Australian Association for Humane Research Inc.

11th April 2005

Ms Jane Southwell
Special Projects – Biotechnology & Ethics
Department of Human Services
GPO Box 1670N
Melbourne 3001.

Dear Ms Southwell,

Re: Draft statement of ethical principles for biotechnology and Map of ethical controls and guidance.

The Australian Association for Humane Research Inc. (AAHR) welcomes this opportunity to comment on the above document.

AAHR certainly endorses the promotion of various biotechnology activities (such as phage display, nanotechnology and pharmacogenomics) insofar as they offer promise for advancement in human health through eliminating the use of non-human animals. We cannot however, support any biotechnology activity whose outcome depends on the inclusion of, and/or reliance on, animal use. Our position is based on both ethical and scientific grounds.

Comments specific to the draft document:

4. What is an ethical principle?

This section considers human interests only. The field of ethics is widespread and certainly not restricted to the terms in which humans treat each other.

Whilst there is a great deal of variation between the different moral frameworks, most approaches to morality can be categorised as either utilitarianism or deontology.

In its basic form, utilitarianism, one of our most common moral frameworks, requires that our moral obligation is to obtain the maximum of happiness for everyone concerned.
According to Singer, the characteristic that entitles a being to equal consideration of interests is its capacity for suffering and/or enjoyment or happiness. Other characteristics such as intelligence, rationality or skin colour are arbitrary. Similarly, Jeremy Bentham has stated "The question is not, can they reason? Nor, can they talk? But *can they suffer?*" (1)
Under these criteria, animals are considered to have interests in not suffering and should therefore be included in our moral frameworks.

5.1 The statement is intended for use primarily by those involved in utilizing biotechnology, at any point along the continuum from research to commercial product. It is also aimed at members of the public by providing ***an open and accountable set of ethical standards against which the activities of the biotechnology sector can be assessed****.*

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1 Jeremy Bentham, *Principles of Morals and Legislation*, The Extended Circle, Jon Wynne-Tyson, 1990.

It was suggested during a recent Victorian seminar (2) that there was a need for open communication between researchers, opponents and the public, and that Australian research was open to public scrutiny. I should mention here, that this has certainly not been our experience, having been refused entry to three separate research facilities despite being told that there was no secrecy! Institutions that conduct animal research never have, and never will be, open to public scrutiny due to competition between researchers, and in order to protect them from criticism for their immoral activities.

An article which appeared in the UK Guardian newspaper last year referred to a "public which doesn't necessarily understand the issues". We believe that this exemplifies the dangerous perception that researchers are the authority who should not and cannot be questioned. This unfortunate conclusion has allowed users of animals to continue their unethical and unscientific work unabated for too long. With such work being shrouded in secrecy, the public is denied access to knowing the truth of what is actually happening and are therefore not able to make an informed judgment, nor can they object accordingly.

6.2 *Respect for the public good.*
The recognition that our activities as individuals take place in a broader and collective context of social and institutional relations. 'Public good' has a special value that is wider than a 'good' relating to persons as individuals. These broader public goods define the type of society within which individuals live out their lives
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Reliance on animal tests has been proven throughout history to be detrimental to the public good.

Researchers cite a number of examples of which they consider the use of animals to be integral. However they do not provide any measure of how the perceived 'successes' compare with the number of delays and disasters animal use has caused throughout history. For example:

- 85% of drugs that reach clinical trial fail to attain general distribution (which certainly questions the efficacy of animal tests). (3)
- The development of the Polio vaccine, often cited by researchers as an example of the necessity of animal experiments, was long delayed due to misleading results from primate experiments. This was stated under oath by Dr Sabin (inventor of the polio vaccine) (4)
- Penicillin was delayed for 50 years and blood transfusions for more than a century.

We are constantly reading news headlines that breakthroughs have been made in the cure against cancer yet today it remains one of the greatest killers in the Western world. What we don't hear are the many drugs that are recalled on a daily basis – drugs that have been "successfully" tested on animals and have later proven to be dangerous to human health.

Such delays and disasters certainly suggest that the use of animals in these tests do NOT benefit 'public good'.

6.3 *Respect for animals and their intrinsic value.*

The recognition that animals have an intrinsic value both in their being and in relation to human culture. This requires a commitment to the humane treatment of animals by

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2 '***Challenging Times'***, Annual Scientific Procedures Seminar, Victorian Institute of Animal Science, Attwood. 17th December 2004

3Dr Robert Coleman of Pharmagene PLC, giving evidence at the House of Lords Select Committee on Animals in Scientific Procedures (April 2002) UK.

4 Dr Ray Greek MD, Proof of Evidence supplied to University of Cambridge in response to their planning appeal for a proposed primate research facility.

*people and, **when appropriate**, that the welfare of animals takes precedence over the interests of people.*

Whilst commendable that it has been recognized here that non-human animals do have an intrinsic value, the inclusion of the words 'when appropriate' reinforces the argument that their welfare will NEVER take precedence over the interests of people.

It is unfortunate that many people do not consider that non-human animals have a moral status that is on par with that of humans. Many such views have originated from religions which teach that animals exist to provide for humans, or that humans posess a 'soul' and non-human animals do not. For this reason, if researchers consider that there may be ANYTHING to gain from using animals - whether it be financial gain or academic recognition - the welfare of animals will certainly always take second place.

6.7 Probity
The recognition that activities are conducted honestly, truthfully, impartially, and with due regard for transparency of process.

Our comments provided under 5.1 also applies to this principle. We do not consider that animal research is ever 'transparent' or open to public scrutiny.

7.1(a) Have persons likely to be affected by decisions been consulted about the proposed biotechnology activity?

This would be impossible to attain. Likely 'victims' of pharmaceutical or biotechnological errors do not have sufficient knowledge of the consequences in order to provide an informed contribution to such a consultation.

The recent public consultation conducted by the NHMRC about clinical trials of xenotransplantation provides the perfect example. The possible emergence of a zoonotic pandemic could result in dire consequences for an uninformed and non-consenting public. Individuals who may have had no prior knowledge of, nor likely gain from, xenotransplantation procedures would be exposed to great risk.

With continued emergence of new zoonoses from unexpected sources, the inability to diagnose potential xenozoonotic viruses with current tests and their unknown pathogenic behaviour, the chances of cross-species infection seems to be exceedingly and unacceptably high. Even more alarming is that, even if detected, the viruses are largely untreatable.

Not only would clinical trials of this research be exposing the organ (or tissue) recipient to major health risks, but these risks would also be extended to the recipient's carers and families and the wider community. Considering that viruses may initially show no obvious signs of disease and may spread beyond the recipient into the general population before they become evident, at what stage will researchers deem their patients as no longer carrying any risk? And during that period before the disease is identified or acknowledged, how many people are likely to have been exposed to that disease? We do not consider that the general public would be prepared to accept the risk of introducing another potentially untreatable human epidemic such as HIV/AIDS or bovine spongiform encephalopathy (BSE). Certainly an individual has the right to expose themselves to any risks involved in scientific research but to further expose that risk to the wider community, who have NOT given consent, is highly unethical. Indeed the number of individuals that could suffer and die from a new epidemic could greatly exceed those potential lives which xenotransplantation was supposed to have saved in the first place.

7.1 (f) Does this biotechnology activity meet an identified need by improving human health or otherwise enhancing the quality of human life?

Please refer to our comments under 6.2. Reliance on the use of animals in research for human health sets a dangerous precedent.

Extrapolation from animals to humans can and does result in dangerously misleading outcomes. The reason is due to species differences. Different species have a different genetic make-up and it is on the genetic and molecular level that variances occur. Results can differ between different sexes of the same species, different strains, and even due to different housing conditions or levels of stress within the same species. So if such differences can occur within the same species then it's negligent to extrapolate from say a rat to a human – two totally different species with a totally different genetic make-up. Researchers also often claim that animals are used because they need to test in a living system rather than on isolated cells or tissue, however an entire living system creates more variables which can further affect the outcome of any results.

Another problem is that quite often a disease that is being researched does not appear in its natural state but instead is artificially induced in the research animal. This can result in the same symptoms being expressed but the underlying illness is not the same as in its human form. Treatments then try to cure the symptoms of the falsified illness but is not addressing nor curing the real problem.

7.2 (a) Has balanced information been made available to the public so far as to foster informed public discussion of biotechnology related issues and to allow for the expression of any public concerns about a particular development?

No. The public are largely unaware of consequences and have been subjected to years of marketing ploys by pharmaceutical and biotechnology companies. Our comments under principle 7.1 (a) also apply to this section.

7.2 (c) Is the biotechnology activity consistent with accepted ethical standards of professional practice?

For reasons outlined throughout this document, we consider the use of animals in medical research to be highly unethical.

7.2 (d) Is the proposed biotechnology research activity of sufficient scientific merit that it does not produce results of questionable validity or duplicate other research unnecessarily?

For reasons outlined throughout this document, we consider that the use of animals certainly questions the validity of research. And due to the lack of a central register there will ALWAYS be cases of unnecessary repetition. Our comments under 7.3 (a) (below) explain further.

7.2 (f) Do individual researchers and scientists, with the advantage of the education, skills and knowledge to use biotechnology, demonstrate appropriate social stewardship by respecting the trust placed in them by the wider community?

If the activity involves animal use then we consider it to be an abuse of trust.

7.2 (h) Is the biotechnology activity adequately secured so that it not be used or applied to destructive ends such as in biotechnological weaponry?

We do not consider that there could ever be sufficient safeguards put into place that could ensure that this could not occur. As stated by Prof. Peter Collignon, Infectious Diseases Physician and Microbiologist at The Canberra Hospital, "If one were trying to design an experiment to induce animal viruses to adapt from humans and then spread from person to person one would be hard-pressed to come up with a better experiment than xenografts."

7.2 (j) Has a social impact study been undertaken for this biotechnology activity where there are likely social implications flowing from it?

This certainly did not occur in the case of the NHMRC consultation on xenotransplantation as it was considered beyond the scope of the discussion paper. However we consider the issue of animal use in medical research to be of major relevance to the community. There are already concerns by the public that hospital funding is insufficient to meet our current needs - eg a shortfall in hospital beds, operation waiting lists, outbreaks of disease due to insufficient staffing/cleaning. We consider that a full review of animal research is far overdue and should be conducted to address the real costs to the community in terms of compromised health, financial costs of drug recalls, an analysis of harm caused as compared with any perceived benefit etc.

7.3 In relation to respect for animals and their intrinsic value.

This section seems to bear a vague resemblance to promotion of the 3R's, of which AAHR does NOT support. Ethics committees, the Code of Practice, animal welfare legislation and promotion of the 3R's does NOT justify the cruelty that research animals are subjected to, nor do they offer protection from the pain and stress they will inevitably endure. It is widely known within the anti-vivisection movement that such formalities and regulatory bodies are deficient in protecting the interests of the animals and provide no reassurance that they will not suffer.
Providing better housing, environmental enrichment, less stress and more "humane" procedures only serves to falsely reassure the public that the animals are being cared for and treated humanely. It does not address the issue that the animals shouldn't be there at all.

7.3 (a) Have alternatives to the use of animals in biotechnology research been sought wherever possible?

Whilst researchers are encouraged to seek alternatives wherever possible there seems to be no provision for policing this requirement. This is likely to be because of competition within the research industries and the subsequent reluctance for sharing information. The lack of a central register or database for sharing this information means that many thousands of animals are likely used for research that has already been conducted elsewhere – probably unpublished, making a search for this information virtually impossible.

7.3 (b) Have the minimum possible number of research animals needed to produce credible results been used and a justification provided for the determined number?

Credible results can only be achieved if the number of animals used is zero.

7.3 (d) Has a properly constituted Animal Ethics Committee reviewed the biotechnology research proposal?

The presence of ethics committees, and in particular, inclusion of a category C member (animal welfare representative) is often used by researchers to promote a 'clean' image of the industry to the public - as an assurance that the care and use of animals is sanctioned by those with a concern for their welfare and/or rights. However this is not the case. Most category C persons serving on an ethics committee are opposed to the use of animals in research. Their presence is to ensure that the animals are protected as much as possible but only within the scope of the Code of Practice. The committees are dominated by institutional members. In 1998 a survey of category C members was conducted by Animals Australia. The responses received revealed that**:**

- One third of respondents are "not happy with the way decisions are made" on their AEC;
- Half stated that "researchers failed to adequately answer the most crucial questions on the

proposal forms, particularly those dealing with justification for the research and the availability of alternatives or refinements";

- Half the respondents indicated that they had experienced "animosity or aggression from researchers on the AEC during decision making"; and

- Almost that number also indicated that "pressure is brought to bear on them to go with the status quo".

7.3 (e) Is the use or development of transgenic animals avoided if the transgenic animal is likely to experience intense suffering or be deprived of significant forms of natural expression?

The production of transgenic animals should never be permitted.

In the creation of transgenic source animals, animals suffer from the processes of surgical embryo retrieval and embryo transfer.

During the microinjection process for example, the host mother must be injected with hormones to ensure she is at the right stage of ovulation. The significant manipulation of the animal's ovulation and oestrus cycle that takes place to ensure the availability of adequate embryos can lead to over-stimulation of the ovaries causing painful ovarian cysts or enlarged ovaries.

Animals can also become considerably stressed from the exposure to additional hormones, collection of eggs and implanting of the fertilised eggs.

Due to a lack of efficiency in the microinjection process, genes can often fail to reach the right target cells within the embryo and can cause painful abnormalities or even death.

The presence of a transgene may also affect the animal's ability to perform normal behaviour. Beltsville pigs for example (genetically modified to express additional growth hormones), experienced such extreme welfare problems that normal behaviour was impossible for them. They suffered from lethargy, lameness, lack of coordination, thickened skin, gastric ulcers, severe synovitis, degenerative joint disease, pericarditis and endocarditis, cardiomegaly, paraketosis, nephritis and pneumonia.

Even in cases where the resulting transgenic animal does not suffer from any abnormality, there would have been an enormous number of animals 'wasted'. Only a very small percentage of animals born through this process display the required trait. The remainder cannot be used for their intended purpose and are subsequently euthanased.

7.5 (a) Is the biotechnology activity undertaken in a way that causes harm to, or puts at risk the safety of, persons, animals or the natural environment, where such harm or risk is out of proportion to the expected benefits?

All reliance on animal tests puts people at risk.

7.5 (c) Do risk assessments of the biotechnology activity identify the possible long-term effects so these may be taken into account in risk management strategies?

This would be most difficult – if not impossible – to assess. In the case of a zoonotic pandemic for example, newly-formed viruses could take years – maybe even several generations – to become evident. During such a large time-span it may likely have spread widely and irreversibly.

7.5 (d) Are systems in place to cease or recall any biotechnology activity or genetically modified product that is having, or has had, demonstrable negative effects on human health, safety or the environment?

As per previous comment, it could be too late once the product is released into the environment or community.

7.6 (b) Have the interests of those most likely to be affected by this biotechnology application been taken into account in a manner compatible with the aim of a just society?

Please refer to our comment under 7.1 (a).

7.7 (f) Are responses to requests for information from the community met promptly and accurately, subject to specific privacy or commercial-in-confidence restrictions?

Refer to comments under 5.1.

7.8 (b) Is the biotechnology activity carried out in a transparent and open way with public scrutiny as far as is possible given the constraints of commercial-in-confidence requirements?

Again, we refer you to our comments under 5.1.

Summary.

We acknowledge that our comments throughout this paper are specific to the use of animals in research. We appreciate and support the role of biotechnology in the advancement of medical progress, however we stress that such progress can never be attained should we continue with the current trend of using animals.

Yours sincerely,

Helen Rosser
Chief Executive Officer
Australian Association for Humane Research