Expansion and politicization of the international bioethics concept

Volnei Garrafa 1

Abstract

Latin America and Brazil have particularly played an important role in the recent expansion and politicization of the international bioethics agenda, based on the Universal Declaration on Bioethics and Human Rights of UNESCO. The present study is a brief history about this process, by relating contemporary ethical issues to the world current economic and sociopolitical crisis, that justify the need for concrete changes in the field of applied ethics. Analyzing certain situations in which bioethics is failing or not applied as it should, this paper shows the urgency of starting to analyze the moral conflicts found in our times in a different way.

The purpose of the discussion is to review some conservative views of bioethics that avoid to uncover real problems related to social inequalities, by proposing new theoretical and methodological work references for the future. Its conclusion suggests some measures and changes, from epistemological and practical natures, necessary when facing bioethical issues from now on.

Key words: Bioethics. Democracy. Policy. Public health. Brazil. Latin America.

Resumo

A América (afina e o Brasil, particularmente, tiveram importante papel na recente ampliação e politização da agenda bioética internacional, fundamentada na *Declaração Universal sobre Bio12ca e Direitos Humanos* da Unesco. O presente estudo faz um breve histérico deste processo, relacionando os problemas éticos contemporâneos com a atual crise econômica e sociopolítica mundial, que justificam a necessidade de mudanças concretas no campo da ética aplicada. Analisando certas situações nas quais a bioética vem falhando ou não se manifestando como deveria, mostra a urgência de se passar a tratar de modo distinto os conflitos morais constatados hodiernamente. O objetivo da discussão e revisar algumas concepções conservadoras da bioética que evitam desnudar os reais problemas relacionados com as desigualdades sociais, propondo novos referenciais teóricos e metodológicos de atuação futura para a mesma. Conclui sugerindo algumas medidas e mudanças epistemológicas e práticas necessárias ao enfrentamento das questões bioéticas daqui para a frente.

Palavras-chave: Bioética. Democracia. Política. Saúde pública. Brasil. América Latina.

Resumen

Ampliación y politización del concepto internacional de bioética

Latinoamerica y Brasil, particularmente, han tenido importante función en la reciente ampliación y politización de la agenda bioética internacional, fundamentada en la *Declaración Universal sobre Bioética y Derechos Humanos* de la UNESCO. El presente estudio realiza un breve histérico de este proceso, relacionando los problemas éticos contemporáneos con la actual crisis económica y sociopolítica mundial, que justifican la necesidad de cambios concretos en el campo de la ética aplicada. Analizando ciertas situaciones en las cuales la bioética ha fallado o no manifestándose como debería, se nota la urgencia de pasarse a analizar de modo distinto los conflictos morales constatados actualmente. El objetivo de esta discusión es revisar algunas concepciones conservadoras de la bioética que evitan desnudar los reales problemas relacionados con las desigualdades sociales, proponiendo nuevos referenciales teóricos y metodológicos de actuación futura la bioética. Concluye sugiriendo algunas medidas y cambios - epistemológicos y prácticos - necesarios al enfrentamiento de las cuestiones bioéticas de ahora en adelante.

Palabras-clave: Bioética. Democracia. Política. Salud pública. Brasil. América Latina.

Address

Caixa Postal 04367; CEP 70904-970, Brasilia/DF, Brasil.

He declares that there is not any conflict of interest.

^{1.} Post-doctor garrafavolnei@gmail.com - UNESCO International Bioethics Committee/IBC; Latin American and Caribbean Bioethics Network/Redbioética, University of Brasilia (UNB), Brasília/DF, Brazil.

Latin America played a reference role in the recent expansion and politicization of the international bioethics agenda that was consolidated - crucially with the Universal Declaration on Bioethics and Human Rights (UNESCO DUBDH) in 2005 1. Until late 1990s, the international bioethics thematic pointed to massive biomedical and biotechnical issues. However, in Latin America - and Brazil in particular at this time some already begun to work hard in the academic world to expand their territory of study, reflection and action. The Brazilian Bioethics Society (SBB, founded in 1995) and the UNESCO Latin American and Caribbean Bioethics Network (Redbioetica, created in 2002 and formally established in May 2003) were decisive in this regard.

The benchmarks that have stimulated the SBB and Redbioetica to tread through this new critical path have a direct relationship with the guidelines of the official world congresses organized by the International Association of Bioethics (IAB) in Tokyo/Japan (1998) and Brasilia/Brazil (2002): the latter entirely organized by SBB. The official themes chosen for the two events - Global Bioethics and Bioethics, Power and Injustice - stimulated the discussions regarding the deepening of the contradiction found between the presumed universality of the four Georgetown principles, proposed for bioethics from the United States of America (U.S.A) and Europe, and the need for cultural diversity to be respected in each place, with all its different moral nuances, becoming quite evident, too, the need to expand the bioethics agenda beyond biomedical and biotechnological issues 2.

The first meeting regained Potter's ³ pioneering ideas related to globalization of bioethics, the wisdom in the application of knowledge and respect for environmental issues; the second contributed to the opening of discussions regarding the need to respect the moral plurality, and proposing the expansion and politicization of the international ⁴, bioethics agenda, giving more visibility to health, social, and environmental issues ^{5,6}.

Background - a bit of history...

Alastair Campbell, then president of the IAB, was in Brasilia in March 1998 during the II Brazilian Congress of Bioethics, held months before the event in Tokyo, the central theme of which was established by his inspiration. Impressed with the paradox and contradictions that he saw between the country's capital and the visit he subsequently made to the public hospital in the densely populated and problematic slum of Heliopolis, in Sao Paulo, where a seminar was organized two days after the congress at the public hospital, he expressed in the *President's Column* published in the spring edition of the IAB News Europe that year that, after the visit, he began to realize the nature of bioethics quite differently:

I had a vision of how difficult it must be to sustain a public health service with minimum resources and massive problems of poverty. I saw the environmental challenge posed by massive urbanization without adequate infrastructure to support it. Meanwhile, I met people determined to find a Bioethics that makes a genuine difference to the health of their countries and the quality of its development (...) The "Global Bioethics" should not be a neocolonial ambition that serves to keep people conformed to our paradigms of moral behavior or even to persuade them to argue in our way of thinking 7.

The theme of public and collective health, specifically, has been worked in the context of bioethics by Brazilian researchers since the early '90s. In his preface to the book published in the country in 1995, Berlinguer, mastermind of the Brazilian Health Reform and former member of the UNESCO International Bioethics Committee (IBC), thus expressed himself:

(...) I very much appreciated the interpretation of health policy as a means to make people less unequal and more equitable society (...) This book represents the first successfully substantial attempt to address the issue with an optics that starts from the experience of a great country

in the Southern Hemisphere of the world, rich in popular movements and cultural experiences, and plagued by poverty and injustice, without being trapped to the borders or boundaries, but rather, linking to the European philosophical traditions and the international bioethical ⁸.

Several texts by national researchers of the time (among them, especially Schramm ⁹ and Fortes ¹⁰) already promoted the natural proximity between bioethics, the universal right to access to health and political reasons that often imply in better or worse quality of life for people and communities. From the global expansion of the neoliberal market model in the 1990s, the multiple crises that began to plague the world at the start of the twenty-first century especially the 2001 terrorist attacks in New York and the acute economic crisis of 2008, which continues today, early 2012 - stripped bare a perverse sociopolitical context: the social wealth and power remain in the hands of a few, environmental degradation is still growing and the majority of the population continue to be far below the benefits of development.

The search for new paradigms of production and consumption, and other types of social life requires the reappropriation of the policy for citizenship, as well as the construction of new public spaces to discuss alternatives for the development, debate until now blocked by the prevailing economistical view, which promotes growth at any cost and ignores its negative effects on society ¹¹.

The concept of *Gross National Happiness* adopted since the '70s in Bhutan, a small kingdom wedged in the Himalayas between China and India, defines that the basic principle to ensure happiness is that the economy must serve the welfare of the population. This is quite different from what we saw in the recent global economic crisis referred to above, when unimaginable sums of public money enough to end poverty and social exclusion in the peripheral world - were applied by the central capitalist countries to prevent the breakdown of large private companies, in order to maintain production, the virtual guarantee of jobs and the survival of the system ¹¹.

For decades, in the second half of the 20th

culo XX, century, the International Monetary Fund (IMF) intervened heavily in the economies of Latin American countries, demanding the region's governments not to interfere in the destinies of the private sector, enabling the breakdown of traditional companies like Varig for example, to mention one of numerous Brazilian cases. When the crisis came to the North, the capitalist recipe reversed itself: government such as the U.S. outrageously helped companies such as City Bank, General Motors or Ford not to go bankrupt. Two weights and two measures, or rather, "do as I say, but not as I do," as read in any wide circulation newspaper at the time.

Since what is discussed here is directly related to better or worse quality of life and survival of individuals and peoples, it seems appropriate that bioethics in the coming years begin to incorporate into its discussions the concept of biopolitics, developed by Foucault ¹², as well as the concept of *biopower*.

A contribution originated in Latin America and which retrieves "old news" in the debate on "development" is the concept of good living, ancient philosophy of life of indigenous societies in the Andean region, particularly (especially) in Bolivia and Ecuador, which already included it in their constitutions. In this concept, wealth does not count much, that is, the things that people produce, but what the produced things specifically provide for people's lives. In the formulation of the good living philosophy are not considered only material goods, but other references such as the individual's knowledge, his social and cultural recognition, spiritual and ethical codes of conduct followed by the society to which he belongs, his relationship with nature, human values, and vision of the future 13.

In this context, the economy must be guided by living in solidarity, without misery, without discrimination, ensuring the need for dignified survival of all. Good living expresses the assertion of rights and social, economic and environmental guarantees. All people equally have the right to decent living, guaranteeing them health, nutrition, clean water, pure oxygen, adequate housing, sanitation, education, a job, work, rest and leisure, physical culture, clothing, retirement.

Many of the ideas expressed here from the Latin America root epistemological bioethics foundation, built and supported by SBB and Redbioetica over the past two decades, were eventually incorporated in the UNESCO Universal Declaration on Bioethics and Human Rights ¹⁰, approved in October 2005 after more than two years of intense discussions and struggles.

The long process of approval includes substantially the so-called Buenos Aires Charter, from November 2004, when 27 bioethicists, representing eleven Latin American countries, manifested internationally so as to strike against the contents of a DUBDH version that until then introduced markedly biotech and restrictive content to the interests of the peripheral countries ¹⁴.

The extraordinary IBC/UNESCO meeting promoted in Mexico City five years later, in November 2009, was timely for Latin America to claim - and have recognized in this important international event - the paternity of the idea of inclusion of health and social issues in the context and politicization of the Declaration, necessary and indispensable, of these questions¹⁵.

The extraordinary IBC/UNESCO meeting promoted in Mexico City five years later, in November 2009, was timely for Latin America to claim - and have recognized in this important international event - the paternity of the idea of inclusion of health and social issues in the context and politicization of the Declaration, necessary and indispensable, of these questions" 16-19, defending their interests for a supposed unnecessary and disorderly expansion, according to them, of the knowledge they already held in their monopoly niches based on the four principles initially proposed, others just stood in absolute silence, contemptuous and critic, opposite the driving idea of an expanded, more free and liberating bioethics, which won the clash and starts to spread worldwide.

Panorama in 2012 - reasons that require changes

The twenty-first century has brought new features, including the economic crisis and the failure of the neoliberal market, with a worsening of the situation and increase in vulnerability for the

world's poorest populations. Bioethics was not immune to it at all. On the contrary, the concepts directly related to the unbridled expansion of the model of global capitalism were also directly applied to the conceptual and practical context of bioethics in various situations, especially in the field of multicenter clinical research in which we highlight, for example, topics approved by the Seoul/2008 version of the Declaration of Helsinki (DH), such as the flexibility of using placebo (action popularly known as "double standard") and sponsors' lack of commitment towards the study subjects after the study, aspects analyzed below.

As a result, along with some erosion of its original concept, we can see, besides the recurrence of old problems (e.g., the scandalous affair of the research developed by the National Institute of Health -NIH/USA in Guatemala in 1947, where thousands of people, including children, were deliberately inoculated with venereal microorganisms), the emergence of relatively new situations (like the double standard for clinical research) that need to be addressed by specialists concerned with promoting a bioethics truly committed to justice, citizenship and human rights, according to the benchmarks proposed by the United Nations, and particularly by Unesco. The construction and putting into practice of new global initiatives for the organization of bioethics task forces, such as the Centre for Bioethics and the UNESCO Base Program for the Study of Bioethics, and the recent creation of the International Association for Education in Ethics (IAEE) international entity with new basis, are part of this context, with the aforementioned Redbioetica.

This means that subjects with unilateral and exaggerated emphasis on autonomy and isolated and informed in advance individual decisions (informed decision-making), for example, are no longer sufficient to the global. My main purpose in this article, therefore, is - from the current global economic and sociopolitical situation and the need to move in a different way to examine the ancient moral conflicts (individual and corporate) and the new situations that begin to present themselves — to demonstrate the need to: a) review certain conservative bioethical views that avoid revealing the real problems of social inequality

still existing in the contemporary world; b) propose new theoretical and methodological references especially related to different future forms of practical activity in the realm of bioethics.

Some old problems and new ones in which bioethics is failing (or not manifesting, as it should)

Instead of foreseeing that the application of the neoliberal capitalist model could generate so many powers concentrated in the hands of so few, and maintain the continuity of so many injustices and social problems, a significant portion of the international bioethics community members - especially in the developed countries - applied completely wrong ethical recipes to the issues that were under their control and responsibility. The following five different situations are presented briefly, among many others, where such things happened (and still happening).

The commercialization of clinical trials and ethical review of research with humans

Investments of rich countries' transnational laboratories are increasing in recent years on tests with new drugs aimed at diseases that affect patients in these countries, but executed in poor countries and with a low economic level. A relatively recent study showed that of 1,556 new drugs developed in the world between 1974 and 2004 only 10 were for diseases common in poor countries²⁰- including in this list malaria and tuberculosis, the number of new drugs goes up to 21. This indicates that during the past 30 years i.e., the period in which participation in multicenter clinical trials in poor countries has increased significantly - just over 1% of pharmacological innovations were directed at diseases that predominantly affect the populations of these countries²¹.

Recent changes to the Declaration of Helsinki regarding the "more flexible" use of placebo and the lack of commitment from sponsors regarding the study subjects after its termination,

observed at the World Medical Assembly (WMA), held in October 2008 in Seoul/Korea, demonstrate that the international capitalist pressures not only won but also revealed the insensitivity of the capital against the suffering of millions of people around the world. Submitting the health of people to economic goals is unacceptable, according to Redbioetica in the Cordoba Declaration on Ethics in Research with human beings ²² in November 2008 (less than a month after the Seoul meeting). It is recalled that this last statement was approved unanimously in a meeting attended by 300 bioethicists from ten Latin American countries.

The Cordoba Declaration stated that the new version of the HD can seriously affect the safety, welfare and rights of people who participate as volunteers in medical research protocols in the world 22. The research ethics committees in most countries of Africa, where a significant number of clinical studies is carried out with international cooperation, are composed in their majority of properly "trained" members by sponsoring countries in accordance with the laws, rules and interests of those countries. Through "free" offers of intensive courses for the "training of young researchers from Latin America" (or "dressage courses," if readers prefer) the NIH and other U.S. agencies have been trying in recent years, also to attract the region researchers to its rules and ways of acting, unfortunately with the participation and support from technical and local bodies, as has happened in Argentina, Brazil, Chile, Peru and Venezuela.

Informed consent and social vulnerability

The informed consent forms (IC), known in Brazil as informed consent terms (ICT), were incorporated as mandatory in the analysis of international clinical research protocols, as if all the people who sign them were autonomous, with the known exceptions. But few are the studies that deepen the subject in common situations in

peripheral countries, for example, functional illiteracy - people who cannot interpret what they read, a topic that directly relates to social vulnerability.

Social vulnerability relates to the structure of people's daily lives. Among the situations that generate social vulnerability in research in peripheral countries, may be mentioned: the country's low research capacity; socioeconomic disparities in the population; low education level of people; inaccessibility to health services and specific vulnerabilities related to women and racial and ethnic issues, among others ²³.

The meaning of vulnerability leads to the social context of frailty, lack of protection, weakness, (un)favor - disadvantaged populations - and even abandonment, encompassing various forms of social exclusion, alienation or isolation of population groups with respect to benefits provided by development ²⁴. The use of ICT should be reviewed with respect to its real effectiveness, as in the peripheral countries socially vulnerable people sign documents without full knowledge of the circumstances and consequences of their act.

Moreover, international multicenter and complex studies with new drugs often have long ICT (some even with more than 20 pages), a fact observed by the author and informally supported by several CEP members throughout the country. These ICTs prove to be absolutely incomprehensible to ordinary citizens, hampering understanding by exactly the main stakeholders: the research subjects. Future bioethics propositions must promote the replacement of these ICT by simpler, direct and effective control forms through trained ethics committees, that are truly independent, active and present throughout the process of research and not only in the original protocol evaluation as usually happens in most cases, for example, in the committees accredited in Brazil.

Truly shared benefits

Article 15 of DUBDH defines that the sharing of the benefits of biomedical research is a duty that every Member State of the United Nations must commit to comply.

If rich countries were actually willing to make political decisions with such commitment, the theme could have profound implications for how future scientific policies and health strategies would be formulated worldwide. This means that: a) even when the studies were conducted in developed countries, they would be committed to sharing the benefits of this study, particularly with developing countries (Article 15 of DUBDH); b) for a comprehensive health strategy to become reality, the development of national research policies in the rich part of the world to include sustainable projects is necessary, so the benefits of their programs may be shared with developing nations, particularly in those poor countries with low economic income²⁵.

Article 13 of the Declaration, which deals with "solidarity and cooperation," proclaims that solidarity between human beings and international cooperation for this purpose should be stimulated1. International cooperation in bioethics, in turn, is justified in Article 15, which deals specifically with research with human beings, the commitment to consider the specific needs of developing countries, communities and vulnerable indigenous populations. While in Article 13 solidarity figures as the moral legitimacy value of international cooperation practices, Article 15 provides examples for effective sharing of benefits from research conducted in the field of science.

The solidarity expressed in DUBDH, therefore, requires a different look - both bilateral and horizontal - between people, groups or sectors that are in different historical and social situations, compared to which ones are trained to support others unselfishly, without being concerned with any material return or otherwise. And when this solidarity occurs between different countries - the most powerful and organized supports other interests in addition to really help in a situation of temporary or permanent fragility – we are up for a real framework for cooperation.

However, unfortunately there are constant reports on ancient and recent history in which the humanitarian actions of solidarity, offered by certain nations, only lent themselves to different forms of exploitation and to take advantage over time of those who, allegedly, were willing to "help," handicapping even more the people in need of support.

Social responsibility and health

This is a theme that both the U.S. and the European bioethics have historically set aside, except for a few more socially committed authors, such as Berlinguer²⁶, Callahan²⁷ and Daniels²⁸, until the UNESCO Universal Declaration on Bioethics and Human Rights gave it striking international visibility, incorporating to the context of responsibility the theme of the right of access to health for all people (Article 14).

The article considers that, in addition to define that promotion of health and social development should be the core goal of any democratic government, (to) enjoying the highest attainable standard of health is a fundamental right of every human being. This would require that the progress of science and technology should provide: a) access to quality health care and essential medicines, including those specifically for women and children's health, because health is essential to life itself and it must be regarded as a social and human asset; b) access to adequate nutrition and safe water; c) improvement of living conditions and environment; d) elimination of individuals' marginalization and exclusion for whatsoever reason; and e) reducing poverty and illiteracy 1.

A recent study developed in Brazil shows the original path traveled specifically by bioethics in formulating the country's indigenous lines of study and research, from the relationship between these lines and the historical process that consolidated the national Health Reform, which includes the issue of health as a factor social inclusion ²⁹. Theoretical categories emerged from this study, which are perfectly in line with Unesco's recommendations relating to the social dimension of the issue

and that relate to particularly vulnerable groups or segments; with the power relations based on the identification of social inequalities; with the quality of people's lives and with their own human rights ³⁰.

The universal access to health, thus, becomes part of the new century's bioethics agenda, seen as a right of citizenship, being the responsibility of the States to provide the minimum necessary for people to live with dignity. At this time of global corporate development, with so much science and technology available, health - as well as education - cannot continue to be seen as ordinary consumption objects accessible only to those privileged people who have material resources to acquire them, as if they were any commodity, available on the market.

Conflicts of interest

The power of the pharmaceutical market is an indisputable reality. The pharmaceutical industry ranges from first to fourth place among the main profitable activities in current world, only competing with the international big banks ³¹ and with the warfare weapons and drugs markets. In 2005, this industry's market moved about 590 billion dollars and only eight companies accounted for 40% of the global financial movement that year³².

In parallel, there are approximately 80 thousand representatives of pharmaceutical companies in the U.S., which gives a ratio of one representative for every 7.8 physicians' 33 a similar proportion was found in Germany, UK and France 34, which shows the degree of investment that companies make in advertising and sales promotion. All these data allow us to assess the severity of conflicts of interest involving the pharmaceutical industry, researchers and physicians, given that the industries sponsor studies, researchers are their executors, and doctors are those who apply the results to the population 35. Unfortunately, there are relatively few scientific papers produced in the field of bioethics that are concerned with analyzing such contradictions.

In this specific topic, one cannot fail to record the unbalanced composition of the National -

Technical Commission on Biotechnology (CTNBio), run by the Ministry of Science and Technology, responsible for analyzing the security and release to the market of genetically modified organisms (GMO). This committee is composed by more than 30 members, mostly researchers and technicians related to this field of knowledge. Despite being linked to public universities, many of them keep commitments work publicly known multinational companies, (which are) directly interested in the subject, such as Monsanto, Pfizer and others. I believe that this flagrant conflict of interest in such a situation is unequivocal because the judging individual (person who judges) is the same one involved in the production of those products subject of discussion for market release.

Still regarding CTNBio, it is necessary to stress that the few representatives from (of) the so called social control sector, that formed its original composition, abandoned it already in the early days of its operation because they had their minority positions repeatedly repealed in unbalanced discussions and votes recorded in said agency. It is worth noting also that bioethics representatives were never part or even invited to the commission - a fact seen as natural, routine, and even essential in similar commissions that exist in developed nations.

Measures and changes needed to meet the old and new problems

New theoretical and practical measures became necessary and even indispensable for bioethics to continue (to maintain) maintaining, at this beginning of the century, its international corporate and academic acceptance to strengthen itself and be able to(o) meet the new and old problems, as well as the challenges facing this historic moment through which the globalized world is going through.

1. Effective use of the Universal Declaration on Bioethics and Human Rights principles and benchmarks

The principles and references contained in DUBDH should be pursued by countries, institutions, and people who agree with them

While it is correct to say that international declarations do not have absolute and uniform internal legal effect on all domestic legislations, it is unquestionable that they have legal value, which affects all States. Therefore, they have a high advisory and educational value character ³⁶. To Andruet, it is possible to say that this legal value has now turned into legal force ³⁷.

Despite the historic strength of the nonbinding standard expression to define the content of statements, it is desirable that this content shall start to be interpreted as an indirect part of the national laws, according to Gross-Espiell 38. A positive initiative in order to give more strength to the principles contained in the Declaration is related to the stimulus for organizing neighboring countries groups' official forums to construct regional agreements (MERCOSUR, for example). Such a legitimacy that, although not yet achieving the force of law, goes beyond the sense of non-binding standard, approaching recommendations for possible practical applications in the signatory countries themselves ³⁹. Over time, it would be desirable that - increasingly - countries would incorporate into their legislation the principles contained in the articles approved by them in the Declaration.

2. Construction of new international human protection frameworks

It is desirable that all problems mentioned herein and which refer to the differences observed in the living conditions of people from different places on the planet do not keep on happening in the near future, including for the very security of countries' inhabitants. The growing phenomenon of migration of millions of people from south to north is evidence of this new type of "insecurity". The world cannot any longer - morally live with the contradiction of having places where people live on average more than 80 years (Japan, USA, Western Europe) while in others they do not reach even 40 years (Burkina Faso, Sierra Leone etc).

It is essential, therefore, to create a new system of global justice that aims to reduce and eliminate exploitation and inequality towards a better sharing of benefits. In this sense, new international human protection frameworks, as well as those focused on better corporate organization, should begin to be built by the community of nations with the support of bioethics and its experts and representatives.

3. Construction, review and/or strengthening of national control standards and bioethics committees and ethics in research

International standards are essential to indicate the direction to be followed in the development of scientific research in each country. However, the particularities and needs of each country should - definitely - be considered so that, for example, clinical trials of diagnostic, preventive or therapeutic methods, such as globalized social activities, are carried out while respecting fundamental human rights ^{23,40}.

In addition to good regulation and control standards, it is essential that the ethical control mechanisms shall function properly and that the various ethics committees start to act in an increasingly active, participatory and, if necessary, intervening way. The presence of population social control (duly technically and ethically prepared) is indispensable in this context.

A recent example occurred in Peru, where until recently there were not any national ethical regulation on standards for research with human beings, until two officials from the Ministry of Health were enrolled in a distance learning course that UNESCO Redbioetica (UNESCO) promotes annually on the subject. As a final required course paper, they proposed a National Ethics Regulatory Program for Research in the country. These students reported that, in spite of the huge backlash by the drug companies and medical professionals related to them, that were used to work with the support of some so-called "independent research ethics committees," the Minister of Health, with the President's support, nationally implemented

the proposal, which is in full operation, preventing abuses practiced until then in this country against the most vulnerable individuals, especially those who participated in clinical trials.

4. Establishment of reliable and balanced references in the construction of a new bioethics' discourse and practice

Some measures are necessary to enable coping in the future with new problems and to update and strengthen the joint building capacity (capacity building). Accordingly, certain categories or references are indispensable for the achievement of concrete and useful objectives. Among others, the following may be mentioned, which we proposed some time ago from the findings of seminars developed by Redbioetica UNESCO: dialogue, argumentation, rationality, coherence, consensus, and decision, 41,42 explained below.

Dialogue

It is the exchange or discussion of ideas, opinions and concepts for solving problems, understanding and harmony. The dialogue is aimed at mutual understanding between the parties. It is the exchange of ideas, opinions and information among the subjects ⁴³. In order for dialogue to exist, it is essential to reach minimal consensus ⁴⁴.

Argumentation

Argumentation is the means by which one attempts to prove or disprove a thesis, convincing the listener of its truth or falsity. It is any reason, proof, demonstration, evidence or motive capable to capture consent and induce persuasion or belief; it is the reason that is responsible for giving credibility to a doubtful topic.

Rationality

Rationalism is the recognition of the authority of reason. Reason, in turn, is the faculty of mind that consists in thinking consistently ⁴⁵. In rationalism, we admit a class of truths derived from the direct intuition of the intellect.

Expansion and politicization of the international bioethics

which are beyond the reach of sense's perception and which oppose empiricism. Rationality plays a decisive role in the discussions, preventing them from being sterile, and in the search for ethical consensus.

Coherence

Means order, harmony and connection within a system or set of knowledge, expressing the conformity of propositions to a criteria rule. The argument is considered to be consistent when its parts are connected together, particularly when such relation is in accordance with a pattern or model. It is frequent to regard consistent things as compatible⁴⁶. The bioethical discourse and practices should be consistent.

Consensus

It refers to the existence of an agreement among members of a particular social unit with respect to principles, values, standards or objectives desired by a community, as well as the means to achieve them⁴⁷. There are degrees of consensus, because a complete consensus usually is not achieved. Consensus plays an important role in the development of public policies, for example, in setting health priorities in the face of an inadequate budget. The different types of ethics and bioethics committees or boards often need to build consensus from differences. Both arguments such as rationality, dialogue and consistency are important theoretical and practical tools in the search for consensus.

Decision

It is the act of defining the position taken collectively by a commission or committee, through dialogue and reaching consensus, and effectively bringing it to practical application in reality,

so that analyzed problems are solved effectively.

Final considerations

With the emergence of bioethics in the mid 1970's, it is undeniable to record that significant progress took place regarding the construction and application of theoretical and methodological proposals in the field of applied ethics, in order to improve the lives and livelihoods of people and communities on the planet, according to the original goals of this new territory of scientific knowledge. The recent economic and sociopolitical world crisis brought to the surface enormous moral contradictions with regard to individual and public behaviors worldwide, making it necessary for bioethics to update its calendar and be incorporated alongside the democratic sectors fighting for decreased injustice and the right of access for the largest possible number of people and communities to the benefits of scientific and technological development.

In the macro sense of ethical and sociological analyses, this means that instead of continuing to propose an ethical universalism from the core countries that, in most cases, reaches the peripheral countries with the airs and force of true moral imperialism 48 with articulate and exported ideas without the necessary filter and context adaptation to the needs of the least developed nations, it is essential that a new bioethics, more dynamic and politicized, build and put at the disposal of nations of minimum and communities, needing most consumer goods for human survival, a set of concrete theoretical tools, and scientific methods which, while respecting the historic diversity of each place, enables the pursuit of their own destinies in a cooperative manner, without spurious interference and with due dignity.

Article developed from a lecture at the opening roundtable of the IX Brazilian Congress of Bioethics, held in Brasilia, Federal District on 08.09.2011.

References

- Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração Universal sobre Bioética e Direitos Humanos [internet]. Genebra: Unesco; 2005 [acesso 30 ago 2009]. Disponível: hOp://unesdoc.unesco.org/images/0014/001461/146180por.pdf
- 2. Garrafa V, Pessini L. Bioeica: poder e injusiça. São Paulo: Loyola; 2003.
- 3. PoOer VR. Bioethics: a bridge to the future. New Jersey: Prenice-Hall; 1971.
- 4. Wickler D. Combinação bioeica e poliica. In: Garrafa V, Pessini L. Op. cit. p. 15-6.
- 5. Benatar S. Discurso do presidente. In: Garrafa V, Pessini L. Op. cit. p. 25-33.
- Garrafa V, Porto D. Intervenion bioethics: a proposal for peripheral countries in a context of power and injusice. Bioethics. 2003:17(5-6):399-416.
- 7. Campbell A. President's Column. IAB News. 1998; 7 (Spring):1-2.
- Berlinguer G. Apresentação. In: Garrafa V. Dimensão da eica em saüde püblica. São Paulo: Faculdade de Saüde Püblica USP/Kellogg Foundaion; 1995. p. i-iii.
- 9. Schramm FR. Bioeica: a terceira margem da saüde. Brasilia: Editora UnB; 1996.
- Fortes PAC. lica e saüde: questOeseicas, deontolégicas e legais, tomadas de decisOes, autonomia e direitos do paciente: estudo de casos. São Paulo: EPU; 1998.
- 11. Caccia-Bava S. Bem-vindas as novas ideias. Le Monde Diplomaique-Brasil. 2009;27:3.
- 12. Foucault M. Nascimento da biopoliica. São Paulo: Marins Fontes; 2009.
- 13. Garrafa V. Redbioeica: una iniciaiva de Unesco para America Laina y el Caribe. Rev Redbioeica. 2010;1(1):4-16.
- 14. Carta de Buenos Aires sobre Bioeica y Derechos Humanos. Secretaria de Derechos Humanos de Argenina/Redbioeica Unesco. Revista Brasileira de Bioeica. 2005;1(3):317-22.
- 15. Garrafa V. Redbioeica: a Unesco iniiaive for Lain-America and Caribbean. 16th Session of the Internaional Bioethics CommiOee of the Unesco; 23-25 nov 2009; Mexico City.
- Landmann N, Schücklenk U. From the Editors Unesco 'declares' universals on bioethics and human rights - many unexpected universal truths unearthed by UN body. Dev World Bioeth. 2005;5(3): iii-vi.
- 17. Williams JR. Universal draft declaraion on bioethics and human rights. Dev World Bioeth. 2005;5(3):210-5.
- 18. Benatar D. The trouble with universal declaraions. Dev World Bioeth. 2005;5(3):220-4.
- 19. Gracia D. La declaracién universal sobre bioeica y derechos humanos: algunas claves para su lectura. In: Gross-Espiell H, Gémez-Sánchez Y, organizadores. Declaracién Universal sobre Bioeica y Derechos Humanos de la Unesco. Granada: Editorial Comares; 2006. p. 9-27.
- Chirac P, Torreele E. Global framework on essenial health R&D. Lancet. 2006;367(9522): 1.560-1.
- 21. Garrafa V, Solbakk JH, Vidal S, Lorenzo C. Between the needy and the greedy: the quest for a just and fair ethics of clinical research. J Med Ethics. 2010;36(8):500-4.
- 22. Associação Medica Mundial. Carta de Cérdoba sobre lica en Invesigacién con Seres Humanos. Revista Brasileira de Bioeica. 2008;4(3-4):81.
- 23. Lorenzo C. Los instrumentos normaivos en eica de la invesigacién en seres humanos en America Laina: análisis de su potencial eficácia. In: Keyeux G, Penchaszadeh V, Saada A, coordenadores. Iica de la invesigacion en seres humanos y poliicas de salud püblica. Bogotá: Universidad Nacional de Colombia/Redbioeica Unesco; 2006. p. 167-90.
- Garrafa V, Prado MM. Tentaivas de mudanças na Declaração de Helsinki: fundamentalismo econâmico, imperialismo eico e controle social. Cad Saüde Püblica. 2001;17(6):1489-96.
- Lorenzo C, Garrafa V, Solbakk JH, Vidal S. Hidden risks associated with clinical trials in developing countries. J Med Ethics. 2010; 36(2):111-5.
- 26. Berlinguer G. Quesioni di vita: eica, scienza, salute. Torino: Einaidi; 1991.
- 27. Chanson MJ, Callahan D, editors. The goals of medicine: the forgoOen issues in health care reform. Washington: Georgetown University Press; 1999.
- 28. Daniels N. Just health care. New York: Cambridge Univertsity Press; 1985.
- Porto D. Bioeica e qualidade de vida: as bases da pirâmide social no coração do Brasil [tese].
 Brasilia: Universidade de Brasilia; 2006.
- 30. Porto D, Garrafa V. A infiuência da reforma sanitária na construção das bioeicas brasileiras. Ciênc Saüde Coleiva. 2011;16 (Supl 1):719-29.
- 31. St-Onge JC. L'envers de la pilule: le dessous de l'industrie pharmaceuique. 2^e ed. Montreal: Les Ediions Ecosociete; 2008.
- 32. Mello DR, Couinho A, Santos GE, Araüjo T. Análise bioeica do papel do estado na garania ao acesso a medicamentos. In: Garrafa V, Mello DR, Porto D, organizadores. Bio9:ca e vigilância sanitária. Brasilia: Anvisa/Cátedra Unesco de Bio9:ca da UnB; 2007. p.15-34.
- 33. Moynihan R. Who pays for the pizza? Redefining the rela:onship between doctors and drug companies. 1: entanglement. Brit Med J. 2003;326(7400):1189-92.
- 34. Willerroider M. Making the move into drug sales. Nature. 2004;430(9698):486-7.

Expansion and politicization of the international bioethics

- 35. Lorenzo C, Garrafa V. Ensayos clinicos, estado y sociedad: donde termina la ciencia y empieza el negocio? Salud ColecGva. 2011;7(2):166-70.
- GOmez-Sánchez Y. La DeclaraciOn Universal sobre BioeGca y Derechos Humanos: un balance de su vigencia. In: Casado M, coordenadora. Sobre la dignidad y los principios: análisis de la DeclaraciOn Universal sobre BioeGca y Derechos Humanos de la Unesco. Madrid: Civitas; 2008. p. 565.
- 37. Andruet AS. Comunicabilidad de la Declaración Universal sobre BioeGca y Derechos Humanos en la legislación la Gnoamericana y del Caribe. 16th Session of the Interna Gonal Bioethics CommiZee of the Unesco; 23-25 nov 2009; Mexico City.
- 38. Gross-Espiell H. La DeclaraciOn Universal de BioeGca y Derechos Humanos de la Unesco y la DeclaraciOn de Santo Domingo sobre BioeGca y Derechos Humanos. Revista Brasileira de BioeGca. 2007;3(1):7-13.
- Garrafa V. Convenção Regional do Mercosul sobre BioeGca: uma proposta da Cátedra Unesco de BioeGca da UnB. In: Barbosa SN, organizador. BioeGca em debate: aqui e lá fora. Brasilia: Ipea; 2011. p. 147-55.
- Garrafa V, Lorenzo C. Helsinque 2008: redução de proteção e maximização de interesses privados. AMB Rev Assoc Med Bras. 2009;55(4):514-8.
- Garrafa V, Azambuja LEO. Epistemologia de la bioeGca: enfoque laGno-americano. Revista Brasileira de BioeGca. 2007;3(3):344-59.
- 42. Garrafa V, doZow M, Saada A, coordenadores. Estatuto epistemolOgico de la bioeGca. Mexico: Unam/Unesco; 2005.
- 43. Habermas J. La inclusiOn del otro. Barcelona: PaidOs; 2005.
- 44. Neri D. Filosofia moral. São Paulo: Loyola; 2004.
- 45. Bunge M. Dicionário de filosofia. São Paulo: PerspecGva; 2002.
- 46. Abbagnano N. Dicionário de filosofia. São Paulo: MarGns Fontes; 1999.
- 47. Post SG, editor. Encyclopedia of bioethics. New York: Thompson Gale; 2003. vol. 2.
- 48. Garrafa V, Lorenzo C. Moral imperialism and mulG-centric clinical trials in peripheral countries. Cad Saüde Püblica. 2008;24(10):2219-26.

