French Republic

THE PARLIAMENTARY OFFICE FOR SCIENTIFC AND TECHNOLOGICAL ASSESSMENT

LIFE SCIENCES AND SOCIETY: THE BIOETHICS LAW OF TOMORROW

PUBLIC HEARING ON THURSDAY 29 NOVEMBER 2007 ORGANISED BY:
MR ALAIN CLAEYS, MEMBER OF PARLIAMENT FOR VIENNE, AND
MR JEAN-SEBASTIEN VIALATTE, MEMBER OF PARLIAMENT FOR THE VAR

Summary

A few recommendations

The need for more coherent domestic bioethics legislation and more effective cohesion with the international commitments of France, which has still not ratified the Oviedo Convention on the Rights of Man and Biomedicine signed in 1997, was affirmed.

However, there is a need to avoid excesses and avoid "corrupting ideas", whether they result from scientific zeal, financial considerations, a lack of humanism in experimentation, or a search for benefits derived from successful experiments, but which are questionable on ethical grounds.

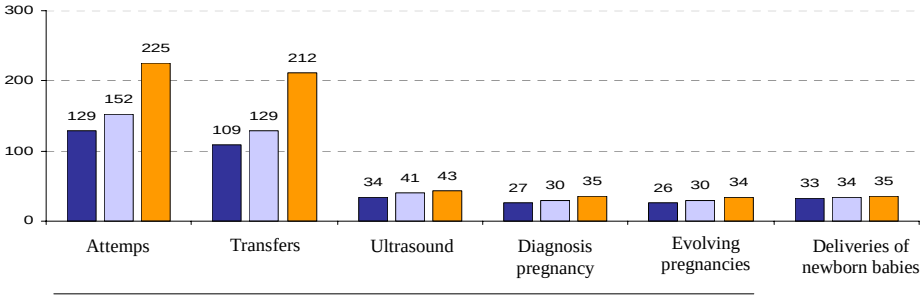
Should bioethics legislation determine basic principles or be subject to constant revision ?

For certain, ethics should not be in a state of continuous flux. Legislation should lay down simple permanent principles and not attempt to transform itself into a catalogue of best practices, better dealt with by independent bodies. Ethics must reflect the founding principles of reciprocity and solidarity written into French law: the negotiable nature of the human body, non-commercialisation of living organisms, and the principal of free donations.

Do we need to determine a framework capable of providing a rapid response to changes brought on by accelerating scientific and technological progress in a globalised and media-saturated environment? Or should we, on the contrary, rely on more permanent solutions, less affected by sudden change? Should we precisely determine in a framework law, the terms of reference of a certain number of independent agencies entrusted with validating or questioning practices, thereby avoiding rigid definitions of practices destined to become rapidly obsolete? An assessment of the role, missions and operations of the Biomedicine Agency, the National Consultative Committee on Ethics (CCNE) and the various bodies with which they have relations, should provide answers to these questions.

Rights to children or rights of children?

While appreciating the benefits brought by medically assisted procreation (MAP) for the sterility of couples wishing to have children, it has to be noted that such techniques remain cumbersome: waiting periods of more than two years, a lack of oocytes in France, and a success rate of less than 25%. The problems raised by MAP cover the three pillars - anonymity, consent



The number of immediate transfers exceeded the number of transfers of frozen embryo

IVF In vitro fertilisation
CIS Cytoplasm injection of spermatozoids
TFE Transfers of frozen embryo

2005 results

OPECST - Assemblée nationale 233 bd Saint Germain 75355 Paris 07 SP - tel : +33 1 40 63 88 15 - fax : +33 1 40 63 88 08
Sénat 15 rue de Vaugirard 75291 Paris Cedex 06 - tel : 33 1 42 34 25 58 - fax : 33 1 42 34 38 55 - www.assemblee-nationale.fr - www.senat.fr

and free treatment - which apply to every area of bioethics legislation. Anonymity represents the strumbling block of MAP. The ability of children to discover their biological origins is not equitable: possible with the agreement of the biological mother in the event of anonymous birth followed by adoption, but not possible for children born as a result of the donation of gametes or oocytes, a situation which might be considered as infringing the rights of such children. The desire to know one's biological origin will express itself, and increasingly so, a thanks to continuing scientific progress in the area of genetics. In addition to the existence of parallel civil status files held by doctors, the anonymity of donors of gametes and oocytes is bound to generate many difficult situations. What information can be given to children on the circumstances surrounding their birth? Many debates on the subject of MAP brought on by the limitations or prohibitions introduced by the Law of 2004 concerning access to this form of assistance, but which neither single women nor homosexual couples can benefit from, will undoubtedly arise.

Prohibition on the transfer of embryos post-mortem and use of substitute forms of maternity

Should it be easier to obtain medically assisted procreation by imitating more permissive neighbouring countries, for example those which allow the insemination of single women? In which case why deprive children of knowledge of their paternal ancestry?

The lifting of the prohibition on Surrogacy is bound be debated. This form of MAP, in which three to five persons can be involved, sometimes with a total absence of biological relations between the parents that receive the child, can lead to a commercialisation of procreation and the existence of a "contract", illegal in France. The risk of financial or psychological exploitation of the surrogate mother by other women who either cannot or do not want to bear the child, has been denounced. Such an approach clearly indicates the desire of adults to consecrate a "right *to* children", but sometimes at the expense of rights *of* children. Science therefore has the power to restore a much stronger form of parental authority than in the past. The large number of persons involved in the process of procreation has resulted in a disassociation of sexual, biological and social aspects but also a fragmentation of parenthood: genealogical identity is fundamental and structuring for all human beings.

What use should be made of preimplantation diagnosis?

The risk of eugenics and the temptation of the perfect baby have been denounced. Nevertheless it has been recognized that doctors will need to accept that preimplantation diagnosis can be applied in cases of certain types of predisposition to cancer. Growing knowledge of the exceptionally serious hereditary character of illnesses may lead to greater utilisation of preimplantation diagnosis. Should we accept an enlargement with safeguards in the form of commissions and agencies? This is a tremendous challenge, made more acute with the development of predictive genetic tests.

Genetic tests

Carried out on individuals for a number of reasons, genetic tests enable individuals to be identified in the civil (search for filiation) or penal domains (identification of the author of a crime or offence, and are used as an instrument of diagnosis in the framework of symptomatic illnesses or for predictive purposes to detect the risk of developing an illness for which there are no therapeutic measures or reliable preventive recommendations.

In France, legislation limits the use of such tests, which must be either based on medical prescriptions or ordered by a court. Nevertheless, the possibility of obtaining such tests through the intranet outside the specific framework of French legislation will probably have an impact on behaviour. The use of tests can lead to conflicts between respect of individuals and the right to know, but also the right not to know. To what extent should such information be effectively protected, shared or ignored? In identifying groups at risk, what is the frontier between the positive aspect of facilitating more relevant treatment, and discrimination? Investigative techniques based on new technologies certainly offer the prospect of rapid diagnosis. But in a globalised context, they pose ethical problems that are difficult to resolve.

A debate on individual rights to information will probably occur in the near future. Once it is possible to find out that information exists, individuals can claim access to such information. Nevertheless, carrying out tests that are not associated with therapeutic or preventive action is questionable: revealing an unfavourable prognosis can change an individual's perception of his existence, irrespective of the uncertainty of the prognosis. Furthermore, it can modify the perception that society or other individuals have of the individual.

Development of such tests reflects a desire to obtain a maximum amount of information on individuals, a need that continues to grow with technical progress, in particular in the area of computing and communications. In a decision that has to be considered extremely cautious, the Constitutional Council admitted that the gathering and use of genetic characteristics outside the medical domain is likely to infringe the principle of human dignity. We need to find legally precise criteria indicating what is acceptable and already accepted and what is unacceptable. Current debates on genetic tests in international bodies and in particular the European Council should shed light on this.

Research on embryos

Research on human embryos is forbidden under article 25 of the law of 6 August 2004. However the first paragraph provides an exception, for a period of five years, beginning on the date of publication of the degree by the State Council, i.e. 6 February 2006: "*research can be authorised on embryos and embryo cells if it is likely to enable major therapeutic advances, provided this cannot be obtained by alternative, equally effective methods, given the current state of knowledge*". Three options will be available from October 2011: either return to the previous situation, extend the moratorium, or liberalise and depenalise embryo research, equivalent to lifting all restrictions.

In December 2006, OPECST pronounced in favour of lifting the moratorium (report of Mr Alan Claeys on research and functioning of human cells). Will recent work on the potential of adult stem cells transform the basis of the debate? This is one of the arguments advanced to revise the somewhat restrictive and extremely ambiguous measures contained in the law of 2004 which subordinates research on embryo stem cells to there being likely therapeutic applications, notwithstanding the fact that we need to avoid generating illusory hopes about the short-term impact of scientific progress.

Which is why fundamental research as such should be preserved. Research on human embryo stem cells should remain possible to better understand the mechanisms behind their pluripotence, their ability to produce a wide variety of different tissues and their immortality, enabling a large number of such cells to be produced.

Clearly, the fecundity of animal research can help avoid many of the ethical problems involved in human embryo research. Fifteen years were needed to progress from mouse embryo stem cells to human embryo cells, more than 10 years to go from cloning a sheep to a primate, and less than a year and a half to go from the non differentiation of mouse cells to the non differentiation of human cells. In spite of this, animal research will not be able to replace human research.

The status of the in-vivo foetus

Increasingly, requests about the status of in-vivo foetuses are received after road accidents or medical accidents and in particular following the Saint-Vincent de Paul case. This question merits examination, particularly as it arose again following the decision of the Appeal Court of 6 February 2008 indicating that the establishment of a civil status certificate for a child without life does not have to depend on either on the length of the pregnancy or on the weight of the foetus.

Transplants

The question of presumption of consent will be discussed. Almost certainly it will be necessary to retain this measure.
On the other hand, a lack of legislation protecting living donors was noted as they can suffer from family pressures preventing them from taking decisions calmly, particularly

complications and sequels can occur ; the fact that medical expenses are covered is insufficient if the donor, as a result of the transplant, loses his job and is unable to provide for his family, or dies. It does not seem equitable to encourage donors to donate and then leave them to deal with any personal or family catastrophes that might occur. This however is one of the consequences of the 2004 law which enlarged the circle of potential donors. Such questions need to be examined in the light of the notions of solidarity and free healthcare to which French legislation remains attached.

Emerging issues which the 2004 law does not deal with directly

The growing pace of research in life sciences in the areas of nanotechnology, information technology and neurosciences is also leading to growing convergence of these technologies. This dual phenomenon of a an enlargement of the field of life sciences and a process of acceleration is making it increasingly difficult, both for society and legislators, to define appropriate legislative responses. Nanotechnologies make brain implants possible, but also allow computers or artificial limbs to be manipulated by thought. This begs the question of how individuals make use of these advances; we need to make sure that they do not become prisoners of such possibilities but are able to use them for their own benefit.

This extension of the scientific field is fuelling growing hopes that the new technologies will contribute to the treatment and prevention of illnesses. An upsurge of diagnostic techniques using neuroimaging has strengthened such hopes. Neuroimaging enables increasingly perfect images to be obtained and facilitates the establishment of linkages between the neuro image and brain functions. We have moved from treatment to diagnosis, from chemistry to biology and in turn to nanotechnology, a trend which did not have the same degree of clarity when the 2004 law was adopted.

Currently, an entirely new field of investigation is emerging. It concerns the exploration of the mechanisms of the brain which govern our memory, thoughts, emotions and behaviour. In this new and fascinating area, there are signs that while we may try to use such information to understand human complexity, we may fall into the trap of reducing this complexity to what can be observed. We now have many ways in which we can intervene in the nervous system either with chemical molecules or more invasive procedures such as neuro imaging, transcranial magnetic stimulation, implants or neuroprosthesis. These procedures have been made possible, whether in a medical context or in extra medical circumstances, as a result of the use of psycho stimulants.

From a medical standpoint, there exists a considerable disparity between the extremely strict regulations governing medicinal drug use and very weak or inexistent regulations on neuro imaging procedures and non-invasive measures which are not necessarily subject to market authorisations.

Neurosciences enable increasingly relevant and precise associations between the functional maps of brain activity and individual behaviour such as aggressivity, impulsiveness and violence. In Anglo-Saxon countries, neuroscience has already been solicited to determine criminal responsibility. Increasingly strong security concerns are prompting governments to look for biological indicators of the dangerousness of individuals. Should we give way to this temptation?

Conclusions

On many occasions, demands have been made for the public to be provided with precise information on bioethics issues and for a debate to be launched, at an early stage and without any preconceived ideas, on a revision to the bioethics law. This year, 2008, France will assume the presidency of the European Union. It must not turn out to be a "blank year" for bioethics, which the postponement to 2009 of the bioethics conference might suggest. On the contrary, the occasion must be seized to assert the principles and values which form the basis of the originality of French bioethics legislation, a particularly sensitive subject for public opinion. The presidency of the European Union should be an opportunity for France to promote its values.

March 2008