Australian Association for Humane Research Inc.

5 September 2002

Project Officer – Xenotransplantation
Health Ethics Section
NHMRC (MDP 100)
GPO Box 9848
CANBERRA ACT 2601

Submission on the Draft Guidelines and Discussion Paper on Clinical Xenotransplantation Research

The Australian Association for Humane Research Inc. is totally opposed to the public health risks posed by xenotransplantation. The continued allocation of vast sums of money for such dubious research, when there is a lack of financial support for vital areas of medical research, a crisis in the health care system and the increased suffering which will be inflicted on laboratory animals are matters of great concern.

Introduction

The prospect of commercial cross-species transplantation or xenotransplantation – which has been attempted since the early 20th century – has created huge financial incentives for biotechnology and pharmaceutical companies. While some researchers and animal research advocates are optimistic about xenotransplantation's potential, others are calling for a moratorium on the technology which, they say, is a threat to public health and the environment, has an appalling track record, is expensive, and unnecessary. These concerns have not been satisfactorily addressed by xenotransplantation's proponents, who have overstated the technology's potential benefits to the public..

The Public Health Risks

1. Transplanting living animal organs into humans circumvents the natural barriers (such as skin and gastrointestinal tract) that help prevent infection, thereby facilitating the transmission of infectious diseases from animals to humans.
2. Many viruses, as innocuous as the common cold or as lethal as Ebola, can be transmitted via a mere cough or sneeze. An animal virus residing in a xenograft recipient could become airborne, infecting scores of people, and causing a potentially deadly viral epidemic of global proportions akin to HIV or worse.
3. Viruses that are harmless to their animal hosts, can be deadly when transmitted to humans. For example, Macaque herpes is harmless to Macaque monkeys, but lethal to humans.

4. There is no way to screen for viruses that are not yet known. Proceeding with xenotransplantation could expose patients and non-patients to a host of new animal viruses which could remain dormant for months or years before being detected. Xenotransplantation could thus be viewed as a form of involuntary human experimentation.
5. Xenotransplant proponents claim that they will breed "germ-free" animals, thereby diminishing the risk of viral transmission. But it is impossible to breed "germ-free" animals since no animal can remain completely free of parasites or endogenous viruses. In fact, genetically engineered animals are more susceptible to a host of diseases because of weaker immune systems.
6. Breeding animals for xenotransplantation would create a host of environmental problems (including soil and groundwater contamination) associated with the disposal of animal waste, and the carcasses of genetically modified animals and their offspring. Conventional farming and rendering operations have yet to solve these problems which continue to threaten public health.
7. Proposed regulatory oversight of xenotransplantation procedures is likely to be highly flawed. In all areas of human activity, particularly where there is money to be made, the potential for error, negligence and fraud exists.

In addition, many kinds of cells behave unnaturally when torn from their familiar surroundings. Because cells from transplanted animal organs migrate in the human body, attempt to adapt to their new environment, and integrate themselves inside human cells, a virus that was transmitted from baboons or pigs to humans, could permanently incorporate itself into human chromosomes. Such a virus would remain in the human body even if the animal organ were subsequently removed, as in the case of "bridge organs". No animal, whether transgenic or otherwise, can remain completely free of parasites or endogenous viruses.

No array of preliminary precautions and detailed screening programs can guarantee negligible risk, which should be an absolute requirement for xenotransplantation. Risk assessment is a precarious "science" which is often subject to enormous economic and political manipulation. The outcome of most risk assessments depends on a risk assessor's subjective selection and interpretation of data (including statistical analyses). Ultimately, risk assessment is a hypothesis that can only be tested and validated by the occurrence of the very event one is trying to prevent.

The dismal track record of previous animal-to-human organ transplant attempts is being ignored by the technology's proponents.

In short, the following criticisms of xenotransplants are 1) epidemiological and public health risks; 2) medical and scientific shortcomings; 3) concerns that xenotransplantation would diminish the importance of preventive health programs and personal responsibility for health, and that it would 4) consume already scarce resources that should be allocated towards practical, safe and cost-effective health maintenance measures.

In view of the above, we advocate an indefinite freeze on all forms of experimentation and clinical application of xenotransplantation technology. There should be no funding at any stage of xenotransplantation's development.

"In my opinion, putting animal cells and tissues or organs into humans is kind of like playing Russian roulette."
Alan Berger, a member of the US Secretary of Health's Advisory Committee on xenotransplantation (Newsday, New York, 20 August 2002, quoted in New Scientist, 24 August 2002).

E. M. Ahlston,
President
Australian Association for Humane Research Inc.
PO Box 779
Darlinghurst NSW 1300
(02) 9360 1144

We are indebted for the above to the Medical Research Modernization Committee in New York. Their report "A Layperson's Guide to the Problems with Animal-to-Human Organ Transplants" was compiled by Alix Fano, M.A., Murry J. Cohen, M.D., Marjorie Cramer, M.D., F.A.C.S., Ray Greek, M.D., Stephen R. Kaufman, M.D.

Diseases Acquired from Non-Human Primates

1. Bertielliasis; 2. Campylobacteriosis; 3. Entamoeba histolytica; 4. Entamoeba polecki; 5. Giardiasis; 6. Hepatitis A; 7. Herpesvirus simiae (B virus); 8. Herpevirus tamarinus; 9. Leprosy; 10. Marburg virus; 11. Measles; 12. Monkeypox; 13. Mycobacterium bovis; 14. Mycobacterium tuberculosis; 15. Oesophagostomiasis; 16. Salmonellosis; 17. Shigellosis ; 18. Simian immunodeficiency virus; 19. Tanapox; 20. Tularemia; 21. Yaba virus.

Diseases Acquired from Pigs

.
1. Anthrax; 2. Ascaris suum; 3. Botulism; 4. Brucella suis; 5. Cryptosporidiosis; 6. Entamoeba polecki; 7. Erysipelothrix rhusiopathiae; 8. Flavobacterium group llb bacteria; 9. Influenza; 10. Leptospirosis; 11. Pasteurella aerogenes; 12. Pasteurella multocida; 13. Pigbel; 14. Rabies; 15. Salmonella cholerae-suis; 16. Salmonellosis; 17. Sarcosporidiosis; 18. Scabies; 19. Streptococcus dysgalactiae (group L); 20. Streptococcus milleri; 21. Streptococcus suis type 2 group R); 22. Swine vesicular disease; 23. Taenia solium.

Diseases Acquired from Cattle

1. Actinomyces pyogenes; 2. Anthrax; 3. Brucellosis; 4. Campylobacteriosis; 5. Cowpox; 6. Cryptosporidiosis; 7. Escherichia coli O157:H7; 8. European tick-borne encephalitis; 9. Foot and mouth disease; 10. Giardiasis; 11. Leptospirosis; 12. Mycobacterium bovis; 13. Pseudocowpox; 14. Q-fever; 15. Rabies; 16. Salmonellosis; 17. Streptococcus zooepidemicus; 18. Taenia saginata; 19. Yersinia enterocolitica.

The full text of the MRMC's report on xenotransplantation, including references, is available at www.mrmcmed.org.