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Bioethics, law and European integration

ABSTRACT

Bioethics is always described as implying a multidisciplinary and pluralistic approach of the issues encompassed. No doubt that the law and lawyers have deeply contributed to its origin and present development. However, conversely to the United States, it seems that bioethics has opened some new perspectives to the law in Europe. First, it forced the law to move out of its own frontiers and to apply its reasoning to life sciences issues with the consequence that some consider that the legal norms are used to legitimate unlawful practices while others believe legal norms have imposed binding conditions to the free development of science and technology. Second, Europe is the only region of the world where biomedical techniques are subjected to legal and sometimes binding harmonisation. In some way, we may conclude that the role played by the law in the elaboration of European bioethics is just an example of the important role of the law in the European integration.

I) The political dimension of bioethics and law in Europe

There is a specific dimension of the transformation of patient-physician relationship in Europe. It concerns the fact that most European countries have developed social security systems and that, consequently, the new biomedical development raises the issue of access to health care as a global socio-political issue.

Therefore, law more than ethics plays in Europe a role in defining the conditions of accessing new medical technology and in elaborating a public policy in this field.

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When looking back to the recent history of Bioethics and Law in Europe, we see the emergence of mechanisms to produce new norms outside the medical and scientific community. What is interpreted as the end of a paternalistic ethical system, also common to the bioethics movement in the USA, is also the symbol that law is viewed in Europe as an appropriate way to bring bioethics issues at the forefront of a societal debate.

The counterpart of this "political" appropriation of Bioethics – in the traditional meaning that it has become a question for citizens' discussion- is the fact that the law might be perceived as imposing a new "paternalistic" approach, not the one of the medical ethics but the one of the State imposing to individuals rules based on a collective idea of good, happiness or of what is a normal social behaviour.

A) Bioethics, law and democracy

The idea that bioethics will stop the *confiscation* by the medical profession of the decision making process on the ethical issues raised by the progress of medicine implies that Society would be able to define democratic ways according to which individual and collective choices could be made. Naturally, the process of making law in Western democracies could serve as a practical example: public debate in Parliament and courts are good references and rational way of reasoning is a good methodology. So the idea came that once appropriate institutions would have been set up, they might be incorporated or their work might be used in the process of elaborating the norms necessary to organise and regulate the new techniques.

1) Bioethics, law and the (new) institutions

A significant outcome of the end of the XX century Bioethics success story is certainly the growing role of new and renewed institutions in producing and applying bio law.

Among the newly created institutions, we may clearly distinguish those in charge of assessing and discussing bioethical issues from those in charge of applying the legislation.

- The first category encompasses both "**the pilgrim mothers**" of the bioethics institutions, those created in the 1980s in different European countries (the Warnock Commission in the UK, the Benda Commission in Germany, the Braibant Committee in France or the Santesuosso Committee in Italy) to deal with reproductive and genetic technologies and the now expanding category of National Bioethics Committees (France 1983, Denmark 1986…).
  Although those commissions have not been instituted on the framework of a

law reform commission, they all add in mind the issue: should we legislate? Even the new National Bioethics Committees which were set up as standing committees with a mandate to organise ethics discussion very early raised the same question and were influential in suggesting to governments and parliaments to move to legislation while their opinions also served as references in court disputes.

Therefore parliamentary committees reorganised themselves to tackle with bioethical issues: special commissions were set up; offices for technology assessment were incited to deal with such issues.

- The second category gathers **bodies which are part of the regulating process** adopted to rule specific biomedical technologies. Some do it on a broad scale at the national level such as the Human Fertilisation and Embryology authority in the UK or the Biomedicine Agency in France. Others do it on case by case review: IRBs for research on human beings or transplant or genetic therapy committees…Both produce bylaws or "case law" according to their mandate. They merely interpret or apply the existing legislation more than they create it but they have anyway a very concrete role for those who are either practising the technologies concerned or applying to benefit from them.

Whatever is the ethical issue concerned, a clinical case, a biomedical protocol or a broader societal issue; there is today at least one body to look at it. Public ethical institutions have clearly replaced professional associations at the forefront of the bioethics debate. This change in dealing with bioethical issues raised another important feature: the capacity of the mandated institutions to work democratically. For that, they have to be inspired by the legal practice and develop a due process of law in the specific area of bioethical issues.

2) Bioethics institutions and the due process of law

Ethical issues have moved everywhere from the closed professional world of doctors and scientists to the global world of public arena. But contrary to the United States, Europe is not essentially relying on the concept of autonomy to institute more democracy in the decision making process in bioethics. Legal procedure plays an important role in bringing some legitimacy to the institutions in charge with bioethical issues.

- **The search for sanitary democracy** is a recurrent issue in reframing the health systems in Europe by the turn of the Millennium and bioethics poses even more difficult problems.

  For example, how can a national bioethics committee be inspired by the due

process of law?

It certainly means that contradictory arguments have to be identified and discussed, that the process of elaborating an opinion should be transparent and that the opinion should be argued.

Regarding the agencies in charge with the regulation of technologies and practices, how can we be sure that they do not re-create a closed world for experts that will leave outside lay persons and public representation? How can we be sure that their decision will not be biased by conflict of interests?

A more sensitive question would be

- **How can we prevent** the review of research protocols or individual clinical cases by ethics bodies giving birth to an "**ethicocracy**"? Transparency, rational reasoning and possibility to appeal are necessary as a counterpart of the authoritative role of those new bodies in making decisions. Efforts have been made in different European countries to improve this process but this is too often a task which is the consequence of major dysfunctions of the system.

We may say that the XXI century marks the triumph of bioethics institutions because we now have five categories of such institutions in Europe: national bioethics committees, ethics research committees, high technology ethics committees (on genetics, organ transplant, biotechnology…), clinical (or hospital) ethics committees and academic or professional ethics committees. At least, the first 3 categories are usually regulated by law. But, we do not have yet a global perception of what is the result of this integration of bioethics institutions in law policy making. Does it really lead to more democracy in the field of biomedicine and biotechnology or are we entering into a "Brave new world"?

B) Bioethics, law and the "Brave New World"

The marriage of law and bioethics is a feature of the techno-scientific society. The law is necessary to facilitate social transformation and to alleviate the fear of the progress. But in doing so, the law might raise some ambiguity: it could either support a positivist approach to consumerism in the field of biomedicine or create a new dogmatism which will limit individual freedom, scientific creativity and entrepreneurship.

1) Biolaw and the positivist approach to consumerism in the field of biomedicine

A common point between bioethics and biolaw could in fact put biomedical issues in the public arena where choices are not only made by the physicians following the traditional medical ethics. While admitting that new biomedical technologies raise

issues that concern the individual rights of the patients as well as some societal choices, bioethics and biolaw however keep their eyes wide open on the practice. They try to be references for existing practices in suggesting and sometimes imposing limits and conditions to health care providers and patients. Globally, they offer a set of norms to rule the different techniques and to make them socially acceptable rather than to challenge the legitimacy of such techniques.

In doing so, bioethics and biolaw may be viewed as derived products from biology rather than sub branches of ethics and law. In supplying the traditional medical ethics, which most patients criticized for its paternalist attitude and which many physicians thought it was no more in capacity to bring appropriate answers to the ethical legal and social issues generated by the reproductive and genetic revolutions, biolaw developed a practical and concrete approach to facilitate the access to the new techniques in the respect of individual rights. But it did not really challenge the philosophy and organisation of the techno-scientific society.

It therefore contributed and reinforced some of the main characteristics of our postmodern society: individualism and subjectivity, on the one hand; materialism, consumerism and reification of the human body, on the other hand.

For this reasons, opponents to this positivist approach think that it is not enough to introduce some ethical questioning to the way we produce our law. They argue about the necessity to substantiate our legislation on strong fundamental values rather than on bioethical discussion and procedural norms.

2) Biolaw and the risk of a new dogmatism

What may be obvious in the convergence of ethics and law in the field of biomedicine is a common will to found the set of rules governing the new technologies on strong values. To guarantee that the development of medicine and science will not serve to build a Brave New World, we need to recall what is perceived as symbols of a humanist philosophy: Judeo-Christian references and human rights principles. The implementation of existing rights as well as the emergence of new rights is totally constructed for the benefit of the protection of what is human either as an individual person (and parts of it) or as a collective body (the human species).

Globally, we may proclaim that ethics and law contribute together in the designation of these fundamental values. Sometimes, ethics has a determining role in this consecration although law does not ignore the principles which are commonly designed as fundamental values. This is the case with the informed consent principle but also with the concept of dignity.

In other cases, the process is working the other way around as with the principles of privacy and non discrimination which have been broadly applied in the field of genetics and access to health services.

But, the idea and practice of establishing a set of fundamental rights may be confusing.

It might mean that the benefactors of such rights are entitled to claim the application of the rights in the different areas of biomedicine and that those rights are universal, authorise limited exceptions and may serve as references to develop derived principles.

The fundamental rights approach could also be a way to introduce in the legal system the idea that the rights designed as fundamental are at the top level of a new hierarchy of norms, no more grounded on a formal distinction but essentially based on their substance.

Due to the fact that they contribute to define what is human, one of the main characteristics of such rights is their transcendence which means that they surpass all other rights and principles. They offer some objective definition of the "human nature" and find references in the concept of *jus naturalism* and also in religious belief. We may therefore fear that they will reintroduce some form of dogmatism and absolutism in our law. The controversy rose by the utility and applications of the concept of dignity but also the ongoing discussion about embryo research are good illustrations of such risk.

Although the consequence of this ethico-legal approach is well known in US Bioethics, it might be more influential in Europe because in most countries biomedical research and its applications are largely relying on a State and Society support. Law therefore plays in Europe an important role in implementing the different national policies in the field of life sciences.

As some of these policies are restrictive while other are more permissive, there is in Europe a specific geography for Biolaw which differs considerably from the US traditional distinction between federal regulation (only binding for the researchers asking for federal funds) and State law which may be unexistent in many areas of bioethics. Consequently harmonising legislation in Europe is the only way to make the idea that fundamental values could rule biomedical issues without infringing upon individual human rights acceptable.

II) Legal harmonisation of biomedical legislations: an original method to resolve contradictions

The legal approach to bioethics issues is also an interesting example to demonstrate how the diversity of European approaches may live together and move to substantiate fundamental principles. Although the margin of discretion of the national legislations is still great in deciding how far the beginning of life should be protected or what is the positive duty of a State in providing death with dignity, European States have accepted in different ways to join a competitive dynamics in which law is a key instrument.

A) The law as an instrument of competitive dynamics

Originally conceived as an economic community based on coal, steel and uranium, the European Community progressively embraced broader areas of jurisdiction to facilitate the emergence of a global European market whose products and services could easily compete abroad. Legal harmonisation became a way to integrate this global market but life sciences issues demonstrated soon the limits of technical harmonisation without the support of common European values.

1) The industrial and economic need is a strong incentive to regulate

It seemed obvious that if Europe would like to play a significant role in the international competition, its industry had to benefit from rules that would facilitate the circulation of goods and services. This task has been accomplished for drugs and blood products and for medical professionals. However, in 1995, it failed to be realized for biotechnology and patents but after a new proposal was put on the table in 1996, finally a European regulation was adopted in July 1998. Obviously, this demonstrated that it was no more possible to answer the industrial approach without looking also after the ethical issue.

Let us put aside for a moment the quarrel of words and ideologies to revisit the European policy on biotechnologies, and more particularly the role of the law by asking a double question: what is resulting from 20 years of European legal rationalization in this field? And does this result bring a satisfactory response to the concerns expressed by the public opinion? Our feeling is that the extraordinary development of the regulation on biotechnologies did not make us escape a deep social crisis of confidence between scientists and political decision makers, on the one hand, and the citizens, on the other hand, with the fear of a biotechnological apocalypse. And in this frontal opposition of views, the law had a key role for each party, which was to legitimate the social choices and to transpose them in concrete reality. This is the

marriage between social values and reality that constitutes the legitimacy of the European legal system.

2) The ethical dimension is necessary to make techno-scientific regulation socially acceptable

The new biomedical technologies are often presented as the only real challenge to our social organization, creating a risk for the human and even the human species by offering more and more sophisticated possibilities to manipulate, for example, procreation, heredity and in a near future the human brain.

Let me explain why I believe it is not a good approach to bioethics issues. The problems which are posed to us are in fact due to the conjunction of different social attitudes, the importance of which will depend on the cultural context. These attitudes can be summed up as follows: the unlimited search of new scientific knowledge, the irresistible pursuit of individual happiness, the importance of money and business, the role of institutional structures and ideology.

- The first two attitudes concern primarily **the physician - patient relationship**. Traditionally, the Hippocratic medical practice was based on the specificity of the relationship between the patient and the physician. The physician benefited from the patient's confidence because his/her duty was to act only for the direct and personal benefit of his/her patient.
  Of course, we have known for a long time that physicians had to face in some circumstances opposite interests: either private interest - should a physician tell the family the nature of the illness a patient is affected with? - Or public interest when it is necessary, for example, to prevent the spreading of epidemics?
  But the major changes in modern medicine arise from the fact that biomedical research has now been integrated as a normal aspect of the medical progress: "ethically necessary but necessarily immoral" as observed by Prof. J. Bernard the honorary chairman of the French National Bioethics Committee. Consequently, as soon as the patient became the subject of biomedical research, healing the patient was no longer the unique goal of the medical practice.

Another element of the transformation of this relationship is to be found in the greater role played by the patient himself. Higher education and further development of individual rights have led to a greater consideration of the autonomy of the patient. Paternalism is less and less accepted but more patients, as they are now better informed of the new medical advances, have stronger views about their wishes and would like them to be satisfied by the physicians. People want to decide about their own treatment but they also want to decide about their own quality of life and death, about the moment they will procreate and the characteristics of their offspring.

What they require from the health care providers is more and more the satisfaction of their personal desire and happiness than it is a therapeutic treatment.

Therefore, the pursuit of further knowledge by the physician on the one hand and the pursuit of happiness by the individual on the other hand could progressively transform the physician-patient relationship on a purely legal convention losing its specific characteristic which implies a mutual respect of each partner.

- Such a consequence has probably already occurred in **circumstances when business is prevailing over medical considerations**:
  We could certainly ask why so many physicians are interested in industrial countries to develop new reproductive technologies, the financial cost of which is high. But we all know what a couple could do to get a desired child. We are sometimes surprised to hear of the existence of very modern genetic centres providing with genetic medicine a few people in countries where general hospitals cannot usually face their normal duties.
  New technologies are also a good way of advertising the ability in medicine or simply the ambition to be viewed as a person who is at the forefront of the new medicine.
  Sometimes these events are good successes: it was the case with Prof. Chris Barnard's first heart transplant or with the birth of Louise Brown due to B. Edwards & A. Steptoe, but this is not always the case so it is the reason why it appeared necessary to include an ethical approach to the European regulatory policy.
  It largely concerns the ethical review of biomedical research. Since 1991 the European Union Biomedical Research Program has included specific research incentives for bioethical issues related to medical research.
  It also covers the assessment and the regulation of a wider range of bioethical problems at the European level.
  After having set up two *ad hoc committees* (on embryo research and human genome research) the European Union instituted in 1991 a standing group (on ethics of biotechnology) to advise the Commission on ethical aspects of European regulations draft.
  The other European organization, the Council of Europe, which is an intergovernmental institution for cooperation, has had such a standing body since 1983: this is the now called the steering committee on bioethics (CDBI), which prepared many recommendations (on genetic issues, reproductive technologies, human experimentation...), the European convention on biomedicine and human rights and is presently pursuing its mission to elaborate protocols to the European convention on bioethics.

B) The law as a key instrument to substantiate European values

1) The European methodology

The funding basis of the European regulation appears very different, not to say contradictory.

a) The pragmatic approach

This is mainly the approach of the European Union whose jurisdiction is essentially concerned with economic affairs. In this perspective although the bioethical approach cannot be regarded as subsidiary, its necessity is imposed, not by theoretical considerations, but by the fact that some industrial applications of research have raised great concerns in the public. European authorities are now aware that any specific policy could pose major political issues in term of protecting the consumers, the environment or simply assuring the public that these questions, but also fears and anxieties, are taken into account.

This is the meaning of the European Commission statement declaring that "the Commission has expressed a clear wish to build a Europe for science and technology which should both promote the European development and be respectful of the rights of each European citizen".

This is the reason why the Commission has set up the above mentioned Group of advisers on the ethics of biotechnology the mandate for what can therefore be regarded as complex and difficult. The group should have indeed a dynamic approach taking into account the acceleration of scientific knowledge which is a permanent incentive to reform our regulation.

As proved by the first years of activities of the group this task, although it does not ignore the general human rights perspective, is merely accomplished through a case by case approach in which political aspects are sometimes more important than legal aspects.

Until the turn of the millennium, the ethical implications of some technical or economic issues were less apparent in the European Union regulatory process.

Although biomedical research funded by the European Union has by contract to obey some ethical guidelines (good clinical practices, or specific guidelines for embryo research or human genome research), these guidelines are not, strictly speaking, European rules imposing obligations to the Member States. They are only conditions that a contractor, the European Union, is imposing to a co- contractor in order for this co- contractor to benefit from a European grant.

Regarding what is properly called the European regulations; only a few texts are specifically referring to ethical issues: we can quote the 1989 directive on blood products which mentions the ethical rules adopted by the Council of Europe and the 2001 directive on clinical trials which mentions the role of ethics review committees. But for many, the 1989 regulation was not deemed as being very efficient because the ethical rules were mentioned as an objective to fulfil with and not as an obligation to compel with.

Another text, a draft, attempted to include ethical considerations. It concerned the issue of patenting biotechnology but as these considerations did not appear to make ethical issues as prominent, the European Parliament rejected the bill. The new one which was introduced in 1996 and adopted in 1998 was more explicit about ethical issues, especially the prohibition to patent the human body and its components and to ban germ line gene therapy.

Indeed, the recent history of these European regulations proves how illusory it could be trying to incorporate different preoccupations in the same text. It could mean that the enforcement of Human Rights provisions in the field of biomedical sciences should probably follow a different process of harmonisation.

b) The human rights approach

It is presupposed that bioethics is not an isolated problem and should be treated as part of a common heritage encapsulated in the European Convention on Human Rights - the common European heritage.

The concept of a human person, which has such a tremendous importance in bioethics and in law, is naturally a theoretical category invented by philosophers but it is also largely the heritage of the three funding elements of the European culture: Greek philosophy, Roman law and Judeo-Christian beliefs.

Since it was formulated at the end of the XVIII century, the principle that each man is a human person with equal rights has been used as a key political operative concept which was progressively incorporated into the legal system. The European Convention on Human Rights has been since 1950 the living example of this recognition of the central value of the human person in "die Europaïsche Weltanschauung".

The status of the human body but also our concept of filiations is deeply related to this perspective.

The human body cannot be separated from the human person: man is both a physical and a non-physical entity. Therefore, the legal protection granted to the human person does also apply to the human body as far as the person has a legal existence.

The concept of filiations also plays an important role in contributing to the identification of each man as a single person having his/her own biological and social origins.

Since it is an individual physical integrity and an individual private life which are primarily at stake, the Human Rights are in a prominent position, and particularly articles 2 (right to life), 3 (right to be protected against treatment contrary to human dignity), 8 (right to privacy), 12 (right to marriage) and 14 (right not to be discriminated) of the European Convention.

However, the way these principles can be implemented and enforced in the biomedical field is not so simple because of the divergences existing in national legislations or practices as we mentioned above. So, there is a need for a process which allows some European harmonisation. It could be done in two ways: the jurisprudence of the European Court of Human Rights and the elaboration of new Human Rights instruments.

- Case law derived from the European convention on human rights

Far from ignoring questions resulting from the development of the biomedical sciences, the case-law of the Convention contains some "surprises".

These involve both the replies to questions submitted for examination and the approach used to analyse the cases considered.

-Thus, regarding the first aspect, the principle of free and informed consent by the person concerned has been recognised explicitly in connection with medical experiments. It is also known that, to the extent that everyone's right to life also applies to the foetus, this protection is not absolute.

Moreover, while the case-law does not yet directly provide a solution to all problems connected with the life sciences, guidelines may be identified. They are based, on the one hand, on the definition of certain concepts - inhumane treatment, private life or interference - to which reference can clearly be made for the purpose of clarifying our discussion.

On the other hand, some "case-law policies", such as the recognition that, in certain circumstances, the State has positive obligations and the importance given to a realistic approach towards family ties, are likely to create a move towards the development of the Convention, the more so because the development of the legal and moral environment is also taken into account as the case-law develops.

Therefore not too much should be expected from strengthening existing rights in the Convention, but some aspects of the Convention favour a development of cer-

tain rights. It is up to the Convention organs of control to determine the outline of these on a case-by-case basis, while distinguishing what is simply a new application of a positive right from the start of new rights.

- New instruments specific to the biomedical field

Within the Council of Europe, after the Parliamentary Assembly called for it, this task was mandated in 1993 to the steering committee on bioethics. The committee, which is a multidisciplinary committee, was however mandated with a regulatory objective: to propose principles that could be applied to regulate the different fields concerned with bioethics.

- - It spent a 7 year period in drafting recommendations, which although not binding, were accepted by Member States to implement and guide their domestic rules.
  Genetics, human research, prenatal diagnosis, medical data and privacy, end of life, reproductive technologies and embryo research were the areas for which the Committee produced important works. Except the last two fields, all its recommendations were adopted by the Committee of Ministers and we can hope they have progressively inspired the different national legislations.

- - However, as all the scientific areas were not covered and as it became important to set up a link between the above recommendations and the European Convention of Human Rights, the Committee was entrusted in 1990 to prepare a draft European convention on biomedicine.
  This instrument is a framework convention which means that it gathers in one text a set of fundamental principles that should be applied to all biomedical technologies: respect of human dignity, free informed consent, protection of the vulnerable, equal access to services, protection of medical privacy, ban on germ line gene therapy, right to be compensated from damages due to medical or scientific activities...This clearly shows the bridge existing between Human Rights and biomedical issues.
  But to enforce the above mentioned principles, it was also agreed that annexed protocols to the Convention with detailed provisions for each technology would be elaborated. At present four protocols have been adopted (human cloning, biomedical research, organ transplants and genetics).This methodology is very flexible because it allows to add a new protocol each time it appears necessary. And in the meantime, it is always possible, if there is no specific protocol, to refer to the general principles encapsulated in the text of the Convention itself.
  If such a methodology can permit reaching some kind of consensus on sub-

stantial issues - although conflicts of views are still existing and important - it raises more difficulties when the question of a following up procedure is raising. In fact, the Members States rejected the idea to have the Court of Human Rights as direct judiciary recourse but they also refused to create any *ad hoc* body to follow the implementation of the Convention. But as the convention is binding for member States, it may be used as a reference in court to support the recognition of new rights and to solve individual cases.

Conclusion

Bioethics is not only the ethics of life; it is the ethics of society

I believe that as responsible persons, we exercise our own autonomy but we also share with our co-citizens a common duty towards the community.

Consequently, we have to find the appropriate rules to regulate conflicts of interests but also to promote a common interest which should rely on the respect of human dignity, personal rights as well as social solidarity.

Therefore, the policy approach to bioethics is less difficult that it could appear. We do not need new values, new rules to govern those issues because there is no reason not to use the existing rules which govern democratic society. But I agree that they are still major difficulties in implementing those principles to the different technological fields. It will take time and will imply respect for the diversity of cultures and opinions. However, it should not lead to forgetting the political will to promote an open and non-authoritarian European legislative framework for biomedical sciences.