

**Final Report to the European Commission
on the Project
Basic Ethical Principles in Bioethics and Biolaw
1995-1998
Part B**

1. Project Title:

Basic Ethical Principles in Bioethics and Biolaw

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7. Background / Rationale:

The BIO-MED II-project, *Basic Ethical Principles in Bioethics and Biolaw*, 1995-1998 was coordinated by Peter Kemp as director of *Centre for Ethics and Law*, Copenhagen, and connected to the project of the Danish Research Councils, *Bioethics and Law* 1993-1998. The financial support from five Danish Research Councils to the Danish project has permitted that the centre was already established in 1993 and that from late 1995 the ground was ready for the reinforced concerted action according to the EU-project. The two projects have been of mutual benefit, because the aim was nearly the same: clarifying the Basic Ethical Principles in Bioethics and Biolaw according to ethical discussions, legislation and/or legal administration concerning bioethical issues, in particular in European countries. In the first two years of its existence the Centre has taken contact with many other centres for bioethics and/or biolaw, and thanks to the European project the network was reinforced and enlarged. Thus there was a substantial background at the *Centre for Ethics and Law* in Copenhagen, when the EU project started.

8. Objectives and Primary Approaches:

The objectives of the proposed project on *Basic Ethical Principles In Bioethics and Biolaw* was to provide early warnings for new bioethical and social issues concerning biomedicine and health research. It was considered that the great problem in bioethical discussion was the limits of the principle of respect for autonomy. It was realised that children, incompetents, senile demented, mentally handicapped and generally all the people who, perhaps without realizing it, are strongly dependent on other people or who are victims of blind despair, are intellectually and/or physically incapable of protecting themselves. The problem was: does respect for the individual only consist in the respect of its autonomy? Is the principle of selfdetermination the only basic ethical principle of social and individual responsibility in the field of bioethics and biolaw? In order to answer these questions, the project wanted to examine and discuss three other principles: the principles of dignity, integrity and vulnerability. Then a collaboration between 22 partners was established and four large meetings were coordinated by the *Centre for Ethics and Law* as administrator of the project. A documentation unit was created that has served the project during the whole project period by collecting and registering documentation, giving service to students, researchers, politicians, official institutions and the public, compiling relevant bibliographies, and publishing as much documentation as possible.

9. Methods, Statistics, Ethical Aspects:

The methodology has implied the followings aspects:

- (1) Analysis of existing literature and interviews with key actors in order to describe the current status and future developments of bioethics in the field of different biomedical technologies. Description of impacts of present or future applications to be expected in European countries.
- (2) "Translation" of basic ethical principles: autonomy, dignity, integrity, vulnerability etc., into typical situations of medical practice in the field of biomedical technology and therapy, in the form of different scenarios, in order to confront key actors in interviews with the situations described. The contents of the scenarios has been transcribed into questions suitable for a representative survey.
- (3) Establishment of the network of partners and enforcing this network by exchange of papers and collecting information and by travels of the coordinator, the rapporteur and the head of documentation to the different working places of the participants.
- (4) Organizing meetings for all partners in order to (a) stimulate the debate on bioethics and biolaw between the participants, (b) having new insight in different approaches on bioethics and biolaw in the European countries, (c) collecting working papers of research and biolegal information, (d) preparing the second volume of the enlarged final report (including individual partners' and guest speakers' contributions, (e) discussing the first volume of the enlarged final report and looking for agreement between partners on policy proposals.
- (5) Creating and developing the *Documentation Unit for European Bioethics and Biolaw* (headed by a scientific archivist) in connection with the international documentation files already established at the *Centre for Ethics and Law* in Copenhagen.
- (6) Organizing two international conferences on Bioethics and Biolaw including papers from outstanding persons in bioethics and biolaw

10. Results, Discussion, Conclusion:

a. Research:

Since June 1997, Jacob Dahl Rendtorff was employed as Project Rapporteur. In this capacity he has visited most partners and a number of other experts in Europe to obtain material for the preparation of the enlarged

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final report, which he wrote together with the Project Coordinator, Peter Kemp and which will be published under the title *Basic Ethical Principles in European Bioethics and Biolaw*, probably by the *Centre for Ethics and Law* in collaboration with the *Institut Borja de Bioètica*, Barcelona. The first volume presents the research that was carried out at the Centre for Ethics and Law in close collaboration with the partners. The second volume presents research results and views of individual partners in relation to their particular fields of bioethics and biolaw. It also contains papers delivered by the distinguished guests at the meetings.

But even though the partners have worked very hard on the discussion of the basic ethical principles, and many of their views are present, final responsibility for the positions taken by the enlarged final report rests with only two people, the Project Rapporteur and the Project Coordinator. This is due to the impossibility of achieving complete unanimity on the philosophical reflections and the desire not to pressure anyone into such an agreement. The opinions and research results of individual partners are expressed in the Working Papers (5 volumes, see list of publications below - point 11) and in the Second Volume of the Report. It must be emphasised, however, that the work could never have born fruit without the close collaboration of the project partners. The partners have provided valuable insights into national debates, legislation and legal practice and they have contributed with important philosophical clarifications of the principles. As a result of the final meeting of the Research Project at the Institute Borja in Barcelona in November 1998, a great majority of the partners (16) also agreed on some Policy Proposals to the European Commission ("The Barcelona Declaration"). These proposals, on the basis of the discussion of the Project Report, present the views of the mentioned partners on the role of the ethical principles in a future European bioethics and biolaw. They are integrated (together with a French translation) in the first volume of the enlarged final report and they have also been published by the *Centre for Ethics and Law* in two separate leaflets, in English and in French respectively.

The enlarged final report is not merely a neutral "observer's summary", but represents an active and engaged view of the basic ethical principles. The subject of the report should be seen as "ethical politics", rather than "moral epistemology". Instead of falling into the "relativistic trap" of giving the principles any and every possible meaning, the report provides them with a specific interpretation. The view taken is not dogmatic nor blinkered, the report is aware of both the many different ways of justifying the principles and of alternative understandings of the values of autonomy, dignity, integrity and vulnerability. But at the same time we must recognise that there is no way of justifying the principles that is not integrated with, and dependent on, a specific ethical theory. Therefore, the enlarged final report gives a description of the principles that may be seen as being founded on and stemming from the particular philosophical position which has been developed at the Centre for Ethics and Law over the last five years. But though the enlarged final report reflects this specific philosophical position it also takes the time to describe the cultural differences in the interpretation of the principles in the various European countries.

There is, however, still a long way to go. The enlarged final report does not give an exhaustive, final presentation of the ethical principles. We are simply trying to identify the principles as four important ideas or values for a European bioethics and biolaw. We do not conclude that they are universal everlasting ideas or transcendental truths but rather that they are reflective guidelines and important values in a post-conventional human rights culture. It is a very tentative manner of putting the principles into play and of clarifying their conceptual, philosophical and cultural background. We are describing four values or normative ideas that people often use and that they find important for their life and existence. The enlarged final report gives an overview of the facts and opinions on the basic ethical principles in different European countries. Such an analysis of the principles simply presents a range of uses, descriptions and understandings of the principles in different biomedical contexts and cultures. But even if the analysis may be fairly tentative and pluralistic, it is our opinion that there are limits to the possible uses of the principles, and where we feel it appropriate we present our proper philosophical views on the matter. These opinions are listed in the *Coordinators Conclusions* (cf. the enlarged final report, chapter VIII on "Perspectives for Discussion"), which should be distinguished from the partners' Policy Proposals to the European Commission. The latter is highly significant as a philosophical and political agreement between experts in bioethics and biolaw from many different countries in Europe.

b. Documentation:

To the enlarged final report we have added a "Report on the Documentation Work" (Annex I) prepared by Margareta Broberg, the Head of Documentation. An important aim of the Biomed Project has been to develop the *Centre for Ethics and Law* as a Documentation Centre for European Bioethics and Biolaw. The present Project Report could not have been carried out without this effort of the documentation staff to facilitate study and research within the field of bioethics and biolaw. Among other things they have created bibliographies in important fields of bioethics and biolaw, e.g on reproductive technologies, on cloning and on human dignity in ethics and law. This pioneer task has been even more important in a time where there are few public documentation centres that attempt to document the interdisciplinary field of "Basic Ethical Principles in Bioethics and Biolaw", in accordance with the EU Project.

The holdings of the documentation unit (Jan. 1999) include the following categories:

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books (about 700 titles), chapters from books, encyclopedias
publications and papers from international organizations and societies
series of journals, journal articles
newspaper articles
grey literature
biological literature, laws, guidelines

There is also a separate collection of brochures, bio/ethical centers' information and documentary material from Health Organizations, such as the WHO, and from Ministries of various countries and Boards of Health.

c. Meetings

The following meetings have been organized:

- (1) Small meetings between members of the Coordinator's staff and members of staff from different partners
- (2) Small meetings with key-persons in international bioethics and biolaw
- (3) Four meetings between all partners (in Copenhagen 1996, Sheffield and Utrecht in 1997, Barcelona in 1998)
- (4) Two international conferences on Bioethics and Biolaw in Copenhagen (financed by private funds as well as separate grants from DGXII) : 29th May to 1st of June 1996, 3rd to 6th of June 1998. The proceedings from these meetings will be published by the international editor, Rhodos, Copenhagen.

C. The Coordinator's Conclusions:

1. Four ethical principles ought to be considered in their mutual connection as basic principles of European bioethics and biolaw: autonomy, dignity, integrity and vulnerability. These basic principles should be made more explicit in future European policies on bioethics and biolaw in order to protect all citizens confronted with biomedical technology.

I. Understanding of the Principles

2. All four principles express dimensions of the human being which must be respected and protected, and three of them - dignity, integrity and vulnerability - also concern respect for and protection of animals and living organisms.

3. Autonomy should not only be interpreted in the liberal sense of "permission" given for treatment and/or experimentation, instead five aspects of autonomy should be put forward: 1) the capacity of creation of ideas and goals for life, 2) the capacity of moral insight, "self-legislation" and privacy, 3) the capacity of rational decision and action without coercion, 4) the capacity of political involvement and personal responsibility, 5) the capacity of informed consent. But autonomy cannot express the full meaning of respect for and protection of the human being. Autonomy remains merely an ideal, because of the structural limitations given to it by human weakness and dependence on biological, material and social conditions, lack of information for reasoning etc. We must recognise the human person as a situated living body. A number of human individuals such as minors, coma patients and mentally ill persons cannot be considered having autonomy.

4. Dignity should not be reduced to autonomy. It says more. Although originally a virtue of outstanding persons and a virtue of selfcontrol in healthy life - qualities which can be lost, for instance by lack of responsibility or in extreme illness - it has been universalised as a quality of the person as such. It now refers to both the intrinsic value of the individual and the intersubjective value of every human being in its encounter with the other. Thus it expresses the outstanding position of the human individual in the universe as being capable of both autonomy in rational action and involvement in a good life for and with the other in just institutions. Respect for the dignity of human being is respect for its inviolability in common life. Dignity concerns both oneself and the other: I must behave with dignity, and I must consider the dignity of the other; I must not give up civilised and responsible behaviour, and the other should not be commercialised and enslaved. Human rights are built on this principle of dignity.

5. Integrity accounts for the inviolability of the human being. Although originally a virtue of uncorrupted character, expressing uprightness, honesty and good intentions, it has, like dignity, been universalised as a quality of the person as such. Thus it refers to the coherence of life that should not be touched and destroyed. It is coherence of life which is remembered from experiences and therefore can be told in a narrative. It is the life-story of a person, the narrative unity or history of human society and culture, the natural grown coherence in the life of animals and plants and finally the created wholeness of the world which makes the conditions for all life. Therefore respect for integrity is respect for privacy and in particular for the patient's understanding of his or her own life and illness. In bioethics and biolaw the idea of integrity expresses the untouchable core, the inner nucleus of life, that must not be subject to external intervention. It is the most important principle for the creation of trust between physician and patient, because it demands that the physician listens to the patient telling the story about his or her life and illness.

6. Vulnerability concerns integrity as a basic principle for respect for and protection of human and non-human life. It expresses the condition of all life as able to be hurt, wounded and killed. It is not integrity as completeness in any sense, but the integrity of life that must be respected and protected as vulnerable.

Vulnerability concerns animals and all self-organising life in the world, and for the human community it must be considered as a universal expression of the human condition. The idea of the protection of vulnerability can therefore create a bridge between moral strangers in a pluralistic society, and respect for vulnerability should be essential to policy making in the modern welfare state. However, vulnerability has been largely misunderstood in modern society, as if all vulnerability, i.e. suffering, abnormality, and disability, should be eliminated in order to create perfect human beings. Respect for vulnerability is not a demand for perfect and immortal life, but recognition of the finitude of life and in particular the earthly suffering presence of human beings.

II. Applications of the Principles

7. All four principles should be developed as the foundation of European bioethics and biolaw in different fields of practice by expressing respect for persons as ends-in-themselves.

8. The principles do not abolish cultural variations in Europe, but demand subsidiarity, i.e. that each European society applies the principles according to their specific convictions.

9. The principles should be applied and considered in relation to the concrete context of biomedicine and medical practice. They are not deduced from abstract reflections, but induced from particular situations of application.

10. The principles should be strengthened by the creation of National Ethical Councils in all European societies. These should be employed to protect the citizen by giving advice concerning application of the principles.

11. The fact that the principles are institutionalised in different ways in the European countries should be respected whether they are expressed in a comprehensive biomedical legislation, as in France and Norway, or in a more liberal framework as in Denmark and The Netherlands. On the other hand the principles have greater importance as general guidelines for a harmonisation of European policy in bioethics and biolaw.

12. Respect for the four principles implies respect for the human body as an indication of the required respect for the dignity and vulnerable integrity of human persons.

13. The four principles as a whole should not be interpreted in an anthropocentric fashion. Rather they involve the integration of the human person in a larger life-world of living nature.

14. The principles of dignity, integrity and vulnerability applied to animals and living organisms should be the basis for legislation and legal practice on these matters. The extension of the sphere of legal and ethical concern to apply to the whole biosphere, nature and animals is necessary in an age of increased human responsibility in relation to the whole world.

15. The four principles should be promoted in the framework of solidarity and responsibility, i.e. as responsibility of somebody (or something) for somebody (the society). Their application corresponds to their integration in an ethics of care, which takes care of civilisation and secures the self-realisation of human individuals in the welfare state. This involves that social insurance should be integrated in the collective responsibility of society. The basic principles in the civilisatory movement constitute a change of interpretation, from a contractual rights claim to a protective rights claim confronted with technological development as the basis for the application of the principles in the different fields of biomedicine and biotechnology.

16. The basic principles must be considered as an interpretation of the patient-physician relationship in clinical treatment. This means that integrity and identity are becoming integrated accounts of the good life. Respect for persons in a communicative process is essential to the philosophical clarification of the physician-patient relationship. They are therefore the foundation of informed consent. Understanding informed consent as a "pacte de soin" includes the integration of the basic principles in clinical practice. The idea of this consent has emerged as reaction to physician paternalism. It is a support for the establishment of patients' rights in all national legislations. It should be extended to include patients' rights and patient democracy.

17. As part of good clinical practice the principles must be applied to the protection of human subjects in biomedical research. They should be paramount in the evaluation of projects for medical research, taking into account the insufficiency of the autonomy principle for protection of research subjects. This means that human dignity and vulnerable integrity also place limits on experimentation. But participation in experiments could be a generous and dignified sacrifice of the individual, who can be thought of as serving humanity. The principles must also lead to the minimisation of risks and be used to protect against a pure instrumentalisation of research subjects.

18. Research ethics committees should include the participation of representatives of "lay" people, i.e. people representing human and social sciences and the world of art and literature. Having another linguistic competence than physicians normally have, these "lay" people can contribute with important ethical knowledge in order to understand the risks and the needs for protection of research subjects in medical experiments.

19. Artificial procreation of human beings by reproductive technologies should be evaluated according to the dignity, integrity and vulnerability of the persons involved and of the future individual. No reproductive process should be performed that results in individuals that are physically and/or psychologically weaker than other individuals. Donor anonymity in artificial procreation should be prohibited as a violation of the dignity and integrity of the child, because he or she has no possibility of obtaining true knowledge of the genetic father or

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mother, i.e. the lifestory before birth. Infertility treatment might be thought of as a challenge to the dignity of the woman's human body, but as a human response to infertility, experienced as a very unhappy state of being, it is also an expression of the dignity in the relationships between persons.

20. In human genetics the principles imply that the human person should not be reduced to the genetic structure and the human genome should not be commercialised. Genetic intervention should be performed with due respect for the "genetic heritage" or integrity of human history having an unchanged genetic identity. Bodily integrity should be respected in the genetic enhancement of human beings. This means that genetic integrity refers to a narrative personal and social coherence of values that should not be changed by society. Thus it is important to stress the need to protect genetic integrity and vulnerability and the right to "privacy", so that people with "bad genes" are not discriminated against.

21. Despite the lack of consensus about the status of the human embryo in Europe, the principles can and should be applied to embryo protection. It is possible to claim a progressive differentiation of the relation between the principles and the development of the human person. This means that a gradualistic conception of respect for the unborn human life is possible. Thereby a third way between utilitarianism and fundamentalism can be adopted. Embryo autonomy is difficult to admit, but embryo dignity means that the embryo acquires some integrity or life coherence which must be protected as far as possible. It is considered as a "potential person", as a future human individual and participant in society and as such it is a symbolic expression of the destiny of humanity. But since it is not a person in its final integrity, embryo experiments can in some very strict cases be admitted, presupposing that the embryos are in a very early stage.

22. Since the integrity of the body implies that corporeal life is an intimate part of the individual, some kind of organ donation can be conceived as a generous act based on donor's autonomy, patient's self-determination and the informed consent of both. Also, the body is an expression of the dignity, integrity and vulnerability of the human person. This means that organs cannot be commercialised. They must be defined as "res nullius" and as generous gifts. The dead and dying always have dignity and the integrity of the dying person must not be violated. Donor anonymity in organ transplantation may be seen as a protection of integrity and psychological and corporeal privacy. But a complex and ambivalent logic of the gift cannot be avoided and anonymity should be further discussed.

23. In order to respect autonomy and secure responsibility and solidarity in organ procurement amongst people, a system of registration of refusals or acceptance should be introduced so that the citizen's personal decision is clear.

24. It is important to protect the autonomy, dignity and integrity of vulnerable groups in society. This respect for the principles should be an integrated part of health care practice in hospitals, nursing homes, psychiatric hospitals and other institutions and activities where society has special responsibility towards vulnerable populations.

25. Assisted suicide and euthanasia can be tolerated in extreme situations, but the idea of a "dignified death" should not include the legalisation of active euthanasia which could be a "slippery slope" towards a violation of the autonomy of the weak and sick person. The debate on euthanasia needs more clarity surrounding the concept of autonomy. As claimed by several philosophers (Locke, Kant) euthanasia is not the logical consequence of the idea of autonomy as self-legislation and insight into the moral law. Further, autonomy and dignity are not the same. We must keep the distinction between active and passive euthanasia at some level. The idea of a mild death is paramount, but palliative care and good pain treatment are essential in the hospital setting and this is contrary to euthanasia.

26. The extension of the application of the principles to animals and nature involves moving away from an anthropocentric and towards an antropocentrifugal interpretation of them. Animal integrity must be institutionalised in legal regulation. This presupposes a more comprehensive understanding of the ethical significance of animals than is the case in the use of the concept of animal welfare. Further, it must be recognised that human dignity depends on our treatment of animals. The intrinsic value of animals, determined by their way of life, must be put forward as a guideline for legislation. It should also be attempted to apply the principles to the natural world as such. General use of the idea of the dignity of creature (*Kreatur*) might be an interesting accomplishment of already established concepts of biodiversity and life integrity.

27. On the basis of their pluralistic interpretations in the different European countries, the principles are very important as guidelines and reflective ideas for developing a common policy, when it is thought appropriate, necessary and in accordance with respect for the principles of subsidiarity in the EU institutions and the Council of Europe. This realisation of the basic principles helps to develop a new generation of human rights in international bioethics and biolaw.

D. The Policy Proposals ("THE BARCELONA DECLARATION") of 16 Partners of the project:

A. Preamble

This document is the result of a process of discussion undertaken in a three-year EU BIOMED research project by a group of 22 partners based in different countries within the enlarged European Economic

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Community and coordinated by the Centre for Ethics and Law in Copenhagen. The partners were drawn from several different disciplines and horizons but their common interest was in ethical questions raised by the progress in modern biomedicine and biotechnology.

This process consisted of four big meetings (Copenhagen, Sheffield, Utrecht, Barcelona) and ongoing debate between the partners. It resulted in a two-volume publication (*Basic Ethical Principles in European Bioethics and Biolaw* Vol. I-II) together with a series of Working Papers as a first step towards stimulating and supporting a wide democratic debate about the most controversial questions in bioethics and biolaw. The first volume is co-authored by Jacob Dahl Rendtorff and Peter Kemp, but it was extensively discussed by the partners who participated at the final meeting in Barcelona in November 1998. The second volume contains particular papers by the partners relating to the project.

This short discussion document with policy proposals is aimed at a number of audiences, at decision-makers in the European Union at all levels, at educators at every level, researchers and practitioners, but most importantly at citizens generally within Europe (not just within the European Union). Its aim is to stimulate and assist a broader controversial public debate on some of the most vital and conflictual questions of our times. These questions have to be discussed not only in relation to the local European environment but in a globally sensitive way. The questions are not simply about the welfare of humans but also about social equity, the welfare of animals and the sustainability of the global environment.

In this document, you will find some remarks about the context within which the partners believe that the issues should be debated, four principles that the partners think are helpful guiding ideas in carrying forward the contemporary debate, and an agenda revealing some of the leading questions and some proposed pathway responses.

Indeed, the partners offer this document as experts but also in the spirit of responsible citizenship. In particular, it would be unethical for the partners to impose their specific proposals suggested below. Thus, it is the partners' explicit intention, and the purpose of this document, to facilitate critical democratic debate and responsive and accountable decision making.

B. Context

For the purposes of discussion of policy proposals, the partners worked with the idea that the value of "autonomy" (networked with integrity, dignity, and vulnerability) should be placed in the context of care for others - a context that already presupposes an ethic of solidarity, responsibility and justice (fairness). However, it is important that the idea of "autonomy in the context of care for others" itself should be placed in the broader context of biomedicine and biotechnology, economy, and culture in Europe in the late decades of the Twentieth Century.

First, the accelerated development of biomedicine and biotechnology - particularly in the area of genetics - has created (and is creating) many new possibilities but also it is posing many questions about the place of humans, animals, plants, and the environment (both natural and social). These are questions that the partners believe need to be debated as widely as possible and as a matter of urgency, but without the need being felt to arrive at hasty conclusions. However, there are considerable difficulties in articulating the terms in which such issues are to be framed and discussed, let alone resolved. The proposals below identify four key terms of reference for such a debate (namely the four principles of autonomy, dignity, integrity, and vulnerability) as well as outlining some policy suggestions indicated by these regulative basic concepts in a normative context.

Secondly, the proposals should be read as a contribution to a process of dialogue and debate about bioethical and biolaw policy in Europe. To a considerable extent, policy in Europe already reflects a culture of care for others - witness, for example, the *Council of Europe Convention on Human Rights and Biomedicine*, which was finalised while this project was underway. There is also considerable support in Europe for the principle of non-discrimination and the long-term sustainability of the environment. However, there can be little doubt that Europeans share the sense, first, of a responsibility for, and a responsibility to, others (the sense that others really do matter), and secondly a responsibility for ecological viability. Nevertheless, we are still marking out the conceptual terrain on which we can meet to express our agreement but also our disagreement. The four principles of autonomy, dignity, integrity, and vulnerability, are, we think, important features of that terrain. It is not claimed, though, that these principles represent the whole of that terrain, nor indeed the only way of expressing an ethic of care for others and the quality of the global environment. The way they have been articulated is driven by the wish to achieve an open consensus. While the group agreed that the four guiding ideas are central to the analysis of bioethics and biolaw there was a considerable disagreement about a substantive interpretation of the guiding ideas and in particular the notion of dignity,

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while there were total agreement on the importance of articulating the notion of vulnerability. It should also be made clear that any application of the four guiding ideas will depend heavily on the particular interpretation of the principles.

Thirdly, the proposals offer a conceptual framework within which Europeans can debate issues of bioethics and biolaw. It should not be thought, however, that a common language implies an easy resolution of the matters to be discussed. Facilitating debate is one thing; resolving value differences is another matter altogether. Each of the four regulative principles presented in the next section should be regarded as guiding ideas for debate and decision-making. However, these principles are open to competing interpretations; the precise relationship between each of the principles will be informed by more general theoretical positions taken by disputants; and which life forms are to be included within the idea of the "other" (whether as a rights bearer or as one with interests to be protected and promoted) is contestable, as is the relationship between humans and the natural environment.

Fourthly, the framework is offered at one level for use within the European Union, as an economic community within the global market. Within this market, it must be understood, that biotechnology and biomedicine represent highly competitive global business. The market involves a process of exclusion which operates at a number of levels. At one level, citizens have difficulty in intervening in decision-making in this market. This document seeks to compensate for this democratic deficit. At another level, this post-national market operates to exclude the underprivileged throughout the world, North as well as South. Although this document has been drafted by Europeans for debate amongst Europeans, as we have emphasised, biotechnology is a global business. Whereas the significance of it being a global business is that the ethic of care for others knows no regional boundary, the significance of it being a global 'push' business is that ethics must address the commercial investment and imperatives driving modern biotechnology. That is to say, agreed positions within European bioethical debate will not be defensible if they neglect the interests of non-Europeans. Nor will they be effectively promoted if they fail to engage with commercial practice.

Finally, it is worth drawing out a crucial sense in which we (even the autonomous) are all vulnerable. The ethic of care for others is not simply a matter of protecting those who are incapable of acting autonomously (the most vulnerable forms of life). Rather, it is an ethic that builds on the premise that we are all capable of being wounded by the uncaring (and sometimes paternalistic) actions of others.

Despite recognition of complexities, in applying the four guiding ideas in context, the group was nonetheless able to tentatively agree on the following prescriptions, at least in principle:

C. Articulations

1. *Autonomy* should not only be interpreted in the liberal sense of "permission" given for treatment and/or experimentation. Five qualities should be considered: 1) the capacity of creation of ideas and goals for life, 2) the capacity of moral insight, "self-legislation" and privacy, 3) the capacity of reflection and action without coercion, 4) the capacity of personal responsibility and political involvement, 5) the capacity of informed consent. But autonomy cannot express the full meaning of respect for and protection of the human being. Autonomy remains merely an ideal, because of the structural limitations given to it by human finitude and dependence on biological, material and social conditions, lack of information for reasoning etc. We must recognise the human person as a situated living body. Autonomy in relation to small children, persons in coma and persons that are mentally ill should remain an open question.

2. *Dignity* is the property by virtue of which beings possess moral status. There are several contested conceptions of dignity in European culture. Dignity is, variously, identified with the capacity for autonomous action, the capacity for experiencing pain or pleasure, being human (in the biological sense) or being a living organism or even system. Acknowledging various definitions our view is that it is nonetheless possible to argue successfully that human beings have duties towards the nonhuman part of living nature.

3. *Integrity*. The idea of integrity expresses the untouchable core, the basic condition of dignified life, both physical and mental, that must not be subject to external intervention. Therefore respect for integrity is respect for privacy and in particular for the patient's understanding of his or her own life and illness. Integrity refers to the coherence of life of beings with dignity that should not be touched and destroyed. In relation to human beings it is coherence of life which is remembered from experiences and therefore can be told in a narrative. It is the lifestory of a person, the narrative unity or history of human society and culture. Some would also include the natural grown coherence in the life of animals and plants and finally the created wholeness of the world which makes the conditions for all life.

4. *Vulnerability* expresses two basic ideas. (a) It expresses the finitude and fragility of life which, in those capable of autonomy, grounds the possibility and necessity for all morality. (b) Vulnerability is the object of a moral principle requiring care for the vulnerable. The vulnerable are those whose autonomy or dignity or integrity are capable of being threatened. As such all beings who have dignity are protected by this principle. But the principle also specifically requires not merely non interference with the autonomy, dignity or integrity of beings, but also that they receive assistance to enable them to realise their potential. From this premiss it follows that there are positive rights to integrity and autonomy which grounds the ideas of solidarity, non-discrimination and community.

D. Applications

5. The four guiding ideas or principles do not abolish cultural variations in Europe as long as they comply with the principle of subsidiarity.
6. The application of guiding ideas should not be restricted to the human sphere; dignity, integrity and vulnerability might also be considered as a basis for legislation and legal practice in relation to animals, plants and the environment.
7. Each country should have a national health service based on the principle of social insurance.
8. A Patients' Charter, specifying patient rights and a role for patients in health care policy decisions, should be enshrined in the legislation of all European countries.
9. Patients have the right to consent and refuse treatment and experimentation.
10. Lay persons should sit on research ethics committees.
11. Children born as a result of gamete donation have a right to information about their genetic parents, but donors should have no responsibilities or duties to such children.
12. Embryos should be accorded a proportional moral status according to their degree of development.
13. There should be protection of animals and the bio-sphere in legislation.
14. Anonymity of organ donors should be further discussed.
15. Euthanasia and other end of life decisions should be the subject of extensive debate and public consultation.
16. The commercialisation of human tissue, including the human genome and organ donation should be the subject of extensive debate and public consultation.

The policy-proposals were signed by the following partners:

1. Francesc Abel, Spain
2. Mylène Botbol-Baum, Belgium
3. Roger Brownsword, England
4. Jean-François Collange, France
5. Geneviève Delaisi de Parseval, France
6. Torben Hviid Nielsen, Norway
7. Teresa Iglesias, Ireland
8. Peter Kemp, Denmark
9. João Carlos Loureiro, Portugal
10. Catherine Manuel, France
11. Madeleine Moulin, Belgium
12. Rui Nunes, Portugal
13. Francesco Rubino, Italy
14. Jan Helge Solbakk, Norway
15. Georges Thill, Belgium
16. Helge Torgersen, Austria

Final Report to the Commission on the Project *Basic Ethical Principles in Bioethics and Biolaw*, 1995-1998, p.10
The policy proposals were made at the last meeting of the Project in Barcelona, November 1998. They are reprinted in the Final Project Report (two volumes) on *Basic Ethical Principles in European Bioethics and Biolaw*, Institut Borja de Bioètica, Barcelona & Centre for Ethics and Law, Copenhagen, 1999, which contains an extensive discussion of the four guiding ideas and their applications.

Comments from Partners to Policy Proposals, see Volume II of the Final Project Report.

11. Project Related Publications:

(a) Newsletter and Working Papers (not on sale) for the EU project:

A *Project Newsletter* was published in February, 1997.

Since then, the following Working Papers have replaced the Newsletter:

Working Papers. Research Projects * 1997

Working Papers. Biolaw in Europe * 1997

Working Papers. Research Articles ** 1997

Working Papers. Research Projects *** 1998

Working Papers. Research Projects ****, Biolaw in Europe ** 1999

(b) Publications by the Centre:

En folder om livskvalitet. August 1997 (booklet)

Reproductive Technologies. A Bibliography. September 1997 (also accessible on the Centre for Ethics and Law's website)

Reproductive Technologies. An Updated Bibliographical and Supplementary List. February 1998 (also accessible on the Centre for Ethics and Law's website)

Om kloning. En folder fra Center for Etik og Ret. November 1997 (booklet)

On Cloning. European and International Instruments. National Legislation. Bibliography. May 1998 (also accessible on the Centre for Ethics and Law's website)

Registrant over Center for Etik og Ret's Danske, Internationale og Udvalgte Andre Landes Lovstof m.v. København 1998

Women and Health. A Bibliography. December 1998

Dignity, Ethics and Law. A Bibliography. January 1999

(c) Publications by Members of the Staff of Centre for Ethics and Law:

Peter Kemp, Mette Lebech og Jacob Rendtorff: *Den bioetiske vending [The bioethical Turn]*, *En grundbog i bioetik, Spektrum, København, 1997*

Peter Kemp: "L'intégrité" in *Studies in Ethics and Law: From Ethics to Biolaw*, Vol 7., Copenhagen 1998 (= "L'Intégrité de l'être incarné" in *Incanation, textes réunis par Marco M. Olivetti, Biblioteca dell'Archivio di Filosofia, Cedam, Roma, 1999*, p. 309-322)

Peter Kemp: "Four Ethical Principles in Biolaw", Paper at the Second International Conference on Bioethics and Biolaw, organised by Centre for Ethics and Law, Copenhagen, June 1998.

Anne Mette Maria Lebech: "Dignity versus Dignity" in *Studies in Ethics and Law, Vol. 7*, Centre for Ethics and Law, Copenhagen 1998

Jacob Dahl Rendtorff: "The second international conference about bioethics and biolaw: European principles in bioethics and biolaw" in *Medecine, Healthcare and Philosophy 1*: 271-274, 1998, 1998 Kluwer Academic Publishers. Printed in the Netherlands.

Jacob Dahl Rendtorff: *Bioetik og Ret. Kroppen mellem person og ting*, Gyldendal, København, 1999

(d) Publications by Partners and Invited Guests (=IG):

Irma Arnoux (IG): "The Legal Status of the Body in French Law" in *Working Papers, Biolaw in Europe*, Vol I, Centre for Ethics and Law, Copenhagen 1996

Irma Arnoux (IG):: "The Fundamental Principles in the Law of Bioethics" in *Working Papers, Research Projects Vol II*, Centre for Ethics and Law, Copenhagen 1997

Francesc Abel: "Decisions on Selective Treatment of the Neonate: Basic Norms for Action", in *Working Papers, Research Projects Vol I*. Centre for Ethics and Law, Copenhagen 1997

Deryck Beyleveld and Roger Brownsword: "Human Dignity, Human Rights and the Human Genome in *Working Papers, Research Projects, Vol III*, Centre for Ethics and Law, Copenhagen 1998

- Final Report to the Commission on the Project *Basic Ethical Principles in Bioethics and Biolaw*, 1995-1998, p.11
Mylène Botbol Baum: "The Necessary Articulation between Autonomy and Vulnerability" in *Working Papers, Research Projects, Vol III*, Centre for Ethics and Law, Copenhagen 1998
- Mylène Botbol-Baum: "La notion de dignité et droit de l'homme dans le discours sur le droit de mourir".
Manuscript, Bruxelles 1998
- Mylène Botbol-Baum: "Quelles conditions pour rendre les termes éthique et bioéthique compatibles?",
Manuscript, Bruxelles 1998
- Charles A. Erin: "Some Reflections on the Harrisian Concept of Personhood in *Working Papers, Research Projects, Vol I*, Centre for Ethics and Law, Copenhagen 1997 (reprinted in the final report, Volume II).
- Charles A. Erin: "Some Comments on the Ethics of Consent to the Use of Ovarian Tissue from Aborted Fetuses and Dead Women", in *Working Papers, Research Projects, Vol II*, Centre for Ethics and Law, Copenhagen 1997, p. 103ff. (reprinted in the final report, Volume II)
- Javier Gafo, José Ramón Amor: "Society and Mental Deficiency: "Amidst Protection and Respect" in *Working Papers, Research Projects*, Centre for Ethics and Law, Copenhagen 1997
- Torben Hviid Nielsen: "Medical Technology at the Edges of Life. Abortion and Euthanasia as Politics in the Norwegian Welfare State": "From Deadly Sins to Accepted Moral Acts, Public Perception of Abortion and Euthanasia in Norway, 1969 - 1995" in *Working Papers IV*, Centre for Ethics and Law, Copenhagen 1999 (reprinted in the final report, Volume II)
- Gilbert Hottois: "Dignité et marché du corps", Paper at the 2nd International Conference on Bioethics and Biolaw, organised by Centre for Ethics and Law, Copenhagen, June 1998.
- Teresa Iglesias: "Bioethical Directives and Debate" in *Working Papers, Biolaw in Europe*, Vol I, Centre for Ethics and Law, Copenhagen 1997
- Joao Carlos S. G. Loureiro: "A European Status of the Human Embryo" in *Working Papers, Research Projects, Vol III*, Centre for Ethics and Law, Copenhagen 1997
- Ramos Montes, Joseph Maria, Llovet Haye et al., Institut Borja di Bioetica: "Mental Competence and Consent in Severe Mental Disorders", in *Working Papers IV*, Centre for Ethics and Law, Copenhagen 1999 (reprinted in the final report, Volume II)
- Manuel, C. Hairion D., Giocanti D., Auquier P., Terriou P., Reviron D., San Marco J.L.: "The Great Principles according to the Convention on Human Rights and Biomedicine" in *Working Papers, Research Projects, Vol III*, Centre for Ethics and Law, Copenhagen 1997
- Manuel, Catherine, Pellissier, Veronique, Hairion, David, Auquier, Pascal: "Arguments pour et contre le clonage humain" in *Working Papers, IV*, Centre for Ethics and Law, Copenhagen 1999
- Madeleine Moulin: "La vulnérabilité entre sciences et solidarité", *Working Papers, Research Projects, Vol III*, Centre for Ethics and Law, Copenhagen 1998, p. 73ff. (reprinted in the final report, Volume II).
- Johanna Kits Nievenkamp (IG): "The Convention on Human Rights and Biomedicine" in *Working Papers, Research Projects, Vol III*, Centre for Ethics and Law, Copenhagen 1997 (reprinted in the final report, Vol II)
- Michael Nentwich (IG): "Biolaw in Austria: A Survey", in *Working Papers, IV*, Centre for Ethics and Law, Copenhagen 1998
- Rui Nunes, Alexandra Antunes, Miguel Ricou, Helena P. Meld: "Mental Consent and Rehabilitation of Deaf Children", Manuscript, Barcelona 1998.
- Rui Nunes, Alexandra Antunes, Miguel Ricou, Helena P. Melo: "Informed Consent and the Rehabilitation of Deaf Children" in *Research Projects, Working Papers, Vol III*, Centre for Ethics and Law, Copenhagen 1997
- Veronique Pellissier, Pascal Auquier, Dominique Hairion, Catherine Manuel: "Les enjeux du clonage humain et au plan international et dans différents pays" in *Working Papers, IV*, Centre for Ethics and Law, Copenhagen 1999

Egbert Schroten: "Transgenic Animals and Government - Policy in the Netherlands" . Manuscript, Utrecht 1997.

Egbert Schroten and others: "Ethical Questions around Animal Biotechnology: The Dutch Approach", Manuscript, Utrecht 1998.

Egbert Schroten: "From a Moral Point of View: Ethical Problems of Animal Transgenesis", in *Transgenic Animals. Generation and Use*, 1998.

Michael Singleton: "From Singularity to Solidarity. The Fundamental Relevance of Man/Animal Interrelations to Basic Ethical Norms" in *Working Papers, Research Projects*, Vol II, Centre for Ethics and Law, Copenhagen 1997.

Bettina Schöne-Seifert: "Moderne Medizinethik" in *Encyklopädie der Angewandte Ethik*, 1997

Jan Helge Solbakk: "Vulnerability As a Bridging Factor Between Moral Strangers", in *Working Papers, Research Projects*, Vol I, Centre for Ethics and Law, Copenhagen 1996,

Jan-Helge Solbakk: "The Concept of Goodness in Medical Research" in *Working Papers*, Vol III Research Projects, Centre for Ethics and Law, Copenhagen 1997

Jan Helge Solbakk: "Ethical Aspects of Cloning. A Socratic View", Manuscript, Oslo 1998

Ghislaine J.M.W van Thiel and Johannes JM van Delden: "Dealing with Patient Autonomy in Dutch Nursing Homes" in *Health Care in Later Life* 1997 2 (3), p. 177.

Georges Thill, in collaboration with Dominique Lambert: "Towards a Responsible Reshaping of Bio/Ecoethics. Animal Experimentation and Production in Question and Enlightenment on Animal Right, Welfare and Epistemology", Paper at the First International Conference on Bioethics and Biolaw, organised by Centre for Ethics and Law, Copenhagen, May-June 1996.

Mary Warnock (IG): "Reproductive Technologies: The Ethics of Provision", in *Working Papers, Research Projects*, Vol. II. Centre for Ethics and Law, Copenhagen 1997 (reprinted in the final report, Volume II).

(e) The Enlarged Final Report:

Basic Ethical Principles in European Bioethics and Biolaw, planned to be published in two volumes by the Centre for Ethics and Law in collaboration with the Institut Borja de Bioètica, Barcelona.

(f) Policy Proposals to the Commission

The Barcelona Declaration, published by the Centre for Ethics and Law, Copenhagen, June, 1999

French translation by Mylène Botbol-Baum: *La Déclaration de Barcelone*, publiée par le Centre de Recherches en Ethique et Droit, Copenhague, Juin, 1999

12. Deliverables for Exploitation:

The *Documentation Unit for European Bioethics and Biolaw* established at the Centre for Ethics and Law in Copenhagen has collected available information on public debates, experiences and philosophical, legal and sociological reflections in bioethics and biolaw in the European countries and in other countries from which the EC-countries can learn something in this matters.

The Working Papers contains articles presenting research in European bioethics and biolaw and two volumes collect presentations of the current state of *Biolaw in Europe* (1997) and *Biolegal Updates* (1999)

The enlarged final report is a substantial work which both analyses and discusses basic principles and national differences in European bioethics and biolaw.

The Policy Proposals published in English and French inform the European public and in particular politicians and legislators on both national and EC-level on the work done by the project partners and their ideas for a European policy in bioethics.

13. Acknowledgements:

Final Report to the Commission on the Project *Basic Ethical Principles in Bioethics and Biolaw*, 1995-1998, p.13
Thanks to all the partners who have contributed to the report, whether by participating in discussions, giving assistance or supplying information. In particular, we acknowledge our debt to all the 22 Project Partners from 14 European countries. In addition, we wish to thank the officers of the Directorate C 12 of the Commission, José Elizalde, Laurence Cordier and Hugh Whittall for their valuable help in preparing the report and for their continuous support throughout the Project Period.

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cc: *Basic Ethical Principles in European Bioethics and Biolaw*, two vol. (manuscript),
The Barcelona Declaration,
La Déclaration de Barcelone