

Fundamental Rights Concerning Biomedicine in the Constitutional Treaty and their Effect on the Diverse Legal Systems of Member States

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A. Introduction

The Constitutional Treaty¹ was thought to address the new challenges occurring in front of the enlarged Europe in relation to the rapidly changing international political, economic, social and cultural circumstances. In this respect, the problem of the new quality of the European Union is being repeatedly disputed. If the EU is to be something more than an arrangement for inter-state cooperation, the Union has to be able to act rationally on a collective basis, in a way that different interests or preferences will give priority to seeking agreement over self-interest maximization. The question of whether the EU envisaged in the Constitutional Treaty represents a deeper form of integration can be answered by examining its ability to achieve consensus on conflicting issues and to form a common will about how to solve common problems.² The field in which the most controversies arise nowadays is that of biotechnology and biomedicine.

Through the decoding of the human genome and development of biotechnologies we gain control over processes, which until now seemed to be uncontrollable and unforeseeable. The “line between the chance and the choice, forming the basis of our value system is shifting”³. This change is marked by great ambivalence. On the one hand, the advance of biological sciences carries a promise of benefit to humans,

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¹ Treaty Establishing a Constitution for Europe, Dec. 16, 2004, 2004 O.J. (C 310) 53 (hereinafter CT).

² E.O.Eriksen, *The question of Deliberative Supranationalism in the EU*, 43 (Arena, Working Paper No. 99,1999), available at www.arena.uio.no/publications/wp99_4.htm.

³ JUERGEN HABERMAS, *THE FUTURE OF THE HUMAN NATURE* 25 (2003).

since combined efforts of reproduction medicine and genetic engineering open up the prospect of gene-modifying interventions for therapeutic goals. On the other hand, modern genetics enables the cloning of human beings and gene manipulations, which may lead us to eugenic practices – entirely discredited in the course of the 20th century. This prospect casts a peculiar light on a condition of our normative self-understanding. Concerns focus on radical changes to the terms of human existence, to the currency of human relationship, to the boundaries of inclusion and exclusion, and to our cultural understanding of birth, life and death.⁴

Consequently a whole range of values, such as human dignity, personal autonomy, relief of human suffering, welfare of the child and society's well being, come into conflict. Within a state they are being transposed into the sphere of law and emerge as conflicts of fundamental rights, such as between the right to life and bodily integrity or the freedom of research and the duty of governments to best serve the health needs and other fundamental rights of their citizens. "The problem, [facing the government] (...) is precisely how conflicting claims are to be settled in the interest of the widest possible contribution to the interest of all, or at least of the great majority."⁵

This paper aims to address the problem of whether the constitutional provisions constitute a coherent European approach towards the controversial issues concerning biomedicine. Consequently, the answer to the question whether we can already speak of New European Bioethics and whether an approximation of the diverse European regulations is to be expected in the future has to be sought. Therefore, first of all, the normative differences between Member States and the underlying philosophical traditions need to be shortly presented. In the second part of the paper, the analysis of the EU competences as regards the area of public health and biomedical research will proceed. This will be followed by the interpretation of the legal limitations such as human dignity, which have been imposed on the latter in the course of the development of European law. As a conclusion an attempt to outline the prospective development of the European bio-law will be provided. The analysis will concentrate on the vertical effect that the constitutional provisions have upon the Member States.

⁴ DERYCK BEYLEVELD & ROGER BROWNSWORD, HUMAN DIGNITY IN BIOETHICS AND BIOLAW 6 (2004).

⁵ BETH SINGER, PRAGMATISM, RIGHTS AND DEMOCRACY 127 (1999) (quoting JOHN DEWEY, LIBERALISM AND SOCIAL ACTION (1935)).

B. European Diversity

The development of a European framework is perceived as a great challenge, for the Member States of the European Union are divided as to the legitimacy of the research and the approach to take to regulate it. Tensions within and between countries occur, as they try to balance these competing requirements, as for example in the field of stem cell research or pre-implantation genetic diagnosis (PGD). There are differences between regulatory and legislative positions, or lack of regulation, in the countries involved. This lack of consensus is largely grounded in conflicting views of the moral status of the embryo, but may also reflect a demarcation of what are understood to be legitimate areas for statutory intervention. Hence, in Denmark, Belgium, Finland, France, Greece, the Netherlands, Spain, Sweden and the UK embryo research (as well as PGD) is permitted, whereas Austria, Germany, Ireland and Italy have a ban. Luxemburg, Poland and Portugal have no specific rules on any of these problems.

The legislative and regulatory frameworks, where they exist, have their origins in, and are subject to, historical, political and cultural particularities. For instance, the common law system is much more empiric, pragmatic and more susceptible to improvisation, attributable to specific historic developments, in the course of which judges and lawyers of the Crown played a crucial role.⁶ British law is also rightly associated with Mill's ideology of robust individualism coupled with Benthamite utilitarianism, as well as political and economic liberalism.⁷ The price of liberty is that the mere preference of the majority (or of the "community") must give way to the preferences of the contracting parties. Consequently, human dignity is seen primarily as a source of individual autonomy which should be respected. It will rarely be interpreted in a way that could possibly lead to a limitation of personal autonomy and the freedom of contracts that is crucial to the common law system. It is, thus, said to be conceptualized as empowerment rather than constraint.⁸ Apart from what has been stated above, what affects policy-making processes is the long parliamentary tradition which resulted in the constitutional principle of the supremacy of the Parliament.

On the other side of the European normative scene one can find Germany with its abstract and theoretical restrictive approach. Like the rest of the continent it is deeply rooted in the Kantian moral philosophy, which orders treatment of the

⁶ KONRAD ZWIEGERT & HEIN KOETZ, AN INTRODUCTION TO COMPARATIVE LAW 68 (1998).

⁷ BEYLEVELD & BROWNSWARD, *supra* note 4, at 1-47.

⁸ *Id.* at 1.

moral agent as an end and never merely as a means. Still, to a much larger extent the German legislation has been determined by the historic experience of the Nazi regime, which tried to implement their discriminatory social theory through national programs of eugenic practices. In Austria and Italy the law has been deeply affected by the philosophy of ontological personalism, stemming from the Christian tradition, in which the absolute right to life is ascribed to a human being from conception onwards. This subjective right is thus inferred from the mere potentiality of an entity to develop into a person in the future. This broad apparent interpretation is strictly connected with the concept of human dignity. It has been argued that in continental Europe human dignity is predominantly being interpreted as a constraint.⁹ Thus, the *continental understanding* of human dignity implies not only a duty to respect the dignity of others, but also not to compromise one's own dignity, even if such a compromise would be intended by the person at stake. It also requires acting in a way that is compatible with the vision of human dignity that exists in a particular community. Consequently, if hypothetical conflict between dignity and autonomy occurs, the idea of the former predominant in the society will precede and limit the latter.

In Poland and Portugal the lack of specific regulations seems to be the consequence of both the influence of the Catholic Church and the great economic, social and cultural changes that have been taking place for the last 15-20 years. Conservative morality coupled with the victorious march of economic liberalism seems to create rather unfavorable conditions for a bioethical debate. Interestingly enough it seems to be the medical environment, which, being predominantly conservative, prevents the changes. This great dissonance between the legal and philosophical traditions of the EU Member States constitutes a substantial impediment to the unification of bio-law.

C. The Constitutional Treaty

I. Charter of Fundamental Rights of the EU

1. General Remarks

Principles of liberty, equality, solidarity and respect for human rights constitute among others the founding values of the EU. The Charter of Fundamental Rights of the EU, incorporated into the Constitutional Treaty (CT) as Part II, contains a whole range of social rights, including, quite surprisingly for a document of this sort, both categories of human rights, namely those of the so-called first and second

⁹ *Id.* at 34.

generations. For the first time at the supranational level a due regard is given to the area of biomedicine in a legal act, intended to obtain a legally binding force.¹⁰

First of all, drawing inspiration from the 1948 Universal Declaration of Human Rights, it proclaims the inviolability of human dignity, which must be respected and protected and confirms everyone's right to life.¹¹ Secondly, it introduces the right to the physical and mental integrity of a person, stemming from Art. 3 of the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the application of biology and medicine (European Biomedicine Convention). The Charter's right encompasses the free and informed consent of the patient as well as the ban on eugenic practices, commoditization of human body parts and the human reproductive cloning.¹² Thirdly, broadening the scope of the well-established non-discrimination principle, it prohibits discrimination on grounds of genetic features. Finally, it declares the freedom of scientific research and the right to preventive health care. All these rights and freedoms constitute a quite admirable catalogue. However, as we all know, due to a whole range of different provisions their scope of application has been drastically constrained. Consequently, the normative dimension of the Charter appears to be extremely complex and ambiguous.

2. *Limitations*

First of all, Art. II-111 CT restricts the applicability of the Charter's rights primarily to the institutions, bodies of the Union, and Member States in compliance with the principle of subsidiarity. This is usually understood to have waived the horizontal effect of the Charter, namely the one between citizens. Moreover, the requirement to respect the Charter's rights is binding on the Member States only when they act in the scope of Union law. This limitation aims to prevent any reliance on the norms of the Charter in relation to mere domestic law of the Member States in areas which are still not determined by EU law. On the other hand, some argue that it will be extremely difficult to explain this distinction between national and EU law to the citizens.¹³ Also, in view of the fact that EU law is increasingly invading

¹⁰ The symbolic role and standard-setting function of the Convention on Human Rights and Biomedicine cannot be denied. Still, the fact that it has been ratified only by an extremely small number of states substantially limits its actual legal impact.

¹¹ The European Convention, *Updated Explanations relating to the text of the Charter of Fundamental Rights*, 828 CONV 1 (July 18, 2003).

¹² *Id.* at 6.

¹³ EUROPEAN UNION COMMITTEE, 14th REPORT: THE FUTURE OF EUROPE: "SOCIAL EUROPE," 2003-14, HL Paper 79 (2003) at ¶ 13, available at <http://hcl1.hclibrary.parliament.uk/notes/sps/snsp-02906.pdf>.

domestic law, it may be presumed that this distinction will not have a long life, like in the USA as regards federal and state law.¹⁴ As regards the horizontal effect, it is believed that the ECJ could well solve the problem of Art. II-111 CT (similarly to that of the horizontal effect of EU-Directives). It could, thus, declare under certain circumstances the liability of Member States to an individual for losses caused by the lack of implementation of the Charter provisions (hence conferring the Francovich doctrine).¹⁵

Further restrictions are foreseen by paragraph 2 and the second sentence of the paragraph 1 of Art. II-111 CT.¹⁶ They confirm that the Charter may not have the effect of extending or modifying the competences conferred on the Union. Consequently, the obligation for the Union's institutions to promote principles laid down in the Charter may arise only within the limits of these same powers. The foregoing provisions create a solid constraint in areas, where the ambitions of the Charter exceed the catalogue of competences of the Union. However, one should remember that the extension of competences is not tantamount to an extension of EU law as such, in a frame of a regulatory development of community law within the existing competences. The discussed article does not seem to prohibit the latter. Thus, the EU institutions are perfectly allowed to extend current EU law for instance in the field of health protection or research, for in doing so they are not extending the field of application of EU law beyond the powers defined in the Constitution.¹⁷ Of course, at the same time they have to pay attention to Art. II-112 (2) CT, which imposes the obligation to exercise fundamental rights under the conditions and within the limits defined in other parts of the Constitution.¹⁸

All these reservations result in a quite blurred picture of the protection of fundamental rights and make their normative effect rather vague. The fact that the rights of the individual have possibly been curtailed by the horizontal clauses is rightly viewed as unsatisfactory, since it does not really meet the objectives layed down by the Constitutional Convention. Thus, such an approach scarcely serves the interests of transparency or makes those rights visible to the citizen.¹⁹ On the other

¹⁴ A.T.J.M. JACOBS, THE FENCES SURROUNDING THE CHARTER OF FUNDAMENTAL RIGHTS IN THE NEW EUROPEAN CONSTITUTION 8 (2004), available at www.tilburguniversity.nl/faculties/frw/research/schoordijk/ctld. (P.J.G. Kapteyn)

¹⁵ *Id.* at 4.

¹⁶ Art. II-111 CT.

¹⁷ JACOBS, *supra* note 14, at 5.

¹⁸ Art. II-112 (2) CT.

¹⁹ HL Paper, *supra* note 13, at para. 84.

hand, the limits of the enforceability of the Charter rights allowed the UK, the most radical opponent, to agree to the incorporation of the Charter in the Constitutional Treaty, and thus to ascribe it, even if limited, a legally binding force. This widely discussed ambivalence is particularly visible in relation to the specific fundamental rights concerning biomedicine.

II. Biomedical Research in the Constitutional Treaty

1. Freedom of Research

“From the perspective of the liberal state, the freedom of science and research is entitled to legal guarantees, for any enhancement of the scope of technological control over nature is bound up with the economic promise of gains in prosperity and with the political prospect of enlarging the scope of individual choice.”²⁰ The European Union seems to share this view. Thus, by means of Art. I-3 of the CT the promotion of the scientific and technological advance constitutes one of the Union’s objectives.²¹ To achieve this goal Member States confirmed as a fundamental right the freedom of research and have equipped the EU with a range of shared competences. The former has been ensured by means of Art. II-73 of the CT, the freedom of scientific research and the respect for academic freedom²²; the latter by provisions to be found in Part III of the CT.

Thus, the freedom of scientific research and the respect for academic freedom can be deduced from the freedom of thoughts and expression stated in Art. 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR). It includes the right “to receive and impart information and ideas without interference by public authority and regardless of frontiers”, which constitutes the basic conditions for each individual’s self-fulfillment²³. Despite the fact that no explicit reference has been made, the Charter’s freedom could be also related to the Art. 15 of the European Biomedicine Convention.²⁴ It justifies the freedom of scientific research in the field of biology and medicine not only by humanity’s right

²⁰ HABERMAS *supra* note 3, at 25.

²¹ Art. I-3 CT.

²² Art. II-73 CT.

²³ European Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, art. 10(1), 5 E.T.S. 13.

²⁴ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine), Apr. 4, 1997, art. 15, 164 E.T.S. 5.

to knowledge, but also by the considerable progress its results may bring in terms of the health and well-being of patients.²⁵ Such an extensive interpretation, if approved by courts, could appear to liberalize the area of research in the EU. This quite remote link could be drawn through the provision of para. 5 of the Charter's Preamble according to which the Charter reaffirms the rights as they result, among other sources, from the case-law of the European Court of Human Rights.

However, following the international standards, the freedom of research contained in the CT is not absolute. The horizontal clause of Art. II-112(1) CT provides possibility for constraints, as long as they respect the essence of the freedom. Additionally, by means of Art. II-112(3) CT academic freedom can be subject to the limitations under conditions enumerated in Art. 10(2) of the ECHR. In the same vein, the Charter does not prevent Member States from applying accordingly Art. 15 of the latter document, which under special circumstances allows the derogation of Convention's rights. On the other hand, the effect of the freedom of research needs to be analyzed from a much broader perspective.

In order to prevent Art. I-3 and Art. II-73 CT from becoming a *dead letter*, the EU is entitled by means of Art. I-14 CT "to carry out activities, in particular to define and implement programs"²⁶ in the areas of research and technological development. Para. 3 of the quoted provision ends by stating that "the exercise of that competence shall not result in Member States being prevented from exercising theirs". It gives each country the ability to raise the competitiveness of its products through research, avoiding at the same time the confrontation over this in such controversial matters as embryonic stem cells.

2. EU Competences

Further provisions may be found in Art. III-248 to III-251 of the CT; however, they do not constitute a substantial modification, in comparison to the existing provisions of Art. 163-173 TEC. Art. III-248 CT establishes a European Research Area in which researchers, scientific knowledge and technology circulate freely, and encourages it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Constitution. This is a more ambitious rendering of Art. 163 TEC, which

²⁵ EXPLANATORY REPORT TO THE CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE, Dec. 17, 1996, art.15, 164 E.T.S. 17, available at www.conventions.coe.int/Treaty/en/Reports/Html/164.htm.

²⁶ Art I-14 CT.

simply provides that the EU shall “have the objective of strengthening the scientific and technological bases of Community industry”.²⁷ Art. III-250(2) CT specifies that the Commission’s initiatives in this area would aim to establish “guidelines and indicators, the organization of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.”²⁸ It also provides that the EP should be kept “fully informed.”

In my view, it is the foregoing provisions coupled with the freedom of research guarantee that have the biggest influence on the development of biomedicine and bioethics in the EU. Due to this EU competence it eventually became possible to finance stem cell research projects through the recent Sixth Framework Program (2002-2006). Despite such progress, problems still emerge. Researchers feel insecure and exposed to risk, since in some countries certain kinds of embryo research and gene patenting are penalized.²⁹ Nevertheless, the powers and duties conferred upon the Union, strengthened in the Constitutional Treaty, seem to be flexible enough to encourage the exchange of knowledge. Thus, the bigger the demand of the market and the need expressed by the researchers, the deeper the harmonization of standards that can be expected. This is actually already happening. The researchers of the Eurostem project have recommended that the funding policy of the EU should be aligned and made consistent with the principles identified in the framework program and should not disadvantage researchers in any Member States.³⁰ Moreover, the reinforced non-discrimination principle coupled with the free movement of persons, goods and services will inevitably encourage the approximation of bio-law at the supranational level. First signs of harmonization are already present in the European Constitution, which sets minimal standards of biomedical practice. Furthermore, what is even more important, it treats human dignity as the source of all human rights and as a border line for any interference with personal autonomy. Is the European bioethics promoted by the EU permissive or restrictive? What impact do these *delimiting* principles have on the creation of common philosophical and most of all legal standards?

²⁷ The Treaty establishing the European Community, Dec. 24, 2002, 2002 O.J. (C 325) 163 [hereinafter EC Treaty], available at www.europa.eu.int/eur-lex/lex/en/treaties/dat/12002E/htm/C_2002325EN.003301.html.

²⁸ Art III-250(2) CT.

²⁹ Louise Irving, *Creating an Ethical Framework for Stem Cell Research in Europe*, 305 BIONEWS 1 2 (2005), available at www.BioNews.org.uk/commentaries.lasso (quoting John Harris).

³⁰ *Id.* at 3.

*III. The Limits of Biomedical Research and Practice*³¹*1. Human Dignity and the Notion of Personhood*

The Charter of Fundamental Rights of the EU takes into consideration the circumstances that procreation and birth are losing the element of natural uncontrollability that so far was essential for our normative self-understanding. The first article of the Charter (Art. II-61 CT) proclaims the inviolability of human dignity that should be respected and protected.³² In accordance with the explanatory report, human dignity of the *person* is not only a fundamental right in itself, but also constitutes the real basis of fundamental rights. This definition is vague and ambiguous. "If the interpretation of morally saturated legal terms like 'human right' and 'human dignity' tend to be counter intuitively construed in too broad a sense, they will not only lose their power to provide clear conceptual distinctions, but also their critical potential."³³

In order to identify the distinctive elements, it may be reasonable to analyze the right to life, guaranteed by Art. II-62 CT, which is ascribed to "everyone". The term "everyone" (as reaffirmed in the Explanatory Report to the Charter) is copied from the language of the ECHR. In neither document is this term defined. However, in the case *Paton v. Great Britain*, the European Commission of Human Rights³⁴ stated that the term "everyone" does not include in its scope the nasciturus. The limitations foreseen in Art. 2 of the ECHR apply only to persons already born and can be applied neither to a fetus, nor to an embryo. "Everyone" seems to refer to the potentially contested concept of a bearer of human rights. This is to be contrasted with the notion of "human being", apparently signaling "a generally accepted principle that human dignity and the identity of the human being [must] be respected as soon as life begins."³⁵ Nevertheless, in the recent case of *Vo v. France*, The European Court of Human Rights has reminded that the convention institutions have not "ruled out the possibility that in certain circumstances safeguards may be extended to the unborn child. (...) It is also clear from an examination of these cases that the issue has always been determined by weighing up various and sometimes conflicting, rights or freedoms...".³⁶ How can we then

³¹ The analysis is mostly based on BEYEVELD & BROWNSWORD *supra*, note 4.

³² Art II-61 CT.

³³ Eriksen, *supra* note 2, at 36.

³⁴ *Paton v. Great Britain*, App No. 8416/79, 19 Eur. Comm'n H.R. Dec. & Rep. 244, para. 24 (1980).

³⁵ See, *supra*, note 24 at 5.

³⁶ *Vo v. France*, 2004-VIII Eur. Ct. H.R. para. 80.

define the bearer of human rights, if it is understood differently in each of the Member States?

If we start with the view that the possession of human rights extends only to developed humans, who have their faculties, then “everyone” will not include “every living person”. In this view, the paradigmatic bearer of human rights will be the person who is able to exercise his or her rights. If we take a less restrictive view, we might hold that “everyone” covers all independent human life, that is, all humans from the cradle to the grave. Even in this less restrictive view, though, there are non-qualifying members of the human species, such as embryos, fetuses, and the like. This is not to say that potential qualifying human beings merit no protection but simply that, in the absence of a functioning capacity for practical reasoning or independent existence, the case for protection of such life forms cannot be made out as if they were bearers of human rights. We might, however, also hold that “everyone” includes “every instance of human life, biologically defined”. In this relaxed view, the possession and protection of human rights applies from conception onwards. In this respect, the European Court of Human Rights has held that “it is neither desirable, nor even possible as matters stand, to answer in the abstract the question whether the unborn child is a person for the purposes of Article 2 of the Convention.”³⁷

The Constitutional Treaty appears to follow the above mentioned reasoning. Therefore, it seems to foster a compromise, already applied in the Biomedicine Convention. While those, who cannot agree that the conceptus is a bearer of human rights, are to be allowed to persist with this belief, all Member States are required to accept that, in the name of human dignity, the conceptus is a protected entity. This, however, is not without any implications for the centrality of autonomy; it is not as though dignity simply functions to protect life where autonomy runs out. Rather, if embryonic and fetal life “is protected under the cover of respect for human dignity, then the autonomous choices of researchers [e.g. to create, test, manipulate, and store embryos] and of women must be measured for the legitimacy against, not only the general regime of human rights, but also against the special dignity-based regime protecting such early human life”³⁸. By reference to respect for human dignity, embryonic and potential human life forms have a protected moral status. The acceptance of human dignity as providing direct protection for early human life represents, at the very least, a significant change to the terms of debate. It almost certainly signals a much more restrictive approach to early-stage biomedical interventions.

³⁷ *Id.* at para. 85.

³⁸ HABERMAS, *supra* note 3, at 33.

2. *Discrimination on the Ground of Genetic Features*

Even greater ambivalence is related to the non-discrimination principle, stated in Art. II-81 CT, by means of which the prohibition of discrimination on the grounds of genetic features was introduced.³⁹ It goes in line with the limitations stemming from the value of human dignity. However, the practical effect of this may cause great concerns. This provision, which draws on Art. 11 of the Biomedicine Convention, does not create any power to enact anti-discrimination laws. It only addresses discriminations by the institutions and bodies of the Union themselves, when exercising the power conferred on them by Member States, and by Member States when they are implementing Union law. Surprisingly enough Art. III-124 CT, which confers power on the Union to adopt legislation and encourage harmonization, does not mention genetic feature as a discriminatory ground.⁴⁰ This state of law, which stems probably from the highly differentiated labor and insurance legal systems, should be viewed as unsatisfactory, for it will prolong the harmonization of such an important aspect. It is a well known fact that insurers and employers constitute extremely important pressure groups, which attempt to circumvent any final solutions as regard genetic tests. The conflict of interests appears so great that regulation meets horrendous obstacles even at the national level.

IV. Biomedical Practices

The attempt to create a modern act, which would address the most important problems resulting from the rapid biotechnological developments, is reflected in the drafting of Art. II-63 CT. It guarantees the right to bodily and mental integrity, which has been recognized by the ECJ in 2001.⁴¹ Apart from confirming the well established principle of free and informed consent, it contains “the prohibition of eugenic practices, in particular those that have as their goal the selection of persons”, as well as “the prohibition of the reproductive cloning of human beings”.⁴² All these provisions are based on the Biomedicine Convention; thus, due regard must be given to it in the course of their interpretation. Stemming from the concept of human dignity they also constitute further limitations to the freedom of medical and academic research.

³⁹ Art II-81 CT.

⁴⁰ Art III-118 CT.

⁴¹ Case C-377/98, *Netherlands v. EP and the Council*, 2001 E.C.R. I-7079, paras. 199-215.

⁴² Art II-63(2) CT.

The first paragraph, that acknowledges the conception of personal autonomy, seems to be rooted in both the Kantian moral philosophy and Mill's liberal individualism. This seemingly clear article may cause problems in situations, where the *person* is not capable of judging his/her own action, as in the case of pre-personal life. It is commonly accepted that in the course of the medical procedure (e.g. *in vitro* fertilization) the burden of decision is conferred upon the gamete provider (donor). What happens, however, if the interests of the donor conflict with the interests of the recipient? The problem becomes even more complex in the case of preimplantation genetic diagnosis (PGD). Here the embryo, which undergoes a test and at the beginning, is treated as a patient⁴³ and, if a genetic disorder is detected, will have eventually to be discarded. Whose informed consent is needed then? The CT does not provide any answer to these problems, leaving the solution to each of the Member States. The only limitation seems to stem from the obligation to respect and protect human dignity. The reasons have already been stated above. Moreover, it is also questionable whether such a detailed issue should be regulated at the constitutional level.

Personal and mental integrity goes along with the ban on the so-called commoditization of body parts. The need to prevent such a tendency has been also recognized in the above mentioned European Court of Justice (ECJ) decision, concerning EU Directive EC 44/98.⁴⁴ A prohibition of trafficking in human beings in Art. II-63 CT is said to stem directly from the cornerstone principle of respect for human dignity. The fact, however, that the Directive has been implemented only by a few countries raises the question of whether in the field of gene patenting it is possible to speak of common, European-wide standards? From a European perspective it can be hard to see how particular moral conceptions of the individual countries can feasibly be accommodated in a collective patent system. The ECJ did point out that the directive sets out the framework for the concept of the patentability. The directive regulates an area in which there are no actual authorities as yet. Thus, further jurisprudence of the ECJ will have to clarify the specific provisions. It is, however, at least arguable that the idea of human dignity constitutes a good reason for restraining certain forms of biocommerce. The Constitution, therefore, signals a European view that freedom of contract should be so limited.⁴⁵

⁴³ The case of PGD raises some confusion as to who is actually the patient. Is it the mother or the embryo? The answer to this question depends largely on the concept of the patient-doctor relation. A liberal approach will see the mother as a patient, whereas a more restrictive one will speak in favor of an embryo. See ZBIGNIEW SZAWARSKI, *Ethics and prenatal screening*, IN BIOPOLITIK GRENZENLOS- STIMMEN AUS POLEN 107-121 (Heidi Hofmann ed., 2005).

⁴⁴ Case C-377/98, *Netherlands v. EP and the Council*, 2001 E.C.R. I-7079, paras. 199-215.

⁴⁵ BEYLEVELD & BROWNSWORD, *supra* note 4, at 217.

As far as the ban on eugenic practices is concerned, it relates to situations “in which selection programs are organized and implemented, involving campaigns for sterilization, forced pregnancy and other acts deemed to be international crimes in the Statute of the International Criminal Court...”⁴⁶ It is, however, interesting that no reference has been made to prenatal testing and PGD, that may also lead to such an outcome. It is exactly the risk of discriminatory practices and negative eugenics that lies behind the controversies around PGD. Yet, if PGD for medical reasons can be justified under such provisions, would the same apply to sex selection for social reasons? The fact that in this respect the legislator did not follow the solutions provided by the Biomedicine Convention, banning the sex selection for non-medical reasons, may suggest that such an omission was intended. It is noteworthy that although such sex selection on social grounds is not permitted in any Member State, the number of adherents to this solution is gradually increasing.⁴⁷

Unlike the former provisions, the absolute ban on reproductive cloning should be viewed positively. It is in fact the only issue, as to which the international community is able to reach a compromise. Its significance is therefore indisputable. However, one should not forget that its effect does not exceed the scope of Union law. It follows the solution of the additional protocol adopted on reproductive cloning by Council of Europe.⁴⁸ The Biomedicine Convention uses the term *person* in relation to the post-natal phase of human life, whereas the term *human being* seems to be broader and applies to the whole human species, regardless of the phase of its development. It means that by referring to “human beings”, the Charter prohibits the cloning not only of an existing person, but also the reproductive cloning of embryos. Real problems occur in respect of the so-called therapeutic cloning. The difference lies purely in the purpose of the procedure. Reproductive cloning aims at the birth of a cloned child, whereas the latter is used only for research purposes. The Charter neither authorizes nor prohibits any cloning other than reproductive forms of cloning. It means a more restrictive approach can be chosen by Member States. This provision is important insofar as embryo research programs include cloning of human beings, such as the program recently granted

⁴⁶ The European Convention, *Updated Explanations relating to the text of the Charter of Fundamental Rights*, 828 CONV 1 (July 18, 2003).

⁴⁷ HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, SEX SELECTION: OPTIONS FOR REGULATION. A REPORT ON THE HFEA'S 2002-03 REVIEW OF SEX SELECTION INCLUDING A DISCUSSION OF LEGISLATIVE AND REGULATORY OPTIONS para. 84-92 (2003).

⁴⁸ Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Jan. 12, 1998, No. 168, 1 E.T.S. 2, available at <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=168&CM=1&DF=&CL=ENG>.

to a team at the Newcastle University by the Human Fertilization and Embryology Authority in London.⁴⁹

D. Conclusions

Ethical biopractice needs guiding values that cover those cases where the capacity for autonomous judgment is impaired or not yet developed. To put it another way, where there is respect for autonomy, autonomous actors can take care of themselves, but non-autonomous human life must be protected. The new European bioethics takes dignity, integrity and vulnerability to be the guiding protective values alongside autonomy. It becomes clear that its agenda, in correcting for the weight given to autonomy, is not about restoring physicians' power over their patients but about asserting collective control over individual choice. Thus, the "European bioethical project could be said to be both, ambitious and modest. Its ambitiousness resides in its attempt to articulate a vision of human dignity that commands acceptance across a region as pluralistic as Europe; its modest nature, by contrast, resides in its lack of concern with defensibility beyond acceptance – if X is accepted, then X requires no further justification. Or to put it another way, the project is more interested in breadth (of acceptance) than in depth (of justification)."⁵⁰ When the acceptance of a biopractice is broad enough within a community and later reaches the critical point within a state, then a change of legislation will follow. The same inference seems to have been applied to the supranational level. One could ask whether these traditional European value orientations, however worthy, have not already become merely out-of-date fashions.

On the other hand, from the sociological perspective, it is unlikely that society's acceptance of the alliance between state and technology will lessen, as long as the instrumentalization of "humanity's inner nature"⁵¹ can be medically justified by the prospect of better health and a prolonged lifespan. The wish to be autonomous in the conduct of one's own life is always connected with the collective goals of health and the prolongation of lifespan. The history of medicine, therefore, strongly suggests a skeptical attitude toward any attempt at "moralizing human nature".⁵²

⁴⁹ The Treaty establishing the European Community, Dec. 24, 2002, 2002 O.J. (C 325) 163 [hereinafter EC Treaty], *available at* www.europa.eu.int/eur-lex/lex/en/treaties/dat/12002E/htm/C_2002325EN.003301.html.

⁵⁰ BEYLEVELD & BROWNSWORD, *supra* note 4, at 248.

⁵¹ HABERMAS, *supra* note 3, at 48.

⁵² HABERMAS, *supra* note 3, at 32 (*quoting* W. VAN DEN DAELE, DIE NATUERLICHKEIT DES MENSCHEN ALS KRITERIUM UND SCHRANKE TECHNISCHER EINGRIFFE (2000)).

Nevertheless, it ought to be remembered that no science will relieve common sense, even if scientifically informed, of the task of forming a judgment on the latest achievements of the biotechnological revolution.⁵³ If J. Habermas is right, and this seems to be the tendency, a further liberalization of the European legislation should proceed.

Paradoxically, the Union's motto, "Unity in diversity", expressed in Art. I-8 of the CT could enable this process.⁵⁴ It seems to reflect particularly the approach taken in the document as regards the most controversial issues. Together with the principles of subsidiarity and proportionality underlined in a number of instances, it leaves space for differentiation and will presumably be used by Member States to preserve sovereignty. Within modern societies, however, there is a plurality of values and competing views about the notion of good life among different groups, local communities and cultures. Democratic pragmatism describes the mental state of a many-voiced public, where the arguments of both majority and minority should be heard. The modern state is premised on the axis: right of individual – safeguarding of individual rights. As a response the European Constitutional Treaty underlines, in a number of different ways, the fact that the Union is a community of shared values. "These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail."⁵⁵ At the same time, the Constitutional Treaty aims at making it possible for different groups and subgroups to live together under shared law. They have to resolve their conflicts through the medium of law, while the Union remains, in principle, neutral regarding different conceptions of the good life.

Nevertheless, the Constitutional Treaty sets out a common standard, to which all state-parties had to assent. Moreover, the framework for deliberative processes in the Constitutional Treaty itself, even if extremely complex, has been set. The increasing role of the European Parliament constitutes an important element of the development of a common sphere, where an open and unconstrained dialogue could be undertaken. Critics have often pointed out that the Constitutional Treaty, due to its ambiguity and complexity, does not meet its primary goal of bringing the Union closer to the citizen. Still, despite its limited scope of application, the significant role of the Charter is not merely symbolic. It should not be forgotten that, after all, through their incorporation into the CT fundamental rights will

⁵³ HABERMAS, *supra* note 3, at 109.

⁵⁴ Art I-8 CT.

⁵⁵ Art I-2 CT.

become legally binding. Apart from what has been said, there is the possibility that the rights and principles set out in the Constitutional Treaty will in practice impinge on national policy and practice and limit the freedom of Member States even in areas that remain clearly within their competence. It may prove difficult for a state to resist pressure to change and to align itself with the Charter. Where the competences are mixed and even where the Union has a supporting competence, the "higher" Union standard will inevitably exert pressure on national governments.⁵⁶

Moreover, Art. II-112 CT indicates three sources for the content of Charter's rights, namely EU law, the ECHR and national law. The still existing lack of efficiency and cohesion resulting from the parallel application of three systems of human rights protection will most probably be reduced by the accession of the EU to the ECHR, as provided by Art. I-9 CT.⁵⁷ Thus, a further approximation can be expected, especially now that para. 5 of the Preamble of the Constitutional Treaty opens the possibility for the extension of the sources from which the ECJ will draw inspiration. This could also result in future harmonization. This process is obviously reciprocal, since impulses run in two directions: from the Member States to the Union and from the Union to the states. There is no reason why this should change with the new Constitution. Thus, the conclusion cannot be revolutionary. The Constitutional Treaty may not be perfect, yet it constitutes progress. It is the only possible compromise that could be reached at this point of time and at this level of unification. For this reason its significance should not be underestimated. Whether pragmatism will be the guiding principle of biomedicine in the enlarged European Union in the future is still to be seen.

⁵⁶ Lords Select Committee on the EU, 6th Report: The Future Status of the EU Charter of Fundamental Rights, 2003-3, H.L. Paper 48 at 98-99.

⁵⁷ The European Convention, Working group 2, "Incorporation of the Charter/Accession to the ECHR", Modalities and consequences of incorporation into the Treaties of the Charter of Fundamental Rights and accession of the Community/Union to the ECHR 17-22, 116 CONV 02 (Jun. 18, 2002).

