

The French Legislative Approach to Bioethics with Special Reference to Human Reproduction

İNSAN ÜREMESİ DİKKATE ALINARAK FRANSA'DA BİYOETİGE YASAL YAKLAŞIM

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SUMMARY

As in other Western European countries (Germany, the U.K.), the French legislative process lasted nearly ten years, giving the evidence of the difficulties to find solutions acceptable by the society as a whole. In France the initiative to stimulate a public debate came from the Government which set up in 1983 a National Advisory Bioethics Commission and organized in 1985 a public forum on Genetics, Procreation and Law. Soon, the opinions adopted by the National Bioethics Committee were considered as possible working documents for a possible legislation and in 1986 the Prime Minister appointed an ad hoc Committee in charge with drafting a bill.

However its report (From Ethics to Law) published in 1988 suggested so many new legislations that researchers and physicians sometimes strongly reacted against it considering that such regulations would seriously limit research activities. Consequently, the Government asked for further reports on different aspects (comparative law genetics, prenatal diagnosis) before submitting to Parliament, in 1992, three bills (on the status of the human body the new biomedical technologies, and data protection and medical research). It is only after the 1993 General Election that those bill were finally debated and adopted in 1994. Although the French Constitutional court ruled the laws were in conformity with the principles of Human Rights, still many controversial issues have not been yet resolved (what kind of rights, studies could be authorised on embryos in vitro? What do decide with frozen embryos?) Therefore it has been decided that after 5 years the Parliament will reopen its debate on those issues.

Key Words: New reproductive technologies, Law reform, Public debate, France

T Klin J Med Ethics 1997, 5:1-5

The important developments in biomedicine during the past 20 years have raised fundamental issues which question social principles and therefore the attitude of

Geliş Tarihi: 16.10.1996

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T Klin J Med Ethics 1997, 5

ÖZET

Diğer Batı Avrupa ülkelerinde (Almanya, Birleşik Krallık) olduğu gibi sorunlara toplumun tümünce kabul görecektir çözümlerin bulunabilmesi için yol sağlayan yasama süreci yaklaşık on yıl sürmüştür. Fransa'da toplum içinde tartışmayı başlatacak hareket hükümetin 1983'te Milli Biyoetik Danışma komisyonu kurması ve 1985'te Genetik, Üreme ve Kanun Halk Forumu organize etmesi ile hükümetten gelmiştir. Kısa süre sonra Milli Biyoetik Komitesince kabul edilmiş düşüncelerin gelecekteki yasama işlemleri için esas kabul edilebileceği öngörüldü ve 1986'da başbakan bir karamame yayınlarak bir Ad Hoc komitesini görevlendirdi.

Komitenin 1988'de yayınladığı Elikten Kanuna adlı raporu o kadar fazla yeni kanun tavsiyesinde bulunuyordu ki zaman zaman araştırmacılar ve doktorlar tarafından bu tür düzenleme/erin araştırmaları ciddi oranda engelleyeceği iddiasıyla şiddetli tepki gördü. Daha sonra hükümet, 1992'de üç kanun tasarısını (insan bedeni ve yeni biyomedikal teknolojiler, bilgi saklama ve tıbbi araştırma) parlamentoya sunmadan önce değişik konular (genetik, prenatal tanı üzerine karşılaştırmalı kanunlar) üzerinde raporlar istedi. Ancak 1993 genel seçimlerinden sonra bu tasarılar tartışıldı ve 1994'te kabul edildi. Fransız Anayasa mahkemesi bu kanunların insan Hakları ile uyumlu olduğunu kabul etmesine rağmen hâlâ bazı tartışmalı konular (Embriyolar üzerinde in vitro çalışmalar, Dondurulmuş embriyolar hakkında kararı kimin vereceği) çözüme ulaşmamıştır. Bu nedenle parlamento bu konular üzerinde beş yıl sonra yeniden tartışma açma kararı vermiştir.

Anahtar Kelimeler: Yeni üreme teknikleri, Yasal reform, Fransa, Kamuoyu

T Klin Tıbbi Etik 1997. 5:1-5

ethics and law. In particular, the new reproductive technologies have posed controversial questions. By dissociating sexuality and procreation, they demonstrate the power that man has acquired over his own kind, and emphasize the difficulty of defining what is a family in our industrial society.

The procedures applied to embryos in vitro have regenerated the debate concerning the status of the embryo and the right to life. Genetics issues and gene

therapy require also responses to important questions. Should we accept and realize all that is technically possible? Are current ethical guidelines or legislation adequate to ensure the "good" practice of these new technologies? France was concerned very early with these complex questions when, at the beginning of the 1970s, artificial insemination by donor (AID) became a common medical procedure to provide infertile couples with children.

However, the intrusion of surrogacy, posthumous insemination and the increased use of genetic testings catapulted these questions into the public arena, making it difficult for the public authorities to maintain a neutral position in this debate. It is now possible to draw from this debate some conclusions concerning the perspective of law reform in France in this area.

THE FRENCH STRATEGY

While agreeing that science is progressing faster than law, French lawyers (jurists) were divided in their conclusions, some believing that biomedical sciences should be considered as an epiphenomenon which should not lead to any major change in law, while others urging such changes.

The professionals' views were also very ambiguous. While a majority would accept professional guidelines and required such guidelines to be approved by law, a stubborn minority still believed that such questions should remain a matter for the individual relationship between physicians and their patients. As regards public opinion, a large percentage viewed with considerable respect the physicians and biologists who developed new technologies. On the other hand some groups opposed, for example, reproductive manipulations which deprive human embryos of their potential for life. This confusion coupled with the lack of a spontaneous and productive controversy on the major issues posed by reproductive medicine, left the government with the task of initiating the French debate.

To achieve this, the government proceeded in two stages. The first consisted in encouraging a wide discussion, within the community to see how far it was possible to reach a consensus, secondly when opinion seemed to agree on some ethical principles, there was the aim of making an effort to take into consideration the necessary legislative reform. These stages will be discussed in the following two sections of this article.

I. FROM DISCUSSION TO ETHICS

To clarify the complex debate on the question of whether or not to legislate, the government favoured two means: promotion of discussion on this matter: and the development of a specific forum where appropriate ethi-

cal guidelines could be established and supported by a large consensus.

A. The Promotion of Debate

This was principally based on two governmental initiatives: the organization of a national colloquium and the formulation of a report providing a complete overview of the views expressed in the field of reproductive technologies by experts and members of the public.

1. *Genetics, Procreation and Law (1985)*

Although the government was firmly persuaded that some choices should be made in due course, it was also convinced that the different opinions should be clearly discussed before such choices could be made. The first concern, then, was to create the best opportunity for a debate. It was felt that the organization of a colloquium was more appropriate as a method of reaching this goal than the setting up of a National Commission.

The diversity of opinions expressed during the colloquium did not permit the reaching of immediate conclusions, except on two points. The first one concerned the social consequences of the new biomedical technologies. For example, sociologists and anthropologists reminded the conference of the existence of other family institutions in different human societies.

As the second point, the essential principles such as anonymity of donors or access being limited to heterosexual couples on which the current French practice of reproductive medicine were based, were broadly questioned.

The requirement for legislation was not therefore felt to be so great, and the conclusion was the need of a moratorium on legislation. However, it was agreed that it should also take the advantage of the public debate to obtain a better knowledge of the numerous views of the different component parts of the French Society on questions which still appeared controversial.

2. *Report on Artificial Procreation*

The need to pursue the investigations led the government to instigate a broad study of opinions.

The conclusion of this analysis was the minimization of the positive aspects of reproductive technologies, and of the prenatal diagnosis which also carries some risks and potential drawbacks and to suggest that an adequate balance between the method and the results of such techniques would require the imposition of some specific rules. These rules should not be inferred from the practice of biomedicine but rather derive from a pluralistic concept of the society.

The difficulties involved and the time needed in defining these ethical principles have demonstrated the

importance of the role which could be assumed by a specific forum such as a National Ethics Committee.

B. The National Ethics Committee

How could a pluralistic society agree on common principles concerning biomedical issues? To be able to give an answer to this question, it was decided that a new and independent authority should be set up, which would act as a forum to discuss issues raised by biomedical research.

This Committee has had two main activities. The first is to advise on ethical issues raised by research in the field of biology, medicine and health care. Questions can be brought to the Committee by Members of the government, presidents of the two Houses of Parliament, or by any public institution involved in research. But the Committee has also the authority to decide itself which particular important issues in this area should be discussed.

The Committee is not designed or empowered to review individual experiments, which is the task of local ethical committees, but has only to consider major social issues. However, some advice may be given in relation to specific experiments -for example, the new abortion pill, Mifepristone (RU 486)- when they can have far-reaching effects.

The Committee acts as an advisory body and, as such, its advice is not enforceable.

Thus, the Committee is supposed to work as a moral authority, and its decisions circulate widely in professional circles as well as in the public arena.

The Committee's second main activity is to function as a forum for a discussion of the issues with both professionals and members of the public. To fulfil this task, the Committee organizes an annual two-day meeting where accomplished and prospective work is presented. These meetings also become on occasion to allow public participation in the related debate.

The 40 members of the Committee belong to four categories and are appointed for four years. Half of the membership is renewed every two years. The Chairman is appointed by the President of the Republic with five other members representing religious and philosophical groups. 17 members are chosen by different authorities in the light of their special competence in the field of bioethics. The remaining 17 members belong to research Institutes.

Such a composition makes the Committee a real forum for debate.

During the past 10 years the Committee has issued 50 statements which consider the following topics:

Human experimentation

The use of human tissues or cells

The new reproductive technologies

Prenatal diagnosis

AIDS

The abortion pill

Local ethics committees

The testing for drug addiction in employment

Genetic fingerprints

Gene Therapy

Commercialization of the Human Body

Euthanasia

Epidemiological databanks

Being the first body which has the responsibility for considering major moral issues rather than exclusively technical and specific matters the Committee is a rather unusual institution within the French administrative organization. As such, its multidisciplinary membership is of real importance and contributes much to the success of its work.

As a consequence of this work, many groups in the society became aware that a common position could be reached on bioethical issues. This was apparently due to the existence, in the national culture, of general principles on which many people could agree.

The use of this philosophy as a basis for the solution of biomedical issues made it obvious that some legal and coherent conclusions could be drawn in accordance with the existing French legal system.

This is the reason why the government decided to proceed further down the same path.

II. FROM ETHICS TO LAW

In 1988, the Conseil d'Etat (the state council) reported to the Prime Minister, and the proposals contained in the report were considered by a governmental working group which prepared a draft bill on "bioethics and human rights" for submission to the Parliament. But this draft was considered too detailed and a new report was ordered in 1990 which gave birth to 3 new bills.

A. The Report of the Conseil d'Etat

At the beginning of 1988, the group finished its work and came to the conclusion that legal regulation was a necessity.

Its proposals for legislation covered such areas of bioethical issues as human experimentation, the use of human tissues and human by-products, and artificial

reproduction, prenatal diagnosis, the use of human embryos as well as research data banks and ethics committees.

The Commission explained the necessity of such an important legislative process. In stressing the risks that the present development of biomedical sciences could create for the human person and the Society at large.

One of the main principles underlying the philosophy of the report is the non-commerciality of the human body and its components.

It means that, while recognizing and promoting the principle of donation of organs, gametes and the report limited such donations to certain conditions so on, aimed to protect the human person against its own right to autonomy. Therefore it chose to prohibit surrogate motherhood as well as "post mortem" insemination and suggested strict conditions for human and embryo research. The development of ethics committees was also encouraged by the report as a means to control the enforcement of those conditions.

As a consequence of this highly regulative approach, the propositions of the report were very much criticized. On one hand, those who preferred ethical guidelines and non-infringement of state regulations in the medical and scientific field could not approve such suggestions. On the other hand, those who wanted that artificial procreation should be strictly limited and embryo research prohibited, considered the report as a victory of scientific views.

Therefore the government did not push forward the drafting of the bill on human rights and biomedical sciences. At the end of 1990, however, MsLenoir was required to prepare a new report taking into account the international developments in bioethics,

B. The Report. "The Frontiers of Life"

Understandably, the main objective of this document published in 1991 was to find a more pragmatic approach to the French bioethics legislative process. At that time this question became particularly important because the Parliament, which was neglected by governmental initiatives, decided to prepare its own report on the question and even voted in 1988 a private member's bill on human experimentation. The philosophy of the reporter, titled "The frontiers of life: a French biomedical ethics" is the same as in the report of the Conseil d'Etat. The difference is that, taking into account the complexity of the debate in many respects, proposals for legislation are limited to the use of DNA fingerprints, medical research data banks and the prohibition of any commercial arrangement concerning the human body, its components and byproducts.

Concerning artificial procreation, the report proposed a non-vote parliamentary debate taking into account the therapeutic purposes of such techniques, the prominent interest of the future child and the respect due to the dignity of the human embryo.

Apart from these measures, the report was full of practical considerations concerning the practice of ethics committees, the teaching of bioethics, and international cooperation.

Finally, the government accepted to go a step forward, and bills were prepared under the responsibility of three departments.

The department for Research elaborated a text which once adopted, authorized the breach of confidentiality of personal medical data for the use of epidemiological research.

The text prepared by the Department of Health concerned mainly the donation of organs and human products as well as the application reproductive technologies. It limited the use of such techniques to therapeutic purposes and, concerning organ transplants, updated the 1976 Act to take into consideration further medical developments.

Finally, the text of the Department of Justice related to the status of the human body and suggested to insert in the Civil code an explicit formulation of principles such as the respect of the integrity of the human body, the respect of the human genetic heritage, the respect of the rule "res extra commercium", the respect of the anonymity of gametes donation and the respect of privacy in the use of genetic testing.

When these three bills came to in the Parliament ad hoc Commission on Bioethics, there was a highly responsible discussion, and M.P's amended the texts to include sensitive issues such as the question of spare embryos.

Although this decision was taken on a free vote basis, it probably frightened once more the government. Discussion which would take place during the 1992 spring session was postponed to the fall session. At time, no one was expecting the Parliament to have any more time for debate. However, after the 1993 general election which brought a new majority in Parliament, discussions were resumed and due to the activities of Prof.J.F.Matee who reported on the bills, the three texts were finally accepted in July 1994. It is therefore difficult to conclude about the French approach to legislation for the time being.

Legal and social assessment of bioethical issues have been quite very comprehensive. The discussion in

professional circles was at a high level. However, debate in the community at large, although promoted by new institutions such as the National Bioethical Committee, has not been sufficient to give a clear view of what policy the government could propose. The last point was that politicians felt consequently very uneasy to make political choices in this field.

But as the same facts could probably be mentioned for Germany or the United Kingdom, which have also passed legislations in the field of bioethics, we should probably recognize that the democratic decision-making process was meeting with the same difficulty in France. It is my hope that the European Convention on Bioethics, which is presently under drafting in the Council of Europe, could be a challenge for my country .