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Eidgenössische Ethikkommission für die Gentechnik im ausserhumanen Bereich
Commission fédérale d'éthique pour le génie génétique dans le domaine non humain
Commissione federale d'etica per l'ingegneria genetica nel settore non umano
Swiss Ethics Committee on Non-human Gene Technology

Statement on the draft bill of the Federal law relating to the transplantation of organs, tissues and cells (Transplantation Law, TxG)

Mandate of the ECNH

In accordance with the Federal Council's mandate, the ECNH issues statements on adherence to the ethical principle of respecting the dignity of creation and of preserving the safety of humans and the environment. According to Art. 120 Para. 2 of the Federal Constitution, the dignity of creation must be respected. The ECNH Statement on the draft of the present Law thus relates primarily to the ethical aspects of xenotransplantation with regard to animals.

Procedure

The Ethics Committee welcomes the present comprehensive proposals for regulating transplantation medicine. It notes, however, that there is almost no discussion on the ethical aspects of xenotransplantation with reference to non-human animals.

The ethical evaluation of xenotransplantation from a human point of view defines the evaluation of animal considerations. In the opinion of the ECNH, the ethical aspects of animal use cannot be judged independently of the human aspects. The smaller the chances of successful xenotransplantation due to the associated risks, the more weight is carried by the animal aspects in the overall ethical evaluation of xenotransplantation. The safety and risk of xenotransplantation therefore represent the background against which ethical aspects of animal use must be discussed.

Because such basic considerations are missing from the explanatory report and from the proposed legislation for the TxG, the elements the ECNH considers to be fundamental to the discussion of xenotransplantation are presented in the first part of the Statement. The ethical aspects of xenotransplantation will be made visible and will also be placed in the context of the discussion. In the second part of the Statement, reference is made to individual Articles of the draft law, and in the third part, to the explanatory report of the TxG. With regard to the Statement on the explanatory report, we refer at this point especially to the explanations in parts 1 and 2.

c/o Bundesamt für Umwelt, Wald und Landschaft, CH-3003 Bern / Office fédéral de l'environnement, des forêts et du paysage, CH-3003 Berne / Ufficio federale dell'ambiente, delle foreste e del paesaggio, CH-3003 Berna

I. General ethical considerations of xenotransplantation in the TxG

Overview of contents of general ethical considerations

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   c) Difference between cell and organ transplantation
   d) Human and social ethical aspects
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4. Public discussion

2. Elements of the ethical discussion of xenotransplantation

The ethical discussion of xenotransplantation takes place within the context of basic questions arising in transplantation medicine in general. These include questions of our relationship to death and mortality, of our personal understanding of ourselves, and of the relationship between humans and animals.

Initially, the problem of hyperacute rejection of organs was the central issue in the medical research on xenotransplantation. Since the 1990s the problem of infection has also been a focus of research. A comprehensive ethical discussion remained in the background and was primarily concerned with these problems of safety. With advances in technology the ethical discourse has, however, gained new dimensions: the objectives of xenotransplantation are now being discussed. The objectives must be judged anew according to the state of the technology.

An overall ethical evaluation required the consideration of all aspects and impacts of xenotransplantation. As ethical discourse developed, the ethical questions of animal use thrown up by xenotransplantation have gained in significance. They profoundly influence the acceptance or rejection of xenotransplantation. The ECNH is therefore of the view that it is not enough to orient the legal regulation of xenotransplantation only solely towards protecting human beings.

A provisional set of elements for an ethical evaluation of xenotransplantation is given below. In the view of the ECNH, these must be discussed and considered as part of the explanatory report and possibly also in the draft law.

a) Basic medical prerequisites for xenotransplantation

- Suitability of animal species for transplantation to humans
- Overcoming the risk of rejection
- Overcoming the risk of xenozoonoses
- Suitability of the animals for the specific breeding and keeping conditions

These basic medical prerequisites must be fulfilled before the animals can be considered as sources of organs. In addition to the medical feasibility, other aspects of xenotransplantation must be discussed and taken into account in an ethical evaluation.

b) Difference between research and application

The question arises of whether the phases of research and application must be differentiated in an ethical evaluation of xenotransplantation. Discussion of the use of primates and apes in preclinical research is significant here. Since, in the ECNH's opinion, the ethical problems of animal use in relation to the phases of research and application are different in severity but not in principle, we do not make any such differentiation in the ethical evaluation here.

c) Difference between cell and organ transplantation

In addition, it may be questioned whether cell and organ transplantation should be differentiated. Hyperacute rejection, physiological intolerance and risks of infection arise primarily in the xenotransplantation of organs. These problems usually affect transplantation of cells from other species less, for example because of encapsulation. The ECNH however considers that animals are subjected to the same procedures for both cell and organ transplantation. The ethical discussion would change fundamentally only if in vitro techniques were available and cell lines could be used instead of primary cells.

Nevertheless, it should be borne in mind that research into cellular transplantation is more advanced relative to the transplantation of whole organs. The different scientific maturity of the different procedures is ethically significant. This should be taken into account when weighting the different aspects of xenotransplantation in the evaluation of interests. The clinical application of an immature technology would, in the ECNH's opinion, contravene the principle of beneficence.

d) Human and social ethical aspects

Impact on the subjective perception of identity

A further aspect that must be examined from an ethical point of view is the impact of the transplantation of animal cells, tissue and organs on the patient's subjective perception of his or her identity and the possible psychological stress associated with this.

Impact on objective perception of identity
Independent of the individual concerned, the impact of transplanting animal cells, tissue and organs on the objective perception of human identity should be discussed, in terms of altering human self-understanding in general.

Economic issues associated with xenotransplantation
The overall evaluation of xenotransplantation also requires an economic context. This should include both economic and business aspects.

Care must be taken to ensure that the cost-benefit distribution is fair. In view of the risks – which currently cannot be estimated - the ECNH is of the opinion that an individual (patient) benefits while the risks of xenotransplantation (danger of transmitting new pathogens from animals to humans, high healthcare costs) are the responsibility of society.

The fact that the individual patient is not protected from risk should also be taken into account. Organ rejection, severe side effects and limited quality of life due to the long-term (possibly lifelong) monitoring should be expected. This monitoring, with its associated costs, will also extend to the partners of patients.

The ECNH believes that the new problems of allocation associated with xenotransplantation (i.e. availability of organs and the fair distribution of available organs) should be discussed.

The possibilities of profits opened up by xenotransplantation should also be included in the overall evaluation, as well as the danger of monopolies.

e) Ethical aspects of animal use

Xenogeneic source and recipient animals in preclinical trials
If xenotransplantation is to be regarded as an option, the acceptability of apes as xenogeneic source or recipient animals in preclinical trials of xenotransplantation should be considered critically. In the view of the ECNH, the evolutionary closeness of non-human primates and humans should be taken into account. In addition, the use of more common laboratory animals, in addition to pigs and primates, should also be considered.

Extent of animal consumption
The ECNH believes that, in addition to the species of animal used in the xenotransplantation, the consumption of these animals in terms of numbers should be considered in the ethical evaluation. Because of the low success rate of the targeted genetic modification, a high proportion of so-called excess animals should be expected, which cannot be used for further breeding or to establish a stock population.

Severity of intervention in the animal
A further aspect of the ethical evaluation of xenotransplantation is the particularly stressful vivisection needed to research the rejection mechanisms, the risks of infection, and physiological compatibility.

f) Alternatives

As part of an ethical evaluation, research trends and alternatives to xenotransplantation should be taken into account. If the trend were towards stem cell engineering, for example, this would influence the ethical justifiability of using animals for xenotransplantation. In this connection the need to promote alternative research approaches must also be discussed.

2. The dignity of creation in the TxG

In Art. 120 Para. 2, the Federal Constitution requires that the dignity of creation be respected. According to Art. 29a Para. 2 LPE of the Gen-Lex draft, which was approved on 19 December 1999 by the Federal Council and passed on to Parliament, animals should be protected in their dignity for their own sake, in their species-specific properties and ways of living.

With regard to the Animal Protection Law, the ECNH in its Statement of 17 November 1999 suggested putting injury to dignity into more concrete terms. The existing Animal Protection Law protects the animal from unjustifiable pain, suffering, fear and injury. Even if these four criteria represent the main damage to animal dignity, a majority of the ECNH believes that the Constitutional term protects the animals more comprehensively. The ECNH suggested further criteria for injury to dignity:

- Intervention in appearance
- Humiliation
- Complete instrumentalisation

Xenotransplantation assumes extensive interventions in a significant number of animals. In the view of the ECNH it must therefore be evaluated not only from the point of view of human ethics, but also giving ethical consideration to animals.[1] Putting the Constitutional principle “dignity of creation” into concrete terms is also considered necessary for the Transplantation Law.

In the opinion of the ECNH, damage to the dignity of animals is not prohibited per se. If, however, a gene technological procedure affects the dignity of an animal, an evaluation of the use interests of humans and the interests of animal protection are urgent. Only if an injury to dignity can be justified because of overwhelming interests is the constitutionally protected dignity of the animal respected despite the intervention.

[1] The ECNH regrets that the Federal Ethics Committee on Human Gene Technology has not yet been appointed; this would concern itself specifically with the human ethical aspects of gene technology. An exchange and an engagement with the respective aspects of evaluation are considered to be important and worthwhile because of the different viewpoints of the two Committees.

3. Evaluation of interests

An evaluation of interests determines, evaluates and weighs up the various interests against each other. Existing alternatives, with which harm to an animal could be avoided or reduced, play a role in the evaluation insofar as they influence the weighting of the interests.

The ECNH is of the opinion that the following interests should be included in the assessment of xenotransplantation:

Ethical interests with reference to humans for and against xenotransplantation

- Saving life
- Individual health of the patient
- Quality of life
- Safety/risks
- Public health
- Social ethical interests:
  - Subjective perception of identity (psychological stress for the patient)
  - Objective perception of identity (change in human self-understanding)
  - Distributive fairness / distribution problems relating to xenotransplants
- Economic interests:
  - the economy: fair distribution of costs, availability (xenotransplants as a substitute for allotransplants of which there is a shortage, or as a substitute for drug therapy), danger of monopolies
  - business: prospects for profit, danger of monopolies

Ethical interests with reference to animals

- no distress (suffering, pain, fear or injury)
- no additional injury to dignity (intervention in appearance, humiliation, unjustifiable instrumentalisation)
- no (excessive) consumption of animals

Result of the evaluation of interests by the ECNH:

A two-thirds majority of the Committee is in favour of a moratorium on the xenotransplantation of organs and tissues. Clinical research on humans should not be permitted at the present. The ECNH is unanimously in favour of a moratorium on preclinical research using apes.

A minority of the Committee is in favour of permitting the xenotransplantation of organs in principle, but with the express limitation that preclinical research using apes should not be permitted. Clinical research using humans should, on the other hand, be permitted.

A minority of the Committee would like to extend the moratorium on the use of apes to all primates. A further minority of the Committee is in favour of a general moratorium that would not permit any research on xenotransplantation, either in preclinical or clinical phases, on any animals.

The following factors are, in the ECNH's view, decisive for the result of the evaluation:

Lack of scientific basis
The scientific basis for xenotransplantation is considered to be generally insufficient. In the view of the ECNH, not only are the medical risks inadequately clarified; so is the ethical evaluation of xenotransplantation, especially in relation to the dignity of creation. There is also a lack of social discourse on xenotransplantation. In view of this starting position, a clear majority of the ECNH considers it to be irresponsible to carry out clinical trials on humans at the present.

Weighting of the ethical interests of animals
The ethical evaluation of the animal aspects of xenotransplantation is dependent on the evaluation of ethical ones concerning humans. However, since, in the ECNH's opinion, the human ethical aspects are largely unclear, the animal aspects become overwhelming. The greater the ethical problems in terms of humans, the greater will be the need to legitimise interventions in the dignity of creation in animals.

Prohibition of the use of apes
The ECNH believes that prohibiting the use of apes to produce organs or in preclinical research is in line with the ethical consensus. The evolutionary closeness of these animals to humans, and their developmental ability, are decisive factors.

Available alternatives
In the overall evaluation, the ECNH believes the existing alternatives to xenotransplantation should be considered. The availability of alternatives influences the weighting of interests in xenotransplantation.

4. Public discussion

The ECNH considers public discussion, including the ethical aspects of xenotransplantation and involving the dignity of creation, to be a significant element in the support of any legal regulation.

The ECNH therefore believes that a mandate should be formulated in the TxG, according to which the Federal Council should promote public discussion about the chances and risks, perspectives and problems of transplantation medicine in general and of xenotransplantation in particular.

II. Individual legal provisions

Chapter 1: General provisions

The ECNH notes that the Law lacks a concrete definition of the "dignity of creation", which is constitutionally protected, and of ethical aspects with regard to animals in general.

Art. 1

The protection of the dignity of creation is an important objective of the Constitution, in addition to protecting human dignity. The ECNH therefore recommends giving this constitutional objective in the Article of Purpose under subpara. a, in the same sentence as human dignity:

This Law shall:

a. protect human dignity, personality and health in the use of transplantation medicine on humans, *as well as the dignity of creation*.

Art. 4

Article 4 in its present form is directed only at those who handle organs, tissues or cells. A majority of the Committee, however, considers it necessary to insert an additional paragraph into Article 4, which would oblige the authorities to observe the precautionary principle. The precautionary principle would therefore be regulated in relation to the general conditions.

A minority of the ECNH also pleads for deletion of the expression "according to the state of science and technology". In their opinion, the state of science and technology does not provide a reliable criterion for the safety of xenotransplantation. Therefore, those who handle organs, tissues or cells must take all measures to ensure that the health of humans or animals is not put at risk.

Chapter 8: Handling animal organs, tissues and cells

Art. 52

Para. 1
Subpara. a: The ECNH points out the contradiction that the Law requires the risk of infection to the population to be ruled out, according to the state of science and technology, in order for xenotransplantation to be authorised, while the explanatory report states that an infection risk to the population cannot be ruled out. Furthermore, it should be discussed whether protecting the dignity of creation requires that the infection risk to animals should also have to be eliminated.

Subpara. c: Instead of making authorisation dependent on “no other treatment of comparable efficacy” being available, the issuing of authorisation should be linked to the lack of alternative methods of treatment.

Para. 2:
As stated in Subpara. a, the risks associated with xenotransplantation require long-term monitoring of the patient. This - possibly lifelong - monitoring and registration involves not only the patients but also their partners, because of the risk of infection that cannot be ruled out. The consequences for the patient and for society (e.g. data protection, financial burden on society) should be presented, opened up for discussion and possibly regulated further.

As in Article 49, a separate Article following Article 52 should establish that the recipient patient must give informed consent.

Art. 53

In the opinion of the ECNH, the condition should be stated clearly here a person who keeps source animals must ensure their wellbeing and provide a suitably designed, animal-friendly environment for them. The handling of animals should not just be regulated for the sake of human safety, but also for the sake of the animals and their wellbeing. In the evaluation of the ethical weightings the special conditions of xenotransplantation should be considered, especially the particularly high level of instrumentalisation. The possibility that the Animal Protection Law can cover these special conditions should be examined. If referral to the requirements of the Animal Protection Law is found to be insufficient, additional, specific regulations should be incorporated in the Transplantation Law.

We also refer to the ECNH Statement of 17 November 1999 on the production of genetically modified animals for medical purposes, as part of the Statement on the dignity of creation in animals.

Art. 55

In relation to liability regulation, we point out that the long latency of viruses that can cross species boundaries makes establishment of liability difficult or even impossible. It remains unclear who assumes liability, to protect the injured party in such cases.

Art. 56

According to the present formulation, the Federal Council may prescribe insurance or other form of guarantee to protect the injured party, and regulate its extent and duration. This delegation to the Federal Council should be formulated as an obligation, i.e. the Federal Council shall prescribe a guarantee.

Art. 59

Para. 1
The ECNH considers that the list of Federal Council regulations lacks a referral to the constitutional term “dignity of creation” being further concretised at legislative level. Provisions on accompanying research should also be incorporated.

Further points should be added, including the promotion of alternatives to xenotransplantation (prevention, promotion of allotransplantation, gene therapy, bioartificial organs etc.), and the duty to inform the public and to promote dialogue about xenotransplantation, in particular the ethical aspects, e.g.:

Subpara. i (new): the Federal Council shall promote alternatives to xenotransplantation with the aim of halting xenotransplantation and the associated use of animals when appropriate other therapeutic approaches are available.

Subpara. k (new): the Federal Council shall promote public information on and discussion of all aspects of xenotransplantation.

Chapter 9: Clinical trials

Art. 62

Para. 4
Parallel to Art. 52 Para. 1 subpara. c, a subpara. c should be inserted here, in which the issue of authorisation for clinical trials using xenotransplants is linked to the prerequisite that no other method of treatment with comparable efficacy exists.

Art. 65

Para. 2
The present provision requires only the ethical examination of the scientific quality of the clinical trial. The objective of the experiment should also be examined from an ethical point of view.

Para. 3
The Ethics Committees must have not only the professional knowledge and experience required to evaluate the trials, but above all the ethical competence as well, so that an ethical examination can be assured.

Para. 4
The ECNH considers it to be desirable for the same criteria covering the regulations on ethics committees to be valid for the whole of Switzerland.

III. The explanatory report

The Constitutional term “the dignity of creation” should, in the opinion of the ECNH, also be put into concrete terms in the TxG. Since there are no references to the ethical aspects of xenotransplantation with respect to animal use either in the introductory part (pp. 16-19) or in the other Articles (Chapter 8, pp. 110-116), we refer to the details in part I and notes on the individual provisions in Part II of the Statement for the fundamental discussion of the ethical aspects of animal use in xenotransplantation.

28 February 2000