New Belgian Law on Research on Human Embryos: Trust in Progress Through Medical Science

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The new Belgian law on research on embryos in vitro accepts all types of research directed at therapeutic purposes and at increased medical knowledge. This includes research for germline and somatic gene therapy, therapeutic cloning, and the development of embryonic stem cell lines. As this presupposes the creation of embryos for research, this too is allowed. Other goals like sex selection for nonmedical reasons, eugenic practices and reproductive cloning are prohibited. In general, the law expresses a belief in the importance of freedom of research and the acceptance of ethical pluralism in society.

KEY WORDS: Belgium; cloning; embryo in vitro; ethics; research.

INTRODUCTION

Belgium is one of the last countries in Europe to regulate the field of medically assisted reproduction. The legislative reticence can be explained by a dichotomy within society on most ethical issues. The present government, with for the first time in decades the Christian democrats in the opposition, has voted both a liberal euthanasia law and a progressive law on research on embryos in vitro.

The law on research on embryos in vitro was voted on April 3, 2003. It has three important goals: 1) to determine the conditions under which research on embryos can be performed, 2) to prohibit eugenic practices, and 3) to prohibit reproductive cloning. From the explanatory note, two important elements can be lifted which underlie the position taken in the proposal: the belief in the importance of freedom of research and the acceptance of ethical pluralism in the Belgian society. Just before the vote in the Senate on December 5, 2002, the initiator stated, "It is impossible, useless and dangerous to try to block the progress of knowledge . . . It is difficult to abandon such responsibility when it is not inevitable, unless one adheres to

a mystic approach that glorifies nature and has more trust in chance than in reason."

ALLOWING BY DEFAULT

The editing of the law was governed by the rule that "everything that is not forbidden by this law is allowed." The initiators point out that the law does not prohibit germline gene therapy and therapeutic cloning and that *a contrario* these applications are allowed. This reasoning was also important for the application of sex selection. Article 5, § 5 states that research or actions directed at sex selection are forbidden except when the selection is meant to prevent sex-linked diseases. During the discussion of the law proposal, there was a major row in the media about the collaboration of a Belgian physician in the application of the sperm-sorting method to have a child in the context of family balancing. Because of this event, the clause in the original article "to perform an action to select embryos according to sex" was changed into "to perform an action to select the sex." By omitting the reference to embryos, also manipulations on gametes are forbidden.

Research should have a therapeutic goal or contribute to a better knowledge of fertility, infertility, transplantation of organs and tissues, or the

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prevention or treatment of diseases. In the first proposal, research on embryos in vitro was allowed when it contributed to a better knowledge of serious genetic or congenital diseases and of oncology. In the final version, research is allowed when "it contributes to a better knowledge of . . . the prevention and treatment of diseases" (Art. 3, § 1). The removal of the specifications, and more specifically of the qualification "serious," made the law more liberal. This extension of the permitted research was the object of a long and hard discussion with the members of parliament who wanted a more restrictive formulation. By allowing embryo research for all kinds of diseases, the opponents judged that too little respect was shown towards the embryo. In a similar vein, they wanted sex selection of embryos to be restricted to serious diseases. However, since listing and categorizing diseases was considered unfeasible and impractical, the qualification was dropped.

The extension of the goals of research was mainly meant to incorporate the future development of stem cell therapy. Except for one paragraph which forbids the commercial use of embryos, gametes and embryonic stem cells (Art. 5, § 3), no mention is made of stem cell research although this development played an important role in the discussion. Contrary to the law in The Netherlands, which installed a 5-year moratorium on the creation of embryos for research, and thus indirectly on embryos created by somatic cell nuclear transfer, the Belgian parliament opened the door and awaits future developments.

RESTRICTIONS

The research on human embryos is limited by a number of generally accepted restrictions. Research should be based on the most recent scientific findings and be conducted according to the methodology of scientific research. It can only be performed under the supervision of a specialist in a laboratory of a university center that is recognized as a center for reproductive medicine. Research on embryos is only allowed until the 14-day limit (not including the freezing period). Finally, there should be no other research method that is equally effective. In addition, a number of limitations are enumerated regarding the type of research conducted. Human embryos may not be implanted in animals and no attempts should be made to create chimaera or hybrids. Embryos on which research has been conducted should not be placed into a woman except when the research had a therapeutic

goal for the embryo itself or when it concerns an observational method that does not harm the integrity of the embryo (Art. 5, § 2). Three specific actions are forbidden in the law: sex selection for nonmedical reasons, reproductive human cloning (Art. 6) (which means that reproductive cloning is not considered as a possible treatment for infertility), and research or actions with a eugenic goal. Eugenics is defined as "the selection or improvement of nonpathological genetic characteristics of the human species." Although the members of parliament probably had some examples in mind when accepting this article, both the term "nonpathological" and "human species" may cause problems. If the "allowed by default" rule is applied on this definition, it seems to imply that the selection or improvement of nonpathological characteristics of an individual person is permitted since only such actions on the human species are mentioned. Moreover, the question has been raised whether the enhancement of the human immunological system would be forbidden by this article or not.

RESEARCH EMBRYOS

As expected, the permission to create embryos for research stirred up the emotions. Article 4, § 1 states that the creation of embryos for research is forbidden except when the research goal cannot be achieved by research on supernumerary embryos and when the conditions of the law are fulfilled. The initiators of the law proposal refer to the development of technologies like in vitro maturation of oocytes and cryopreservation methods to justify the creation of embryos in some circumstances (Belgian Senate, 2-695/1, 2000/2001, p. 4). Moreover, they explicitly denied that there is a morally relevant difference between research on supernumerary embryos and the creation of embryos for research. The subsidiarity principle is considered as an important expression of the respect for the embryo; embryos should only be created when the research is not possible on supernumerary embryos. In practice, this restriction will make little difference. Given the abundance of frozen embryos available for research, no researcher would consider creating additional embryos without a serious reason. Connected to the possibility of creating embryos for research, a new paragraph was introduced to protect women from abuse and exploitation. A number of (female) philosophers pointed out that the creation of embryos for research presupposes that oocytes are available (1). When

stem cell research and therapy will take off, the demand for oocytes may increase steeply. Some members of parliament consider the risks of ovarian stimulation for the health of the women as too high. Although the risks are acceptable when procreation is intended (either by themselves or others), they are considered disproportional when the goal is scientific research and stem cell collection. The opponents of ovarian stimulation to obtain oocytes for research argued that a stimulation cycle is very demanding and may even cause infertility in the donor. Eventually, three conditions to protect the woman from coercion were accepted: she should be of age, have given written consent, and the stimulation must be scientifically justified.

INFORMED CONSENT

All persons concerned should give free and informed consent in writing for the use of their gametes or embryos for research purposes. Article 2, § 4 stipulates that in the case of supernumerary embryos, the people concerned are the persons for whom the embryos have been created. In the case of the creation of research embryos, the persons involved are those whose gametes are used. They should receive information on the provisions of the law, the technique to obtain the gametes, the purpose, methodology and time period of the research or treatment, and on the advice of either the local ethics committee or the Federal Commission (Art. 8). They should be informed explicitly by the researcher that they have the right to refuse to donate and to change their mind until the start of the experiment. Dissent by one of the donors blocks the experiment.

THE EUROPEAN CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

From the early start of the discussion of the law proposal, the pressure emanating from the European Convention on Human Rights and Biomedicine (2) was a major reason for the legal regulation of the field. Belgium, given the importance of the European institutions in the country, tries to be a good European pupil. Most conservative parties insisted on signing and ratifying the Convention. The ratification of the Convention would have been an easy way to avoid discussion in Belgium itself and would severely restrict later options in the national legislation. The

same strategy was successfully applied in Italy where the Convention was signed by an exclusively catholic committee without any public discussion (3). However, in particular Art. 18, which prohibits the creation of embryos for research, was unacceptable for some parties in Belgium. The conflicting views on the ratification of the Convention were clearly expressed in the advice of the national Advisory Committee on Bioethics (4). One group wanted ratification because the Convention provided a much needed protection of human dignity, while the other group saw it as a major threat to the principle of freedom of scientific research (5). Until now, Belgium has neither ratified nor signed the convention.

Art. 36 of the Convention permits national states to make a reservation if national legislation exists which contradicts the rules of the Convention. After the present law is voted, Belgium is expected to sign the convention. According to the State Council (Conseil d'Etat), Belgium should make a reservation for Art. 13 and Art. 18 of the Convention (6). Art. 13 of the Convention states that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants." However, since no prohibition on germline gene therapy is included in the law, this technology is accepted. Article 5, § 4 only forbids research and actions directed at eugenic purposes. As a consequence, germline gene therapy to correct pathologic characteristics is allowed. The initiators of the law proposal could not see the rationale behind the present prohibition of this type of gene therapy: if it is good to cure a disease in one person, it is good to liberate the descendants of that person from the same disease (7). This makes Belgium one of the few countries (together with Denmark and Slovakia) in Europe to accept germline gene therapy in general (8). Art. 18, second clause of the European Convention states that "the creation of human embryos for research purposes is prohibited." This article conflicts with the new Belgian law since the creation of embryos for research is allowed if the goals cannot be reached by research on supernumerary embryos. The United Kingdom also derogated from this clause as it conflicts with their national legislation.

CONTROL

The research projects are approved in two steps. Firstly, the project should be presented to the ethics

committee of the local hospital. This committee issues an advice within 2 months. If a negative advice is given, the project is rejected. If a positive advice is given, the project is presented to the Federal Commission for medical and scientific research on embryos in vitro. This Federal Commission is established by the present law (Art. 9, § 1). The Commission is composed of four physicians, four doctors in the sciences, two lawyers, and four experts in ethics and social sciences. It has the following tasks: to gather information on the different research projects on embryos, to prevent scientifically unjustified repetition of experiments, to evaluate the application of the law, to compose recommendations for law making initiatives, and to make recommendations regarding the application of the law for the benefit of the local ethics committees (Art. 10, §. 1). It should examine all research projects for which the local ethics committees have given their approval and should reach a decision within 60 days. The project is approved if less than two thirds of the members have given a negative evaluation. There has been some discussion about the strange formulation of the approval procedure. The end result of this rule evidently is that it will be difficult to reject a research proposal once approved by the local ethics committee.

CONCLUSION

The new Belgian law on research on embryos in vitro allows all types of research as long as they serve a therapeutic purpose. Research for germline and somatic gene therapy, the creation of embryos for research, the use of embryonic stem cells and therapeutic cloning are not forbidden by the law. Consistent with the focus on therapeutic interventions, ac-

tions directed at other goals, like sex selection for non-medical reasons, eugenic practices and reproductive cloning, are forbidden. Within the range of medical research, the law confines itself to a more procedural approach; it outlines the framework of guidelines and institutions which should control and examine the research projects on embryos. With the exception of the rule that supernumerary embryos should be used first, no restrictions regarding the way research should be conducted are present.

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