Commission of the Episcopates
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COMECE

Science & Ethics

volume 2

COLLECTION OF OPINIONS
PREPARED BY THE BIOETHICS REFLECTION GROUP

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Commission of the Episcopates of the European Community

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SEXUAL AND REPRODUCTIVE HEALTH
POST-COMA UNRESPONSIVENESS
HUMAN ENHANCEMENT
NON-COMMERCIALISATION OF THE HUMAN BODY

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INTRODUCTION

1. For more than thirty years now, COMECE, the Commission of the Bishops' Conferences of the European Union, which comprises 26 Bishops representing all Member States of the EU, has been accompanying the process of European integration, and offering its reflections. COMECE is now a partner of the EU institutions in the dialogue foreseen by Article 17 (3) of the Treaty on the Functioning of the EU. Its Secretariat monitors and analyses current EU policy and legislation concerning, *inter alia*, research, health and other matters with relevance to the field of bioethics.

2. Since 1996 the Secretariat of COMECE has maintained a Reflection Group on Bioethics comprising 15 Bioethics experts representing some of the Bishops' Conferences. Such experts provide a rich exchange of views facilitated by their multi-disciplinary backgrounds including theological, philosophical, legal, medical and other scientific disciplines. Members meet twice a year to discuss the impact of scientific advances and biotechnological innovations for mankind. This is done normally with the contribution of invited external experts, either from the EU institutions or other entities.

3. The present booklet brings together the formal outcomes, in Opinions (and one Report) of the meetings of the Group held in 2008 and 2009, already available online at www.comece.eu. It follows a first publication, volume number one, assembling previous Opinions issued in the period 1996 to 2007. The subjects covered now include *non-commercialisation of the human body, human enhancement, state of post-coma responsiveness* and so-called *sexual and reproductive health*. Nevertheless, in all cases, the bottom line is always human dignity.

4. The Catholic faith has throughout the ages stimulated scientific advances and technological developments. On the one hand, the knowledge of our surrounding reality, considered a sign of God Himself, was always understood, indeed, as a deepening of the divine mystery; and, on the other hand, human beings are seen as co-creators who imprint a specific dynamic of change on the world. These activities, however, should neither violate the natural order of reality itself, which is an expression of the infinitely good and wise will of God, nor human dignity which stems, in the final analysis, from the divine affiliation. In the same sense it is enshrined in Article 2 of the Convention of Oviedo that the "*interests and welfare of the human being shall prevail over the sole interest of society or science*."

5. The present reflections are directed towards firstly Catholic people, especially those who shall serve God and the common good by directly taking care of the *res publica*. These reflections, underpinned as they are by a deep anthropology, should however also arouse the interest of all men of good will, engaged in a frank, non-prejudiced and constructive dialogue, as relativism should never be the price of the consensus longed for in such a fundamental field.

February 2012

Mgr. Piotr Mazurkiewicz

Secretary General of COMECE

REPORT FOLLOWED BY AN OPINION
OF THE BIOETHICS REFLECTION GROUP

THE TERM 'SEXUAL AND REPRODUCTIVE HEALTH' AND ITS MEANING AT INTERNATIONAL AND EUROPEAN LEVELS

MEETING OF 22 MARCH 2010

EXECUTIVE SUMMARY AND RECOMMENDATIONS

Whereas

i) The term '*sexual and reproductive health*' is deeply ambiguous, for the reasons given below.

ii) This term was coined to legitimise international action and pressure to curb demographic growth, and it is now used, in the name of health, to legitimise abortion and other highly contentious practices[1], without being clearly defined, giving rise to deep ambiguity.

iii) Under the concept of '*sexual and reproductive health*', abortion appears unduly as a right, in contradiction with a strict interpretation of international law and European legislation.

iv) There is even a movement – involving several international organisations and UN agencies, and above all the bodies that monitor the application of treaties and conventions and certain NGOs – that seeks abusively to exploit this ambiguity in order to promote abortion, either through legislation, as a right, or at a practical level, by expanding access to abortion services.

v) Therefore, when the term '*sexual and reproductive health*' is used, it is usually interpreted subsequently by the agents of this movement in the above-mentioned sense, which prompts political decision-makers of different countries to do the same.

vi) The repeated use of the term – in declarations, resolutions, recommendations, etc. – tends to bring the phrase into common use and contributes, through customary law, to the establishment of a 'right', despite the reservations made by many countries, the primary actors in international law, and although it is not mentioned in any convention or universal international treaty.

Because of these considerations, it is highly recommended:

vii) To refrain from using the terms '*sexual and reproductive health*' or '*sexual and reproductive healthcare*' in the official documents of the European Union; to

1 The major passages of the Report and Opinion also apply to practices such as sterilisation or recognition of a 'right of the child' in the name of what is referred to as '*sexual and reproductive health*'.

vote against its use or for its deletion whenever its use is included in any draft official document.

viii) Also to refrain from the use of similar and even more problematic terms such as 'reproductive services' or 'sexual and reproductive rights'.

ix) To replace these terms, where they are used in draft texts, with the expressions 'health of the mother and child' or 'maternal and child health', which are more appropriate expressions that are less subject to ideological use.

x) To stipulate that the term adopted as a replacement excludes destructive interventions, such as abortion, which compromise prenatal and postnatal care or even the future of the unborn child, as well as the health, wellbeing and dignity of the mother.

xi) Where it is not possible, in a specific case, to avoid the use of the term '*sexual and reproductive health*' (or 'sexual and reproductive healthcare', 'services' or 'rights'), to clearly stipulate that, in accordance with international law and European legislation, this expression does not include destructive interventions such as abortion (as in x *supra*).

xii) To ensure that such terms are translated in such a way that the above-mentioned ambiguities are not re-introduced through biased expressions in other languages. It might be useful in such cases to refer to the clarification given above (in x *supra*).

xiii) To ensure that the European Union does not exceed its competences in matters of health, as established in Article 168 of the Treaty of the Functioning of the European Union. Such competences are strictly defined – with regard to the ample responsibilities of Member States in this field – and evidently include no competence relating to abortion.

REPORT

1. INTRODUCTION

On 25 February 2010, the European Parliament adopted a Resolution in which it "[*stresses] that sexual and reproductive health and rights are an integral part of the women's rights agenda, and that it is essential to step up efforts to improve women's reproductive rights and health, both in Europe and globally*"[2]. This Resolution made reference to the Fourth World Conference on Women that took place fifteen years earlier in Beijing, in September 1995, and issued proposals on the efforts to be made to achieve the objectives set by the Programme of Action drawn up at the Conference, in particular 'gender equality' between women and men and the elimination of all forms of discrimination against women.

In 2010 the European Parliament adopted other similar declarations[3]. In 2006, the European Parliament and the Council had adopted a Regulation laying down general provisions establishing a European Neighbourhood and Partnership Instrument, with fields of cooperation that included "*supporting policies to promote health, education and training*", which included not only measures to control the main diseases, but also "*access to services and education for good health, including reproductive and infant health for girls and women*"[4]. Another Regulation was adopted in the same year on financing health development cooperation in certain countries "*with a central focus on the related Millennium Development Goals*

2 Resolution of the European Parliament of 25 February 2010 on Pekin + 15 – United Nations Platform for action on Women's rights and gender equality, paragraph 9. http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B7-2010-0118&language=EN.

3 Resolution of the European Parliament of 10 February 2010 on equality between women and men in the European Union, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0021+0+DOC+XML+V0//EN; Resolution of the European Parliament of 25 March 2010 on the effects of the global financial and economic crisis on developing countries and on development cooperation, http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2010-0089&language=EN. Taking a different stance, the Resolution of the European Parliament of 16 December 2010 on the Annual Report on Human Rights in the World 2009 and the European Union's policy on the matter, which in paragraph 93 calls for "*an increase in the attention devoted to the child's needs (…) including appropriate legal protection, before as well as after the birth, as foreseen by both the Convention on the Rights of the Child and the Declaration of the Rights of the Child*" (http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0489+0+DOC+XML+V0//EN.

4 Regulation (EC) no. 1638/2006 of the European Parliament and of Council of 18 December 2006, ec.europa.eu/world/enp/pdf/oj_l310_en.pdf.

(MDGs), namely reducing child mortality, improving maternal and child health and sexual and reproductive health and rights as set out in the Cairo Agenda of the International Conference on Population and Development (ICPD), addressing poverty diseases, in particular HIV/AIDS, tuberculosis and malaria"[5]. *According to the same Regulation, under the thematic programme "Investment in Human Resources*" funding has been set aside for actions in the domains of "*actions to improve reproductive and sexual health in developing countries and to secure the right of women, men and adolescents to good reproductive and sexual health and provide financial assistance and appropriate expertise with a view to promoting a holistic approach to, and the recognition of, reproductive and sexual health and rights as defined in the ICPD Programme of Action, including safe motherhood and universal access to a comprehensive range of safe and reliable reproductive and sexual health care and services, supplies, education and information, including information on all kinds of family planning*".

It is important to note that the fifth MDG – improving maternal health – in concrete terms means "*reducing by three quarters the maternal mortality ratio between 1990 and 2015*" and "*achieving universal access to reproductive health services between now and 2015*". Notwithstanding other situations that cause maternal mortality, the emphasis was placed on controlling 'unsafe abortion' (an expression introduced by the Cairo Programme of Action), establishing a link between safe abortion and legal abortion. However, according to the World Health Organization, 'unsafe abortion' is the cause of only 13% of cases of maternal mortality.

Prior to this, on 25 June 2005, the first amendment of the Partnership Agreement between the ACP countries and the European Union signed in Cotonou on 23 June 2000, introduced in Article 25 on development of the social sector, among the cooperation objectives, one of promoting HIV/AIDS control, while safeguarding sexual and reproductive health and women's rights. The term '*sexual and reproductive health*' thereby entered into the official language of the European Union in matters of external relations.

5 Regulation (EC) no. 1905/2006 of the European Parliament and of the Council of 18 December 2006 establishing a financing instrument for development cooperation, http://eur-lex.europa.eu/lex/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0041:0071:EN:PDF. This Regulation replaced Regulation (EC) no. 1567/2003 of the European Parliament and of the Council of 15 July 2003 on aid for policies and actions on reproductive and sexual health and rights in developing countries. This Regulation provides an example of the poor quality of the legislative process which always results from references made to the "Cairo Agenda of the International Conference on Population and Development" (1994) or to the 'Millennium goals' (see Article 4, 2, b), i)), because these texts contain ambiguous expressions such as '*sexual and reproductive health*' (see below).

Just like any innovation in legal language, this raises questions. In the above-mentioned texts, what does the term '*sexual and reproductive health*' mean? Where does it come from, in what context, and for what reasons was it coined? Is it clearly defined, or is it used today in various senses to cover different realities depending on the authors and bodies that promote its use? Is the field it covers quite diverse and extensive? Does it imply specific rights, as the passage quoted from the Resolution of 25 February seems to indicate? In this case, are these already recognised fundamental human rights, or will it be necessary to recognise them as new fundamental human rights?

2. MANY SERIOUS HEALTH PROBLEMS

Although the English language term '*sexual and reproductive health*' now seems to be well and truly established; in the French versions of official texts we find two different expressions: '*santé sexuelle et reproductive*' (or '*génésique*') and '*santé en matière de sexualité et de reproduction*'. The second has the advantage – and the ambiguity – of not appearing to be a technical term, and to indicate a broad domain that covers many serious health problems.

According to UNICEF, in 2007 more than 9.2 million children under the age of five died of largely preventable diseases. Malnutrition, poor hygiene and the lack of access to safe water contribute to more than half of these deaths. Two thirds of both neonatal and young child deaths — over 6 million deaths every year — are preventable.

Half a million women die in pregnancy each year, most during delivery or in the first few days thereafter. There are birth-related disabilities that affect many more women and go untreated like injuries to pelvic muscles and organs or to the spinal cord[6].

Existing low-cost, low-technology and high-impact interventions such as vaccines, antibiotics, micronutrient supplementation, insecticide-treated bednets, improved breastfeeding practices and adoption of safe hygiene practices can prevent unnecessary maternal and child deaths and reduce malnutrition[7].

In addition, in the developing countries almost half of births are not attended by qualified personnel. Their safety could be significantly improved by the presence of a trained provider with midwifery skills and transport to referral services where emergency obstetric care can be provided[8]. Millions of lives could be saved in this way.

There is clearly much to be done in developing countries for the health of mothers, infants and children. And much to do also throughout the world to host, support and care for women victims of physical or sexual violence, to inform them about

6 Cf. UNICEF, Child survival and development, http://www.unicef.org/childsurvival/index.html.

7 *Ibidem*.

8 Cf. UNICEF, Goal: improve maternal health, http ://www.unicef.org/mdg/index_maternalhealth.htm.

sexually transmitted diseases and how to prevent them, and where necessary to screen for them and provide care. Although they are still insufficient, the efforts already made have resulted in a reduction in perinatal mortality and rapid demographic growth in some countries, which raises the issue in a new form of responsible parenthood and the means used to achieve this objective. Abortion remains widely practiced in many countries, in defiance of the right to life of many unborn children. Whether it is legal or not, it has heavy consequences for the health and even the life of their mothers. Undeniably there are many health, legal and moral problems in the fields of human sexuality and reproduction.

3. THE CONCEPT OF '*SEXUAL AND REPRODUCTIVE HEALTH*' AND ITS ORIGINS

These health, legal and moral problems are now widely mentioned in the reports, recommendations and action plans drawn up by various United Nations agencies under the single heading of '*sexual and reproductive health*'. This is often associated with the expression 'sexual and reproductive rights'. This makes one wonder whether these texts demonstrate an express desire to reduce these problems to the health dimension alone, and to base rights on this same concept of health, excluding any other moral or legal consideration.

The initial preoccupation seems to have been the growth in world population rather than health! The term 'reproductive health' appeared during the 1960s in scientific reviews (gynaecological reviews in particular) or publications engaged in the promotion and dissemination of family planning. At the outset it was intended to control births worldwide in response to very rapid demographic growth, frequently overlooking the fact that such growth is also, if not mainly, the result of a reduction in mortality rates. The aim could be described as neo-Malthusian[9]. It soon became one of the priorities of the UN and its agencies.

Since its foundation, the UN has been conducting demographic surveys and has displayed great concern about population issues. In 1947 the Commission on Population was founded; then in 1969 the United Nations Population Fund (UNFPA), one of the aims of which was to help governments to formulate demographic policies. "*In the 1960s, however, the extraordinarily rapid rate at which the world's population was growing became an urgent concern*"[10], states the Encyclopedia of the Nations, published by the United Nations.

The First World Conference on Population, which took place in Bucharest in 1974, adopted a global plan of action that stressed the relationship between population

9 Cf. Lino CECCONE, Santé reproductive, in: *Conseil pontifical pour la famille, Lexique des termes ambigus et controversés sur la vie, la famille et les questions éthiques*, Paris, Éditions Téqui, 2005, p. 899-903.

10 Technical cooperation programmes – United Nations Population Fund (UNFPA), http://www.nationsencyclopedia.com/United-Nations/Technical-Cooperation-Programs-UNITED-NATIONS-POPULATION-FUND-UNFPA.html.

factors and economic and social development. The General Assembly affirmed that this plan was an instrument of the international community for the promotion of economic development[11]. 'Birth control' and 'family planning' were therefore officially first put to work in the interests not of married couples, but rather in order to limit world population which, according to this point of view, is a means to development in the different countries.

There was a widespread conviction at this time that it was not enough to draw up plans and allocate resources to a global fund. No results could be achieved without the active participation of the population, and in particular women. It was therefore necessary to persuade them, allow them to participate in private and public decision-making, and therefore to give them the possibility of access to a sufficient level of education.

In 1974, a memorandum from the United States National Security Council called for an in-depth study of the impact of world population growth on American security and international interests[12]. The response came up with a raft of recommendations. It set targets for reductions in world population growth rates and recommended the development of family planning services and the educational level of the population – in particular that of women – in countries with very strong demographic growth rates. At the same time, it warned against the distrust that would lead in certain countries to the conviction that this demographic policy had 'imperialist motivations'[13]. It was necessary to avoid giving rise to suspicions that the developed countries were seeking to ensure their supremacy over other countries. The Report therefore recommended frequent reminding that the aid addressed the dual concerns of making effective "*the right of the individual couple to determine freely and responsibly their number and spacing of children*"[14], and combating poverty due, according to the Report, to an excessively high birth rate.

Here we see the emergence of the language of the rights of couples. The political objective – to limit demographic growth to safeguard world stability – is formulated as the right of the individual couple to 'family planning'.

11 *Ibidem*.

12 Cf. Stephen D. MUMFORD, The Life and Death of NSSM 200, Chap. 3 : The NSSM 200 Directive and the Study Requested, www.population-security.org/11-CH3.html.

13 The NSSM 200 Directive, cited by: Stephen D. MUMFORD, The Life and Death of NSSM 200, Part 2, Policy Recommendations. www.population-security.org/28-APP2B.html.

14 *Ibidem*.

This was followed by a proliferation of international conferences stressing the correlation between, on the one hand, development and environmental problems and demographic growth, and on the other the health and wellbeing of individuals and the recognition of women's rights. The first international conference explicitly dedicated to women was held in Mexico in 1975, which was declared as International Women's Year. In his opening address, the Secretary General of the Conference, Mrs Sipilä, declared that it was high time to note that the denial of women's rights and opportunities was at the root of our development problems and socio-economic ills, including illiteracy, malnutrition, mass poverty and uncontrolled population growth.

In 1984, during the International Conference on Population in Mexico, it was decided to intensify international cooperation and seek greater efficacy on demographic issues. Several recommendations were drawn up with this purpose: access for all, including adolescents, to family planning, the involvement of governments and cooperation with Non-Governmental Organisations (NGOs), whose role is deemed important. According to Article 11 of the final declaration, "*improving the status of women and enhancing their role is an important goal in itself and will also influence family life and size in a positive way.*"[15]

The Rio summit, organised by the United Nations in 1992, highlighted demographic trends and factors because of their influence on the environment and on development, and called on countries to apply appropriate policies and action programmes, seeing them as a means of achieving "*good health; improving the quality of life of the people; improvement of the status and income of women*"[16].

All these international meetings therefore display the same concerns: world population growth and the difficulty of curbing it. This is combined with health considerations, especially women's health seen as both the outcome of demographic control and as an argument for obtaining the cooperation of the population in efforts to control demographics. Increasingly individualist perspectives are introduced, with the emphasis no longer on the decisions of spouses, but on the sexual behaviour of individuals from adolescence onwards.

15 United Nations, Report of the International Conference on Population, Mexico City, 1984, Declaration, Article 11, http://www.choike.org/documentos/conf/ICP_mexico84_report.pdf.

16 UN Department of Economic and Social Affairs, Division for Sustainable Development, Action 21: Chapter 5, Demographic Dynamics & Sustainability, § 5.16, http://www.un.org/esa/dsd/agenda21/res_agenda21_05.shtml.

4. THE CAIRO CONFERENCE

The International Conference on Population and Development, held in Cairo in September 1994, marked a real turning point. The term 'reproductive health' was explicitly given pride of place. Of the sixteen chapters in the Programme of Action, an entire chapter is devoted to it.

"*Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this last condition are the right of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law*[17]*, and the right of access to appropriate health-care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant. In line with the above definition of reproductive health, reproductive health care is defined as the constellation of methods, techniques and services that contribute to reproductive health and well-being by preventing and solving reproductive health problems. It also includes sexual health, the purpose of which is the enhancement of life and personal relations, and not merely counselling and care related to reproduction and sexually transmitted diseases*"[18]. However the Programme of Action also stipulates that "*Governments should take appropriate steps to help women avoid abortion, which in no case should be promoted as a method of family planning*"[19].

Defined in this way, the concept of 'reproductive health' extends its scope to the wellbeing of the person in every aspect of sexuality and procreation. How can healthcare services take responsibility for resolving all problems in these fields and

17 This implicitly refers to abortion, where it is not against the laws of the country.

18 Report of the International Conference on Population and Development, Cairo, 1994. Programme of Action, Chapter 7, Reproductive rights and reproductive health, Principles of action, § 7.2, http://www.un.org/popin/icpd/conference/offeng/poa.html. Cf. also § 13.14. and § 8.25 of the Programme of Action. § 13.14.: "*Basic reproductive health services (…) would include the following major components, which should be integrated into national basic programmes for population and reproductive health: (…) b) (…) abortion,(as specified in paragraph 8.25*". § 8.25.: "*In circumstances where abortion is not against the law, such abortion should be safe*".

19 *Ibidem*, § 7.24.

ensure 'general wellbeing' in terms of sexuality? In a written note submitted at the end of the Cairo Conference, the delegation of the Holy See warned against such an extension of the term and declared that the Holy See "*will continue to work, along with others, towards the evolution of a more precise definition of this and other terms*"[20].

Such a question merits all the more for being posed as the text goes on to discuss fundamental rights. "*Bearing in mind the above definition, reproductive rights embrace certain human rights that are already recognized in national laws, international human rights documents and other consensus documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health*"[21].

The delegation of the Holy See stated that the "*final document (…) recognizes abortion as a dimension of population policy and, indeed of primary health care, even though it does stress that abortion should not be promoted as means of family planning and urges nations to find alternatives to abortion. The preamble implies that the document does not contain the affirmation of a new internationally recognized right to abortion*"[22]. It then expressed a reservation, saying that regarding "*the terms 'sexual health' and 'sexual rights', and 'reproductive health' and 'reproductive rights', the Holy See considers these terms as applying to a holistic concept of health, which embrace, each in their own way, the person in the entirety of his or her personality, mind and body, and which foster the achievement of personal maturity in sexuality and in the mutual love and decision-making that characterize the conjugal relationship in accordance with moral norms. The Holy See does not consider abortion or access to abortion as a dimension of these terms*"[23].

The text achieved by consensus (with many reservations voiced by various countries) does not in itself have the force of international law. It has never been ratified by the various countries, but resorts to affirmations. From international conference to international conference we see such affirmations being reiterated. In the hope, no doubt, that one day they will be included in a convention and acquire full legal force! It is vital that all those who collaborate in drafting texts with legal force do not allow themselves to be influenced by such repetition without

20 *Ibidem*, Chapter 5, Adoption of the programme of action, § 27.

21 *Ibidem*, Programme of Action, § 7.3.

22 *Ibidem*, Chapter 5, Adoption of the programme of action, § 27.

23 *Ibidem*.

considering both whether they are well founded and their non-binding nature. When a United Nations document is accepted by consensus at an international conference it gains a degree of authority, without being binding on nations or prevailing over their legislation.

The accumulation of resolutions, declarations and recommendations, such as those mentioned in this Opinion, whether they are adopted by international conferences or by the internal organs of international organisations, coalesce to form what is commonly referred to as 'soft law'. Together with the acts of the States themselves, such as the revision of domestic laws on abortion, they constitute precedents that are often repeated (objective element), and when they are backed by the legal conviction of their binding nature (*opinio juris*, subjective element), they can lead to the formation of customary international law. In this domain, the treaty monitoring bodies (e.g. the United Nations Human Rights Council, the Committee on the Elimination of Discrimination against Women or the Council of Europe Commissioner for Human Rights) have a special role, with frequent recourse to an evolving interpretation, deriving 'new rights' from those expressly enshrined in international legal texts[24] [25] .

The practical result of this is the emergence of a strong and rapid trend of revision by States of domestic laws on abortion, resulting in decriminalisation and increasingly easy access to abortion in an attempt to make it international law. Many countries have amended their legislation on abortion during the past decade; today some forty countries completely prohibit the practice or only allow it where the life of the mother is in danger, and around twenty others are a little more permissive, also allowing abortion in cases of rape or incest.

24 See also the " WHO regional strategy on sexual and reproductive health", 2001 (http://www.euro.who.int/en/what-we-do/health-topics/Life-stages/sexual-and-reproductive-health/publications/pre-2007/who-regional-strategy-on-sexual-and-reproductive-health), which, on page 8, establishes a link between the expression 'fertility regulation' – to which reference is made in the Programme of Action of the Cairo Conference (Chapter 7, Reproductive health and reproductive rights, Principles of action, § 7.2, mentioned above) in the context of the definition of 'reproductive health' - and 'abortion' in the following terms: "*Meeting these objectives (in the field of reproductive health) will subsequently lead to a reduction of the need for women to rely on abortion as a method of fertility regulation*".

25 The San Jose Articles (http://www.sanjosearticles.com/?page_id=2), approved and signed in 2011 by a number of experts from various disciplines, stipulate clearly that "*Treaty monitoring bodies have no authority, either under the treaties that created them or under general international law, to interpret these treaties in ways that create new state obligations or that alter the substance of the treaties. Accordingly, any such body that interprets a treaty to include a right to abortion acts beyond its authority and contrary to its mandate. Such ultra vires acts do not create any legal obligations for states parties to the treaty, nor should states accept them as contributing to the formation of new customary international law*" (Article 6).

This will also have an impact on the jurisprudence of courts such as the European Court of Human Rights, which at present has given the States a broad margin of appreciation in the field of abortion, as there is still a certain diversity of legal solutions on this subject[26].

26 Notwithstanding, Article 6, paragraph 3, of the Treaty on European Union, establishes that "*The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law*".

5 THE BEIJING CONFERENCE

One year later, in September 1995, Beijing hosted the Fourth World Conference on Women, which would be at least as influential as the Cairo Conference. The objectives of sustainable development and environmental protection were not forgotten, but a large part of the discussions and recommendations was devoted to combating all forms of discrimination against women and the promotion of equality and power-sharing between women and men[27]. The representatives of the Holy See were able to affirm: "*Certainly, the living heart of these documents lies in their sections on the needs of women in poverty, on strategies for development, on literacy and education, on ending violence against women, on a culture of peace, and on access to employment, land, capital and technology. My delegation is pleased to note a close correspondence between these points and Catholic social teaching*"[28].

The delegation of the Holy See nevertheless issued very strong reservations concerning important passages in the Programme of Action, mainly because of their highly individualistic and libertarian orientation, and the lack of reflection on the morality of the means of controlling fertility. The Programme of Action certainly showed real concern for the vulnerability of women in sexual matters, the violence to which many are submitted, early marriage and the pressures on girls[29], and in general the unequal power relationships between the sexes[30], but it reiterates, using almost identical terms, what had been said about reproductive and sexual health in the Programme of Action of the Cairo Conference. The relationship and social dimension of human sexuality was not really taken into account in Beijing. In the text there are references to men, women, adolescents, young people and girls, but barely any mention of couples, marriage (except to protect against early or forced marriage) or the family. The exercise of sexuality is presented as an individual affair. All practices in this domain are put on the same level and are also approved, as long as they are '*satisfying and safe*'[31] for the individuals concerned. Sexual education for adolescents is virtually restricted to

27 United Nations, Report of the Fourth World Conference on Women, Beijing, 4-15 September 1995, http://www.un.org/womenwatch/daw/beijing/pdf/Beijing%20full%20report%20E.pdf.

28 Report of the Fourth World Conference on Women, Chapter V. Adoption of the Beijing Declaration and Platform for Action, Reservations and interpretative statements on the Beijing Declaration and Platform for Action, § 12.

29 Report of the Fourth World Conference on Women, Platform for Action, § 93.

30 *Ibidem*, § 98.

31 *Ibidem*, § 94.

sanitary information and to the provision of '*satisfactory services*'[32], while the role of parents is not mentioned at all[33].

Sanitary protection is thus presented as a primary value, to the detriment of any anthropological and moral reflection on human sexuality and its meaning. It is used to justify any means deemed likely to remedy whatever threatens health, such as '*unsafe abortions*'[34]. Admittedly, just like the Programme of Action of the Cairo Conference, the Beijing Platform for Action states that "*In no case should abortion be promoted as a method of family planning. […] Prevention of unwanted pregnancies must always be given the highest priority*"[35]. But, where family planning methods are not available or fail, and "*in circumstances where abortion is not against the law, such abortion should be safe*"[36]. The Platform for Action goes even further and recommends considering "*reviewing laws containing punitive measures against women who have undergone illegal abortions*"[37]. In this context, the Holy See, after recalling that Beijing Conference "*did not include the affirmation of new human rights*", reaffirms, with regard to the interpretation of the terms 'reproductive health', 'sexual health' and 'reproductive rights', that it "*does not consider abortion or abortion services to be a dimension of reproductive health or reproductive health services*"[38].

This summary, however brief, of the Platform for Action of the Beijing Conference enables us to see the fundamental ambiguities. Moreover, there remains much to be done in the field of true equality between women and men. Many of the recommendations put forward deserve to be approved. However a number of highly contentious recommendations were issued by the Conference. By giving pride of place to the poorly defined concept of '*sexual and reproductive health*', the Conference presented under this term an individualistic and reductionist vision of sexuality, granting women an illusory freedom, and remained silent on the gravity of certain moral issues, as well as certain legal, demographic and even

32 *Ibidem*, § 95.

33 *Ibidem*, § 107 e).

34 *Ibidem*, § 97.

35 *Ibidem*, § 106, k).

36 *Ibidem*.

37 *Ibidem*.

38 Report of the Fourth World Conference on Women, Chapter V. Adoption of the Beijing Declaration and Platform for Action, Reservations and interpretative statements on the Beijing Declaration and Platform for Action, § 12. Reservations similar to those mentioned in this point were recently made during the Fourth United Nations Conference on the Least Developed Countries, Istanbul, Turkey, 9-13 May 2011.

health problems. On the subject of abortion, emphasis was placed in the Platform for Action solely on the sanitary conditions for its implementation, overlooking the fact that it negates the right to life of the unborn child, and the potentially serious physical and mental consequences for the mother, whether or not it is a 'safe' abortion.

This prompted many countries to express clear reservations and call for great vigilance in the use of the terms '*sexual and reproductive health*', and even more for '*sexual and reproductive rights*'.

6. WHAT IS ITS LEGAL VALUE?

The Cairo and Beijing Conferences were not content to try to analyse the concept of '*sexual and reproductive health*' and issue recommendations. They sought to present '*sexual and reproductive health*' as a right and even to place them on the same footing as 'human rights'[39], which all countries are required to recognise. The validity of such an attempt should be challenged.

The term '*sexual and reproductive health*' has now entered into international law because of its mention in the Convention on the Rights of Persons with Disabilities[40]- recently ratified by the European Union – and the provisions of this Convention are binding on the States that have ratified it, where they have not stated any reservations. Article 25 states that "*States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. […]. In particular, States Parties shall provide persons with disabilities with the same range, quality and standard of free or affordable health care and programmes as provided to other persons, including in the area of sexual and reproductive health and population-based public health programmes*."

The interpretation to be given to this concept of '*sexual and reproductive health*', as employed in the Convention, cannot lead to the surreptitious and insidious introduction into the international legal order of new rights, in particular the right to abortion, which the States have never wished to introduce into any international convention[41].

Effectively, the special committee set up by the United Nations General Assembly when preparing for the Convention regularly stressed that the term sexual and reproductive health did not create any new human right or any new international

39 Beijing Platform for Action, § 95.

40 Office of the United Nations High Commissioner for Human Rights, Convention on the Rights of Persons with Disabilities, http://www2.ohchr.org/english/law/disabilities-convention.htm.

41 The Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, better known as the Maputo Protocol, includes a 'right to abortion' in the 'sexual and reproductive rights' referred to in Article 14, 2, c). Note however that this Charter is only regional in scope.

obligation for the States[42], and did not change the content of the right to healthcare, as found in Article 12 of the International Covenant on Economic, Social and Cultural Rights[43] and the United Nations Convention on the Rights of the Child[44].

In Article 12, the International Covenant requires the States to recognise "*the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*", and to take the necessary steps to ensure the reduction of the stillbirth rate and of infant mortality and to the healthy development of the child, improvements to hygiene, the prevention and treatment of epidemic, endemic and other diseases and, in general, access to medical services and medical attention in the event of sickness.

Similarly, the United Nations Convention on the Rights of the Child stipulates that "*States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services*". The Convention states that this consists mainly of appropriate pre-natal and post-natal health care for mothers, to diminish infant and child mortality, and to ensure the provision of necessary medical assistance and healthcare to all children, to fight disease and malnutrition, with emphasis on the development of primary health care[45].

These texts are clear. International law requires States to use all means at their disposal to develop public healthcare, fight malnutrition, develop primary healthcare, prevent disease, reduce maternal and infant mortality, and in general

42 Ad Hoc Committee on a Comprehensive and Integral International Convention on the Protection and Promotion of the Rights and Dignity of Persons with Disabilities, Report of the 7th session (New York, 16 January - 3 February 2006), Note 4, http://www.un.org/esa/socdev/enable/rights/ahc7report-e.htm: "*The Ad Hoc Committee notes that the use of the phrase 'sexual and reproductive health services' would not constitute recognition of any new international law obligations or human rights. The Ad Hoc Committee understands draft paragraph (a) [related to the health services, including sexual and reproductive services, to be rendered to the disabled persons] to be a non-discrimination provision that does not add to, or alter, the right to health as contained in Article 12 of the International Covenant on Economic, Social and Cultural Rights or Article 24 of the Convention on the Rights of the Child. Rather, the effect of paragraph (a) would be to require States Parties to ensure that where health services are provided, they are provided without discrimination on the basis of disability.*"

43 Office of the United Nations High Commissioner for Human Rights, International Covenant on Economic, Social and Cultural Rights, http://www2.ohchr.org/english/law/cescr.htm.

44 United Nations General Assembly, Convention on the Rights of the Child, http://www2.ohchr.org/english/law/crc.htm.

45 Convention on the Rights of the Child, Article 24.

provide access to medical services and medical attention in the event of sickness. And all without any form of discrimination.

A large portion of this action concerns what is often referred to, according to the now current terminology, as 'sexual and reproductive healthcare'. Finally, it is important to note that during the final approval, signature and ratification process of the Convention on the Rights of Persons with Disabilities, as a precaution, several States expressed clear reservations about the interpretation of the term '*sexual and reproductive health*', taking into account the position of the Special Committee. In their declarations[46], they state that they understand the expression 'reproductive health' as not including abortion, and Article 25 a), as not creating any right to abortion and not requiring any country to provide access to it.

From the above, we may conclude[47] that the term '*sexual and reproductive health*' as used in the Convention on the Rights of Persons with Disabilities does not imply the recognition of any new obligation under international law or any new human rights[48].

46 United Nations, Rights and Dignity of Persons with Disabilities, Declarations and Reservation, http://www.un.org/disabilities/default.asp?id=475.

47 Cf. Articles 31 and 32 of the Vienna Convention on the Law of Treaties, http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf.

48 A single binding international instrument calls on States that have ratified it and have made no reservations on the subject, to allow medicalised abortion in certain strictly controlled situations. It is regional in scope rather than global. We refer to the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa http://www.africa-union.org/Official_documents/Treaties_Conventions_fr/Protocole%20sur%20le%20droit%20de%20la%20femme.pdf. In Article 14, State Parties undertake to "*ensure that the right to health of women, including sexual and reproductive health is respected and promoted*" and to take all appropriate measures "*to protect the reproductive rights of women by authorising medical abortion in cases of sexual assault, rape, incest, and where the continued pregnancy endangers the mental and physical health of the mother or the life of the mother or the foetus*."

7. ABORTION AND EUROPEAN UNION COMPETENCE

It should be noted that abortion is not included in the competencies of the European Union[49].

In the field of public health (cf. Article 168 of the Treaty on the Functioning of the European Union), the Union has competences to support, coordinate or complement the actions of Member States; in any case "*Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.*" (Article 168, paragraph 7 of the above-mentioned Treaty). The lack of European Union competence with regard to abortion was recognised and declared several times by the European institutions (European Parliament, European Commission and European Council, in response to questions put by Members of the European Parliament). Even the European Court of Human Rights has recognised the diversity of legislative solutions regarding abortion and the broad margin of appreciation of Member

49 This was confirmed on many occasions by the European Commission and by the Council. A few examples on the part of the Commission: **Parliamentary Questions, 27 September 2007**, Written question from Robert Kilroy-Silk (E-4666/2007). Response given by Mr Frattini in the name of the Commission: "*The Commission has no competence to intervene in matters related to abortion which are under the exclusive competence of the Member States*"; **Debates, 26 April 2006**, Question no. 86 from Frank Vanhecke (H-0239/07). Response: "*The Commission does not assume any positions in favour or against abortion, due to the fact that there is no community legislation in this respect*". **Debates, 15 March 2001**, Question no. 23 from Dana Rosemary Scallon (H-0189/01), Question no. 24 from Bernd Posselt (H-0196/01), Question no. 25 from José Ribeiro e Castro (H-0197/01), Question no. 26 from Rijk van Dam (H-0209/01). Response: "*With regard to the special issue of abortion, the Council would remind the honourable Members that national abortion legislation does not fall within the Community's competence*". A few examples on the part of the Council: **Parliamentary Questions, 19 March 2007**, Written question from Emilio Menéndez del Valle (E-4955/06). Response: "*Concerning the right to abortion, the Council would inform the Honourable Member that the issue of abortion from a legal point of view falls under the competence of the individual Member States*". On at least one occasion, the Council went even further, apparently affirming that abortion is not included in the term 'reproductive health': **Parliamentary Questions, 4 December 2003**, no. 3 from Bernd Posselt (H-0729/03), Question no. 4 from Dana Rosemary Scallon (H-0794/03). Posselt: "*The term 'reproductive health' is used increasingly in EU development aid policy and related programmes. What is the Council Presidency's definition of this term, and does it also include the promotion of abortion?*". Response given by Mr Antonione in the name of the Council: "*…we do not accept that abortion should form part of policies on reproductive and birth control education*". Posselt: "*My question, therefore, is this: Does the term 'reproductive health' include the promotion of abortion, yes or no?*" Response: "*No*".

States in this respect.

As for development cooperation in this area (cf. Articles 168, paragraph 3, 205 and 208 of the Treaty on the Functioning of the European Union), it shall be "*conducted within the framework of the principles and objectives of the Union's external action*". The main objective is "*the reduction and ultimately the eradication of poverty*", and the principles are laid down in Article 21 (1) of the Treaty on European Union. They include "*democracy, the rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity, the principles of equality and solidarity, and respect for the principles of the United Nations Charter and international law*". The second subparagraph of the same Article 21 (1) states that "*The Union shall seek to develop relations and build partnerships with third countries, and international, regional or global organisations which share the principles referred to in the first subparagraph. It shall promote multilateral solutions to common problems, in particular in the framework of the United Nations*". Within the legal framework, and considering that there is no recognised right to abortion in the international legal order; that, on the contrary, the right to life is fully recognised (especially in the United Nations Convention on the Rights of the Child[50] to which almost all countries subscribe), we can draw certain conclusions. First, that in the cooperation policy context, the provision and financing of abortion services (even where abortion is legal), or simply the promotion of abortion (in particular where it is prohibited), may be difficult to reconcile with the above principles. The same conclusion can be drawn for partnerships with organisations that do not share these principles, in particular the *International Planned Parenthood Federation* (IPPF). The IPPF, founded by the eugenicist nurse Margaret Sanger[51], is currently one of the most ardent defenders of the 'right to abortion' and, through its members, one of the largest (if not the largest) suppliers of abortion services in the world, often in partnership with United Nations agencies such as UNFPA.

50 The Preamble includes a quotation from the Declaration of the Rights of the Child, which states that "the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth". And Article 2, paragraph 1 of the same Convention stipulates that "*States Parties shall respect and ensure the rights set forth in the present Convention to each child within their jurisdiction without discrimination of any kind, irrespective of the child's or his or her parent's or legal guardian's race, colour, sex, language, religion, political or other opinion, national, ethnic or social origin, property, disability, birth or other status.*" (Convention on the Rights of the Child, http://www2.ohchr.org/english/law/crc.htm). With regional scope, see also the American Convention on Human Rights: "Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception" (Article 4, 1).

51 Cf. Woman and the New Race, 1920, http://www.bartleby.com/1013/1.html.

OPINION

THE AMBIGUITY OF THE TERMS '*SEXUAL AND REPRODUCTIVE HEALTH*' AND '*SEXUAL AND REPRODUCTIVE RIGHTS*'

As demonstrated in the Report that precedes this Opinion, the terms '*sexual and reproductive health*' and '*sexual and reproductive rights*' are deeply ambiguous.

It is incontestable that in the field of human reproduction there are serious health problems and that huge efforts are required to ensure that childbirth and childcare take place in all countries under the best sanitary conditions. From the conventions on human rights and international treaties, in particular the International Covenant on Economic, Social and Cultural Rights, we can deduce a legally recognised right for all persons to education, to an adequate standard of living (and therefore sufficient food), to health protection against epidemics (starting with the development of public health), and to access to healthcare (starting with primary healthcare).

The reverse, on the other hand, is highly contentious: creating a new term, '*sexual and reproductive health*', forcing its acceptance on the international community by referring to it in existing legal instruments, then loading it with different meanings, and attempting to elevate it in this way to a fundamental human right. This could even become a hidden means of promoting at international level representations of personal and social life, action programmes and legal rules that would not have been accepted had they been clearly formulated at the outset.

The repeated use of the term – in declarations, resolutions and recommendations – tends to bring it into common language and make it accepted as a fundamental concept, but repetition does not give it any additional value and only deepens the ambiguity of the language used.

The term '*sexual and reproductive health*' was coined in a neo-Malthusian context. The concept of the wellbeing of persons and families has been advanced to legitimise international action, even to the extent of exerting real pressure to curb

demographic growth, and this has undeniably led to abuse[52].

Being '*satisfactory and safe*'[53] for individuals is not sufficient to determine human sexuality. "*In no sphere of life can the civil law take the place of conscience or dictate norms concerning things which are outside its competence*"[54], but the political authorities are competent to recognise and impose respect for fundamental rights, and in particular: "*every human being's right to life and physical integrity from the moment of conception until death; the rights of the family and of marriage as an institution*"[55]. But these rights go unrecognised where the individualist conception of sexuality prevails and when it is reduced to its health dimension.

In the name of 'reproductive health', certain declarations are attempting to promote the highly contentious 'rights to a child'. More specifically, there is silence on the right to life of all human beings, or it is denied without always being explicitly affirmed in the current use of the expressions '*sexual and reproductive health*' and '*sexual and reproductive rights*'. Under cover of such expressions, the practice of abortion 'under safe conditions' is currently being recommended by international organisations and the bodies that monitor the application of treaties and conventions.

In summary, many steps need to be taken in many countries, with the aid and support of international solidarity, to ensure respect for the fundamental human rights currently recognised and enshrined in international conventions and covenants concerning the health of girls, women and children, and their protection against all forms of violence. However, the ambiguity of the terms '*sexual and reproductive health*' and '*sexual and reproductive rights*' prompts us to express reservations against their use, especially in texts with legal force.

52 The social teachings of the Church are very clear on this subject. Cf. Pontifical Council Justice and Peace, Compendium of the Social Doctrine of the Church, § 234 : "*All programmes of economic assistance aimed at financing campaigns of sterilization and contraception, as well as the subordination of economic assistance to such campaigns, are to be morally condemned as affronts to the dignity of the person and the family. The answer to questions connected with population growth must instead be sought in simultaneous respect both of sexual morals and of social ethics, promoting greater justice and authentic solidarity so that dignity is given to life in all circumstances, starting with economic, social and cultural conditions.*" http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html.

53 Report of the Fourth World Conference on Women, Programme of Action, § 94.

54 Congregation for the Doctrine of the Faith, *Donum Vitae*, Chapter 3.

55 *Ibidem*.

OPINION OF THE BIOETHICS REFLECTION GROUP

ON THE STATE OF POST-COMA UNRESPONSIVENESS COMMONLY KNOWN AS 'PERSISTENT VEGETATIVE STATE'

MEETING OF 26 OCTOBER 2009

1. A STATE OF UNRESPONSIVENESS

In an article published on 1 April 1972 in the British medical journal *The Lancet*, two neurologists, Brian Jennett and Fred Plum, propose the term 'persistent vegetative state' to describe the unusual state that they characterise as 'wakefulness without awareness' and which is present in the post-coma state of a number of patients who have suffered severe brain damage. "*In our view,*" they wrote, "*the essential component of this syndrome is the absence of any adaptive response to the external environment, the absence of any evidence of a functioning mind which is either receiving or projecting information, in a patient who has long periods of wakefulness.*"[1]

The diagnosis of such a state relies on the observation of the patient's behaviour. "*In practice, everything appears to happen as if, after a shorter or a longer period in a coma state, the process of awakening initiates a recovery but then switches off abruptly, leaving the patient in an atypical situation: he is no longer in a coma (his eyes are open, there is a cyclic activity of sleeping and waking) but he is incapable of showing the least sign of conscious activity (he lacks the ability to make contact or interact with other people, he does not manage to communicate by either speech or gesture, he does not make any adaptive response to stimulation).*"[2] The diagnosis can only be confirmed after a careful study of the patient's behaviour both by his family members and a team of care providers specially formed for that purpose. Experience has shown that a lack of attention may lead to failure to notice some signs of the patient reacting to the presence of his family or to changes in his environment.

1 JENNETT B., PLUM F., Persistent Vegetative State after Brain Damage. A Syndrome in Search of a Name, *Lancet*, 1972; 1: 734-737, quoted passage on p. 736.

2 TASSEAU F., Aspects éthiques et juridiques posés par les états paucirelationnels et l'état végétatif chronique, *Annales françaises d'Anesthésie et de Réanimation*, 2005 ; 24 : 683-687, quoted passage on p. 684.

2. THE TERMINOLOGY USED

The word 'vegetative' as proposed by Jennett and Plum reveals their conviction that the life of patients described in this way is no more than "*purely physical, devoid of all intellectual activity and social interaction*"[3] and deprived of all sensory perception. From the absence of any clear sign of awareness, the authors deduce the absence of all awareness, all sensory perception and all brain activity. Therefore to jump from the absence of proof of a reality to the affirmation of proof of the absence of this reality is obviously too hasty.

Since 1972, neuroimagery and tests such as the 'event-related potential' have made enormous progress. It has become possible to observe the activation of certain zones of the brain while they are undergoing various degrees of stimulation. In some cases this leads to a review of the diagnosis based upon clinical evidence.[4] Above all, these tests enable valuable data to be collected on the future evolution of the patient's state, and on the recovery or not of certain forms of reactivity[5][6]. However it is important to acknowledge the limits of the conclusions that can be drawn from these exploratory methods, especially with regard to the level of the patient's awareness.[7]

The term 'vegetative state', as has been suggested by Jennett and Plum, implies a total absence of sensation, of brain activity and of awareness. As has been said above, and as has been confirmed by explorations of brain activity, such an affirmation lacks any foundation if it is extended to every case of 'vegetative state' diagnosed according to the methods currently in use today.[8] What is more, the term has highly pejorative connotations.[9] This has led to a search for new

3 JENNETT B., PLUM F., *op. cit.*, p. 736. Bryan JENNETT restated the same belief in his book *The Vegetative State. Medical facts, ethical and legal dilemmas*, Cambridge, UK, Cambridge University Press, 2002, p. 4.

4 MONTI M. M., VANHAUDENHUYSE A., COLEMAN M. M., et al., *Willful Modulation of Brain Activity in Disorders of Consciousness*, NEJM.org, Feb. 3, 2010.

5 Cf. KRIMCHANSKY B-Z, GALPERIN T., GROSWASSER Z., Vegetative State, *The Israel Medical Association Journal 2006*; 8: 819–823.

6 See BERNAT J. L., ROTTENBERG D. A., Conscious awareness in PVS and MCS. The borderlands of neurology, *Neurology 2007*; 68: 885–886.

7 See BERNAT J. L., ROTTENBERG D. A., *ibidem*.

8 *Idem*.

9 It gives the impression that the life of the patient would be 'purely vegetative', an expression which is commented on later in the section "What can be said of a patient in a persistent state of unresponsiveness?"

terminology.[10] For example, the Australian government's National Health and Medical Research Council recommends the avoidance of the term 'vegetative state': 'Post-Coma Unresponsiveness' should be used instead.[11] In the same spirit, this Opinion proposes the term '*state of post-coma unresponsiveness*' in the sense of a total inability to make any reactive response to stimulation or to changes in the environment. This expression will be used from now on as much as possible for the rest of this Opinion.

The word 'persistent' has also been the subject of much criticism. It includes a prognostic dimension and gives the impression that the state called 'vegetative' will last for a long time, perhaps indefinitely; but experience shows that for most patients this state is transitory as long as they are given proper care and are closely monitored. Thus the working group organised by five scientific societies (*the Multi-Society Task Force on PVS*) has recommended, in a report published in 1994 - and which has since then become authoritative in medical circles - that one should speak simply about the 'vegetative state', and 'permanent vegetative state' from the moment when no reasonable hope remains of ever arousing the patient.[12] This moment depends on the cause of the initial coma.[13] In France, the term 'chronic vegetative state' (*état végétatif chronique*) has come into common use; it is slightly more cautious when used for prognosis, because it makes greater allowance for late awakenings, which sometimes occur, although this is rather exceptional.

10 Cf. KRIMCHANSKY B-Z, GALPERIN T., GROSWASSER Z., *op. cit*., p 819.

11 National Health and Medical Research Council (Australian Government), Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State, 2008. www.nhmrc.gov.au.

12 The Multi-Society Task Force on PVS, Medical Aspects of the Persistent Vegetative State, *The New England Journal of Medicine 1994*; 330: 1499-1508, and 1572-1579.

13 The Working Group cited above has estimated 12 months as the length of time after which a so-called 'vegetative' state can be said to be 'permanent' in cases where the brain injury resulted from a cranial trauma, and three months in cases of brain alteration as a result of oxygen deprivation.

3. DEVELOPMENTS IN PATIENTS IN A STATE OF UNRESPONSIVENESS

As stated above, the state of unresponsiveness can be simply transitory. Awakenings without serious after-effects are rare, but studies show that there is a whole range of developments varying from a good recovery right through to the so-called 'permanent' (or 'chronic') vegetative state and to death.[14] There are many factors that influence the quality of recovery: the nature of the accident causing the initial coma, cranial trauma or oxygen deprivation (through heart attack, drowning, hanging etc), the duration of the state of unresponsiveness, the patient's illnesses, his age, and so on.

Particular mention should be made here of a state which has been for a long time misunderstood and confused with the state of unresponsiveness. About twenty years after the publication of Jennett and Plum's article, a belief spread among quite a number of doctors and others in the medical profession with skills in the careful observation of patients that some of these who had been classified as being in the 'vegetative' state were showing undeniable signs – albeit intermittent and limited – of awareness of their surroundings. With these patients no longer living in the so-called 'vegetative' state but still handicapped by limitations more severe than those normally designated as having 'severe disability', a new term had to be found. Proposals such as 'minimally conscious state'[15][16] and 'minimally responsive state'[17] were put forward. In France the term '*état pauci-relational*', coined at the beginning of the 1970s,[18] was taken up again. Certainly greater justification can be given to terms that admit a degree of weak (but observable) responsiveness, of making contact, of communicating with another person, than to those terms which seem

14 See The Multi-Society Task Force on PVS, Medical Aspects of the Persistent Vegetative State, *op. cit.*, p. 1572.

15 GIACINO J. T., ZASLER N. D., KATZ D. I., et al. Development of practice guidelines for assessment and management of the vegetative and minimally conscious states. *J Head Trauma Rehabil 1997*; 12: 79–89.

16 GIACINO J. T., S. ASHWAL, CHILDS N., et al. The minimally conscious state. Definition and diagnostic criteria, *Neurology 2002*; 58: 349-35.

17 GIACINO J. T., ZASLER N. D. Outcome after severe traumatic brain injury: coma, the vegetative state, and the minimally responsive state. *J Head Trauma Rehabil 1995*; 10: 40–56.

18 See TASSEAU F., Aspects éthiques et juridiques posés par les états paucirelationnels et l'état végétatif chronique, *op. cit.*, p. 684.

to deliver a verdict on the quality of awareness that can not be observed directly[19].

This classification between the states termed 'vegetative', '*pauci-relational*' and situations of severe disability is probably too perfunctory. There is a gradually spreading belief in the existence of a continuum of states that are close to, but still different from, each other.[20] Perhaps some further distinctions will have to be made within the state that is today commonly spoken of as the 'vegetative state'.

19 See BERNAT J. L., Chronic disorders of consciousness, *Lancet 2006*; 367: 1181-1192, quoted passage, p. 1183.

20 See BERNAT J. L., Chronic disorders of consciousness, *op. cit*., p. 1181 and 1183.

4. LENGTH OF LIFE FOR PATIENTS IN A STATE OF UNRESPONSIVENESS

In 1994 the *Multi-Society Task Force on PVS* estimated that the average length of life for patients remaining in a state of unresponsiveness lay between two and five years, and that survival beyond ten years was exceptional.[21] As it turns out, life expectancy is difficult to estimate, because the length of life of a patient who remains in a chronic state of unresponsiveness depends largely on the quality of care and medical treatment provided for intercurrent illnesses. These patients are totally dependent on the people around them. Their care requires a high standard of hygiene, even more so because they are incontinent, they are fed and hydrated by tubes, and in a number of them a tracheotomy has been performed, and this renders them very vulnerable to infections. "*Patients in a vegetative state who are young and not suffering from severe illnesses are capable of surviving for decades with only artificial nutrition and hydration*"[22] but the prevention of these illnesses demands a very high quality of care.

21 The Multi-Society Task Force on PVS, Medical Aspects of the Persistent Vegetative State, *op. cit*., p. 1575.

22 BERNAT J. L., Chronic disorders of consciousness, *op. cit*., p. 1187.

5. THE STRESS ON THE FAMILY AND RELATIVES

The family and relatives are subjected to immense distress. At first, during the coma phase, their questions will centre mostly on the issues of resuscitation, death and life. Later on, during the rehabilitation phase, when attempts are being made to awaken the patient, they will need time to come to understand what the state of unresponsiveness means in reality, and then, in many cases, to understand that it is irreversible. They will then have to come to terms with the reality of the patient's complete loss of all personal expression, the loss of his abilities to make contact, to play his part as a member in family, business and social life. "*This is even harder work than for a deceased, where at least you have tangible proofs of disappearance and of death. Here, with the body staying alive and the face often regaining some of its former expressions, one starts to have doubts about the reality of the irreversibility. The families therefore feel completely helpless... [...] What place can the patient now occupy in the family circle? What does it mean for young children to have a father or a mother in a chronic vegetative state or in a hypo-relational state?*"[23]

Families therefore have an immense need to be helped and supported in order to arrive at a certain degree of adjustment to such a situation. In return, their adjusted behaviour will reassure and support the team of care providers. "*In this climate of reciprocal support, families and professionals often pay greater attention to the person being cared for. Thus, the shared concern of care providers and family members towards patients in the vegetative state may perhaps allow each person to find meaning in this situation.*"[24]

23 TASSEAU F., Coma, éveil de coma, états végétatifs. Ces malades qu'on dit inconscients, *Laennec 1995*; 44 (2): 3-6, passage quoted, p. 5-6.

24 *Idem*, p. 6.

6. FACILITIES FOR CARE

Patients who have suffered severe brain damage that induces a coma obviously have need of specialised care for the entire duration of their state, and consequently they depend on consistent provision of care from the moment of the accident until they enter long-term care. This requires coordination between the emergency services, those for resuscitation, re-education and rehabilitation and those looking after patients in the so-called 'persistent vegetative state'. Any lack of consistency or of available places has serious negative impacts on the quality of care and represents an obstacle to obtaining and getting recognition of the awakening of patients. What is more, it burdens families with the obligation to take their loved one home and to ensure that he continues to receive the very exacting quality of care as described above. Experience shows that, in the absence of a level of out-patient assistance, such a homecoming will severely jeopardise the equilibrium of the family.[25] This economic and organisational dimension has to be emphasised, because it may influence the kind of decisions taken regarding these patients. But, as long as any hope of awakening remains, the patient is entitled to not only the necessary care given to all dependent people and treatment against illnesses that might occur, but also to the stimulation treatment for awakening, and to the prevention of complications such as bedsores, infections of the urinary tract or lungs, stiffening of joints, weakening blood pressure[2627].

25 See BOUCAND M. H., Les patients en EVC. Recherche française d'un consensus éthique, Laennec, 1995; 44 (2): 7-8.

26 Ministry of Health (France), Circulaire DHOS/02/DGS/SD5D/DGAS n° 2002-288 of 3 May 2002 on setting up specialist units for caring for people in persistent vegetative or pauci-relational states, Bulletin Officiel n° 2002-20.

27 See BERNAT J. L., Chronic disorders of consciousness, *op. cit.*, pp. 1187-1188.

7. WHEN PERSISTENCE OF THE CONDITION CAN BE CONFIRMED

Once it has become possible to confirm with a sufficient degree of certainty that it is no longer reasonable to expect the patient to wake up, and that he is now in what is called a 'permanent' or 'chronic vegetative state', certain forms of care no longer make sense, especially those which focus on arousal. But what can be said about other forms of care and medical treatments? The debate on this question is far from over. It will probably be one of the major areas of dispute in bioethics issues in the years to come.

In the past, several so-called 'chronic vegetative state' cases became the focus of intense media interest. The first of these is, of course, Karen Ann Quinlan in 1975. At the end of many lawsuits, her father finally managed to obtain from the American law courts the right to switch off her mechanical ventilator, though her nasogastric feeding still continued. The young girl lived a further nine years after her ventilator had been switched off. Later, there was a flurry of lawsuits in the American courts over the Nancy Cruzan case. In 1983 in the United States she had suffered cranial trauma and prolonged oxygen deprivation as a result of a major car crash where she had not received medical assistance straight away; she survived, but in a state of unresponsiveness. Her family obtained an order of withdrawal of artificial nutrition in December 1990, and she died twelve days later. In the United Kingdom, the House of Lords, in February 1983, agreed to the same withdrawal of artificial nutrition for Tony Bland, a young man whose chest had been crushed by the pressure of the crowd during the football match tragedy at the Hillsborough stadium in Sheffield on 15 April 1989.

More recently, there have been multiple lawsuits and much public commentary and debate over the cases of Theresa (Terri) Schiavo and Eluana Englaro, the former dying in the United States in March 2005 and the latter dying in Italy in February 2009. Both had survived for many years in a state of unresponsiveness and finally succumbed after artificial nutrition had been withdrawn as authorised by the courts in both countries.

On the subject of the care given to people living this way in a so-called 'chronic vegetative state', and for whom there are no further hopes of any sign signalling self-awareness or recognition of another person, the usual questions start coming: "*What is the meaning of living like this?*" "*What is the point of wishing to prolong the lives of these patients?*" "*Would it not be better to stop all artificial means of prolonging life?*"

8. THE ISSUE OF CONTINUING ARTIFICIAL NUTRITION

The question most often asked is the one about continuing or stopping the delivery of water and nutrition by artificial means.[28] To justify their withdrawal, some people place patients in the terminal phase of illness on the same level as patients said to be in a 'chronic vegetative state'[29]. But a great many of the latter are not even ill, *a fortiori* they are not at a final stage of illness. They are able to live on, as long as they are fed and receive adequate nursing and bodily care. Other writers view artificial nutrition as medical treatment. The American Academy of Neurology therefore adopted the following declaration in 1988, the terms of which would be approved later on in many position papers.

"*Treatments which provide no benefit to the patient or the family may be discontinued. A medical treatment that offers some hope of recovery should be distinguished from treatments which only serve to prolong or hold up the process of dying without providing anything in the way of a cure. Medical treatment, including the medical provision of artificial nutrition and hydration, provide no benefit to patients in a persistent vegetative state, once the diagnosis has been established to a high degree of medical certainty*".[30]

This text reveals a lack of reflection about the various functions of medicine and also a confusion between the two meanings of the term 'medical', which may signify either 'performed by a doctor' or 'following an objective related to the field of medicine'. Provision of nutrition and hydration by the artificial means known as 'enteral' requires the hand of a trained nurse carrying out a doctor's orders,

28 The term used most frequently in this Opinion to describe the provision of nutrition is 'artificial nutrition'. This phrase designates what is commonly termed 'enteral nutrition' whereby a tube for nutrition (which can include normal food) is introduced directly into the patient's digestive system. This assumes that the 'nutritional function', i.e. the capacity for assimilation, is conserved and that artificial means are used solely to mitigate the patient's greater or lesser difficulties in swallowing. The need to utilise intravenous ('parenteral') feeding would give rise to other problems and would accentuate the medical dimension of administering the nutrition. This means that not all methods of 'nutrition' are equivalent. On this point see : Committee for Pro-Life Activities, National Conference of Catholic Bishops (USA), Nutrition and Hydration. Moral and Pastoral Reflections, 1992. www.usccb.org.

29 See Opinion of the Council on Ethical and Judicial Affairs of the American Medical Association: Withholding or Withdrawing Life Prolonging Medical Treatment, March 15, 1986. *JAMA 1990*; 263: 4-29.

30 American Academy of Neurology, Position on certain aspects of the care and management of the persistent vegetative state patient, *Neurology, 1989*; 39: 125-126.

positioning a tube passed down through the nose and oesophagus to the stomach, or more usually a surgical operation to insert a tube via the stomach wall. In this sense, these treatments are medical. But the cessation or withdrawal of a medical treatment is justified whenever the treatment brings none of the benefits which were intended, or these benefits are disproportionate to the harm that is caused by administering the treatment.[31] A 'curative' medical treatment is designed to fight against a process of illness (which may or may not lead to death); it must therefore be stopped once it no longer brings any proportionate benefit in this context. The aim of artificial nutrition is not to obtain a cure, or even to awaken the patient, but just to sustain life, an objective pursued by every living thing, even outside any situation of being ill. And thanks to these relatively simple methods, this objective is reached for most of the patients in a state of unresponsiveness, except for those who would no longer be able to absorb the introduced nutrients, in which case the artificial nutrition would no longer serve its purpose. It would become pointless or even, in some cases, dangerous for the patient. It should then be withdrawn.[32]

On the other hand, for most patients in a state of unresponsiveness it would deliver the 'benefit' for which it was intended.[33]

Denying this dimension of benefit implies that the patients themselves are being viewed in a certain way. It is affirming implicitly that they would derive no benefit from being kept alive. Thus, even without people always realising it, the classical comparison between the benefits, risks and 'burdens' of an act of care is abandoned in order to go into another problem area, that of the value and the meaning of a life marked by a number of deficiencies.

31 See Congregation for the Doctrine of the Faith, Declaration *Iura et Bona* on euthanasia and on the respect of due proportion in the use of painkillers, 5 May 1980, www.vatican.va, § IV, Due proportion in the use of remedies.

32 If the question about using 'parenteral nutrition' rises, one should examine each case to find out the reasons for the loss of digestive capacity and consider what benefits would be derived by the patient from such a feeding method, including all its risks.

33 See JEAN-PAUL II, Speech of 20 March 2004 to the delegates at the international Congress on "*Life-Sustaining Treatments and Vegetative State: Scientific Advances and Ethical Dilemmas*", § 4 : "... the administration of water and food, even when provided by artificial means, (.....) should be considered, in principle, ordinary and proportionate, and as such morally obligatory, insofar as and until it is seen to have attained its proper finality, which in the present case consists in providing nourishment to the patient and alleviation of his suffering." http://www.vatican.va/.

9. WHAT CAN BE SAID OF A PATIENT IN A PERSISTENT STATE OF UNRESPONSIVENESS?

To be totally incapable of communicating with other people, incapable of showing the least sign of recognition of those who spend the whole day in providing exacting care is to be in a really desperate situation. Even so, the choice of the term 'vegetative state' is extremely unfortunate. It was only intended, according to those who coined it, to describe a syndrome that was at that time unusual. However, it was not very far removed from an anthropological presupposition. It gave the impression that the life of the patient would be 'purely vegetative', reduced to the common denominator of all living beings, particularly those belonging to the vegetable kingdom, and that nothing would be left that was specifically human[34]. And that is certainly how it is now understood by a great many people today.

Such a representation, if it were to find general acceptance, would lead to linking the recognition of humanity in other people to certain capacities, and to refuse it in the absence of a minimum set of intrinsic qualities. Everybody would then have to provide proof of his humanity, of his dignity as a human being; a dignity which would be lost in the case of too great a change in mental functioning. This would contradict a fundamental affirmation of the Universal Declaration of Human Rights[35] and the beliefs that form the bedrock of the cohesion of European society, "*the indivisible, universal values of human dignity, freedom, equality and solidarity*".[36] It would put in danger not only patients in a so-called 'chronic vegetative state' but also those who are in a state close to it, and also, more generally, people with severe cognitive deficiencies.

The rejection of such a representation leads instead to the recognition that inside every patient in a so-called 'chronic vegetative state' there lives a person in a position of total dependence and extreme vulnerability, who is equal in dignity to every other person, towards whom all signs of true solidarity should be shown, and

34 This is one of the reasons for which the present Opinion suggests that the term 'vegetative state' should no longer be used but rather 'state of unresponsiveness'. See earlier, footnote 9 and the whole section on "The terminology used".

35 "Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world," (opening sentence of the Declaration).

36 Charter of Fundamental Rights of the European Union, Preamble.

who therefore has the right, according to a long tradition, to the hospitality that our society accords to people in the greatest need.[37]

This hospitality consists of administering appropriate means of care. But, in order to live, this person needs above all else to be fed and hydrated. Artificial nutrition and hydration will therefore be considered as an essential part of the care to which these patients are entitled, as long as they achieve the desired effect, and it can be administered by means that do not require sophisticated technology, and that the resources needed to administer them are available.[38]

37 See JEAN-PAUL II, Speech to the delegates at the international Congress "*Life-Sustaining Treatments and Vegetative State: Scientific Advances and Ethical Dilemmas*", 20 mars 2004, § 3 : "*I feel the duty to reaffirm strongly that the intrinsic value and personal dignity of every human being do not change, no matter what the concrete circumstances of his or her life.* ***A man, even if seriously ill or disabled in the exercise of his highest functions, is and always will be a man****, and he will never become a 'vegetable' or an 'animal'. Even our brothers and sisters who find themselves in the clinical condition of a 'vegetative state' retain their human dignity in all its fullness. The loving gaze of God the Father continues to fall upon them, acknowledging them as his sons and daughters, especially in need of help. Medical doctors and health-care personnel, society and the Church have moral duties toward these persons from which they cannot exempt themselves without lessening the demands both of professional ethics and human and Christian solidarity*".www.vatican.va/_

38 On 1 August 2007, the Congregation for Doctrine of the Faith contributed the following commentary on its *Responses to questions of the United States Bishop's Conference regarding artificial nutrition and hydration* : "*When stating that the administration of food and water is morally obligatory in principle, the Congregation for the Doctrine of the Faith does not exclude the possibility that, in very remote places or in situations of extreme poverty, the artificial provision of food and water may be physically impossible, and then ad impossibilia nemo tenetur. However, the obligation to offer the minimal treatments that are available remains in place, as well as that of obtaining, if possible, the means necessary for an adequate support of life. Nor is the possibility excluded that, due to emerging complications, a patient may be unable to assimilate food and liquids, so that their provision becomes altogether useless. Finally, the possibility is not absolutely excluded that, in some rare cases, artificial nourishment and hydration may be excessively burdensome for the patient or may cause significant physical discomfort, for example resulting from complications in the use of the means employed*." http://www.wf-f.org/CDF_Nutrition&Hydration.html.

10. CURATIVE MEDICAL TREATMENTS

Dismissing the justification for artificial nutrition in cases where the persistence of a state of unresponsiveness can be confirmed leads a *fortiori* to the refusal of all 'medical treatment'. That is at all events the position adopted by the Academy of Neurology as quoted above. Conversely, would the fact of assuming that, as a general rule, patients in a so-called 'persistent vegetative state' must be deriving benefit from artificial nutrition lead to making the same assumption for every treatment expected to act on the digestive illnesses or deficiencies that might be discovered in these patients?

Since the 16th century, ethical thinking has led to the conclusion that every person must take reasonable care of his own health, but this duty does not always imply exhausting every available means to save life. Therefore, deciding for oneself to give up a medical treatment is not always a case of suicide, and deciding to stop or not to embark upon a medical treatment in cases of illnesses of a person for whom one is responsible does not necessarily demonstrate a lack of respect for that person's life[39] and for that reason it should not be qualified as euthanasia[40].

For nearly 500 years, different criteria have been formulated for legitimising the withdrawal of medical treatment. The usual distinction is between 'ordinary' and 'extraordinary' means[41], and the criteria of futility, disproportionality[42] and excessive burden of a treatment[43] have been recognised, though applying them is often a sensitive issue.

39 See CRONIN D. A., Conserving Human Life, in *Conserving Human Life*, Braintree, Ma, USA, The Pope John Center, 1989, pp. 1-145.

40 See JEAN-PAUL II, Encyclical *Evangelium Vitae*, 1995, § 65. "E*uthanasia must be distinguished from the decision to forego so-called 'aggressive medical treatment', in other words, medical procedures which no longer correspond to the real situation of the patient, either because they are by now disproportionate to any expected results or because they impose an excessive burden on the patient and his family*". "*Certainly there is a moral obligation to care for oneself and to allow oneself to be cared for, but this duty must take account of concrete circumstances. It needs to be determined whether the means of treatment available are objectively proportionate to the prospects for improvement. To forego extraordinary or disproportionate means is not the equivalent of suicide or euthanasia; it rather expresses acceptance of the human condition in the face of death.*"

41 See PIUS XII, Speech of 24 November 1957 (on reanimation), La Documentation Catholique, 1957; 54: 1605-1610, passage quoted, 1607.

42 See Congregation for Doctrine of the Faith, Declaration *Iura et bona* on euthanasia and on the proportionate use of painkillers, 5 May 1980, § IV.

43 See JEAN-PAUL II, Encyclical *Evangelium Vitae*, 1995, § 65 passage quoted, footnote 40.

The working group which has been quoted several times already, *the Multi-Society Task Force on PVS*, has put forward a classification of relevant medical resources based on their degree of artificiality and substitution for natural life functions. It has defined four levels of treatment: a) high-technology 'rescue' treatments such as cardio-pulmonary resuscitation, respiratory aids using mechanical ventilation, and kidney dialysis; b) various medications, including antibiotics and supplemental oxygen; c) artificial nutrition and hydration; and d) nursing or home care "*to maintain dignity and personal hygiene*".[44]

Given what has been said above, it is clear that nursing actions directed at hygiene, body care and the prevention of all discomfort are always due, as much as possible, to a patient in a so-called 'chronic vegetative state'. There would have to be very strong reasons indeed, carefully weighed up, for withholding nutrition and hydration.

But quite a number of doubts may set in when there are serious complications that are likely to lead to the death of a patient in a chronic state of unresponsiveness. The respect for the patient and for his life implies, as a general rule, the use of currently available medical treatments, especially giving antibiotics in case of infection. But are we obliged to employ every single medical resource, particularly 'high-technology rescue treatments', to try to sustain in such circumstances a life that would naturally have come to an end? While we are always bound to recognise that the patient is a human being, at the same time it is important for us realise the extreme nature of the situation of a correctly diagnosed so-called 'chronic vegetative state'.

The function of medicine is not to set up extreme situations knowingly, and that is the reason why resuscitators are called upon to display proper judgment and caution, and to refrain from unreasonable obstinacy. In the short time after severe brain injuries, the high-technology rescue treatments are usually justified to the extent that any reasonable hopes of recovery remain.[45] The situation is different, however, when it is known that the patient will not regain any possibility of communication, or even any responsiveness. The use of sophisticated technological methods no longer seems justifiable, and it would seem more reasonable to refrain from using

44 See the Multi-Society Task Force on PVS, Medical Aspects of the Persistent Vegetative State, *op. cit*., p. 1577.

45 See the joint opinion of the World Federation of Catholic Medical Associations and the Pontifical Academy for Life, Considerations on the scientific and ethical problems related to the vegetative [state], 18 April 2004. www.academiavita.org After condemning the withdrawal of nutrition and hydration, the opinion continues: "At the same time, we refuse any form of therapeutic obstinacy in the context of resuscitation, which can be a substantial cause of post-anoxic vegetative state."

them.[46] But a decision to withhold any such treatment should then only be taken after consultation with everybody who has some responsibility for the patient, i.e. doctors, other carers, family members and other people who have stayed close, and only after consulting the possible directives that the patient might have been able to draw up prior to his condition.

46 See *Nutrition and Hydration. A Statement of the Catholic Bishops of Pennsylvania*, Revised Edition, Pennsylvania Catholic Conference 1991, p. 17. The bishops of Pennsylvania confirm that the highest level of treatment is necessary in the first stages, when a complete or partial recovery remains probable, and it is only once it has become clear that the patient will not recover that decisions regarding the withdrawal of treatment can be taken (even if this decision becomes more difficult for psychological reasons).

11. CONCLUSION

The state of unresponsiveness gives rise to an extremely disturbing human situation for the patient's family, close friends and carers. It prompts questions about the sense of providing care for these people who no longer speak nor react consistently to any stimulus, and questions about the very meaning of their existence[47]. This situation provokes unease and anxiety in a great number of our contemporaries who believe that death is preferable to life under such conditions. That explains the emotions stirred up by the presentation of such situations in the media, and the passionate debates that follow.

The patient lying in a state of unresponsiveness is still, for all that, a human being, albeit in an extremely vulnerable situation, totally dependent on the people who are willing to care for him. The decisions taken on his case will reveal something of the attitude of the society in which he is living towards its weakest and poorest members.

As long as there remains any reasonable hope that he will regain his ability to communicate with people around him, such a patient has the right to have provided for him all the care that he needs, and also to the medical treatment appropriate to his situation, including, if need be, 'high-technology rescue treatments'. From the moment that the persistence of the state of unresponsiveness can be established, the realisation of the extreme nature, now irreversible, of this human situation leads us to consider what kind of curative medical treatments should be continued or started if an intercurrent illness occurs. But only for very serious reasons, such as the loss of all capacity to assimilate food or the impossibility of providing such care in particularly impoverished areas, can one be released from the duty to provide water and food, even using artificial means, to people who are in such a vulnerable state.

We think of the members of the family of such patients, especially of mothers and spouses, remaining profoundly attached to their loved one no longer able to give any sign of recognition. We think of the health care professionals able to approach these patients and care for them with courage and skill. They have the right to recognition of their actions and the right to infrastructure that is properly adapted to such specialised health care and highly developed assistance.

47 See HILDGEN-HÉMON D., LÉAU C., Soignants et état végétatif, dans: TASSEAU F., BOUCAND M. H., LE GALL J. R., VERSPIEREN P., États végétatifs chroniques. Répercussions humaines, aspects médicaux, juridiques et éthiques, Rennes, France, Éditions École Nationale de la Santé Publique, 1991, pp. 79-90.

OPINION OF THE BIOETHICS REFLECTION GROUP

ON THE PROSPECTS FOR HUMAN ENHANCEMENT BY TECHNOLOGICAL MEANS

MEETING OF 25 MAY 2009

1. INTRODUCTION

The desire for development, even perfection, can be found in every human being and has always inspired humanity in a quest that has undeniably borne fruit, such as in education for all in many countries and in increased longevity.

Rapid technological progress, under the heading of NBIC (nanotechnologies, biotechnologies, information technologies and cognitive sciences), has led to the emergence of a new category of possible applications. We already use cochlear implants, electronic devices to restore hearing to people with severe hearing loss by directly stimulating the hearing nerve fibres via electrodes. We have also succeeded in connecting the human brain to a computer and the internet, with surprising results; however, it can also blur the distinction between humans and machines.

In many cases, these techniques have been developed to combat or prevent disorders and disabilities deemed to be pathological; they have therefore a medical origin. However, the same techniques could be used for enhancement, i.e. to develop, boost or modify the capacities generally found in humans.

There are currently proposals on the table to target these objectives; to develop NBIC techniques to augment human abilities for the benefit of certain individuals, or of humanity as a whole. Some people, referred to as 'transhumanist', even intend to use these techniques to change humans, not just physically but also their thoughts, their vision of the world and their values, and even to create a new human species. In such a context it would seem important to question the concepts of 'human', 'trans-human' and 'post-human'.

A topical debate

These new possibilities for human enhancement are fuelling an international debate, especially in the English-speaking world. The European institutions are getting to grips with the issue with the Science and Technology Options Assessment (STOA) committee of the European Parliament creating a working group to review the issue. The European Group on Ethics in Science and New Technologies at the European Commission (EGE) had already presented an Opinion in 2005 (no. 20) on the '*Ethical Aspects of ICT implants in the human body*' (ICT stands for Information and Communication Technologies). The European Group on Ethics also deemed that, at the time of writing its Opinion, because of the rapid development of these technologies, which raise both hopes and fears in society, a review of the Opinion may be necessary within three to five years (§ 6.5.6). That time has now come.

2. DEFINITION AND TECHNIQUES

2.1 Definition

A widely accepted definition of human enhancement is attributed to Douglas[1] (2007): "*The use of biomedical technology to achieve goals, other than the treatment or prevention of disease.*"

As we can see, the field of human enhancement, defined in this way, is large and complex, and the definition is far from precise. The concept can be applied to very different activities such as the use of caffeine, the use by students of Ritalin to stimulate the central nervous system in order to boost their ability to concentrate, or the creation of new capacities that humans do not normally possess, such as the ability to perceive infra-red light, or establishing a direct connection between the brain and a computer.

2.2 Techniques

In order to assess the different forms of human enhancement, we need to distinguish between the ends and the means.

- **The ends**

The STOA committee working group on human enhancement proposed the following four categories[2]: cognitive enhancement, mood enhancement, body enhancement and enhanced life span.

The classic example of cognitive enhancement, already mentioned above, is the use of *Ritalin* – a medicinal product designed to help people suffering from attention deficit hyperactivity disorder (ADHD) – by persons in good health to improve their powers of concentration.

Mood enhancement includes the use of antidepressants by healthy subjects or the implantation of electrodes in the brain for deep cerebral stimulation, in situations other than sickness (such as Parkinson's disease) for which stimulation might be used as a medical treatment.

1 Douglas, T. "*Enhancement in sport and enhancement outside sport*", *Studies in ethics, law and technology. Questions of human enhancement.* Volume 1, Issue 1 (2007), cited in the publication of the Dutch institute Rathenau: "*Future man – no future man*", June 2008, page 9.

2 http://www.europarl.europa.eu/stoa/events/workshop/20090224/background_en.pdf.

Body enhancement covers the fields of cosmetic operations, research into brain-computer interfaces (already used experimentally to help tetraplegic patients to communicate with computers and thereby with the external world), genetic modifications to enhance certain bodily functions, and finally the full range of prostheses, some of which can be very sophisticated and boost abilities (such as abnormal muscular strength or skeletal strength).

Enhanced life span means slowing down the ageing process using suitable drugs or even replacing organs.

- **The means**

There is a great variety of means that can be used for the purposes of human enhancement, including:

- *nutrition* (such as caffeine, functional foods, etc.)

- *pharmaceutical products* (such as *Ritalin*, which is used by healthy people to enhance their ability to concentrate)

- *implants and prostheses* (such as cardiac stimulators, cochlear implants, artificial retinas, neuro-implants such as electrodes for deep brain stimulation, chips integrated into the nervous system, etc.)

- *Brain-machine interfaces* (experiments performed to date by Professor Warwick[3]; in the longer term other applications may be found)

- *Pre-implantation diagnosis* to select human embryos.

- **Reversibility / non-reversibility**

A distinction needs to be made between means (for example, irreversible genetic modifications) which produce permanent changes; and others (such as the majority of pharmaceutical products) which have reversible effects.

3 Professor Kevin Warwick was the first to experiment with RFID chips (Radio Frequency Identification) (1998); the company "*Verichip*" has been selling RFID implants in the United States since 2004 for patient implantation in hospitals for rapid identification. (Source: http://www.technovelgy.com/ct/Science-Fiction-News.asp?NewsNum=199). At the "Baja Beach Club" in Barcelona, VIP clients pay automatically for what they consume using a chip implant for identification (BBC News 29 September 2004: http://news.bbc.co.uk/1/hi/technology/3697940.stm).

3. ETHICAL CONSIDERATIONS

3.1 Promoting health and human enhancement

There is an important distinction between 'treatment' – restoring homeostasis to an organism altered by sickness or a physical disorder – and 'enhancement' or modification of the functions or abilities of the organism beyond their normal level. The frontier between them is rather blurred, especially as culture has an influence on perceptions of health and sickness. It may be quite clear in some fields, but hard to pin down in others.

Each new technique must therefore be examined in depth in order to distinguish between any clearly 'therapeutic' applications, and others that should be classified as a quest for 'enhancement' of human capabilities.

3.2 Expectations

These new techniques give, or are claimed to give, individual benefits, and this creates expectations among the population. It is fair to ask whether such expectations are sometimes excessive, and whether fashion has had an effect, which could cause us to neglect the traditional means of human development (education, teaching, lifestyle, eating habits, developing interpersonal skills, etc.). One might also wonder whether new technologies are expected to provide benefits in terms of individual effectiveness and therefore competitive social advantages, to the detriment of solidarity with the weaker members of society.

Naturally these new technologies have important applications in combating different forms of handicap, such as cochlear implants for persons who are profoundly deaf in both ears, artificial retinas[4] for the blind, brain-computer interfaces for those suffering from locked-in-syndrome, etc. In such cases they could be considered as 'treatments', which means that in each individual case we have to take into account not only the expected benefits, but also the associated risks and the resulting deprivations, the cost and the burden for society. Many of these techniques are still in the experimental stage and their use may prove to be

4 An intraocular retinal prosthesis uses an external system to capture and process the image data and then send the information to an implant. The implant then decodes the data and stimulates the retina with a sort of electrical pulse to produce perception. ©USC BMES, http://bmes-erc.usc.edu/research_programs_retinal.htm.

disproportionate or beyond the reach of a particular country.

3.3. Anthropological considerations

This begs the question of the wisdom and limits of 'human enhancement'. Is it a form of human development or only the development of certain abilities?

A distinction needs to be made between the development of certain capacities, such as memory, concentration or even infrared vision, and what could be called development of the whole person[5].

It should also be stressed that human health covers more than just the bodily dimension; it is not solely the absence of somatic illness but includes, according to the well-known WHO definition, a psychological, social and spiritual dimension.

More profoundly, the way in which we see the concept of human enhancement certainly varies according to our conception of the human being.

Men are nothing but biological machines[6], according to Marvin Minsky and other post- or trans-humanists, or rather should we consider people, after Aristotle, as rational beings, or as persons, a veritable end in themselves blessed with incomparable dignity according to the philosopher Emmanuel Kant, or as beings created in the image and likeness of God called on to love their creator and their neighbour?

According to these different concepts, should all human enhancement using NBIC technologies be seen as just an extension of what humans already are; or conversely, must it be evaluated in terms of the attainment of the recognised purpose of human existence that it allows?

5 Note that certain statistics try to assess the development quality of countries based not only on 'hard' concepts such as GDP, but also taking into account data such as the level of child education and access to quality healthcare. A 'human development index' for societies is one such approach to the concept of holistic human development.

6 The theme is far from new! In 1748, the doctor and philosopher Julien Offray de La Mettrie had already published a work entitled *L'homme machine*.

4. SOME CRITERIA FOR ASSESSING ENHANCEMENT TECHNIQUES

4.1. Harmonious development of the person

Given the complexity of the technological and anthropological context, it would seem premature to offer a definitive response. The debate is nevertheless urgent, because certain technologies could profoundly modify humanity. Some authors talk of the extinction of the human species and the advent of a 'trans-human race'. This almost certainly points to illusions concerning the transformative power of NBIC technologies, but nevertheless raises the question of thresholds that must not be crossed in the name of respect for humanity.[7]

Without seeking to modify humanity as a whole, there are those who invoke a 'principle of autonomy', to which they assign a supreme value, in the name of which they call for the freedom of the individual to choose the person they wish to become using new technologies, rejecting any limitation by whatever authority on achieving their desires. This 'principle of autonomy', in the sense of the principle of self-determination, was put forward some thirty years ago by an American bioethics movement. Its authors acknowledged that it was poorly formulated[8]. Anyway, it would be a massive contradiction to reject any social authority in a particular field and then call for the assertion of rights in the same field.

In any case, we need to keep in perspective the harmonious and full development of the person. We therefore have to ensure that the development of such abilities does not come at the price of human impoverishment in general.[9] Above all, we must not lose sight of personal responsibility or prejudice personal identity.

7 Encyclical letter "*Caritas in veritate*" of Pope Benedict XVI:
"74. *A particularly crucial battleground in today's cultural struggle between the supremacy of technology and human moral responsibility is the field of bioethics, where the very possibility of integral human development is radically called into question. In this most delicate and critical area, the fundamental question asserts itself forcefully: is man the product of his own labours or does he depend on God?*"

8 Cf. T. Beauchamp, J. Childress, *Principles of Biomedical Ethics*, 6th Edition, New York, Oxford University Press, 2008.

9 In particular we must ensure that human capacity enhancement is not sought for the benefit of third-parties (increasing productivity for the benefit of industrial firms, acquisition of new attributes for military purposes, etc.).

4.2 Global solidarity, including international justice

We have to ensure that each application does not widen the gap between rich countries and developing countries.

4.3 Justice within each country

At national level, the evaluation of any application of these technologies should take into consideration the social justice dimension in order to avoid any aggravation of inequalities.

Although some people seek to benefit from 'enhancement' techniques for strictly personal reasons, human enhancement technologies are often used to seek superiority over others, leading to inequality and even domination. In sport, this is called doping. But doping is not restricted to the field of sport; it can be found in social life, distorting competition between social agents.

4.4 The precautionary principle: taking into account secondary effects, risks and losses

The precautionary principle requires a careful independent analysis of the risks involved in each application, taking into account the reversibility or otherwise of the effects produced. For example, the effects of deep brain stimulation cannot be evaluated for lack of sufficient data.

4.5 Consent and repercussions on future generations

The general principle governing human experimentation is that all research requires the express and informed consent of the person concerned. This raises serious questions concerning the application of NBIC technologies that could have effects on future generations. In gene therapy, any modification of the genome that could be transmitted to descendents is banned. Such a widely accepted rule should be borne in mind whenever a profound modification of a human being is envisaged using new technologies.

4.6 Case-by-case evaluation

If all of these criteria are satisfied, each technique must still be assessed on a case-by-case basis before being applied to a given person.

5. CONCLUSION

For most of the techniques referred to in this Opinion, prudence demands great caution in their application to healthy persons, given the huge risks that they entail. In any event, every time the use of these techniques is considered, the risks and benefits should be weighed very carefully.

For applications that apply to handicapped people, great care should be taken to avoid crossing the line between therapy and 'enhancement'. Policy-makers should ensure that these new techniques do not aggravate inequalities, but rather reduce them. In the European Union, the European Commission should act with particular transparency regarding research projects with an enhancement component. In addition, it should encourage researchers to seek a dialogue with society, and to consider the long-term effects of their research.

It is hugely important to be aware of what these human enhancement techniques cannot do. They do not provide a means of resolving the key problems of human life: suffering and the lack of trust and love. For the Bioethics Reflection Group, a successful human life includes acceptance of the limits of the human condition.

We therefore call for an in-depth debate on the promise – or illusion – of the creation of a new human condition. We need a wide-ranging discussion in our societies on what is desirable for the future of humanity, and on the values that should guide research and the development of new technologies.

OPINION OF THE BIOETHICS REFLECTION GROUP

ON THE NON-COMMERCIALISATION OF PARTS OF THE HUMAN BODY

MEETING OF 6 – 7 OCTOBER 2008

1. INTRODUCTION

In October 2007, the Bioethics Reflection Group of the Secretariat of the Commission of the Bishops' Conferences of the European Community published its Opinion on the '*ethical aspects of organ donation*'.[1] While fully acknowledging the very understandable wish of the European Commission to take measures to encourage the development of organ transplantation, to 'increase availability' of organs and, with this idea in mind, to raise general public awareness of the needs of people waiting for organ transplant [2] [3], this Opinion highlighted the need for obtaining the necessary consent, and the need to support families faced with the situation of *post mortem* organ procurement.

The Opinion of 11 October 2007 drew attention to a fact on which there seemed to be full agreement at international level. "*Organ donation must always be a donation made free of charge in a spirit of solidarity, that organ procurement must never be decided on financial grounds and that a human organ must never be considered or treated as a commodity*"

1 Ethical aspects of organ donation in: COMECE, Science and ethics, Opinions published by the Bioethics Reflection Group, Brussels, 2008, p. 4-13.

2 Cf. the European Commission's Communication addressed to the European Parliament and Council "*Organ donation and transplantation: Policy actions at EU level*", COM (2007) 275 of 30 May 2007 (http://www.europarl.europa.eu/oeil/file.jsp?id=5531962) .

3 This awareness campaign raises some sensitive issues. It is extremely important to spread understanding of the benefits that a transplant can bring, and thereby to facilitate the acceptance of procuring organs from deceased persons. One should not, however, raise any disproportionate expectations in the general public nor gloss over the fact that, with some rare exceptions, every organ transplant procedure entails a life-long immuno-suppressive treatment which may have serious side effects. Organ transplantation must therefore be regarded as a last-chance treatment and information given out in this field must remain in balance.

2. ORGAN TRAFFICKING AND TRANSPLANT TOURISM

Since that time, representatives of professional medical associations and international institutions have been sounding the alarm over the existence of a veritable trafficking of human organs. "*The many great scientific and clinical advances of dedicated health professionals, as well as countless acts of generosity by organ donors and their families, have made transplantation not only a life-saving therapy but a shining symbol of human solidarity. Yet these accomplishments have been tarnished by numerous reports of trafficking in human beings who are used as sources of organs and of patient-tourists from rich countries who travel abroad to purchase organs from poor people*".[4] "*The shortage of available organs has not only prompted many countries to develop procedures and systems to increase supply, but has also stimulated commercial traffic in human organs, particularly from living donors who are unrelated to recipients. The evidence of such commerce, along with the related traffic in human beings, has become clearer in recent decades*"[5].

Such practices are an unquestionable sign of a widespread 'shortage' of available organs for transplant or, put more precisely, of a serious disproportion between the number of people waiting for a transplant and the resources of official transplantation systems. This imbalance cannot be denied. What conclusions can be drawn from this?

In order to reduce 'transplant tourism', the Declaration of Istanbul[6] has issued an urgent invitation to all countries possessing the resources to ensure their self-sufficiency in this domain, if need be by inter-regional cooperation. Some experts suggest reducing the gap between 'supply' and 'demand' by introducing a trade in organs that would be strictly regulated in a way that would establish it as an 'ethical market'[7]. With this end in view, prices for organs should be set in such a way that it would attract potential sellers and would provide a reasonable payment that would compensate for the risks incurred. Other experts recommend a ban on all sales

4 The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, April 30-May 2, 2008. This Declaration was published by an assembly made up of more than 150 representatives coming from all over the world.

5 The WHO Guiding Principles on human cell, tissues and organ donation, amended text of 26 May 2008. WHO, Document EB 123/5, Preamble, §2.

6 Cf supra, note 4.

7 Cf. Charles ERIN, John HARRIS, An Ethical Market in Human Organs, *Journal of Medical Ethics*, 2003, 29, p. 137-138.

of organs or of other body parts, and instead to provide for 'fair compensation' to cover the time, constraints and inconvenience linked to their removal.

These revelations and proposals clearly show the need for deepening the notion of 'free of charge' and 'non-commercialisation', and to extend the thinking beyond organ donation in order to include donations of tissue and cells[8] which are also part of the rapidly increasing trend today.

8 Only taken into account here is the donation of 'somatic cells'; thus, reproductive cells (gametes, ova and sperm) are excluded.

3. DIGNITY OF THE PERSON, VULNERABILITY OF CERTAIN SOCIAL GROUPINGS

The person from whose body the cells, tissue or organs are removed is currently called the 'donor'. The European Directive of 31 March 2004 uses this term to designate "*every human source, whether living or deceased, of human cells or tissues*"[9]. There have been countless occasions where this term has been abused[10], but at least it shows a conviction that has from the start governed the social acceptability of procurement of human body parts. Any procurement made from a living person for the benefit of another person is in fact a violation of the integrity of the body, not justified by the person's own state of health. The removal of an organ such as a kidney was first of all described as a 'mutilation'[11], but later it only seemed ethically or legally acceptable to the extent that this violation of the integrity of the body had been voluntarily agreed by the person himself for the major benefit of another person, to save his health or even his life. The same is true for the procurement of body parts from a deceased person, which seems to be an unacceptable violation of the corpse in the absence of prior consent of that person or of the agreement on the part of relatives who have competence to speak in the name of the deceased.

The term 'donor' also means first of all that the act is voluntary, consented, free, aware, without duress, directed towards the benefit of another person. It also denotes the concept of being free of charge. All the international institutions[12] follow this line of thinking.

Being free of charge is rendered essential by the recognition of the dignity of the human being and of his body which is inseparable from the person while he is still alive. The body and its parts may not be treated purely as objects, reduced to the

9 Directive 2004/23/EC of the European Parliament and Council of 31 March on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells, Chapter 1, Article 3.

10 Abusive use of this term is already being done in connection with deceased people from whom organs are procured although they are not declared organ donors but while they were living had not opposed the idea of such procurement in the countries where the practice for procurement is based on the modality of 'presumed consent'. It is completely abusive in cases where the procurement is made under duress or on terms of payment while exploiting the vulnerability of certain social groups.

11 Cf. Jean DESCLOS, *Greffes d'organes et solidarité,* Montréal, Editions Paulines, Pars, Médiaspaul, 1993, p. 99-102.

12 Council of Europe, World Health Organization, European Union...

level of traded goods, without revealing a lack of respect due to the person and without violating his dignity[13]. Even after death, a person has the right to respect; neither his body nor any parts of it may be retained by another person, reduced to the status of an interchangeable object, subject to the laws of commerce[14].

There is another reason, linked to the first one, why the donation has to be free of charge, one which has been brought to our attention these days by many institutions. Obtaining human body parts against payment runs the risk of turning into the exploitation of people living in poverty and hence especially vulnerable. "*Payment for cells, tissues and organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermines altruistic donation, and leads to profiteering and human trafficking. Such payment conveys the idea that some persons lack dignity, that they are mere objects to be used by others.*"[15]

13 Cf. Additional Protocol to the Convention on Human Rights and Biomedicine on the transplantation of organs and of tissues of human origin, 24 January 2002, Explanatory Report Article 21 '*Prohibition of financial gain*'. Cf. also JOHN-PAUL II, Speech of 20 June 1991 to the participants of the first International Conference of the *Society for Organ Sharing*, §4, and BENEDICT XVI, Speech of 7 November 2008 to the participants of the International Conference on the theme of organ donation organised by the Pontifical Academy for Life.

14 On this subject see the speech of PIUS XII of 13 May 1956 to the delegates of the Italian Association of Cornea donors and the Italian Union for the Blind, and the speeches of JOHN-PAUL II and of BENEDICT XVI quoted above in footnote 13.

15 WHO Guiding Principles on human cell, tissue and organ transplantation, Commentary on Guiding Principle No. 5

4. LEGITIMATE COMPENSATION AND DISGUISED FORMS OF PAYMENT

In the light of today's debate and of the practices violating human dignity referred to above, it is important to be extremely careful in monitoring that donations of human cells, tissues and organs are voluntary and unpaid. For this it is vital to make a clear distinction between fully legitimate compensation and benefits in financial terms or in another manner that would represent a form (disguised or otherwise) of payment. "*National law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs. Incentives in the form of 'rewards' with monetary value that can be transferred to third parties are not different from monetary payments*."[16] The same goes for the proposal for preferential price tariffs for care not linked to the procurement for any person who might be willing to donate cells, tissues or organs.

The notion of unpaid donation does not however preclude the idea of 'reimbursement', that is, covering the costs of genuinely incurred expenses or loss of earnings as a direct result of the donation, nor does it rule out the idea of compensation for any health complications that can be directly attributed to the procurement. The donation of an organ should not under any circumstance be the source of earnings or similar advantages, but it should not become the cause of financial difficulties either[17].

Furthermore, these donations require the intervention of third-parties, especially of healthcare professionals, and the recourse to using appropriate procedures. This work can and must be paid at the correct price. One cannot but admit that the "*need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation is also accepted*."[18] As a general rule, the actions of procurement should be regarded as forming part of the mission of healthcare professionals (whether they work in public or private institutions), and should be paid for as such without allowing them to claim any specific advantages.

The provision of tissues, and probably even more, of cells, entails tasks of

16 *Ibidem*.

17 Cf. Additional Protocol to the Convention on Human Rights and Biomedicine, on the transplantation of organs and tissues of human origin, Article 21, and the WHO Guiding Principles, Commentary on Guiding Principle 5.

18 WHO Guiding Principles, Commentary on Guiding Principle 5.

preservation and, if need be, of processing, that are not cost free; this cost can only be attributed to the institutions that will be utilising these human body elements that have been more or less modified.

It can happen that the tissues, cells and products taken out of the human body will be subjected to such a degree of processing, before being used for their intended medical purposes, that some people deem that their human origin has been pushed away into the distance and that the products obtained can therefore be allocated a price, and be subject to market rules[19].This might be acceptable as long as the initial human origin and the generosity of the donor's gesture are not forgotten[20]. In such an event, it would be normal that a part of the profit would be allocated to a public service body in recognition of the value of solidarity included in the altruism of the donation. In any case it is vital to check that the consent to the removal is free of charge and granted with complete freedom, and that the currently valid national laws are obeyed.

Article 12 of the EU Directive 2004/23/EC requires that the Member States "*shall endeavour to ensure voluntary and unpaid donations of tissues and cells*"[21]. However, it provides for "*compensation which is strictly limited to making good the expenses and inconveniences related to the donation*"[22].This extension to 'inconveniences related to the donation' raises a serious problem. One may wonder if it is not aimed at recruiting volunteers who are judged currently to be in short supply. This practice would therefore represent a financial stimulus which would be a disguised form of payment; what is more, it would run the risk of exerting pressure on vulnerable people and lead to their being exploited. For these two reasons - rejection in the name of human dignity of any form of payment, and the taking into account the vulnerability of certain social groups - , it would seem to be an ethical imperative to reject 'compensation' for the inconveniences related to the donation.

On the subject of compensation, the EU Member States should therefore exercise greater restraint than the European Directive 2004/23/EC when they are

19 This is particularly true for products extracted from the human body, such as blood clotting factors which in the old days used to be prepared in an industrial manner and used for the treatment of haemophilia. This is also true for certain processing methods applied to human tissues, such as obtaining bone powder that is processed, preserved and mixed together in an industrial manner for use during surgical operations.

20 Taking the human origin into account should lead to the use of these elements or products extracted from the human body being reserved for especially important purposes, such as treatment or medical research. Thus their use in the cosmetics business should be clearly excluded.

21 Directive 2004/23/EC of the European Parliament and Council of 31 March 2004, Article 12.

22 *Ibidem*.

introducing it into their national legislation, by taking care that the 'donations' really are free of charge. But the concern of public health should also spur them to monitor the effectiveness of their systems of collection and redistribution of human cells, tissues and organs, and encourage donations of these parts of the body for therapeutic purposes. For that to happen, they really must make their populations aware of the expectations of those people whose health or even lives could be saved, thanks to the generosity of other people.

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