

## NEWS AND VIEWS

### REPRODUCTIVE HEALTH CARE POLICIES AROUND THE WORLD

#### A Law Affecting Medically Assisted Procreation Is on the Way in Switzerland

##### HISTORICAL BACKGROUND

In a popular vote on 17 May 1992, a majority (73.9%) of the Swiss people accepted a new article (24<sup>noviès</sup>) into the constitution authorizing and directing the Confederation to legislate on the use of the germinal and genetic patrimony as well as on medically assisted procreation (MAP). The principal goal of this article is to enable the passage of a hitherto nonexistent law that would "protect man and his environment against abuses in genetic engineering and procreation techniques."

Less than 2 years later, on 18 January 1994, the Federal Chancellery formally accepted a popular initiative entitled "For the Protection of Human Dignity," directed against the techniques of MAP, prohibiting procreation outside the female body and the supply of gametes by third parties for artificial insemination.

In its message to the Parliament on 26 June 1996, the Federal Council presented a bill on MAP (1) as an indirect counterproposal to the initiative. In doing so, the Federal Council rejected the initiative, which will nevertheless have to be submitted to popular vote during 2000.

Parliament agreed on the definitive version of this bill at the end of 1998; the law was officially

published in 1999, submitted to the people for the right of referendum and will come into effect soon. However, if the 1994 initiative is accepted by popular vote in 2000, the law will become obsolete and Switzerland will then be the only country in Europe to prohibit in vitro fertilization (IVF) and heterologous insemination. On 26 June 1996, the Federal Council also independently promulgated an enactment on blood and organ donations including sperm (2). This regulates how authorizations have to be obtained for sperm banking and withdrawing; it defines the duties of the specialized centers and which screening tests have to be carried out on each organ or by the sperm donor.

##### CONSTITUTIONAL ARTICLE 24<sup>noviès</sup>

The text of constitutional article 24<sup>noviès</sup> is a complex mixture of proposals and statements that have to be clarified through the application law. The article deals not only with the human species, but also with animals, plants, and organisms. In its desire to respect the existence and security of man, animals, and the environment, the article protects "the genetic multiplicity of the animals and plant species" and "human dignity, individuality and family."

Seven items are listed in the article.

1. Interventions in the genetic patrimony of human gametes and embryos are forbidden.

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2. Nonhuman germinal and genetic patrimony is not allowed to be transferred into human germinal patrimony or to be fused with it.
3. MAP is authorized only in cases of sterility or when the transmission of a serious illness cannot be avoided by any other procedure and not to develop particular characteristics for the child or to carry out research. Fertilization of human ova external to the body of the female is authorized only under conditions specified by law. The number of embryos that may be developed exterior to the body of the female shall not exceed the number that can be immediately transferred.
4. Embryo donation and all forms of surrogate motherhood are forbidden.
5. Commerce of human germinal materials and biological products from embryos is forbidden.
6. The inherited genetic signature of a person may not be analyzed, recorded, or revealed without the consent of the individual or in accordance with legal regulations.
7. The individual has access to data concerning his lineage.

This article puts major restrictions on MAP techniques, but the application law still has, in a number of instances, to specify the exact limits of these restrictions. For example, if genetic manipulations in the human are banned (item 1), which aspects of genetic engineering in medicine and biology remain legal? Another law currently being drafted (GEN-LEX) specifically addresses these questions. In the context of assisted procreation, the laws and regulations must define the MAP methods, as well as the term "embryo." If from a legal point of view, the zygote, before syngamy, is considered to be the same as the embryo, then IVF will encounter a serious legal obstacle. Cryopreservation of both embryos and zygotes would then be forbidden and IVF restricted to those embryos immediately transferable. This would limit the practice of IVF, which is specifically authorized in item 3.

With regard to the genetic signature of a person, the laws and regulations must clearly spell out the conditions of access to the genetic information. The right of an individual to access data concerning his lineage is granted in item 7. The laws and regulations must specify how this can be made consistent with the prior item (6) ensuring that the genetic information of individuals is not disclosed. Selection

of the couples treated by donor insemination would occur depending on whether these couples agree to reveal their sterility to the child. For both parents and child, it is conceivable that access to genetic inheritance would have psychological benefits.

### **THE CONSTITUTIONAL ARTICLE 24<sup>noviès</sup> BILL**

The bill, currently under debate in the Swiss parliament, has the child's welfare as an underlying principle and aims for transparency in order to enable infertile couples to be treated optimally.

Both the practice of MAP and the cryoconservation of gametes and zygotes are subject to authorization. While the number of MAP centers is not limited, authorization can be delivered only to a medical doctor who fulfills specific conditions regarding ability, personnel, execution, and information. The medical team must be able to guarantee that the patients have quality care and counseling on medical treatments and aspects of reproductive biology. Sociopsychological care must be warranted to the treated couples.

An annual report respecting the patients' anonymity must be made to the Cantonal Surveillance Authorities. The latter transmit the data to the Federal Statistical Office, which evaluates and publishes the data. The Cantonal Authorities organize regular surveillance and carry out unannounced visits.

The bill institutes a national ethics commission, whose role is to follow medical and biological progress in the fields of MAP and genetics and to develop a complete set of guidelines to the law.

The bill allows IVF and sperm donation. Once the child born of a sperm donation reaches the age of 18, he has the right to know the identity of his genetic father. The donor has the right to refuse to meet the child. If opinions differ, the child's wish to know the details of his biological father prevails over the donor's wish to remain anonymous. The data relative to the sperm donor have to be kept on file at the Federal Civil Registry Office and the child may have access to this information. However, a paternity case cannot be brought against a sperm donor.

The sperm of a given donor can be used for a maximum of eight cases of procreation. Donor selection has to be carried out on the basis of "good medical practice." On this basis, the use

of fresh sperm for artificial insemination would be considered irresponsible. Donors can give their sperm to only one authorized center. No remuneration may be given for sperm donation. The only determining factors in selecting sperm are blood group and phenotype.

The bill prohibits surrogate motherhood, embryo donation, IVF for any reason other than to induce a pregnancy, development of an embryo for research purposes, oocyte donation, development of more than three embryos outside the female body, cryopreservation of embryos, preimplantation genetic diagnosis (PGD), embryo sexing, interventions altering the germinal heritage of gametes or embryos, cloning, chimera, and hybrids.

The term embryo is defined as the product of the union of the nuclei up to the final stage of organogeny, i.e., up to 8 weeks after fertilization (article 2, let. i). Freezing is, however, authorized up to the "impregnated oocyte" stage, defined as "a fertilized oocyte before fusion of the nuclei." The preservation of zygotes is authorized only with the written consent of the couple in question and only in order to induce a pregnancy. The duration of preservation is limited to 5 years. Each partner may at any point revoke his or her consent as regards the preservation and use of the zygotes.

PGD has unfortunately been assimilated to cloning, as the extraction of a "totipotent" cell for the purposes of diagnosis might lead to "potential" cloning. This point has been under heavy debate in parliament, as it contradicts item 3 of the article, which specifically allows MAP when transmission of a serious illness cannot be avoided by any other procedure.

While embryo sexing is forbidden, separation of spermatozoa carrying the X chromosome from those carrying the Y chromosome is allowed only in order to avoid transmitting a serious incurable disease to descendants.

## CONCLUSIONS

Switzerland will soon adopt one of the most restrictive laws on MAP in Europe. However, if the popular initiative entitled "For the Protection of Human Dignity" is accepted in 2000, the practice of IVF and sperm donation will be prohibited. As currently drafted, the law under debate in parliament offers an alternative attitude to such an

extreme position, namely, authorization of most MAP techniques, respect for the unborn child, and provision of a minimal level of support to the patients.

The protectionary measures the law includes could, however, prove contrary to the patients' interests. In prohibiting PGD, it favors the embryo, to the detriment of the child and the patients. In banning oocyte donation, it is not consistent with the sex equality law. In forbidding the development of more than three embryos, it reduces the chances of conception per egg retrieval. In prohibiting research on the human genome, it closes the door on any further scientific development in reproductive medicine. Furthermore, by legally removing the sperm donor's anonymity, Switzerland exposes itself to a series of hitherto unexplored problems, centering on the child's welfare. The law thus diametrically opposes the positive points of the French law of 1994 as described by Cohen (3), namely, the anonymity of donation.

It remains to be seen whether the National Ethics Committee, instigated by law, can fill the gaps and moderate this restrictive legislative framework.

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**M. Germond  
A. Senn**

Reproductive Medicine and Gynecological  
Endocrinology Unit  
Department of Obstetrics and Gynecology  
CHUV  
CH-1011 Lausanne, Switzerland