ETHICAL AND LEGAL ISSUES IN XENOTRANSPLANTATION

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ABSTRACT

In most western countries, there is a ‘human organ shortage’ with waiting lists for the performance of transplantation. In a recent report of the UNOS Ethics Committee it is stated that there are approximately 31,000 potential recipients on waiting lists, but only one fourth of potential donors gave their specific consent.

Xenotransplantation – defined as the transplantation of animal cells, tissues or organs into human beings – is associated with particular ethical dilemmas, namely the problems of efficiency and safety of this medical procedure. The objective of this study is to analyse the ethical dilemmas in xenotransplantation with the background of a personal view of moral life. Also, xenotransplantation will be evaluated as far as the legal regulation of transplantation is concerned. In particular, we will consider patients rights in accordance with existing laws on organ and tissue transplantation, animal research and clinical trials.

INTRODUCTION

In most western countries, there is a ‘human organ shortage’ with waiting lists for the performance of this therapy. In a recent report of the UNOS Ethics Committee it is stated that there are approximately 31,000 potential recipients on waiting lists, but only one fourth of potential donors gave their specific consent. Moreover, all over the world, the absolute number of potential cadaveric donors is well below the needs of the population.

In this human organ shortage context, new technologies are a welcomed expectation of both individual patients and overall society. In particular, xenotransplantation and genetically modified human organs obtained through human cloning and stem cell technology are promising tools for overcoming many untreatable diseases. However, an ethical, legal and economical evaluation should be performed to ascertain if these technologies should be implemented. The ethical debate over xenotransplantation should have as an ethical background a personal view of moral life.

The objectives of this study are: a) to determine if xenotransplantation is a technological imperative in a global society where there is no agreement insofar as the modality of consent for cadaveric human transplantation is concerned; b) to propose some ethical and legal benchmarks concerning a way to implement xenotransplantation; and c) to ascertain if it should be a priority in health care delivery (if it is an economically viable treatment modality), using as background an equal opportunity account of fairness. In particular, we will consider patients right’s in accordance with existing laws on organ and tissue transplantation, animal research and clinical trials.

1- ETHICAL ISSUES IN XENOTRANSPLANTATION

1-A Expressed versus presumed consent

Pluralistic societies have adopted, for a long time now, a pluralism of ethical beliefs and moral viewpoints that are the fundamental expression of personal liberty. The principle of respect for autonomy springs naturally from this perspective. It follows that informed, expressed consent is usually obtained after

2 Disease and disability are properly seen in most European countries as unfair circumstances. Both the biological and the genetic lotteries are unjust to an individual person because they restrict ‘the range of opportunities that would otherwise be open to individuals’. (Norman Daniels. 1996. Justice and justification: Reflective equilibrium in theory and practice. Cambridge. Cambridge University Press; and Norman Daniels. 1989. Reading Rawls. Critical Studies on Rawl’s A theory of justice. Stanford. Stanford University Press.) The equal opportunity rule – in a system-relative account of justice – tries to maintain the ‘normal functioning’ as an ethical standard. Although, ideally, strict equal circumstances should be attained by all citizens in a just society, it is not reasonable, or prudent, to propose such a social contract because it disregards that resources are scarce and must be both fairly allocated and also submitted to democratic accountability.

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the delivery of careful information about the harms and benefits of any medical procedure. Physicians strive not to impose their values and must respect patient’s rights to privacy. With regard to organ transplantation from cadavers there is a wide spread consensus that information accuracy is the paradigm of good clinical practice. This information is instrumental in reaching not only an informed decision but also in determining the true expectations of the patient. Respect for a patient’s autonomy is an indisputable principle of medical ethics.

Both ethically and legally, it is accepted that competent autonomous people are able to give free and informed consent for most medical interventions. Ethical liberty and the principles of equal dignity among human beings and of the non-instrumental value of the human person are considered as the main ethical framework. However, autonomy is not unlimited. Human dignity implies that the human body – as well as body parts – has a symbolic value and therefore its unethical use implies a violation of basic ethical premises. Personal freedom is valued so highly that the Convention on Human Rights and Biomedicine is primarily dedicated to the issue of informed consent and personal freedom. A comprehensive analysis in Beauchamp and Childress, *Principles of biomedical ethics*, as far as the doctrine of free and informed consent is concerned, implies that in pluralistic societies the consent process should be made in accordance not only with the bioethical principle of respect for personal autonomy but also with the principles of beneficence and non-maleficence.

However, with regard to organ transplantation more stringent criteria are required. One of these benchmarks refers to the distinction between expressed consent and presumed consent. The fundamental issue is related to the manifestation of the will after one’s own death. In the context of transplantation from a dead cadaver it must be clearly determined what form of consent is being discussed. In many countries, including the United States, it is a commonly held belief that only expressed consent, through a donor card or any other formal way, is a valid consent.

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In many countries, however, there is the ethical and legal possibility of presuming the consent for organ transplantation from a dead person; in fact, there are common social feelings of solidarity and responsibility and therefore most people, whatever their age and cultural background, would agree to donate organs after death. It is not surprising, then, that expressed consent is not considered a necessity to obtain cadaveric organs for transplantation in these countries. In countries such as Portugal, with a strong Christian tradition, one should expect that altruist donation is regarded as the right action and also as a requirement for full citizenship. However, anyone who feels, for whatever reason, that he or she does not want to be an organ donor, may make note of this through inscription in a National Registry (RENNDA) that links together every major transplantation center.

This perspective over the exercise of consent for organ transplantation also relies on the reluctance many people have to deal with the issues of death and dying. Although most people would, in principle, donate their organs, in fact many would not take the necessary steps for such a donation if consent would need, by law, to be expressed.

Presumed consent is frequently criticized as an ethical and legal fallacy. It is claimed that many people are not truly informed over transplantation issues, and that even if they are, they should not be required to take the necessary steps to show their disagreement. A compelling case is frequently made with regard to the necessity of giving expressed informed consent for organ retrieval. It should be stated that there is a difference between the right action and the right policy. As a policy tool presumed consent meets society’s expectations of having as many cadaveric organs for transplantation as possible. However, despite this, there is a severe organ shortage for transplantation.

1-B Safety of the procedure and the need for psychological evaluation

In the United States of America 62,000 people are waiting for a kidney, liver, or pancreatic transplant as stated by a report of the

6 In Portugal the main reason why people disagree with cadaver organ donation is a mistrust over the concept of brain death. Although a large public campaign was set during the 1990s a few people still believe that cardiovascular arrest is the true moment of death of a human being. Also, there is some mistrust with regards to the application of the medical criteria of brain death. Anecdotal cases of less than perfect application of these criteria in the transplantation setting clearly contributed to this belief.
United Network for Organ Sharing. All over the western world the shortage of human organs is a severe public health concern.

Xenotransplantation – defined as the transplantation of animal cells, tissues or organs into human beings – is associated with particular ethical dilemmas, namely the problems of the efficiency and safety of this medical procedure. The animal species most often used in clinical trials is the pig. The pig has a corporal mass and a body shape more similar to man than most other mammals and, also, it is easy to breed and to develop industrially. There are at least two different safety issues:

1. Transmission of viral and prion animal diseases to humans, directly from the organ to the human receptor;
2. The different, more acute and severe, host versus implant reaction due to the immunology of the xenotransplant.

These are essentially technical problems but they need a clear solution for xenotransplantation to be regarded as a safe clinical procedure. In the ethical review process of this experimental procedure Institutional Review Boards, and other ethics committees, should be aware that for the time being xenotransplantation implies lifelong administration of immunosuppressors and that guidelines are needed to safeguard patients against unrealistic expectations. The chronic treatment with immunosuppressors might be responsible for the transmission of endogenous virus of the pig due to a decreased immunological response of the receptor. It seems, however, that the xenotransplantation of cells and tissues is less prone to develop such a decreased immunological status. Clinical trials involving hepatic and pancreatic cells (diabetes) are under way to confirm this hypothesis.

From the patient/receptor perspective we feel that in the selection process for xenotransplantation clinical parameters should be complemented with psychological evaluation before

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8 The adult African monkey has a body weight varying between 23–30 kg. Therefore, it would be most improbable that its heart would fulfil the cardiovascular needs of an adult human being.
9 If the organ is genetically modified through transgenic breeding, that is through the development of a transgenic animal whose organs are harmless with regards to its rejection by the human body, there is still the problem of transmitting defective genes to the receptor and even to his or her progeny. This unintended form of germ-line genetic engineering needs further ethical and legal analysis.

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and after the transplantation procedure. The purpose of this evaluation is to select appropriate candidates for transplantation of animal organs and to determine any psychological changes that may result from the xenotransplantation process. Only in this way can we be sure that the transplantation was a personal success. It is accepted today that genetic identity, *per se*, is not an ethical determinant. What really matters is personal identity and integrity. It follows that it must be clearly explained to the organ recipient that body totality is not undermined with an animal organ; psychologically, counselling should strive for the acceptance of xenotransplantation as a ‘natural’ treatment or at least as ‘natural’ as any artificial treatments are concerned.

Animal organ recipients should be psychologically evaluated in a collaborative study to determine if this assumption – that there is no difference whatsoever between receiving a human, an animal or a genetically modified artificial organ – is true. Also, issues like self-esteem, self-perception and other personal goals should be addressed. Psychological evaluation in the socio-economic area – in particular issues like personality traits and social integration – should be emphasised.

With regard to xenotransplantation in children, it will be an ethical imperative not only to evaluate the child’s global development after the procedure but also his or her familial adaptation. A structured interview should be held to determine the pattern of relationships between the child and his or her family. The family is usually regarded as the center of the child’s acculturation. Family support is a fundamental step for a paediatric xenotransplantation implant program to succeed. Another important factor is the psychologist’s communication skills. Specific training in communication and counselling is needed.

1-C Animal welfare

Animal use for therapeutic purposes is frequently put into question because its moral status is yet to be defined. Is it ethical to perform research and other forms of destructive interventions on animals?¹⁰ Some authorities regard speciesism as ethically

¹⁰ Tristram Engelhardt feels that ‘persons, not humans, are special’ (1986. *The foundations of bioethics*. New York, Oxford University Press). He also claims that to have a stand in the moral community one must have cumulatively: 1) rationality, 2) self-consciousness, and 3) moral sense. This person-centered construction of the moral community might imply that adult higher mammals
problematic as racism was a few decades ago. Peter Singer speaks of the special place sentient beings have in the moral community.\textsuperscript{11}

However, it is argued by these authors that human dignity springs from the human being itself as a member of the \textit{Homo sapiens} species. This perspective seems to be an essential element to achieve an accepted conception of man. We defend the thesis that every human being is a member of the moral community due to a wide ontological solidarity. That’s the reason why the legal framework considers the human person an actual subject with specific rights attached to him or her. An animal is not a person, neither in the philosophical nor in the legal sense. We believe that animals, even sentient ones, do not have rights, but that they should nonetheless be protected by law and ethics.

Animals need protection for at least two different reasons. Firstly, due to the symbolic value of biological life to human beings; inflicting unnecessary pain and suffering on animals would have a negative impact on the moral community. Human life could be more easily destroyed. Secondly, biological life in itself should be protected because every biological organism, even the smallest one, has some intrinsic capacity that struggles towards life. It can be assumed that life is valuable and that responsibility towards life is an ethical imperative. It might follow that a hierarchic gradient in the phylogenesis is an ethical imperative. For example, monkeys, who are closer to humans, need more protection than pigs or cows. Also, dolphins, who have higher intellectual capacities, deserve more respect than most other animals. It follows that animal research should be conducted with the least possible risk of harm. Only a proportionate reason can justify animal research. Human therapeutic benefit – like xenotransplantation – could be one such proportionate reason.

Animal research is strictly supervised in most western countries so that legal and ethical guidelines must be followed. This is not a specific task of ethics committees but of local health authorities. When the first clinical trials on xenotransplantation are proposed stringent guidelines regarding the use of animals, pigs in particular, must be followed so that suffering can be avoided (that enjoy life and have pleasure) deserve some respect in our society. Nevertheless, it is usually accepted, as stated by Robert Nozick, that animals can be sacrificed only insofar as ‘the benefits of the sacrifice are greater than the loss inflicted’ (1974. \textit{Anarchy, State and Utopia}. New York. Basic Books.)\textsuperscript{11} P. Singer. 1993. \textit{Practical ethics}. Cambridge. Cambridge University Press.
and the whole process of transplantation can be dignified. It is possible that many countries will have specific committees to deal with these issues. Animal Experimentation Committees are a resourceful tool to guarantee that animals are treated with respect and that concern with their own survival as different species is a priority. It must be remembered that genetically modified animal organs, through transgenic breeding, could endanger a particular species.

1-D Allocation of resources

The implementation of any health care system requires that a resource allocation policy must be regulated by explicit criteria. These criteria are associated with the management of both technological and human resources. It is not an easy process to decide who has the right and the power to promote health care access and its delivery. In a resource allocation context, there are different agents – stakeholders – who have different values and priorities leading inevitably to a great difference between its needs and the available resources. There are unlimited health needs but limited resources. Nowadays, most health care systems are faced with the specific problem of an objective incapacity to fulfil those needs. The waiting lists for organ transplantation are quite a good example. There is clearly an attempt to adjust the supply and the demand. The excess of demand of a particular good and its scarcity – in a fair society – must be associated with a fair and accountable process of selection.

An optimisation policy with regard to resource allocation must be performed, but this has been increasingly difficult. There are different motivations and values that must be considered. Governments must decide but their decisions must be democratically accountable; they have different political options and priorities must be set in accordance with these options. The authorities can improve the efficiency of the system through a continuous containment of cost drivers. Cost efficiency may be achieved in a variety of ways (economies of scale, supply costs, etc.) and it is important to assess the relation of potential sources of cost efficiency to the cost drivers. The aim is to ensure a basic level of health care for all. In this context, it is necessary to

develop a fair methodology for making such explicit choices. Governments, following public opinion, may deny an expensive although effective treatment – such as xenotransplantation – in favour of a cheaper one with somewhat less effectiveness.

With the globalisation of the economy, the definition of priorities is a primordial task. But, in this global society, if the supply is global the consumption is local. So, the resource allocation policy cannot be independent of the economic and political conditions of a particular country. In this environment, the financing of sophisticated technology such as xenotransplantation is a controversial issue. If, on the one hand, waiting lists for organ transplantation can be reduced with this process and, therefore, many lives can be saved, on the other hand this treatment may not be cheaper. One may ask if the cost of implementation of such a program must be supported by all citizens, as sophisticated technology implies more costs to the government and to society. The choice is not a simple one. An economic evaluation can be a fundamental tool to help to decide if xenotransplantation can be implemented. Health is a complex good, and trying to quantify this good is a very difficult task. The concept of cost-opportunity is the most appropriate one when the aim is to measure health care related options.

Some authors believe that financial incentives (any material gain or valuable consideration obtained by those directly consenting to the process of organ procurement\textsuperscript{14}) are an ethically justified solution for the problem of trying to overcome the shortage of organs. Such incentives could easily increase donations, improving the efficiency of the health care system. The main argument supporting the financial incentives to organ donation is that increasing the efficiency of the health care system would possibly save lives and decrease the costs related to the alternative treatments of those waiting for transplantation. However, in this environment of financial incentives, questions such as what are the sources of such incentives, and does this policy increase or decrease the actual costs of the system, must be addressed. Some authorities claim that the potential savings to the American health care system may be approximately $30


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million, if only 500 additional donors (and, therefore, 1000 additional cadaveric kidneys) were added to the system.15

However, the scarcity of human organs will encourage the implementation of xenotransplantation technology. An economic evaluation must also deal with the issue of increasing costs of the system related to new and expensive medicines used as immunosuppressors. If the production of these drugs implies more costs, it will be reflected in the sale price. Who will pay this expense? The state, the citizen or society as a whole? The problem here is to know if there is an individual or collective responsibility. Also, if there is an individual responsibility does it imply some kind of collective financing?

Xenotransplantation is a process that involves difficult ethical questions such as safety of the procedure, personal choices, solidarity, government intervention, but also an economic dimension. Its implementation requires that such analysis must be performed.

2- REGULATION ON XENOTRANSPLANTATION: AN INTERNATIONAL APPROACH

2-A Council of Europe

A - Recommendations on Xenotransplantation

The most important example of an international approach in what concerns the regulation of xenotransplantation is the Council of Europe’s Recommendations n.º R (97) 15, and n.º 1399 (99) 1.

The Council of Europe’s Committee of Ministers adopted, on September 30, 1997, Recommendation n.º R (97) 15 on xenotransplantation. This recommendation defines xenotransplantation as ‘the use of living organs, tissues and/or cells from animals, whether genetically modified or not, for transplantation into humans’.

Having in mind both that xenotransplantation may become a practicable therapeutic intervention in the near future, and that there are risks associated with possible transmission of diseases as a consequence of the use of xenografts, this recommendation encourages the Member States of the Council of Europe to establish a mechanism for the registration and regulation of several aspects of xenotransplantation. These aspects are: xenotransplantation.
transplantation programmes that are being performed in the country; basic research and clinical trials that are being proceeded in the field of xenotransplantation; the production and care of the animals that are to be used as ‘source animals’ for xenografts and, as well, the long term follow-up review of xenograft recipients and of xenograft ‘source animals’.

The second recommendation, Recommendation n.° 1399 (99) 1, on xenotransplantation, was adopted by the Parliamentary Assembly of the Council of Europe, on January 29, 1999. In this recommendation, the Parliamentary Assembly recommends that a legally binding moratorium on all clinical xenotransplantations should be rapidly introduced in all the Member States of the Council of Europe and that efforts should be made to make this moratorium a world-wide legal agreement. This moratorium is recommended because of the risk of rejection problems in xenotransplantation, and because the risk of animal diseases spreading from animals to the xenograft patients and from these into the general population remains uncontrollable.\(^\text{16}\) For this last reason, the recommendation suggests that the health risks must be weighed up against the estimated benefits of xenotransplantation and that methods must be found to eliminate any risk to public health.

This recommendation also stresses that there are considerable medical, ethical, scientific, social and legal questions that should be answered before clinical trials involving human recipients of xenografts begin.

As it is well known, these two juridical texts are not binding to the Member States of the Council of Europe, being only what is often called ‘soft law’ – law that although not legally binding tends to have major influence in the evolution of international and national law.

**B – Recommendations on Genetic Engineering and on the Protection of Material of Human Origin**

If xenotransplantation trials involving human recipients were to proceed in any of the Council of Europe’s member states, another two Council of Europe’s recommendations should have to be considered: Council of Europe’s Recommendation 934 (1982) on genetic engineering, adopted by the Assembly on January 26, 1982, and Council of Europe’s Recommendation 1213 (1993) on developments in biotechnology and con-

sequences for agriculture, adopted by the Assembly on May 13, 1993.

Number 3, § iii. of the first of these recommendations, states that ‘freedom of scientific enquiry ... carries with it duties and responsibilities, notably in regard to the health and safety of the general public and of fellow scientific workers and to the non-contamination of the environment’.

Xenotransplantation may raise health problems, since through xenografting, infectious organisms can be transmitted from animals to human beings, who then will suffer from a ‘zoonoses’, i.e., from an animal disease that can also affect human beings, and that can also be transmitted from animals to humans under natural conditions. And, the use of xenografts raises, as well, problems of the contamination of the environment, because in order to reduce the immune response to animal transplanted organs, transgenic animals (for instance, transgenic pigs), are bred to be used for xenotransplantation. These pigs contain human genes in their cells and, as their production may represent a violation of species boundaries, there is a wide spread concern about the potential risks to the environment if they were to be released.

On number 5 of the second of the referred recommendations, the Parliamentary Assembly recognises that ‘biotechnology can also be misused, for example for the production of new diseases or for the creation of animals or plants which could have unwanted effects on specific ecosystems’. The production and the subsequent transmission of new diseases is one of the worst risks of xenotransplantation – the possibility that new diseases appear, called ‘xenozooneses’, diseases of which no human being has ever suffered before, caused by new mutations that can occur when viruses of different species recombine. These new infectious diseases would be transmitted from the ‘source animal’ to the human xenograft recipient and from him to his contacts (family and friends) and to the wider human population, causing major pandemics.

On number 9, § i, the Assembly recommends that the Committee of Ministers should extend its work on bioethics ‘to include issues related to the production, release, use and trade of new living organisms, animals and plants ... , and work for a European harmonisation of legislation in this field’. The production of transgenic animals to provide organs for xeno-

transplantation represents the production of a ‘new animal’ that has, as said before, some human genes incorporated into it. What ethical and legal status should be given to a transgenic primate, or pig? Should there be a European harmonisation of legislation in this field, so as to avoid the production of these animals being forbidden in some countries and allowed in others?

C – Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine

The rules provided for in international conventions that have been duly approved or ratified, can apply in national law of each of the Member States of the Council of Europe, as long as they remain internationally binding with respect to each Member State.

The most important of the Council of Europe’s rules in the field of the developments in biology and medicine are the rules contained in the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, opened for signature in Oviedo, on April 4, 1997. This convention, that has already been ratified by six Member States, entered into force on December 1, 1999.

Although this convention establishes a framework in what concerns allotransplantation (protecting, in articles 19 and 20, human living donors in the context of organ or tissue removal done for transplantation purposes for the therapeutic benefit of the recipient), it does not deal specifically with the question of the removal of organs, tissues or cells from non-human-animals for xenografting.

Nevertheless, if xenografts are successful, in the near future, the offering of a xenograft to an individual patient will have to be considered as a ‘medical act’. Thus, several articles of this convention would be applicable to xenotransplantation. For instance, according to what is laid down in article 5, a xenograft could only be performed after the person concerned had given

18 These states are (according to the information given in http://www.conventions.coe.int) Denmark, Greece, San Marino, Slovakia, Slovenia and Spain.
free and informed consent to it. And, considering what is established in article 10, this person would have as well the right to respect for private life in respect to information about the xenotransplantation.

D – Other Council of Europe Conventions
Xenotransplantation requires the practice of experimentation involving animals that are used as ‘source animals’ for organ and tissue retrievals. Council of Europe’s European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes, opened for signature on March 18, 1986, and the Protocol of Amendment to this European Treaty, opened for signature on June 22, 1998, deal with the issues raised by animal clinical trials. Therefore, their provisions will be applicable to the use of animals for xenografting purposes.

Furthermore, as transgenic animals used for xenotransplantation can be qualified as ‘Genetically Modified Organisms’ (GMOs), since their genetic material has been altered in a way that does not occur naturally by mating or natural recombination, their production, use and release into the environment is considered to be – according to article 2 of Council of Europe’s Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment20 – a ‘dangerous activity’ if it poses a significant risk for man, the environment or property.

2-B United Nations Organisation
Various other international instruments also provide protection and guarantees in the field of the production and release of GMOs. For instance, the United Nations Organisation’s Convention on Biological Diversity, opened for signature on June 5, 1992, lays down, in article 8, that each Contracting Party shall ‘establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health’. This article applies, as well, to the release of, for instance, genetically modified pigs bred to supply organs for xenotransplantation.

20 This European Treaty was opened for signature on June 21, 1993.
And the World Health Organisation presented, on October 28-30, 1997, in Geneva, the Report on Xenotransplantation. In this report, the following conclusions were reached: measures should be required to minimise the risk of xenozoonotic infection, and to maximise safety in the potential use of this new technique; a public debate should be carried out in order to see if there is public acceptance of xenotransplantation; the use of GMOs as ‘animal sources’ for xenografting ‘may be considered acceptable as long as the dignity and identity of humans are respected, human health is protected, and animal welfare is adequately taken into account’.

This report also calls for attention to the economics of xenotransplantation – that consideration should be given to the relative costs and benefits of xenotransplantation to the recipient and to the health care system of each country.

CONCLUSION – THE NEED FOR INTERNATIONAL HARMONISATION OF LEGISLATION

Before clinical trials on xenotransplantation are performed a regulatory framework shall have to be devised in order to assure the respect for the fundamental rights of the people that undergo this kind of treatment and to control the safety and quality of animal organs and tissue for transplantation. Beforehand a cost-effectiveness and a cost-efficiency analysis must be performed to determine if xenotransplantation is cost-effective and therefore if it should be a priority in health care delivery. This regulatory framework will have to consider both the existing law of individual countries as well as international guidelines over this issue. Although most of the states and international organisations have not yet introduced legislation that would clearly and explicitly rule on xenografting, there seems to be an effort to achieve an international harmonisation of legislation in this field of medical and biological developments.

The Romans used to say that *Iustitia is quod ius dicit*. As we can see, in a certain sense, *Iustitia*, the ancient Roman goddess of justice, still has the answer for the apparently absolutely new questions that society raises to law in the beginning of the 21st century – such as xenotransplantation – since these questions refer to the issues of human rights, animal welfare, and so on, that are not at all new for lawyers. But are the questions raised by xenografting really new? After all, was not *Deadelus*, a man who grafted bird feathers to his arms, so that he could escape from his
island prison in Crete and fly to the mainland of Greece, probably the first recipient of a xenotransplant that was successful?

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