for the vulnerable.

International documents, versant on ethical aspects related to research with human beings, within science and technology specific scope, present definitions for vulnerability. In order to clarify them better, these documents present a roll of the so-called *vulnerable groups*. *Belmont Report* lists racial minorities, those who are in economic disadvantage, the sick, and institutionalized[6]. The document from the Council for International Organizations of Medical Sciences – Cioms, *International Ethics Guidelines for Biomedical Researches involving Human Beings*, identifies those who present limited capacity to consent or to refuse consenting, like children and individuals who, because of mental ilness, are incapable to provide informed consent, in addition to people submitted to any kind of hierarchy, elder people, unemployed, prsioners or refugees [7].

Recognition and valuation of vulnerability, mainly when incremented by additional conditions that call for greater specific protection, requires ethical rigor to approach when evaluating and managing additional risks that may occur to individuals or groups of individuals due to this special condition.

Social responsibility, in moral discussion focus, has been constantly pointed as determinant factor, more than a goal, on moral justification and analysis of scientific and technological progress, genetic and environmental interventions, and others without previous regulation *that discards or includes individuals as beneficiaries of the scientific and technological development*[8]. Social responsibility of government with people's health, because it deals with citizens' interests and basic rights, bases primarily in recognizing these rights from the standpoint of human dignity valuation that ensures society to merit this tutelage.

From recognition that health promotion should perform beyond sanitary policies derives the need to promote integration and complementarity among health policies and social policies, in such manner that social development and health promotion are to be seen as the two faces of a same coin. It is insufficient to make large investments in sanitation services of excellence if health socioeconomic conditionings – such as poverty, illiteracy, malnutrition, environmental pollution – finish by endangering decisively the quality of life for a significant portion of our society [9].

Such reflection, stated in the *Universal Declaration on Bioethics and Human Rights* final version, is in certain way advanced by the Chart of Buenos Ayres on Bioethics and Human Rights (*Carta de Buenos Aires sobre Bioética y Derechos Humanos)*. This document results from an event that took place in November 2004, counting on the presence of several bioethics experts from Latin America for the initial discussion of the Declaration. In mentioned document, expert declared to be convinced *that the development of essential human capabilities is only possible when basic needs are met, and through it, human beings need to have access to potable water, food, housing, work, medication, medical care, and public health services, without such guarantees, it is not possible to consider as moral any society*[10].

Bioethics at UNESCO

Unesco's Ethics of Science and Technology Programme aims at promoting considerations in science and technology in the field of ethics through the development of a democratic process to build normative and respect for Unesco's ideal of *true dialogue based in respect to shared values and dignity of each civilization and culture*. UNESCO promotes, with the program, meetings of *ad hoc* groups of renowned competence specialists to reflect on the state of art and to prepare recommendations on ethical, legal, and social aspects deriving from sciences of life, especially genetics, guided toward actions in the specific fields of ethics in science and technology [11].

The International Bioethics Committee – IBC and the Intergovernmental Bioethics Committee – IGBC are this discussion forum framework. IBC, established in 1993, comprises 36 independent specialists who follow progress of the sciences of life and their applications, in order to assure respect for human dignity and freedom. It is considered as the only global forum for profound bioethics discussion about current topics, offering subsidies so each country, specially their legislators, can make reflections about society's choices in elaborating or maintaining national laws, and to decide on different positions [11]. IGBC, in its turn, established five years later, in 1998, comprising 36 UNESCO's member states, whose representatives gather at least every two years to analyze IBC advices and recommendations. IGBC informs IBC on its opinions and submits them, jointly with IBC proposals for actions, to the director-general of UNESCO, who forwards them to member-states, to the Executive Council and to the General Conference [11].

Adoption of the Universal Declaration of Human Genome and Human Rights, in 1997, was the first great conquest of the program approved by the General Conference. The second was the International Declaration on Human Genetic Data, adopted in 2003[11].

Universal Declaration on Bioethics and Human Rights – construction of the declaration

One of the resolutions from the 32nd General Conference session, in 2003, considered *the establishment of universal standards in bioethics regarding dignity, human rights, and freedom, in the cultural pluralism spirit inherent to bioethics as opportune and desirable*. In addition, it invited the director general of UNESCO to prepare a universal declaration on bioethics universal norms – to be submitted for appreciation in the 33rd session[11].

Planning of procedures adopted toward a universal declaration presented three major phases:

a. January to April 2004: written consultation phase to member-states-, by means of questionnaire and debate among intergovernmental organizations and non-governmental organizations and national bioethics committees on the structure and scope for the declaration;
b. April 2004 to January 2005: Project wording phase, which involved six meetings of the wording group comprised by selected IBC members, two meetings

of UN Interagency Committee /Unesco, national and regional consultations, one IBC meeting and one written consultation to member-states;

c. January to September 2005: Project finalizing phase, when a draft of the declaration was presented officially, and appreciated twice (interspersed) by a governmental expert committed, and, finally, appreciated and unanimously approved at the 33rd General Conference session.

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During the Declaration construction process, it is worth noting that IGBC 4th session, IBC-IGBC joint session and IBC extraordinary session, undertaken during the period of January 24-28, 2005 at Unesco headquarters in Paris, showed to be crucial for the declaration final wording definition, since they preceded official presentation of the document, but government experts analysis as well. Corollary, taking advantage of the fact that one this work authors had the opportunity to be part of the Brazilian delegation when meetings took place, it allows us to record this important reflection moment in bioethics for the world and, particularly, in defense of the vulnerable, through guidance do Unesco member-states.

Intergovernmental Bioethics Committee 4th session

Taking place in January 24-25, 2005 and chaired by the Italian delegation representative, this meeting aimed at promoting debate on the 4th version of the declaration project. Its opening conducted by Pierre Sané, assistant director general for Social and Human Sciences and the director general of Unesco representative, who highlighted the endeavor importance for humanity, as model for legislation subsidies that respect dignity, basic human rights and freedom, making it clear that no member-state opposed the initiative.

The director of Unesco's Division of Ethics of Science and Technology, at the time, Henk ten Have, and Michèle S. Jean, then president of IBC, presented, next, the report on progress achieved until the moment and planning of future actions. Michael Kirby, president of the IBC Writing Group, at the time, called attention to the general points of major relevance of the 4th version, such as the respect for life (not limited to human life), complementarity between several principles, inclusion of social responsibility, the attempt to conciliate biomedicine with human rights and the possibility for future updates.

The Brazilian delegation vehemently advocated, during the debate, the clause regarding *social responsibility*, acknowledging the progress of the topic with its inclusion within the scope of the declaration, emphasizing still on the need to a more thorough wording on the topic. Points such as access to medications, the necessity to protect vulnerable people and the non-acceptance of a *double standard* – principle in which safety regulations (especially on new medication or treatment trials) presented by developing countries to be less rigorous compared to developed countries safety regulations - should be specifically mentioned in the clause. Additionally, it recommended also that clause dealing with *transnational practice* would state clearly the non-acceptance of biopiracy acts, traffic of organs and trade of scientific material of animal and human origin.

The debate polarized between Brazil, advocating developing countries standpoint, and Germany, advocating developed countries position. According to the German delegation, the Declaration should restrict to issues related to biotechnology and biomedicine, considering, therefore, inappropriate the clause referring to *social responsibility* and need adequacy of clauses dealing with *sharing of benefits, solidarity and international cooperation and the role of States*, in order to restrict its guidance to biotechnological and biomedical features.

At the end of the meeting, it was approved t IGBC 4th Session Recommendations document, which, *inter alia*, requested reconsideration of some crucial points such as autonomy, informed consent, social responsibility, sharing of benefits, transnational practice, and ethics committee.

The International Bioethics Committee and the Intergovernmental Bioethics Committee Joint session

This meeting, undertaken in January 26-27, 2005, aimed at promoting a joint debate between IBC and IGBC on the 4th version of the declaration project. Initially, a report on discussions carried out by IGBC in previous days was presented, stressing major focus of the debate between delegations from several countries. In the discussion among participants on suggested title– *Universal Declaration on Bioethics and Human Rights* – it was clear that all agreed with prior withdraw of the word *norm,* but there was no consensus on maintaining the expression *human rights*.

The Brazilian delegation recommended that freedom of research be mentioned in document introduction, signaling that it would be taken in consideration, but it should not be treated as a principle, since research should be limited by ethical considerations. Developed countries governmental and academic sectors representatives recommended that freedom of research should be dealt as basic for the progress of science. Another point of view of the Brazilian delegation referred to withdrawing of the *wherever possible* expression from the clause regarding *social responsibility*, which evidently weakened commitment with equality and social responsibility state thereto.

Reflection on the internal organization of the declaration project took most of the time. Observations about the order, grouping, or even titles of articles consumed several hours of the joint session. The Brazilian delegation interpreted the fact as possible developed countries strategies to divert attention to less relevance points and to avoid political debate such as social agenda.

A few delegations recommended that mention on member-states obligations, as the commitment on national report generation, foreseen by the article *IBC and IGBC roles* should not be made. IBC representatives took stand against this recommendation, clarifying that Unesco, as well as other United Nations organizations, have been criticized for preparing declarations that are not duly adopted and implemented by member-states, exactly for not having control and evaluation mechanisms of the recommendations.

It is timely to mention that during the opening of debate about observers participation, World Health Organization (WHO) representative strongly criticized maintenance of the article concerning *social responsibility* in the project, using derogatory terms such as *laundry list* arguing that the article dealt with specific interest of a group of countries and, therefore, without any relation with bioethics. The Brazilian delegation – more specifically, minister Luiz Alberto Figueiredo Machado, and not the Ambassador Antonio Augusto Dayrrel, as mistakenly became public by article of different authorship[12] –, pleading order issue, demanded that comments by international institutions representatives, particularly those from other agencies of the United Nations system, to be restricted to institutions official point of view, and that any kind of personal view was not to be accepted. Adding, still, that Brazil is a membe-State of WHO and that under any circumstance he agreed with the positioning presented by that Organization representative – an attitude criticized by the German delegation but supported by other developing countries representatives, *inter alia*, from Argentina.

This polarization related to bioethics and social issues interface raises attention to what can be considered possibly as one of the most significant contributions in preparation discussions for the final version of the declaration. The working group, until this joint session, in charge to write the text considered bioethics definition as *the realm of systematic, plural, and interdisciplinary study dedicated to theoretical and practical moral issues rose by medicine and by the sciences of life with implications for human beings and for the relationship of humanity and the biosphere*[13]. Discussions then pointed toward new understanding, showing that these definitions presented too much academic features, leading reflection to the necessity to contemplate, in an analogous way, the political features.

Such perspective opens space so reflection on bioethics to be used as an instrument for concrete problems resolution not only in sciences of life (like biology, microbiology, biochemistry, zoology and virology), but, equally, in those detected by social sciences (like political science, sociology, psychology, anthropology). Consequently, *the new bioethics reference definition began to set the concept of a systematic* *plural and interdisciplinary study and ethical issues raised by medicine and by sciences of life and social sciences with implications for human beings and for their relationship with the biosphere, including issues concerning availability and access to scientific and technological developments and their applications* [14].

International Bioethics Committee extraordinary session

This meeting, undertaken in January 28, 2005, opened with Mr. Koïchiro Matsuura's statement, director general of UNESCO, who congratulated all for their effort, recognizing the difficulty to prepare a really universal declaration. The declaration, in his view, should establish a number of principles and procedures that would work as model for legislations from different member-states, such as to encourage dialogue among all involved actors searching for consensus between plural of opinions pointing the path for correct measures. He mentioned also IBC decision in highlighting social responsibility in the context of human rights protection, relating ethical questioning to future generations well-being. According to Mr. Matsuura, *by raising specific issues such as access to health care, food and water, poverty alleviation or environment enhancement, the proposal opens perspectives for actions that go beyond medical ethics as such, pointing once again the necessity for bioethics as part of an open debate, in general, about political and social realms*[15].

Michael Kirby, pleased with established transparency and dialogue, made a report on works undertaken until then, emphasizing the importance of the article about *social responsibility*, which reflect the special situation experienced by developing countries and discussions currently taking place about the topic in specialized circles. Other delegations manifested, still about this article, support to Brazilian standpoint (like Argentina, Egypt and Tunisia), and China suggest that social responsibility should be also mentioned in articles about *sharing of benefits and international cooperation*.

Other topics appeared in the meeting agenda, like the principle of precaution, informed consent of children, the possibility of existence of member-states domestic laws opposing the declaration principles, and responsibility related to biosphere.

Approval of the Declaration

In February 2005, preliminary version of the declaration project was submitted to a new consultation by member-states, by governmental and non-governmental organizations and by other institutions. The first meeting of the committee comprising governmental experts and another IGBC meeting took place in March. In April, the director general of UNESCO presented a progress report to the Executive Council. In June, with the second meeting of the committee of governmental expert and another of IGBC, concluded the final wording of the Project. In October, the

33rd General Conference session[11] appreciated and unanimously approved the *Universal Declaration on Bioethics and Human Rights*.

Contributions of the Declaration to States

The *Universal Declaration on Bioethics and Human Rights*, in its final version, already defines in its title its guiding vocation based in international legislation on human rights, respect for human dignity and basic freedom as essential for the development of bioethical principles presented in it. It acknowledges, at the preamble, freedom of science and technology, emphasizes that scientific and technological development *should search always to promote individuals, families, groups or communities and humanity well-being in recognizing human dignity and universal respect, and enforcement of human rights and basic freedom, while moral sensibility and ethical reflection* are essential to this development process.

Unfortunately, Declaration text did not record in a clear and evident fashion an opposing manifestation to the moral justification for double standard. Notwithstanding, in whereas, there is a statement that *all human beings, without distinction, should benefit* from the same high ethical Standards in *medicine and in science of life researches (*emphasis of authors), what unarguably compromises any kind of double standards advocacy.

It is possible that a more explicit manifestation would make difficult the *Declaration of Helsinki* review approval by the 59th World Medical Association – WMA General Assembly, undertaken in Seoul in October 2008. Thus, it began to contemplate, in items 29 and 32, the possibility of flexibilization of the governing norms on research with human beings, particularly those undertaken in less developed regions, where research subjects do not have access to health care services[16]. As it deals traditionally with one of the most relevant international documents regarding ethical guidelines for designing experimental research with human beings, the fact that WMA, at least apparently, gave in to pharmaceutical sector pressures – with fallacious urgency arguments in search for innovative therapies for health deterioration, but compelled strictly by economic interests – and depriving of the opportunity of not flexibilizing researchers' responsibilities with voluntaries participating in biomedical research, opens a serious prerogative in controlling experiments with human being and awakens mistrust regarding the conquest achieved by the *Universal Declaration on Bioethics and Human Rights* in defending the interests of the vulnerable.

When comparing this text to the *Universal Declaration on Human Genome and Human Rights* and the *International Declaration on Human Genetics Data* it is undeniable that progress achieved by migration of vulnerability, dealt explicitly in the international cooperation theme, toward a specific article in the section of principles

(Article VIII – Respect for Human Vulnerability and Individual Integrity), where the need to protect individuals and groups with specific vulnerability as well as respect for individual integrity stands out.

Naturally, this section of principles presents, additionally, a series of relevant guidelines in terms of preserving the vulnerable from possible harm deriving from scientific and technological practices, such as: a) nonnegotiable requirement related to previous, free and clarified consent based in suitable information; b) guarantee that any discrimination or stigmatization constitutes human dignity, human rights and basic freedom violations and; c) advocacy to share benefits resulting from any scientific research and its technological applications.

Article XIV (Social Responsibility and Health) deserves the merit of inserting in biomedical agenda an annoying reflection for the central countries, but of major importance for the peripheral countries. Its mentioning in the Declaration final text represent a milestone in broadening bioethics conceptual scope, which starts, with approval by Unesco, to contemplate a close interrelation between health promotion practice and measures that aim social development. Now, after approval of the Declaration, governments took the responsibility to foster scientific progress and technological development in such manner that in future its results and products began to see broadening of: access to health care of quality and essential medication; access to suitable nutrition and good quality water; improvement of living conditions and of the environment; elimination of marginalization and exclusion of individuals for whatever reason and, poverty alleviation and illiteracy reduction.

Final considerations

The *Universal Declaration on Bioethics and Human Rights* starts with a strong call to protection of the vulnerable and extends itself, in its principles, emphasizing respect for individuals' autonomy and the need of complete, clear and adequate clarification on obtaining consent of individuals submitted to, among others, to biomedical research. It dedicates special article to vulnerable individuals or groups and assures guidance to respect for their integrity. It rejects performance reflecting double standards and restates social responsibility of State about health. It strives in declaring the principle of benefit sharing and expands all view on respect and protection of humanity and planet future.

Despite the fact that the Brazilian State, to contribute with several initiatives, made efforts to achieve a fairer and equitable society, there is not any doubt that, even been alone in this endeavor, desirable diversities remain in society (the case of biological and cultural), but as well those unwanted (the case of educational level diversity, basic health care access and family income level). Thus, while a small part of around 170 million of Brazilian have access to, for example, to the most recent medical technology advances, such as computerized tomography and last generation drugs, a large portion of the population lives daily with the uncertainty related to a possible meal [17].

It is imperative that, as corollary, the Brazilian State as a whole – considering here federal agencies, with their diverse attributions and competences – acknowledges the need to invest more in the defense of interests of the vulnerable, a topic so dear to our society. Particularly, been present the deadlock aroused with the current review of the *Declaration of Helsinki*, it is legitimate that the Brazilian State, with due support from entities affect by the topic, *inter alia*, the Brazilian Bioethics Society (SBB), makes efforts to enable the evolution of the *Universal Declaration on Bioethics and Human Rights* (been a *declaration, it is not binding) to a* specific protocol (this a rather biding one), in order to strengthen more so the protection of interests of the vulnerable.

Federal Council of Medicine (CFM) manifestation should be mentioned. Its Resolution no. 1,885, of 2008, considers that *there is no scientific evidence justifying ethic indulgence adopted in placebo use by changing current Declaration of Helsinki that maintains bonds of any nature with medical research involving human beings that use placebo in their trials when effective treatment for the researched disease exists prohibited to physicians* [18].

Such manifestation signalizes to Brazilian State not only the need to give priority to bioethics issues in domestic and international legislations as it shows that other institutions, exemplified by CFM, may, depending on articulation, become major allies with significant contributions in domestic and international discussion forum.

Resumen

La Declaración Universal sobre Bioética y Derechos Humanos – contribuciones al Estado brasileño

En este artículo se registra la contribución histórica a la reflexión bioética provocada por la Declaración Universal sobre Bioética y Derechos Humanos (DUBDH), aprobada en 2005 por la Unesco. Centrándose en los aspectos de la vulnerabilidad y de la responsabilidad social, se ponen de relieve e interpreta los factores rectores de Brasil. Trajo una historia de primera mano de las reuniones que precedieron a la consolidación de la Declaración y de su promulgación. El texto concluye mostrando que la DUBDH trajo valiosa contribución al campo de la investigación científica y tecnológica al afirmar que aunque éstos deben gozar de libertad creativa, se guían por los principios éticos que respetan claramente la dignidad humana, los derechos humanos y las libertades fundamentales, con especial atención a los vulnerables.

Palabras-clave: Vulnerabilidad. Responsabilidad social. Estado. Organización de las Naciones Unidas para la Educación, la Ciencia y la Cultura.

Abstract

The Universal Declaration on Bioethics and Human Rights – contributions to the Brazilian State

This article records the historical contribution to bioethical reflection brought by the Universal Declaration on Bioethics and Human Rights (DUBDH), adopted in 2005 by UNESCO. Focusing on aspects of vulnerability and social responsibility, guidelines for Brazil are hereto highlighted and interpreted. It is a first hand account of meetings that preceded the consolidation of the Declaration and its promulgation. The article concludes by showing that the DUBDH brought valuable contribution to the field of scientific and technological research by stating that although they should enjoy creative freedom, they must guide by ethical principles that clearly respect human dignity, human rights and fundamental freedoms, with special attention to the most vulnerable sectors of society.

Key words: Vulnerability. Social responsibility. State. United Nations Educational, Scientific and Cultural Organization.

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