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Update of European bioethics: basic ethical principles in European bioethics and biolaw

*Actualización de la bioética europea:
los principios éticos básicos en la bioética
y el bioderecho en Europa*

Jacob Dahl Rendtorff

Roskilde University, Denmark

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Abstract

This paper presents an update of the research on European bioethics undertaken by the author together with Professor Peter Kemp since the 1990s, on *Basic ethical principles in European bioethics and biolaw*. In this European approach to basic ethical principles in bioethics and biolaw, the principles of autonomy, dignity, integrity and vulnerability are proposed as the most important ethical principles for respect for the human person in biomedical and biotechnological development. This approach to bioethics and biolaw is presented here in a short updated version that integrates the earlier research in a presentation of the present understanding of the basic ethical principles in bioethics and biolaw.

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Keywords: Bioethics; Biolaw; Autonomy; Dignity; Integrity; Vulnerability

* Corresponding author.
E-mail address: jacrendt@ruc.dk

Resumen

Este artículo contiene una actualización a la investigación en materia de bioética que se lleva a cabo en Europa, misma que el autor ha realizado junto con el profesor Peter Kemp desde la década de 1990 acerca de los *Principios básicos de la bioética y el bioderecho europeo*. En este enfoque, se proponen los principios de autonomía, dignidad, integridad y vulnerabilidad como los más importantes principios en materia de respeto a la persona humana en el desarrollo de la biomedicina y la biotecnología. Este escrito presenta una versión breve y actualizada donde se integran las investigaciones precedentes bajo la nueva perspectiva de los principios éticos básicos aplicados a la bioética y bioderecho.

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Palabras clave: Bioética; Bioderecho; Autonomía; Dignidad; Integridad; Vulnerabilidad

Introduction

In the report *Basic ethical principles in European bioethics and biolaw, autonomy, dignity, integrity and vulnerability* (Rendtorff & Kemp, 2000), we (Jacob Dahl Rendtorff and Peter Kemp) presented a European approach to the basic ethical principles of autonomy, dignity, integrity and vulnerability in bioethics and biolaw. That book was the result of a European Union Commission Project in the framework of the Research Program Bio-Med II, 1995-1998, conducted by the Centre for Ethics and Law in Denmark. A result of the research project was, among others, *The Barcelona Declaration*, a set of policy proposals for the European Union. Since that time there has been a continuous discussion on those basic ethical principles and they have been proposed as points of reference for the future developments of the European bioethics and biolaw.

This paper presents a clarification of the foundation and significance of these basic principles (that we shall often simply call “the principles”), with the aim of elaborating the philosophical and conceptual framework for their definition and application.

The starting point will be a presentation of these ethical principles in the context of the primacy of the human person as well as of the ethical and legal status they may receive. This leads to the definition and explanation of each concept and of their mutual relations. Indeed it is important to emphasize that these principles, rather than being mutually exclusive, are interdependent in the protection of human beings in

biomedical research and applications. Moreover the definition of these principles must be considered in connection with the principles of the dissemination of social solidarity and responsibility in the modern European societies, where we are experiencing a transformation of the legal systems towards an extended notion of state responsibility and a concern for the protection of vulnerable and weak persons.

The choice of “autonomy”, “dignity”, “integrity” and “vulnerability” as the four basic principles in bioethics and biolaw expresses the intention to give a solid foundation to the protection of human beings in relation to the rapid developments occurring in biomedicine and biotechnology. Therefore, these principles can be said to express a European Ethical and Legal Culture focusing on the recognition of the autonomy, dignity and integrity of the human being. As such, they are encompassed in the framework of the defence of human rights and the dignity of the human person. In fact, the principles imply basic human rights: the right to self-determination of the individual but also the right to protect the private sphere of the person. Therefore, this investigation interprets the basic principles as being at the same time descriptively ascertainable as an immanent normativity in current bioethical and bio-legal developments and as guidelines for the proposal of a future European policy for bioethics and biolaw.

By fostering respect for persons as ends-in-themselves in a European legal culture the application of the principles must also reflect the cultural differences and local variations existing in Europe. Such a cultural “regionalism” is grounded on the idea of *subsidiarity*, according to which each European state applies the principles in keeping with the particularity of its specific cultural convictions and traditions.

Similarly, the basic ethical principles are applied in different ways in the different concrete fields of biomedicine. They become an integral part of medical practice in the medical institutions. This means that the concepts of autonomy, dignity, integrity and vulnerability are not only *deduced* from universal standards, they are also *induced* from reflection on the particular situations in which they are applied. However, it is important to promote the principles in national legislations and legal practices, for example by the development of National Councils of Ethics in all European states.

At a more basic level, the principles are founded in the anthropology of the bodily incarnated human being. Therefore, the principles stand in close relation to respect for the human body. There is an ongoing “personalization” of the body. Therefore, the human body is an important area of application of the principles, and they constitute the grounds for the inclusion of respect for the human body – as a part of respect for

the human person – in the European legislations on bioethics. This is also the grounds for the integration of the basic principles into medical deontology considered as an integral component of clinical medical practice.

It is also important not to interpret the principles of dignity, integrity and vulnerability in an anthropocentric fashion only. They should envisage the integration of the human person in the large-context and life-world of living nature. To what extent these principles apply to animals and other living organisms, and how they could inspire the legislation on these matters are topics which are currently being investigated. The extension of the sphere of legal and ethical concern to the whole of biosphere, however, is necessary in an age of increased human responsibility in relation to nature and animals.

Definition of the basic ethical principles

Autonomy is not only understood in the “liberal” sense as “permission”. Four further important meanings of autonomy can be put forward: (1) autonomy as the capacity of decision and action without external constraints; (2) autonomy as self-legislation and insight into the moral law; (3) autonomy as self-creation; (4) autonomy as a political concept expressing the political self-determination of the individual. It must be seen as a principle of self-legislation of rational human beings taking part in a universal moral domain. This does not exclude recognition of pluralism as a political fact of modern societies. But it is necessary to work with a more comprehensive idea of autonomy, recognizing the tensions between different conceptions of good. The “republican” sense of autonomy is built on the vision of “the good life for and with the other in just institutions”. This is the basis for privacy, confidentiality and informed consent.

Autonomy is not considered as the only foundational concept in bioethics and biolaw. Autonomy remains essentially an “ideal” because of its structural limitations (e.g., human dependence on external factors, lack of information, limited capacity of reasoning). This limitation is also due to the fact that human existence is embedded in several contexts and affected by a variety of limiting situations, that can make it hard to apply this concept in the case of a number of subjects (e.g., minors, coma patients and the mentally ill).

Dignity cannot be reduced to autonomy. It is defined both as the *intrinsic* value of every person and as a reference value for human conduct. It expresses the outstanding

position of human beings in the universe, from which derives the inviolability of individual human life. Human dignity also expresses the intrinsic worth and equality of all human beings and expresses the moral responsibility of the human person. Due to these characteristics, human dignity entails several moral norms and duties: it imposes respect for the moral agency of any human subject. It means that every person must be considered as a being without a price, and impossible to commercialize. Proudness, degradation and self-esteem are notions essentially related to human dignity in the context of the intersubjective relations between individuals. Finally, dignity concerns metaphysical experiences of human beings in the extreme situations of existence (such as when it is referred to as a “loss of dignity” in certain terminal illness, or of “degrading treatment” in other situations).

The principle of respect for integrity refers to the global sense of human life that should not be destroyed. Integrity is a “coherence” that in a certain sense must not be touched. This coherence, or rather *Lebenzusammenhang* can sometimes be the narrative coherence of a patient’s life or, in other cases, the narrative unity of a human culture. Integrity has four meanings. It can be understood: (1) as totality, wholeness, completeness; (2) as a personal sphere of self-determination; (3) as the virtue of uncorrupted character, expressing uprightness and honesty; (4) the legal notion of integrity refers to the moral integrity of the legal or medical system. In bioethics and bio-law the idea of integrity understood as an untouchable core, “the personal”, that must not be subject to external intervention is the most important: also the personal body must be considered in the phenomenological perspective that entails the self-mastery of the body. The fulfilment of this condition obviously requires a relationship of trust and personal confidence between physician and patient (for instance, there is a close link between identity and integrity, where a personal narrative expresses the life context of the individual; therefore the doctor must pay due attention to this narrative). In this way, integrity is an indication of the right to privacy and its respect measures the virtues of the legal and medical systems.

Vulnerability is closely linked to integrity but it stresses in addition the fundamental fragility of the human condition. Protection of vulnerability is the bridging factor between “moral strangers” in a pluralistic society, and therefore respect for vulnerability is essential to policy making in the modern welfare state. Vulnerability is patently a universal characteristic of the human condition, but its consideration also includes the protection of animals and of the teleological auto-organization of the world. Vulnerability, however, has been largely misunderstood in modern society, which has been guided by a so-called vulnerability-reducing agenda, that aims to eliminate all forms of vulnerability, i.e. suffering, abnormality, deafness and disabili-

ty, to attain “perfect” human beings. Respect for vulnerability must find the right balance between this logic of the struggle for immortality and the finitude of the earthly presence of human suffering. As an expression of the destiny of finitude, the ethical acceptance of vulnerability is the fundamental basis for approaching the human condition.

Medicine faces suffering and death as dramatic expressions of this vulnerability. From the first point of view, its task is that of reestablishing the natural balance of the human body and organism. In this sense it is a normative science, even though it has its foundations in the physiology of the organism. Medicine’s action directly concerns bodily vulnerability; the human person, however, is both object body and lived body. This is why a humanistic medicine must be guided by the application of all the basic principles with the aim of protecting the human person. In particular, respect for vulnerability should be made more evident as the essential foundation of the treatment of human beings in hospitals and the legal system.

The basic ethical principles in different fields of biomedicine

The basic principles can be considered as the foundation of the patient-physician relationship in clinical practice. Respect for the basic principles contributes to improving physician-patient communication. This depends on the fact that integrity and identity are becoming integral constituents of the concept of good life. Understanding informed consent as a “pacte de soin” includes the integration of the basic principles in clinical practice. Therefore, consideration of the respect for persons in a communicative process is essential to the philosophical clarification of the physician-patient relationship and the foundation of informed consent. This is a confirmation of the reaction to physician paternalism that is already present in the Helsinki-Declarations and is a support for the establishment of patients’ rights in all national legislations. It establishes self-esteem and self-respect as the foundation of informed consent. Informed consent should be extended to include patients’ rights and patient democracy, as is already the case in many European legislations.

As part of good clinical practice, the principles are also applied to the protection of human subjects in biomedical *research*. They play a fundamental role in the evaluation of projects for medical research, taking into account the limitations of the autonomy of research subjects. This means that human dignity sets limits to experimentation. But participation in experiments could be a generous and dignifying

sacrifice of the individual, who can be thought of as serving humanity. However, concern for integrity and vulnerability must also lead to the minimization of risks.

As a consequence of the above considerations, research ethics committees could include the participation of representatives of non-scientific disciplines. The Danish legislation, for example, that requires the participation of people representing the humanities, is very significant for research ethics committees. These people representing the humanities could be seen as representing the rights of patients in medical experiments. They have a linguistic and conceptual competence different from those of the medical specialists and can therefore contribute with important ethical knowledge in order to evaluate the participation of research subjects in medical experiments.

Concerning reproductive technologies, the traditional family, considered as a cultural institution regulating generational descent, could be protected by the basic ethical principle of retributive justice. It is argued that the dignity of the child includes the right to this participation in the descent of generations. Even though it may not be contrary to the dignity of the child to be born and raised in same-sex families or single-parent families, this represents an increase in the child's vulnerability, given our present state of culture. Donor anonymity is problematic as constituting a violation of the dignity of the child, because he or she has no possibility of obtaining knowledge of the genetic father. Infertility treatment might be a challenge to the dignity of the human body of the woman, but it must also be admitted that infertility is a very unhappy state of being.

In relation to human genetics, the principles represent a humanistic account of existence wanting to protect the genetic make-up of the human species. This implies respect for the freedom of the individual as an end-in-itself in relation to genetic information and the genome. The human person cannot be reduced to a genetic structure and the human genome should not be commercialized. Genetic intervention should be performed in keeping with our ideals of humanity, where reproductive justice requires an unchanged genetic identity and integrity. Genetic integrity is seen as a part of genetic heritage (*patrimoine génétique*). This means that genetic integrity refers to a personal sphere of intrinsic value that should not be changed by decisions taken by society. It is also ethically important to protect genetic "privacy" so that people with "bad genes" are not discriminated against.

There is no consensus in Europe about the status of the human embryo. However, the basic ethical principles have significance for embryo protection. There is a

progressive differentiation of the relationship between the principles and the development of the human person. This means a gradualist conception of the respect for the unborn human being that has encouraged certain bioethicists to propose what they consider a third way between utilitarianism and “fundamentalism”. According to this view, the embryo is thought of as a “potentiality of person”, as a future participant in society and as such it is a symbolic expression of the destiny of humanity. This is a position which obviously presupposes that there is a difference between human being and person and that, in particular, not every human being is a person. The clarification of this thesis necessarily implies various metaphysical perspectives regarding what is a person and of the personhood of the embryo in particular. Embryo autonomy, for instance, is difficult to accept, but embryo dignity means that the embryo must be conceived as an end-in-itself, and this is also the foundation of the relationship between identity and integrity, where the embryo is conceived as a unique and contingent expression of human life, and these are characteristics independent of autonomy. This explains why the status of the embryo is an ontological issue preliminary to the ethical question of its respect.

In relation to organ transplantation, the body is considered as an intimate part of the individual, and organ donation must be conceived as a generous act based on autonomy, patient self-determination and informed consent. Protection of citizens’ personal sphere of life is important for the use of the principles in relation to organ transplantation. The body is an expression of the dignity, integrity and vulnerability of the human person. This means that organs cannot be commercialized. They must be defined as “*res nullius*”, as generous gifts. At the same time this includes the dignity of the self-organizing human body as an expression of the person. The dead and dying always have dignity and the dying person must not be degraded. Anonymity constitutes a protection of both the integrity and the private sphere of the human body. But a complex and ambivalent logic of the gift cannot be avoided and anonymity should be further discussed.

For the reasons just discussed, organ procurement should be based on agent neutrality. What is important is not so much the choice between an “opting in” and an “opting out” system for organ procurement. To secure responsibility and solidarity among citizens, a democratic state should introduce a system of registration of refusals or acceptance so that the citizen’s personal decision is made clear.

To protect vulnerable populations, society should recognize the limitations of the liberal model of patient autonomy. It should develop care-based ethics instead of a rights-based morality. But this should not lead to paternalism. The intrinsic

dignity of the human being refers to its dignity and self-identity. In this context, the special need to integrate vulnerable populations into society is of paramount significance. This recognition of the sociability of handicapped persons stresses the need to avoid social exclusion. Vulnerable persons must be considered as an integral part of a humanistic culture where they are seen as persons and not discriminated against.

Concerning euthanasia and End-of-Life issues, the right to a dignified death does not include the legalization of active euthanasia which is, in itself, contrary to respect for the intrinsic value of the person. Therefore, assisted suicide and euthanasia can be admitted only in specific, well- defined situations (in virtue of respect for other fundamental principles), but not the legalization of euthanasia as such. The debate on euthanasia is marked by certain confusion surrounding the concept of autonomy. Euthanasia is not the logical consequence of the principle of autonomy understood as self-legislation and insight in the moral law (moreover, autonomy and dignity are not the same). We have to keep the distinction between active and passive euthanasia at some level, and therefore active euthanasia must be prohibited. This understanding of human dignity is opposed to the legalization of euthanasia. Instead, the concept of a “mild death” is worthy of promotion: palliative care and good pain treatment are essential in the hospital setting and this is contrary to euthanasia.

The extension of the application of the basic ethical principles to animals and nature requires moving away from an anthropocentric way of considering them. Respect for animal integrity must be institutionalized in legal regulations. This is an understanding of the ethical significance of animals more comprehensive than the use of the concept of animal welfare. We must also recognize that human dignity reflects itself in our treatment of animals. The intrinsic value of animals, determined by their way of life, must be put forward as a guideline for legislation. An attempt should also be made to include the application of the principles to the natural world as a whole, and the idea of the dignity of creation might be an interesting complement to the already-established concepts of biodiversity and integrity.

The basic ethical principles in a European legal culture

At the legal level the principles are expressions of a “European legal culture”. This can be demonstrated by an analysis of the role of the principles in the different countries of the European Union. The principles appear in this way as the foundation of a European constitutional culture of the protection of human rights. Accep-

tance of the basic principles represents a move from bioethics to biolaw that situates the principles at constitutional level. In this way the principles express respect for the common good and a common *res publica* in European societies as the construction of a just legal order.

It must, however, be admitted that the meaning and importance of the principles are very different in each of the European countries, despite the existence of some common frames for discussion. The situation in the different countries can be summarized in the following survey.

Biolaw and bioethics in Austria are marked by a pragmatic positivistic legal tradition that is limited by Catholic theology and a German-inspired legal tradition of the protection of human dignity and integrity. There is an emerging critique of medical paternalism that leads to an interpretation of autonomy and self-determination from a Kantian perspective. Austria has no specific health law but only some regulation of single biomedical problems.

Belgian society can be seen as advocating a pluralistic approach to bioethical problems in which the notion of autonomy has great importance. Belgium is therefore an interesting test case for the formation of a Common Biolaw for Europe.

Bulgaria is an ex-communist country which has been searching for a new bioethics and biolaw after the end of the cold war. Bulgaria is characterized by the confrontation between Byzantine and Muslim culture and issues of bioethics and medical ethics are therefore considered in terms of confrontation between religion and secularism. Regarding basic ethical principles, multiple interpretations depending on different religious points of view are widely discussed.

In Croatia, there has been special focus on bioethics and biolaw after the country's independence. In particular, due to the importance given to the religious dimension of the approach in this country, special relevance has been given to respect for human dignity and human rights. An important approach to bioethics in Croatia has been the concept of integrative bioethics, developed in South-Eastern Europe, where the contribution of the Croatian Philosophical Society has been important.

In Cyprus, the development of bioethics and biolaw has been marked by the establishment of the National Bioethics Committee in 2001. This has contributed to the internationalization of the debate and legislation on bioethics so that the opin-

ions and decisions of the country comply with general European initiatives in bioethics and biolaw.

In the Czech Republic, or Bohemia, the situation of bioethics and biolaw has been deeply influenced by the communist experience. Although the Czech Republic has been considered as deeply integrated in European culture, the communist regime, after the Second World War, broke this inheritance and challenged political democracy and social welfare. Now, bioethics and biolaw are strongly focused on the protection of fundamental human rights and freedoms, expressed in concern for the basic ethical principles advocated for European bioethics and biolaw.

The Danish situation can be interpreted as being “weakly normative”, where a pragmatic, bureaucratic legal system has slowly become more open to ethical issues. There is still a strong utilitarian trend present in the public debate. This, however, has been opposed by arguments (presented in a very extensive public debate) advocating the establishment of the basic principles of autonomy, dignity, integrity and vulnerability as the ground for bioethics and biolaw.

In Estonia, the debate on bioethics and biolaw was also influenced by the communist experience. However, after the independence there was increasing focus on teaching ethics in higher education. This teaching included general ethical perspectives but also the development of ethics codes of conduct that applied particularly to biomedicine and biotechnology. Legally, Estonia with the other Baltic countries, became more oriented towards concern for basic rights.

The Finnish legal system is characterized by a mixture of Scandinavian pragmatism and a German-inspired natural-law theory. Basic rights of freedom, dignity, integrity and equality are protected by the Finnish constitution. The principles have had some importance in relation to recent legislation on patients’ rights.

French bioethics and biolaw are marked by a strong principlist approach to the basic principles. The French laws on the human body apply the principles to the bodily incarnated human person. The principles are therefore greatly present in the French debate as an interpretation of basic human rights.

Germany is characterized by a strong and extensive presence of the concept of human dignity in the regulation of biomedical ethics. Autonomy, integrity and vulnerability are seen in the perspective of respect for the inviolable dignity of every

human being. In addition, there is great public skepticism towards the technological developments of biomedical science.

In Greece, there is a relatively positive attitude to the new technologies, and the principles are seen in the light of the Hippocratic tradition of medical ethics. Due to the inspiration of Germany in Greek law, the principle of human dignity is widely present in the Greek legislation.

In Hungary, there was increased focus on liberalization and liberal bioethics after the end of the communist regime. Hungary returned to get inspiration from European bioethics and biolaw. The basic ethical principles of autonomy, dignity, integrity and vulnerability are easily integrated into the Hungarian situation where in particular the concept of vulnerability has received special attention.

The Irish situation is characterized by the ongoing search for peace. The Irish constitution is marked by a strong respect for human dignity, related to the sanctity-of-life doctrine. In particular, the state recognizes the protection of the life of the un-born child as essential to the idea of human dignity.

The Italian debate on the basic principles is marked by the opposition between Catholic and secular bioethics. Also American principlism, the human rights approach and personalistic philosophy have had an influence on the Italian debate on bioethics. At the same time there is, in the philosophical debate on natural law, a transition from a metaphysical conception of human nature towards a consideration of concrete bodily nature.

The debate on basic ethical principles in Latvia after Soviet times has focused on how to respect the human person and informed consent in biomedical developments. In particular, it was important to re-establish basic dimensions of bioethics and biolaw in the legal system.

In Lithuania, after the Soviet period there were also efforts for the establishment of a sound legal system of control of bioethical issues. Lithuania has for example developed a comprehensive system of control of biomedical research in order to ensure respect for the human person. In this sense, Lithuania has notably contributed to the protection of human rights in biomedical research and practice.

Luxembourg often follows Belgium and the Netherlands in legislation and regulation on bioethics and biolaw. This was for example the case with the legislation on

ethanasia where the country followed the legislation of the Netherlands, with little difference. However, it could be argued that there is greater concern for dignity than autonomy in Luxembourg.

Bioethics and biolaw in Malta are influenced by the principles of Catholic bioethics as is the case in other southern European countries such as Italy, Spain and Portugal. In the domains of reproductive technologies and genetics there is not so much legislation as in other countries; so Malta tries to comply with international legislation in order to avoid gaps in its own legislation.

The Netherlands have great traditions of tolerance and pluralism, due to the absence of a dominant state and the peaceful co-existence and cooperation of various “pillars”, that is, of coherently organized groups based on religious or political affiliation. It is a society of “overlapping consensus”, characterized by the liberal humanist tradition of tolerance. This means that the Dutch constitution is characterized by the protection of basic rights such as autonomy and bodily integrity.

Norway is a very homogenous country with little pluralism. The Norwegian application of the basic principles is therefore characterized by a strong Lutheranism, and to some degree by a secularized humanistic respect for human dignity and integrity on the one hand, opposed, on the other hand, to the utilitarian values of progress of the welfare state and industrial society. Norway has a realistic and positivistic legal tradition and human rights were not basic to an old constitution and a pragmatically oriented legal system.

The ideas of human dignity, integrity and autonomy are essential elements in the constitution of Portugal, which is a modern welfare state. But Catholic natural law thinking still has great influence as the grounds for social solidarity. In the new democratic society people value the basic principles very highly as fundamental social virtues. Portugal is a sovereign republic based on human dignity.

In Poland, since 1975 there have been efforts to establish a system of research ethics committees and a well-developed structure of hospital ethics committees has been set up. Poland, due to its Catholic tradition of ethics, has strongly focused on ethical principles in relation to a personalistic respect for the human person in bioethics and biolaw.

In Romania, there has been a revival of religion and a concern for values after the decline of the communist regime. Greek-Orthodox religion sets limits on liberal

bioethics. This has implied more focus on a conservative interpretation of the basic ethical principles. Romania is inspired by Southern European bioethics and in particular concern for human dignity is important in the Romanian approach to bioethics and biolaw.

In Slovakia or the Slovak republic, bioethics and biolaw developed considerably after the revolution that ended the communist regime in 1989. More interest appeared for new ethical problems and the basic ethical principles were considered important to deal with these new problems. Important steps were the creation of a national bioethics committee and the establishment of university chairs in the field.

In Slovenia, there is a tradition of respecting human beings in research. The basic ethical principles have been important in this context. A national bioethics committee was created that facilitates debates on biomedical issues and contributes to the protection of the human person in the context of development of bioethics and bio-law.

After the new constitution in 1975, Spain has accelerated its move into a pluralistic society in search of a common value framework. The new liberal and utilitarian values are accompanied by the secularization of Catholicism. And the principles of autonomy, dignity, integrity have great influence on the new democratic society.

Like the other Scandinavian countries marked by Scandinavian legal realism and pragmatism, Sweden had a constitution with little emphasis on human rights. But respect for the basic principles taken as an increasing foundation of human rights is becoming more important in this country.

Switzerland is marked by the most extensive use of the principles due to the fact that the country has introduced the concept of the dignity of creation in its constitution. Bioethics is regulated in the constitution but also in a decentralized way at the level of the different cantons, so there is no uniform regulation of the different bioethical subfields. Yet personal autonomy is very important, for example in relation to political self-determination.

The framework for the debate and discussion of bioethics in the United Kingdom is that of the conflict between utilitarian and human rights perspectives. The regulatory background is multi-layered and the culture is heterogeneous. The human rights perspective defends such rights as autonomy, dignity, equality and respect. Of special influence in the UK is the American principlist approach as well as the utilitarian position.

After the short survey of the *presence* of the basic principles in each country we can try to offer a comparative description of their *development* (i.e. of the level and status of their implementation) in the European countries. Of special interest are the similarities and differences in the development of ethics and law, and this clarifies the possible harmonization of the principles in European legislation. It is certainly difficult to harmonize the European legislations (as can be seen through an analysis of each biomedical field). Nevertheless, it is possible to point out some general interpretations of the principles in relation to various biomedical areas in the different European countries.

Most countries interpret the principles in the light of human rights. This means that bioethics and biolaw are matters of constitutional concern. Most constitutions protect the integrity and dignity of the human bodily-incarnated person and bio-law is a fundamental problem of constitutional interpretation. In Italy, Spain, Greece, Ireland, Portugal, Germany, Malta, Switzerland and to some extent France, dignity, integrity and human rights are explicitly written into the constitution, while countries like Denmark, the United Kingdom, Norway, The Netherlands, Belgium, Luxembourg, Sweden and Austria are more focused on autonomy, although they do attach great significance to the principles without defining them directly in their constitutions. But in these countries we also experience a move towards giving bio-law a constitutional basis. Newer Nordic members of the European Union like the Baltic countries (Lithuania, Latvia and Estonia), follow the concern for human rights in Scandinavian countries. Countries like Poland, Hungary, Bulgaria and Romania also focus on basic ethical principles in relation to respect for human persons in constitutions. In South-eastern Europe, Croatia, Slovakia, Slovenia and the Czech Republic, there is in particular focus on integrative bioethics, integrating different concepts of bioethics with the perspective of the basic ethical principles as an important dimension.

The basic principles of autonomy, dignity, integrity and vulnerability are not only *ethical* principles applied at national level, they are also *legal* principles and they can also be shown to have significance for the development of international law in the EU and the Council of Europe. This legal protection of the human body is carried out in the European Commission, the European Parliament and in the Council of Europe, which has recently drafted a Convention on Human Rights and Biomedicine to be ratified by the various European Countries. Furthermore, European development is reflected in the formulation of Declarations in international law at UN-level. This legal realization of the basic principles can be seen as a fourth generation of human rights or “bio- rights” that implies universal protection of the human person with spiritual and intrinsic value as an end-in-itself.

A humanistic vision of a universal bio-law

The presence of the basic principles in relation to the individual leads to considering the protection of the human bodily nature as a symbolic norm and democratic conception, founded on the ideas of freedom, equality and solidarity. The principles refer to the European conception of humanity, determined by the specificity of the European cultural heritage and it is legally realized in the concept of human rights.

At the same time, the interpretation of the principles varies according to the cultural and political context in each European country, determined by the functioning of the bio-legal sphere of justice between the universal and the culturally determined local features. Bio-legal legislation processes are realized in a tension between the local and the universal, as can be seen in the great differences between the interpretations of the principles in each country. The legislations are formulated in a national context and often contradict the development of a European consensus and harmonization of biomedical questions. But there are limits to cultural particularity because the different countries are bound to respect the international declarations.

The universal conception of human beings can be said to be present in the implicit narratives of bio-law. The hermeneutics of judgement presupposes that law is a narrative phenomenon, where narratives are a part of both legislation and ordinary legal decisions. The “small” narratives, behind every legal decision, are in connection with the great narratives of the constitutions forming the collective narrative of bio-law as the foundation of the vision of human beings built on respect for autonomy, integrity and dignity. This narrative is about the vulnerable human being whose body must be protected in connection with the explosive development of technology. This is manifested in the specific areas of bio-law where the concrete decision-making process contributes to the formulation of the collective narrative.

The general narrative about respect for the bodily human identity is realized in many different ways in the different biomedical fields. The dominant narrative is a story about the unacceptable intervention of science in the human body and the possibility of creating new life and civilizations by the use of biomedical technology. It is the story of the protection of the fragility of democracy confronted with the tendency of modern science to become “Frankenstein”.

The humanistic vision of bio-law concerns protection of the humanity that we want to be. It implies the idea of the free human person, creating and realizing him/

herself in the world. It implies also the protection of the fragile and vulnerable other person, who because of disease and suffering needs help, respect and concern. And further, it is a humanism regarding the responsibility of society for future human beings. Bio-law concretizes humanism as being a protection of the bodily balance and the lived body as norm for technological development. There is a strong continuity in the Western European legal tradition, where a culturally determined norm for human nature is basic to the legal system.

The humanistic vision of the protection of the person is rather negatively defined by the fear of democracy ending up in a totalitarian society. In this way, what is human is defined as a negation. We know what it is not (that it is not “bio-power”), violation of integrity, but it is difficult to give a positive description of human nature. The person must have the right to exist freely and develop him/herself. Everyone must have the right to find his or her way through life and be a surprise for him/herself by keeping his/her integrity and identity.

Against this background, bio-law can be said to imply a triple repartition between a teleological vision of human beings, legal principles and concrete legal rules. The bio-legal vision of human beings, grounded on respect for the lived body and a democratic conception of equality, is based on a general teleological principle, determining concrete legal thinking. The bio-legal principles are realized in factual legislations as the background for detailed regulation of factual questions: in concrete contexts this leads to a compromise between different ethical conceptions, so that a vision of human beings and of the destiny of humanity only can be considered as a general but dominant conception for concrete legislation and legal practice.

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