



Email submission to mckeonreview@secretariat.com.au

Dear Sir Madam,

Humane Research Australia is a not for profit organisation that challenges the use of animals in research and promotes the use of more humane and scientifically-valid methodologies.

We have recently learned of the Review of Health and Medical Research in Australia (McKeon Review) and whilst we acknowledge that submissions have now closed, would be grateful if you would consider our contribution to the discussion.

Our concern with this review is that one of the major drawbacks in medical progress – the reliance on animal models – has not been included in the Terms of Reference, and we consider this should be a major aspect to be considered in a review of health and medical research.

Species Differences

Humans differ from other animals anatomically, genetically and metabolically, meaning data derived from animals cannot be extrapolated to humans with sufficient accuracy.

In fact, the Food and Drugs Administration (FDA), U.S. confirms that nine out of ten drugs 'proven' successful in animal tests fail in human trials. This not only questions the efficacy and very base argument for using animals, but critically raises the question about all the drugs that failed in animals which might have worked in humans. How many discarded cures for cancer?

Understandably, when a drug or other medical treatment is developed it must be tested in an entire living system. Using another species is using the wrong system. Considering the differences that occur on the metabolic, genetic and molecular levels, when applied to an entire biological system those intricate differences become exponential. Pre-clinical testing needs to be conducted in such a way that eliminates the risk of species differences and is instead directly applicable to humans.

Even when genetically modified, there is no single animal model that can accurately mimic the complex human situation. There are far too many unknown variables that cannot all be accounted for. Instead, we now have scientific technologies such as microfluidic chips and microdosing. Not only do these techniques analyse the effects of drugs on an entire living system, they analyse a human living system, eliminating error caused by species differences and resulting in data that is relevant to humans.

A battery of human-specific methodologies in pre clinical testing is far more predictive than depending on data from another species.

Systematic reviews

There will continue to be claims, touting specific experiments, that some animal research has contributed to human clinical knowledge, however this is based on

anecdotal evidence and unsupported claims. It may also be argued however that the same might apply to our own arguments AGAINST animal experiments. It is therefore necessary to consider systematic reviews and meta-analyses if we are to determine the human clinical utility of animal experiments.

The widespread use of animals in medical research is based on the premise that laboratory animals are reasonably predictive of human outcomes. Systematic reviews **do not** support this assumption. There have, in fact, been several systematic reviews conducted in the areas of toxicity testing and biomedical research and the alternatives have been shown to be more predictive of human outcomes.

It's therefore logical that on both ethical and scientific grounds, there are sufficient grounds for a shift toward more humane, non-animal and species-specific methodologies.

Australian legislation

After checking with some legal experts, and with the Principal Medical Advisor of the TGA, what we believe puts Australia in a unique position, is that unlike other countries, Australian legislation does not specifically require animal testing.

Resources

A number of non-profit organizations around the world now focus on funding non-animal research:

The Dr Hadwen Trust [link to <http://www.drhadwentrust.org.uk/>] in the UK

The Lord Dowding Fund [link to <http://www.navs.org.uk/research/>] in the UK.

The MAWA (Medical Advances Without Animals) Trust [Link to <http://www.mawa-trust.org.au>] in Australia.

Similarly, a number of government-funded initiatives are acknowledging the need to further develop and validate non-animal methods of research:

NC3Rs - The National Centre for the Replacement, Refinement and Reduction of Animals in Research is an independent UK organisation established in 2004.

ECVAM - The European Centre for the Validation of Alternative Methods (ECVAM) was established 1991.

ICCVAM - In the U.S., the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was established in 1997.

ZEBET - established in 1989, is the Centre for Documentation and Evaluation of Alternatives to Animal Experiments, which forms part of the German Federal Institute for Risk Management, Berlin.

While other nations forge ahead in the area of alternatives research, Australia sadly lags behind. Instead of committing to actively seek alternatives to animals, Australia focuses on ensuring that our laboratory animals are handled correctly, have comfortable bedding and toys to play with. While such environmental enrichment may clearly improve the lives of individual animals doomed to exist as mere laboratory tools, it does not address the fact that these animals should not be there at all. Instead, it reinforces the justification for using animals and detracts from the importance of finding alternatives.

It seems unjust that in Australia, research that is deemed more ethical and scientifically valid is dependent on charitable groups while animal-based research

continues to receive vast amounts of government funding. If our government and research community were truly committed to the 3R's concept then Australia too would have a government-funded centre dedicated to replacing animals in research. Until this is addressed, Australia will never be at the forefront of medical research.