How to Legislate in Human Reproduction: The French Experience

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How to legislate in human reproduction is obviously one of the most difficult partitions to politically cope with. There are three stages involved in legislating human reproduction: 1) the time to legislate; 2) the time to assess; and 3) the time to reexamine the law.

TIME TO LEGISLATE

The legislation period varies from country to country, but, overall, takes years to complete, i.e., French legislation experienced approximately 10 years of works and debates. For each of us, three stages had to be overcome: 1) knowledge, 2) personal conviction, and 3) social responsibility.

Knowledge is essential to assess the extent of the problems faced by the concerned couples, as well as the involved professionals and society, which are also looking for references adapted to the contribution of new data. It is the duty of a government and a parliament to know the benefits to expect from progress, as well as the dangers to avoid, if they are bound to injure the individual, his/her family, or the community.

Many works and missions have followed, not only before the first parliamentary debate, during the first reading at the National Assembly in 1992, but also long after its closing in July 1994. On these grounds, the report of the Council of State "from ethics to right," in 1988, was used as a basis for the following reports and many preparatory debates.

It is true that we had to wait for the birth of nearly 25,000 children after in vitro fertilizations, to see the creation of a framework and, through it, an acknowledgement of medically assisted procreation practices in the French law. However, the ambition of the legislator went far beyond the plain statutory framework. This occurred, mainly, by writing in the Common Law, general and basic principles, such as the priority of the person, the nonnegotiability and the nonpatrimoniality of all or part of the human body, i.e., the respect of the person and his/her lineage's dignity, as far as the integrity of his/her genotype is concerned.

Out of those principles, many arrangements were made to modify the Code of Public Health (CSP) and the Code of Penal Procedure (CP). Yet, as far as our main subject is concerned, we unanimously agreed on limiting the use of assisted reproductive technologies (ART) to an exclusively medical framework, and not disposing of it as a real alternative to natural procreation, which neighboring countries had chosen before our legislation was complete. Societal choices have also been made concerning the access conditions to ART techniques, reserving them to stable heterosexual couples that are at an age to procreate and are dependent on a medical indication of ART.

In the same sense, without falling in normative dead end, main lines have been created to acknowledge and authorize certain practices. These rely on decrees and regulation to make them applicable, i.e., clinical and biological activities of homologous ART, gamete and embryo donation, preimplantation diagnosis, assent, and permission of the professionals and implied structures, CNMBR-DPN (state authority to manage practices and research).

Testing debates have also divided members of Parliament, expecting the French law to define a status for

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the human embryo and its nature, while, at the same time, scientists themselves find it quite difficult to answer that question all in the same definition. Therefore, it was wisely decided to make arrangements, protecting what could not yet be clearly defined.

Quite judiciously, to make sure that the text modifying the CSP would be applicable, the law placed its own reexamination within 5 years after its issue, the beginning of which was scheduled before July 29, 1999. We cannot but regret the delay of the matter, and the delay of the matter, and the reasons of the delay should be analyzed.

TIME TO ASSESS

To re-examine the law, the following authorities were again referred to: The National Academy of Medicine, The Council of the Doctors Order, The Advisory National Committee of Ethics for Life and Health Sciences, The State Council, and The Parliamentary Board of Scientific and Technologic Choices Assessment (OPECST). Such an assessment is complex because it involves the testimony of the first concerned people, including the treated couples, the professional clinicians and biologists, their representative associations, the state administrative authorities (Health, Research, Justice), and the National Committee of Medicine and Reproductive Biology.

The period of assessment is also a time for great civic debates on the selected society choices and their consequences of daily applications, including epidemiologic investigations and surveys that contribute to an objective analysis of the matters to debate during the reexamination. Finally, the assessment has to take in to account the progress of knowledge and technologies in the last 5 years, as well as the evolution of other internal legislations and international conventions, such as The European Convention of Human Right and Bio Medicine, adopted by the European Council in 1996, which was signed, although not yet ratified, by France.

From all of the available works, many facts and suggestions have been highlighted, including

- the delay of certain application decrees like that of preimplantation diagnosis, which came out 4 years after the law, or, the absence of application decrees concerning the donation and acceptance of embryos by infertile couples. What is the use of legally acknowledging a practice if it cannot be used after?
- the widening of the ART definition to treatments of ovulations troubles, to avoid

the terrible consequences of multiple pregnancies.

- the difficulties of oocyte donation practice and the shortage of donors, of which public opinion is not really aware of, and which are not sufficiently recognized by social organizations.
- the insufficiency of the law concerning the future of the human embryo given up by its parental project, mainly at the end of the consideration time for the couple and the allowed preservation time for the embryo.
- the insufficiently explicit prohibition of reproductives of cellular cloning named “therapeutic,” some possible researches on surplus embryo, basic or with a medical aim, approved of by the authorities legally competent and with the written approval of parents.

TIME TO REEXAMINE THE LAW

It undoubtedly belongs, in the first place, to the executive to set the example of respecting the reexamination delay written in the law, with such a procedure being beyond political cleavages. Who could understand that the law cannot be enforced where it was itself made? That time is submitted to the same chronology as that followed by the legislator during the elaboration of the first texts: acquisitions of new knowledge, personal convictions, and political responsibility, in the first meaning of the word.

Even if it seems obvious that a certain number of principles written in the Common Law could not be questioned, it is not impossible that some questions asked during the reexamination, scheduled for the text 94-654, which modifies the CSP, should lead to the reexamination of other texts including the law on the protection of the person submitted to biomedical research or the Code of Penal Procedure. This depends on the government project and the Parliament, who may or may not broaden the legislative reexamination initially scheduled.

That time is obviously precious for the couples and teams waiting for a disposition liable to improve the efficiency or the safety of a practice, or to make people avoid resorting to medical tourism in a country where the law is more compliant. The quality of the preceding assessment should shorten that delay, only if the time for the reexamination written in the parliamentary calendar is not too far from that of the given works. It is not only a matter of respect for the work done by the experts, but also of the applicability of the law in our State of Rights, as it would lead to normative dead ends, linked to its non-reexamination.

It is for that reason that new dispositions are discussed at the Parliament. A new government agency should make a yearly progress report, not only to the executive, but also to the Parliament, to allow accurate points of the law to be reexamined, without arbitrary delay, due to new acquisitions of knowledge and/or the evolution of morals.

CONCLUSIONS

In the light of the modifications made, the legislator cannot but take the necessary actions not to hamper a duty of research, as it aims at relieving human suffering. Even if these are not perfect solutions, they are the most human to find, to ensure both the respect of the person and that of the great ethical principles, which make our culture. In the ethics of debate lie the seeds of a modern democracy, resolutely facing future.

IN ADDITION

Biomedical ethics appeared in the French law on July 29, 1994, with three acts. One modifies the common law, by stating great ethical principles: the primacy of the person, the respect of human body, the non-negotiability and non-patrimony of it, the integrity of a person's genotype, of his/her descendance and more generally, of the human species. The other two modify the code of public health. The 94-654 law sets the implementation of ART.

After 5 years, Article 21 scheduled a new examination by the Parliament. The reexamination is currently on the way after several years of delay. A number of authorities have been referred to and gave their suggestions, including The National Academy of Medicine and The National Advisory Committee of Ethics for Life and Health Sciences (CCNE). The following peculiar points are to be discussed, including taking care of the evolution of knowledge and morals:

- Definition of the field of Assisted Reproductive Technology, including the changes in sanitary regulations and rules (good practice, hyperstimulation, etc.).
- Social conditions for access to ART (monoparental families, homosexual couples). Do we need a modification of legislation?
- What to do with frozen embryos after separation of the genitors (or death of one of them?).

Research on embryo is strictly forbidden, with very few exceptions, i.e. blocked embryos with no

developmental potential. Research on frozen embryos was abandoned, because separation of the genitors is theoretically possible, but not in the reality. The regulation led to a top complicated/impossible protocol to have access to these embryos. However, the hopes that are opened by stem cells, reinforce the interest and the necessity for basic and applied research on human embryos.

Another relevant point is the necessity to reduce the multiple pregnancies provoked by transfers of too many embryos. There is a real need for better knowledge of early preimplantation embryos. This was passed by a better evaluation of embryo quality, not only based on morphology, but on metabolism. As each mammalian model is unique, we are led to question how to improve culture media, which would lead to quality improvement. What about cloning? Dolly really boosted the debate as to if there is a real need to differentiate and explain therapeutic and reproductive cloning, even if everyone agreed that reproductive cloning is blamable.

Should gamete donation anonymity be preserved for sperm donation? Several European countries keep information, which would allow, after a certain age, the loss of anonymity. The European Convention for Human Rights and Biomedicine states "every person has the right to have access to all the information gathered on his health." This could be contradictory with certain restrictive laws, i.e. French, Spanish, Norwegian. In addition, the restrictions in oocyte donation, in certain countries that maintain a softer regulation, led to a so-called "therapeutic tourism," which complicates the story even more.

There is also severe regulation concerning preimplantation diagnosis, including "avoiding the probability of giving birth to an infant carrying severe genetic disease considered as incurable at the time of the diagnostic." The indications also include translocation carriers with repeated miscarriages and/or therapeutic abortion. Should the indications be extended to older patients, who run a greater risk of chromosomal anomalies?

Again, the reexamination of the law is of great importance, taking care of the evolutions and the differences in the European legislations and the advancement of sciences. Therefore, allowing, at best, a convergence in a universal ethics of the different cultures, sciences, and morals.

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