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Date: 14 December 2009 – The Academy of Medical Sciences

Animals containing human material: Call for Evidence

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the **United Nations Universal Declaration of Human Rights** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.

The SCHB is very grateful to the Academy of Medical Sciences for this opportunity to respond to the consultation entitled **Animals containing human material**. It welcomes the Academy's intention to promote public consultation, understanding and discussion on this topic.

Scottish Council on Human Bioethics Response:

Necessity of public debate

1. For all involved in the human-nonhuman combination debate, it is vital to examine the grounds in favour of and in opposition to creating such entities.
In addition, informed public opinion needs to be given the necessary and appropriate information in order to coordinate a genuine debate about current attitudes towards human-nonhuman combinations, animal issues and human concerns. Openness in the activities of the regulatory bodies, advisory groups and working parties especially in relation to the scientific issues of risks, benefits, safety and monitoring of humans and nonhuman animals is a vital part of providing a framework within which proper informed debate may take place.
2. If the technology is to be accepted and used, it should be demonstrated that:
 - there is a genuine biomedical need for human-nonhuman combinations;
 - there are no appropriate alternative options which are available;
 - the technology is efficacious;
 - the highest possible levels of safety for patients and the wider human population can be guaranteed;
 - all issues of animal husbandry, care, welfare and use are strictly monitored;
 - there are real benefits for patients, families and society and not just for the commercial companies who stand to make a profit from this procedure;
 - there are no other serious ethical reasons that would give rise to concern; and
 - the procedure would not result in considerable offence being taken by a significant proportion of the general public.

Ethical Perspectives

3. To many people, the resulting human-nonhuman entities created by crossing the species barrier would give rise to grave and complex ethical concerns. In crossing the species barrier, the general understanding of what it means to be a human person would no longer be clear cut. Indeed, any ethical appraisal of crossing this barrier should ultimately address the question of whether the combinations of human and nonhuman parts modifies the identity and the rich meaning of what is understood to be human or nonhuman. This is because human beings are generally considered to have a specific human dignity which nonhuman animals do not have.

Human Dignity

4. Like many other terms in ethics and philosophy, 'dignity' has often been used as an empty slogan, or a cover for intellectual undress. Indeed, it cannot be fully accounted for by other concepts such as respect and autonomy, beneficence, non-maleficence or justice. But this does not invalidate the basic idea.
5. In the Oxford English Reference Dictionary, 'dignity' is defined as the '*state of being worthy of honour and respect*¹'. In other words, it incorporates aspects of 'honour' and 'respect' but also of 'value' and 'worth'.
6. In this regard, it should be remembered that the concept of human dignity is not a scientific one. No individual will ever be able to prove whether or not a person possesses human dignity. From a scientific perspective, a human being is made up of a 'large pile of cells' containing about 70% water and a few other chemical compounds who will eventually become, with time, a handful of dust or ashes. Thus one of the problems about bestowing human dignity to others or to oneself is the circular nature of this process. Scientifically, the assignment of human dignity from a 'pile of cells' to another or the same 'pile of cells' does not have any meaning!
7. But although it is not possible to completely determine human dignity, it is something that everyone should always accept is found in every human person to an equal extent. This is in accordance with the **United Nations' Universal Declaration of Human Rights** which affirms in its preamble "*the inherent dignity and...the equal and inalienable rights of all members of the human family*" as "*the foundation of freedom, justice and peace in the world*".
8. It should also be noted that the moral difference between human and nonhuman animals has been presumed throughout the history of law. This is one of the reasons for which nonhuman animals can be killed and used for food or other uses without the killing being considered as murder.
9. Of course, human dignity is compatible with a kind of respect toward nonhuman animals, even if one does not express it with the notion of 'rights'. To uphold that human beings deserve unconditional respect does not inevitably lead to an irrational exploitation of nature. Respect of human beings and respect of nonhuman animals and plants, even at different levels, are not opposing ideas. But the nature of this respect is different in both cases, and that difference (absolute respect in the first case, relative respect in the second) is precisely what makes human dignity. If all animals - including humans - are equal, no one has a dignity, because the notion of dignity implies precisely an intrinsic distinction between the human realm and the nonhuman realm².

¹ *The Oxford English Reference Dictionary, Second Edition*, Edited by Judy Pearsall and Bill Trumble, Oxford University Press, 1996.

² Roberto Andorno, The Paradoxical Notion of Human Dignity, <http://www.revistapersona.com.ar/Persona09/9Andorno.htm>

Biomedical risks

Risks of biological developmental problems

10. In the first reproductive cloning experiment, in February 1997, Dolly the sheep was created after 277 nuclear fusions took place, whereby 8 embryos were obtained giving only one viable lamb³. In the creation of animal-human combinations, especially at the embryological level, it would be expected that a far greater number of pre- and post-natal developmental biological problems would occur.

Risks of creating new diseases

11. It is well known that many animals may harbour in their organs, cells and genome, microbiological and other entities which may cross the species barrier and develop in the host. Unfortunately, the appearance of new diseases resulting from such a crossing over of the species barrier is not a myth. For example, prion diseases, such as Creutzfeldt-Jakob disease, can be contracted by humans by consuming material from animals infected with the bovine form of the disease. Moreover, the HIV virus is very probably of simian origin, and is the cause of a pandemic, in which the animal has ceased to play any part.
12. The infectious risk is sufficiently serious to induce physicians and biologists to publicly raise the question of whether it is ethical to allow humankind to run the risk of devastating and uncontrollable pandemics since human-nonhuman combinations will never concern more than a limited group of procedures. In other words, the procedure may bring about a period of uncertainty (knowing hazards but not the probability relating to their occurrence) and even ignorance (hazards occurring that one did not even envisage) as to the possibility of spreading new diseases.

Legal Perspective:

13. From a legal perspective, it would be useful to consider whether a created human-nonhuman entity would come under animal or human legislation or something more specific and in between.
14. If an entity is considered as a human admixed embryo or fetus, then existing UK legislation, such as the ***Human Fertilisation and Embryology Acts of 1990 & 2008***, would generally be applicable.
15. This uncertainty with respect to legislation in the field of human-nonhuman embryonic entities is confirmed, in the report prepared in 2005 by the **House of Commons Science and Technology Committee** entitled ***Human Reproductive Technologies and the Law***⁴ which indicated that the consideration of human-nonhuman embryonic mixtures is made difficult by the lack of legal definitions.
This is because the ***Human Fertilisation and Embryology Acts of 1990 & 2008*** do not, unfortunately, provide adequate clarifications concerning the specific status and nature of some of the created human-nonhuman embryonic entities.
16. In addition, the varying percentages of animal or human genes in these new biological entities may be less relevant to their status than the fact that they have been created by elements of two different species. For example, the claim that some hybrid embryos created through the use of animal eggs and a human nucleus can be considered as 'human' because they will be 99.9% human and 0.1%

³ Ian Wilmut *et al.*, *Nature* 385, 810-13, 1997

⁴ House of Commons Science and Technology Committee, *Human Reproductive Technologies and the Law*, Fifth Report of Session 2004-05, Vol.1, p 30-32. <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7702.htm>

animal from a genetic perspective⁵ provides only a very incomplete description of the origins of these embryos.

17. Indeed, one could also note that the genetic sequence that can be directly compared between the human and chimpanzee genomes is nearly 98% identical. When DNA insertions and deletions are taken into account, humans and chimps still share 96% of their sequence. At the protein level, 29% of genes code for the same amino-acid sequences in chimps and humans⁶. Moreover, somatic human cells are 100% human but do not have any specific moral value. Thus it is not only the genetic material that matters but the animal egg as well. Indeed, without this egg, no living entity would ever be created.

Philosophical Perspective:

18. From a philosophical perspective it is also possible to consider human-nonhuman combinations from different perspectives which may reflect the debates which have already taken place with regard to early human life. And in this regard, it should be noted that the UK has not reached any agreed consensus on this matter.

Early human-nonhuman embryonic combinations

19. The early human-nonhuman combination can first be considered as just a pile of cells without any moral value whatsoever because, amongst other factors, it is not self-aware and cannot support the concept of autonomy. This may be because:
- The combination is not considered as being an embryo of any sort, or
 - The combination is considered as - or given the benefit of the doubt of - being an embryo but is still accepted as having no moral value.
20. Secondly, it may be possible to consider early human-nonhuman embryonic combinations as - or given the benefit of the doubt of - being embryos endowed with a 'special moral status'. This would be somewhat similar to the manner in which many consider the moral status of an early human embryo. If this is the case then there may be an argument for them to be protected in certain circumstances.
21. Finally, it may be possible to consider early human-nonhuman embryonic combinations as - or given the benefit of the doubt of - being persons endowed with the same moral value as other human persons. If this is the case, then it is suggested that they should be given the same protection as any other person in society.

Later embryonic, fetal and postnatal human-nonhuman combinations

22. With regard to later embryonic, fetal and postnatal human-nonhuman combinations, again different positions can be considered if they are not accepted as having full human dignity as soon as they are created. Thus they may be considered as:
- gradually being endowed with an increasing amount of moral value in relationship to their prenatal development.
 - having full moral value immediately after birth.

⁵ Ian Sample, Stem cell experts seek licence to create human-rabbit embryo, The Guardian, 5 October 2006, <http://www.guardian.co.uk/genes/article/0,,1887689,00.html>

⁶ New Genome Comparison Finds Chimps, Humans Very Similar at the DNA Level, NIH, 2005, <http://www.genome.gov/15515096>

- gradually being endowed with an increasing amount of moral value in relationship to their postnatal development.
- never having any moral value even after birth.

Conclusion

23. For those who believe that an early human-nonhuman embryonic combination is not a person but just a pile of cells without any moral status or human dignity, then their creation should not result in many new ethical problems. This position would be similar to the view which argues that human embryos cannot have any significant moral value before 14 days of development.
24. However, for those who believe that human-nonhuman embryonic combinations cannot be assimilated to 'piles of cells' (and who represent a significant cross-section of the general public in the UK), the creation and destruction of these entities may give rise to profound ethical problems. For them, the mixing at a very intimate level of human and nonhuman biological material may begin to undermine the whole distinction between human and nonhuman animals for which a different understanding of dignity exists. As a result, this may undermine the whole concept of human identity, human dignity and human rights. A blurring of the important differences between what makes human and nonhuman life would be taking place.
25. In addition, uncertainty even exists towards the entity's moral status and whether it is even entitled to full dignity. Thus, for some, the promised biomedical benefits that may result from the creation of such entities do not compensate the risks of destroying entities with full or partial moral status.

Recommendations of the Scottish Council on Human Bioethics:

General Recommendations

- 1. National Ethics Committees of the Council of Europe member states should initiate, as soon as possible, an extensive consultation and reflection relating to the complex ethical questions arising from the creation of human-nonhuman combinations.***
- 2. The Parliamentary Assembly and the Steering Committee on Bioethics of the Council of Europe should address the ethical issues arising from the creation of human-nonhuman combinations, as soon as possible, in a Recommendation and/or a legally binding Convention.***
- 3. In so far as it is possible, a decision should be taken to determine whether a created human-nonhuman entity should come under human or nonhuman animal legislation.***
- 4. The creation of human embryos for research purposes, using human and nonhuman biological material, should be prohibited.***

Human-Nonhuman Transgenesis

- 5. The creation of transgenic nonhuman animals in which some foreign human genes are deliberately inserted into the genome of nonhuman animals should only proceed with extreme caution.***
- 6. Somatic gene therapy interventions in which some foreign nonhuman animal genes are deliberately inserted into the genome of human beings should only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modifications in the genome of descendants.***

Human-Nonhuman Gestation

- 7. The placing of a live human embryo into a nonhuman animal should be prohibited.**
- 8. The placing of live human sperm into a nonhuman animal should be prohibited.**
- 9. The placing of a live nonhuman embryo into a woman should be prohibited.**
- 10. The placing of live nonhuman sperm into a woman should be prohibited.**

Human-Nonhuman Hybrids

- 11. The creation of an embryo possessing cells containing both human and nonhuman chromosomes should be prohibited.**
- 12. The mixing of human and nonhuman gametes should be prohibited.**

Human-Nonhuman Somatic Cell Nuclear Transfer

- 13. The insertion of a human cell nucleus or chromosomes into a nonhuman egg stripped of its chromosomes enabling an embryo to exist should be prohibited.**
- 14. The insertion of a nonhuman cell nucleus or chromosomes into a human egg stripped of its chromosomes enabling an embryo to exist should be prohibited.**

Human-nonhuman Chimeras

- 15. Xenotransplantation should only take place if the procedure respects all national and international legal instruments such as the Council of Europe Recommendation (2003) 10 of the Committee of Ministers on Xenotransplantation.**
- 16. The incorporation of human stem cells into post-natal nonhuman animals should proceed with extreme caution. Moreover, such a procedure should only take place if it can be demonstrated that the cells cannot contribute to the germline or give rise to specifically human brain functions in the nonhuman animals.**
- 17. The incorporation of human stem cells into post-blastocyst stages of nonhuman embryos should only take place if it can be demonstrated that they cannot contribute to the germline or brain cells of the nonhuman animal.**
- 18. The incorporation of nonhuman stem cells into post-blastocyst stages of human embryos should only take place if it can be demonstrated that they cannot contribute to the germline or brain cells of the human being.**
- 19. The incorporation of human pluripotent or totipotent stem cells into a nonhuman blastocyst or its preliminary embryonic stages should be prohibited.**
- 20. The incorporation of nonhuman pluripotent or totipotent stem cells into a human blastocyst or its preliminary embryonic stages should be prohibited.**